SUNSHINE ACT MEETINGS

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

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

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.
EPA establishes exemptions from the requirement of a tolerance for certain inert ingredients used in pesticide formulations.
EPA proposes tolerance for pesticide chemical Naled.

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

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

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.

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

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

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

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).
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>
</thead>
<tbody>
<tr>
<td>NRC</td>
<td>USDA/ASCS</td>
<td>NRC</td>
<td>USDA/ASCS</td>
<td>USDA/ASCS</td>
</tr>
<tr>
<td>DOT/COAST GUARD</td>
<td>USDA/APHS</td>
<td>DOT/COAST GUARD</td>
<td>USDA/APHS</td>
<td>USDA/APHS</td>
</tr>
<tr>
<td>DOT/NHTSA</td>
<td>USDA/FNS</td>
<td>DOT/NHTSA</td>
<td>USDA/FNS</td>
<td>USDA/FNS</td>
</tr>
<tr>
<td>DOT/FAA</td>
<td>USDA/REA</td>
<td>DOT/FAA</td>
<td>USDA/REA</td>
<td>USDA/REA</td>
</tr>
<tr>
<td>DOT/OHMO</td>
<td>CSC</td>
<td>DOT/OHMO</td>
<td>CSC</td>
<td>CSC</td>
</tr>
<tr>
<td>DOT/OPSO</td>
<td>LABOR</td>
<td>DOT/OPSO</td>
<td>LABOR</td>
<td>HEW/PHS</td>
</tr>
<tr>
<td></td>
<td>HEW/ADAMHA</td>
<td></td>
<td>HEW/ADAMHA</td>
<td>HEW/ADAMHA</td>
</tr>
<tr>
<td></td>
<td>HEW/CDC</td>
<td></td>
<td>HEW/CDC</td>
<td>HEW/CDC</td>
</tr>
<tr>
<td></td>
<td>HEW/FDA</td>
<td></td>
<td>HEW/FDA</td>
<td>HEW/FDA</td>
</tr>
<tr>
<td></td>
<td>HEW/HRA</td>
<td></td>
<td>HEW/HRA</td>
<td>HEW/HRA</td>
</tr>
<tr>
<td></td>
<td>HEW/HSA</td>
<td></td>
<td>HEW/HSA</td>
<td>HEW/HSA</td>
</tr>
<tr>
<td></td>
<td>HEW/NIH</td>
<td></td>
<td>HEW/NIH</td>
<td>HEW/NIH</td>
</tr>
<tr>
<td></td>
<td>HEW/PHS</td>
<td></td>
<td></td>
<td>HEW/PHS</td>
</tr>
</tbody>
</table>

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.
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). 35495

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/HCFA 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/OMA notice new system of records. 35181
DOD/Secy corrects system of records exemption; effective 9-27-75. 35157

MEETINGS—
USDA/FSQS: Expert Panel on Nitrites 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 35224

AMENDED MEETINGS—
HEW/NIH: Allergy and Immunology Research Committee, 7-29–77 35226
Minority Access to Research Careers Review Committee, 7-20–77 35226
National Commission on Digestive Diseases, 7-21 and 7-22–77 35226

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
Automation. 523–5240
Special Projects. 523–5240

Questions and requests for specific information may be directed to the following numbers. General inquiries may be made by dialing 202–523–5240.
CANCELLLED 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, 8-10, 8-16 thru 8-19, 8-22, 8-22, 8-23 and 8-24-77. 35175

AGENCY FOR INTERNATIONAL DEVELOPMENT

 Notices
Authority delegations:
Bangladesh, Mission Director, et al.: loan agreements .............................................................. 35238
Indonesia, Mission Director, et al.: contracting functions ...................................................... 36237
Pakistan, Mission Director, et al.: loan agreements .............................................................. 35239
Philippines, Mission Director, et al.: loan agreements .............................................................. 35238

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
Excepted service:
Arts and Humanities, National Foundation .................................................. 35141
Environmental Protection Agency .................................................. 35141
Interior Department .................................................. 35141
Labor Department .................................................. 35142
National Aeronautics and Space Administration .................................................. 35141

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

COMMERCE DEPARTMENT

 See Economic Development Administration; National Oceanic and Atmospheric Administration.

 HIGHLIGHTS—Continued

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/FDA .................................................. 35345
 Part VIII, HEW/HCFP .................................................. 35495
 Part IX, Labor/ESA .................................................. 35507

contents

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.

 Rules
Privacy Act; implementation, correction .................................................. 35197
Notices
Meetings:
Wage Committee .................................................. 35183

DEFENSE MAPPING AGENCY

 Notices
Privacy Act; systems of records .................................................. 35181

 DRUG ENFORCEMENT ADMINISTRATION

 Notices
Schedules of controlled substances:
Econoline, 1977 interim production quota .................................................. 35234

ECONOMIC DEVELOPMENT ADMINISTRATION

 Notices
Import determination petitions:
Abe Levine Knitting Mills, Inc. .................................................. 35178
Ardmore Fashions, Inc .................................................. 35179

 EMERGENCY NATURAL GAS ACT OF 1977, ADMINISTRATOR

 Notices
Emergency orders, etc.: Ammon .................................................. 35177
TUCO Inc. et al.: correction .................................................. 35177

 EMPLOYMENT AND TRAINING ADMINISTRATION

 Proposed Rules
Comprehensive Employment and Training Act:
Manpower programs and grants to areas of high unemployment .................................................. 35317
Notices
Employment transfer and business competition determinations; financial assistance applications .................................................. 35234

Migrant and other seasonally employed farmworker programs:
Fiscal year 1978 State planning estimates and areas .................................................. 35329

 EMPLOYMENT STANDARDS ADMINISTRATION

 Notices
Minimum wages for Federal and federally-assisted construction; general wage determination decisions, modifications, and superseded decisions .................................................. 35507

ENVIRONMENTAL PROTECTION AGENCY

 Rules
Pesticide chemicals in or on raw agricultural commodities; tolerances and exemptions, etc.:
Inert ingredients in pesticide formulations .................................................. 35188
Water pollution: effluent guidelines for certain point source categories:
Petroleum refining; extension of time .................................................. 36159

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

 Notices
Air quality standards; photochemical oxidants; volatile organic compounds, control policy .................................................. 35313
Pesticide applicator certification and interim certification:
State plans:
Alaska .................................................. 36183
California .................................................. 36184
Pesticide chemicals; tolerances, exemptions, etc.; petitions:
Elanco Products Co .................................................. 35186
Mobay Chemical Corp .................................................. 36184
Pesticide registration:
Applications .................................................. 35184
Toxic substances control:
Chemicals, candidate list; availability on magnetic tape .................................................. 36183

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

INTERIOR DEPARTMENT
See also Indian Affairs Bureau; Land Management Bureau.

Notices
Environmental statements; availability, etc.: San Francisco Bay National Wildlife Refuge, Calif. ... 35231

INTERNAL REVENUE SERVICE

Notices
Employee benefit plans: Prohibitions on transactions; exemption proceedings, applications, hearings, etc.; correction ... 32235

INTERNATIONAL TRADE COMMISSION

Notices
Import investigations: Exemptions; aircraft transportation; incidental to; extension of time ... 35174
Tariffs and schedules; rate bureaus, prohibition of rate modifications ... 35175

INTERSTATE COMMERCE COMMISSION

Rules
Motor carriers: Motor carriers and freight forwarders: Exemptions; aircraft transportation, motor transportation incidental to; extension of time ... 35174
Railroad car service orders: Freight car ownership, utilization, distribution, etc. ... 35159

Proposed Rules
Motor carriers and freight forwarders: Exemptions; aircraft transportation, motor transportation incidental to; extension of time ... 35174

Notices
Abandonment of railroad services, etc.: Chicago & North Western Transportation Co. ... 35241
Fourth section applications for relief ... 35241
Hearing assignments ... 35241
Motor carriers: Temporary authority applications ... 35242
Petitions, applications, finance matters (including temporary authorities); railroad abandonment, alternate route deviations, and intrastate applications ... 35245

JUSTICE DEPARTMENT
See Drug Enforcement Administration; Law Enforcement Assistance Administration.

LABOR DEPARTMENT
See Employment and Training Administration: Employment Standards Administration; Pension and Welfare Benefit Programs Office.

LAND MANAGEMENT BUREAU

Proposed Rules
Grazing administration, trespass, etc.: Excessive of Alaska ... 35333

LAW ENFORCEMENT ASSISTANCE ADMINISTRATION

Notices
State comprehensive law enforcement and criminal justice plans: reviewing standards ... 35324

NATIONAL INSTITUTES OF HEALTH

Notices
Meetings: Allergy and Immunology Research Committee ... 35226
Cancer Immunotherapy Committee ... 35225
Cardiovascular Disease Scientific Advisory Committee ... 35225
Cardiology Advisory Committee ... 35226
Diet and Cancer Scientific Review Committee et al. ... 35225
Digestive Diseases National Commission ... 35226
Environmental Carcinogens Clearinghouse et al. ... 35224
Minority Access to Research Careers Review Committee ... 35226
Recombinant DNA Molecule Program Advisory Committee ... 35226
Research Resources National Advisory Council, Planning and Agenda Work Group ... 35226

NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

Rules
Fishery conservation and management ... 35160
Salmon fishery ... 35160

Proposed Rules
Fishery conservation and management: Foreign fishing: foreign participation in U.S. fisheries; inquiry; hearings; (2 documents) ... 35175

Notices
Environmental statements and fishery management plans: availability, etc.: Estuarine sanctuary, Fla.; hearing ... 35179

NATIONAL SCIENCE FOUNDATION

Notices
Meetings: Science Applications Task Force ... 35235

NUCLEAR REGULATORY COMMISSION

Rules
Special nuclear material export license requirements: exception ... 35160

PENSION AND WELFARE BENEFIT PROGRAMS OFFICE

Notices
Employee benefit plans: Prohibitions on transactions; exemption proceedings, applications, hearings, etc.; correction ... 35235

POSTAL SERVICE

Rules
Procurement of property and services: Postal Contracting Manual; transportation and traffic management policies and procedures (2 documents) ... 35158

PUBLIC HEALTH SERVICE

Notices
Coal gasification; standard for occupational exposure; inquiry ... 35226
Vinyl; standard for occupational exposure; inquiry ... 35227

RENEGOTIATION BOARD

Notices
Interest rates; excessive profits and refund; correction ... 35235
Military sales, foreign, exemption; interpretation rescinded ... 35235

RURAL ELECTRIFICATION ADMINISTRATION

Notices
Environmental statements; availability, etc.: Allegheny Electric Cooperative, Inc. (2 documents) ... 35177, 35178
Cooperative Power Association et al. ... 35178

SECURITIES AND EXCHANGE COMMISSION

Notices
Self-regulatory organizations: proposed rule changes: Chicago Board Options Exchange, Inc. ... 35236
Hearings; etc.: Cal-Am Corp ... 35236

SMALL BUSINESS ADMINISTRATION

Rules
Business loans: Bank and lender eligibility, etc. ... 35150

SOCIAL SECURITY ADMINISTRATION

Notices
Hearings: Georgia: AFDC Plan amendment and compliance with State AFDC Plan ... 35228
list of cfr parts affected in this issue

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.

5 CFR
213 (6 documents) 35141
7 CFR
910 35142
915 35142
916 35143
922 35144
945 35144
969 35146
9 CFR
Proposed Rules:
381 35170
10 CFR
70 35160
211 35161
212 35161
460 35163
Proposed Rules:
211 35170
212 35170
430 35170
12 CFR
226 35146
13 CFR
120 35150
21 CFR
5 35151
105 35152
135 35152
310 35155
505 35155
561 35155
801 35155
Proposed Rules:
193 35171
343 35146
22 CFR
501 35156
24 CFR
3282 35156
29 CFR
Proposed Rules:
94 35181
95 35181
96 35181
98 35181
1601 35172
32 CFR
260a 35157
39 CFR
601 (2 documents) 35158
40 CFR
180 35158
419 35159
Proposed Rules:
55 35172
100 (2 documents) 35172, 35173
43 CFR
Proposed Rules:
4100 35174
4700 3534
9200 3534
49 CFR
258 35159
1033 35159
1063 35160
Proposed Rules:
1047 35174
1082 35174
1331 35170
50 CFR
661 35160
Proposed Rules:
661 (2 documents) 35175
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 Title</th>
<th>Pages Affect ed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 CFR</td>
<td></td>
</tr>
<tr>
<td>3 CFR</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>5 CFR</td>
<td></td>
</tr>
<tr>
<td>7 CFR</td>
<td></td>
</tr>
<tr>
<td>9 CFR</td>
<td></td>
</tr>
<tr>
<td>10 CFR</td>
<td></td>
</tr>
<tr>
<td>12 CFR</td>
<td></td>
</tr>
<tr>
<td>13 CFR</td>
<td></td>
</tr>
<tr>
<td>14 CFR</td>
<td></td>
</tr>
<tr>
<td>15 CFR</td>
<td></td>
</tr>
<tr>
<td>16 CFR</td>
<td></td>
</tr>
<tr>
<td>17 CFR</td>
<td></td>
</tr>
<tr>
<td>18 CFR</td>
<td></td>
</tr>
<tr>
<td>19 CFR</td>
<td></td>
</tr>
<tr>
<td>20 CFR</td>
<td></td>
</tr>
<tr>
<td>21 CFR</td>
<td></td>
</tr>
<tr>
<td>22 CFR</td>
<td></td>
</tr>
<tr>
<td>23 CFR</td>
<td></td>
</tr>
<tr>
<td>24 CFR</td>
<td></td>
</tr>
<tr>
<td>25 CFR</td>
<td></td>
</tr>
<tr>
<td>26 CFR</td>
<td></td>
</tr>
<tr>
<td>27 CFR</td>
<td></td>
</tr>
<tr>
<td>28 CFR</td>
<td></td>
</tr>
<tr>
<td>29 CFR</td>
<td></td>
</tr>
<tr>
<td>30 CFR</td>
<td></td>
</tr>
<tr>
<td>31 CFR</td>
<td></td>
</tr>
</tbody>
</table>

**Memorandums:**
- June 29, 1977

**Proposed Rules:**
- 7 CFR
- 10 CFR
- 12 CFR
- 13 CFR
- 14 CFR
- 15 CFR
- 16 CFR
- 17 CFR
- 18 CFR
- 19 CFR
- 20 CFR
- 21 CFR
- 22 CFR
- 23 CFR
- 24 CFR
- 25 CFR
- 26 CFR
- 27 CFR
- 28 CFR
- 29 CFR
- 30 CFR
- 31 CFR

**Federal Register, Vol. 42, No. 131—Friday, July 8, 1977**
reminders

(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.)

Rules Going Into Effect Today

DOT/NHTSA—Anthropomorphic test dummy; dummy calibration test procedures and dummy design specifications. 7148; 2-7-77.

ICC—Intercity motor common carriers of passengers; service, equipment, and facilities. 29309; 6-8-77.

Rules Going Into Effect July 10, 1977

DOT/FAA—Operation Review Program Amendment No. 2; rotocraft external-lead operations. 24196; 5-12-77.

List of Public Laws

This is a continuing listing of public bills that have become law, the text of which is not published in the Federal Register. Copies of the laws in individual pamphlet form (referred to as “slip laws”) may be obtained from the U.S. Government Printing Office.


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. This section is also 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 213.3382 is revoked and amended as set out below:

§ 213.3382 National Foundation on the Arts and the Humanities

(a) National Endowment for the Arts.

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

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 is added as set out below:

§ 213.3394 Special Assistant to the Associate Administrator for Planning.

PART 213—EXCEPTED SERVICE

Environmental Protection Agency

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This amendment extends the exception from the competitive service of 25 additional positions in the Secretarial Science program at Langley Research Center when occupied by students at Thomas Nelson Community College with the provisions that no one may be employed under this authority for more than 1,280 hours in a service year and no new appointments may be made after September 30, 1977. This extension is granted because it continues to be impracticable to examine for these positions.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

William Bohling, 202-632-4533.

Accordingly, 5 CFR 213.3148 (e) is amended as set out below:

§ 213.3148 National Aeronautics and Space Administration

(e) Forty-five positions in the Secretarial Science program at Langley Research Center when occupied by students at Thomas Nelson Community College. No one may be employed under this authority for more than 1,280 hours in a service year. No new appointments may be made under this authority after September 30, 1977.

PART 213—EXCEPTED SERVICE

Department of the Interior

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This amendment excepts from the competitive service under Schedule A temporary staff positions in the Youth Conservation Corps Centers operated by the Department of the Interior. Employment under this authority shall not exceed 11 weeks a year.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

William Bohling, 202-632-4533.

Accordingly, 5 CFR 213.3112(a) (11) is added to read as follows:

§ 213.3112 Department of the Interior.

(a) General.

PART 213—EXCEPTED SERVICE

National Aeronautics and Space Administration

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This amendment 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. This section is also 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 213.3382 is revoked and amended as set out below:

PART 213—EXCEPTED SERVICE

Department of the Interior.

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This amendment excepts from the competitive service under Schedule A one Liaison Specialist to the Director, Office of Regional and Intergovernmental Operations.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

William Bohling, 202-632-4533.

Accordingly, 5 CFR 213.3112(a)(1) is amended as set out below:

§ 213.3112 Department of the Interior.

(a) One Liaison Specialist to the Director.

PART 213—EXCEPTED SERVICE

United States Civil Service Commission

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: The Office of Regional and Intergovernmental Liaison Specialist to the Regional and Intergovernmental Operations is excepted from the competitive service under Schedule C.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

William Bohling, 202-632-4533.

Accordingly, 5 CFR 213.3318(e) is amended as set out below:

§ 213.3318 Environmental Protection Agency.

(e) Office of Regional and Intergovernmental Operations.

(1) One Liaison Specialist to the Director.

PART 213—EXCEPTED SERVICE

Department of the Interior

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This amendment excepts from the competitive service under Schedule A one Liaison Specialist to the Director, Office of Regional and Intergovernmental Operations.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

William Bohling, 202-632-4533.

Accordingly, 5 CFR 213.3148(d) (4) is added to read as follows:

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 is added as set out below:

PART 213—EXCEPTED SERVICE

Department of the Interior
SUMMARY: This regulation establishes the quantity of California-Arizona lemons that may be shipped to fresh market 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 marketing situation confronting the lemon industry.

EFFECTIVE DATE: July 10, 1977.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:
(a) Findings. (1) Pursuant to the amended marketing agreement and Order No. 910, regulating the handling of lemons grown in California and Arizona, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), and upon the basis of the recommendations and information submitted by the 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.

(2) The need for this regulation to limit the quantity of lemons that may be marketed during the specified week stems from the production and marketing situation confronting the lemon industry.

(i) The committee has submitted its recommendation for the quantity of lemons to be handled during the specified week. The recommendation resulted from consideration of the factors covered in the order. The committee further reports the demand for lemons is similar to last week with size 165's and smaller strong and size 140's and larger steady. Average F.O.B. price was $6.33 per carton the week ended July 2, 1977, compared to $6.51 per carton the previous week. Track and rolling supplies at 240 cars were the same amount as last week.

(ii) Having considered the recommendation and information submitted by the committee, and other available information, the Secretary finds that the quantity of lemons which may be handled should be established as provided in this section.

(ii) It is further found that it is impracticable and is contrary to the public interest to give preliminary notice, engage in public rule-making procedure, and postpone the effective date until 30 days after publication in the Federal Register (5 U.S.C. 553), because the time intervening between the date when information upon which this regulation is based became available and the time when it must become effective to effectuate the declared policy of the act is insufficient. A reasonable time is permitted for preparation for the effective time; and good cause exists for making the regulation effective as specified. The committee held an open meeting during the current week, after giving due notice, to consider supply and market conditions for lemons and the need for regulation. Interested persons were afforded an opportunity to submit comments and views at this meeting. The recommendation and supporting information for regulation during the period specified were promptly submitted to the Secretary after the meeting was held, and information concerning the provisions and effective time has been provided to handlers of lemons. It is necessary, to effectuate the declared policy of the act, to make this regulation effective as specified. The committee meeting was held on July 5, 1977.

§ 910.400 Lemon Regulation 100.

(b) Order. (1) The quantity of lemons grown in California and Arizona which may be handled during the period July 10-16, 1977, is established at 275,000 cartons.

(2) As used in this section, “handled” and “carton (s)” have the same meaning as when used in the amended marketing agreement and order.

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

A. C. G. Y. Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This document authorizes expenses of $68,760 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 13, 1977, notice of rule-making was published in the Federal Register (42 FR 30513) inviting written comments.
The 1977-78 fiscal year was published said marketing agreement and order), it is hereby found and determined that:

Proposals set forth in such notice which were matters presented, including the proposal of shipments of California nectarines during the aforesaid period based on the quality and size of the fruit. The amendment is necessary to effectuate the declared policy of the act; (2) the amendment is the same as that specified in the notice; and (3) compliance with the regulations will not require any special preparation on the part of the persons subject thereto which cannot be completed by the effective time.

ORDER No. 916, as amended (7 CFR 915.205 of the amended marketing agreement and order). It is hereby further found that good cause exists for not postponing the effective date hereof until 50 days after publication in the Federal Register (42 FR 30513); and the recommendation for the function of 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; (2) a notice of proposed regulation of shipments of California nectarines from March 31, 1977, shall be carried over as a reserve in accordance with §§915.42 and 915.205 of the amended marketing agreement and order.

It is hereby further found that good cause exists for not postponing the effective date hereof until 50 days after publication in the Federal Register (42 FR 30513); and the recommendation for the function of 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; (2) a notice of proposed regulation of shipments of California nectarines from March 31, 1977, shall be carried over as a reserve in accordance with §§915.42 and 915.205 of the amended marketing agreement and order.

It is hereby further found that good cause exists for not postponing the effective date hereof until 50 days after publication in the Federal Register (42 FR 30513); and the recommendation for the function of 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; (2) a notice of proposed regulation of shipments of California nectarines from March 31, 1977, shall be carried over as a reserve in accordance with §§915.42 and 915.205 of the amended marketing agreement and order.

It is hereby further found that good cause exists for not postponing the effective date hereof until 50 days after publication in the Federal Register (42 FR 30513); and the recommendation for the function of 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; (2) a notice of proposed regulation of shipments of California nectarines from March 31, 1977, shall be carried over as a reserve in accordance with §§915.42 and 915.205 of the amended marketing agreement and order.

It is hereby further found that good cause exists for not postponing the effective date hereof until 50 days after publication in the Federal Register (42 FR 30513); and the recommendation for the function of 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; (2) a notice of proposed regulation of shipments of California nectarines from March 31, 1977, shall be carried over as a reserve in accordance with §§915.42 and 915.205 of the amended marketing agreement and order.

It is hereby further found that good cause exists for not postponing the effective date hereof until 50 days after publication in the Federal Register (42 FR 30513); and the recommendation for the function of 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; (2) a notice of proposed regulation of shipments of California nectarines from March 31, 1977, shall be carried over as a reserve in accordance with §§915.42 and 915.205 of the amended marketing agreement and order.

It is hereby further found that good cause exists for not postponing the effective date hereof until 50 days after publication in the Federal Register (42 FR 30513); and the recommendation for the function of 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; (2) a notice of proposed regulation of shipments of California nectarines from March 31, 1977, shall be carried over as a reserve in accordance with §§915.42 and 915.205 of the amended marketing agreement and order.
PART 922—APRICOTS GROWN IN WASHINGTON

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

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This document authorizes expenses of $3,692 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 mostly a Federal marketing order program regulating the handling of apricots grown in Washington. The regulation will enable the committee to collect assessments from first handlers on all apricots handled during the fiscal year and use the resulting funds for its expenses.

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

FURTHER INFORMATION CONTACT:

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, to 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 carrier 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 $3,692.

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

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 § 922.43 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 (7 U.S.C. 655) 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.
RULES AND REGULATIONS

§ 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) Grade. All varieties—U.S. No. 2 or better grade.

(2) Size.—

(i) Round red varieties—1 1/2 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.

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

(c) Minimum maturity requirements.—

(1) White Rose and red skin varieties: "Moderately skinned."

(2) Norgold variety. "Moderately skinned."

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

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

(d) Inspection. (1) No handler shall handle potatoes unless such potatoes are inspected by either the Idaho 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 (e), (f), 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 of potatoes for the purpose specified in this subdivision (v) shall be exempt from inspection 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 (ii) of this subparagraph.

(ii) Prior to each shipment of potatoes exempt from the foregoing maturity 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.

(f) Pack. (1) When 50-pound cartons (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>Count</th>
<th>Average count</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Larger than 50 count</td>
<td>30 per carton or under</td>
<td>5 per carton or under</td>
</tr>
<tr>
<td>60 count</td>
<td>45 to 55</td>
<td>55 to 65</td>
</tr>
<tr>
<td>70 count</td>
<td>40 to 45</td>
<td>50 to 55</td>
</tr>
<tr>
<td>80 count</td>
<td>35 to 40</td>
<td>45 to 50</td>
</tr>
<tr>
<td>90 count</td>
<td>30 to 35</td>
<td>35 to 40</td>
</tr>
<tr>
<td>100 count</td>
<td>25 to 30</td>
<td>30 to 35</td>
</tr>
<tr>
<td>110 count</td>
<td>20 to 25</td>
<td>25 to 30</td>
</tr>
<tr>
<td>120 count</td>
<td>15 to 20</td>
<td>20 to 25</td>
</tr>
<tr>
<td>130 count</td>
<td>10 to 15</td>
<td>15 to 20</td>
</tr>
<tr>
<td>140 count</td>
<td>5 to 10</td>
<td>10 to 15</td>
</tr>
<tr>
<td>Smaller than 140 count</td>
<td>5 per carton or under</td>
<td>5 per carton 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; and

(ii) Not to exceed 10 percent for oversize.

§ 945.42. Certification requirements.

(1) Certificates shall be completed and returned to the IDOEOPC by the handler responsible for the shipment.

(2) Each receiver shall maintain a record of all shipments received, which record shall include: (i) Date of shipment; (ii) Quantity of shipment; (iii) Quality of shipment; (iv) Name and address of the shipper.

(3) Such record shall be maintained for a period of at least one year from the date of shipment.

(4) Each handler shall maintain a record of all shipments made, which record shall include: (i) Date of shipment; (ii) Quantity of shipment; (iii) Quality of shipment; (iv) Name and address of the shipper.

(5) Such record shall be maintained for a period of at least one year from the date of shipment.

(6) The record maintained by the handler shall be made available to the IDOEOPC upon request.

(7) The record maintained by the receiver shall be made available to the IDOEOPC upon request.

(8) The IDOEOPC may request the handler or receiver to provide additional information as necessary to verify the accuracy of the record.

(9) Failure to maintain records as required by this section shall result in the imposition of penalties as provided by law.
will complete and return to the com­mit­
te such periodic receiver’s reports that
iv) Mail to the office of the com­mit­
tee a copy of the bill of lading for each
Certificate of Privilege shipment
promptly after the date of shipment;
(b) Each shipment directly to the
applicable receiver.
(2) Each handler making shipments
of potatoes for canning, freezing, or
“other processing” pursuant to para­graphes (a) and (b) of this section shall:
(i) First apply to the committee for
and obtain a Certificate of Privilege to
make shipments for processing;
(ii) Make shipments only to those
farms whose names appear on the com­mit­
tee’s current list of manufacturers of
potato products;
(iii) Upon request by the committee,
the shipment reports of each shipment persu­
ant to the applicable Certificate of
Privilege;
(iv) Mail to the committee’s office a
copy of the bill of lading for each Cer­
tificate of Privilege shipment promptly
and at the time of shipment;
(b) Bill each shipment directly to the
applicable processor.
(2) Each receiver of potatoes for
processing pursuant to paragraph (c)
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
those handlers of which they receive
potatoes from the production area for processing
will be used for such purpose and will
not be placed in fresh market channels;
(iii) Report on shipments received as
the committee may require and the Sec­
retary approve.
(g) Minimum quantity exception.
Each handler may ship up to, but not
to exceed, five hundredweight of pota­
toes in each shipment, provided the
inspection and assessment requirements of
this part, but this exception shall not apply to any shipment that exceeds
five hundredweight of potatoes.
Other terms used in this section shall
mean those terms defined in the United States Standards for
Marketing Agreement No. 98 and Or­
ders No. 945, as amended.
(i) Applicability to imports. Pursuant
to section 8e of the act and § 861.1, “Im­
port regulations” (7 CFR 980.1), Irish
potatoes of the long varieties imported
during the effectivity period of this sec­
tion shall meet the grade, size, clean­
liness and maturity requirements speci­
ﬁed in paragraphs (a) and (b) of this section.
Effective date and termination of pre­
vious regulations. This regulation will be
come effective July 15, 1977, and will
supersede § 945.335 which is hereby
terminated upon such effective date.
(Secs. 1-19., 48 Stat. 31, as amended; (7 U.S.C.
601-614).)

Charles R. Brader,
Deputy Director, Fruit and Vegetable
Division, Agricultural Marketing
Service.

PART 999—SPECIALTY CROPS—IMPORT
REGULATIONS
Amendment of Regulation Governing
Imports of Walnuts
AGENCY: Agricultural Marketing Serv­
ce, USDA.

ACTION: Final rule.

SUMMARY: This rule amends the walnut
import regulation. The amendment deletes provisions on inshell walnut qual­
ity requirements, which are obsolete.

EFFECTIVE DATE: July 18, 1977.

FOR FURTHER INFORMATION CON­
TACT:
Charles R. Brader, Deputy Director,
Fruit and Vegetable Division, Agricul­
tural Marketing Service, U.S. Depart­
ment of Agriculture, Washington, D.C.
20250, 202-447-3645.

SUPPLEMENTARY INFORMATION: The regulation governing imports of walnuts (7 CFR Part 999.100) is effective
pursuant to Section 8e of the Agricultural Marketing Agree­
ment Act of 1949, as amended (7 U.S.C.
601-674). Section 8e requires the Secretary of Agriculture to issue, after rea­sonable notice, quality restrictions on
imported walnuts, which are the same as,
used in the respective standards for
domestic walnuts under a Federal mar­
ting agreement. (7 CFR Part 984). Section
999.100(b) (1) of the walnut import reg­
ulation currently states that imported
insheal walnuts shall meet U.S. No. 2
grade as prescribed in the U.S. Standards
for Walnuts (July's Regula) in the Shell
(§§ 51.2945-51.2966 of this title), except
that the total kernel defect tolerance
shall be 15 percent and the tolerance for serious kernel defects shall be 8 percent.
This exception is now obsolete and
should be deleted.

These same requirements, including the tolerances prescribed in the excep­tion, were imposed on domestic walnuts
until December 1978, when the excep­tion was deleted following a revision of
the U.S. Grade Standards November 15, 1986. That revision lowered the total
tolerance for kernel defects in the U.S.
No. 2 grade from 20 to 15 percent and
the serious damage tolerance from 10 to 8 percent—the same as those then pre­
scribed under the marketing order.

Based on the foregoing, and all other relevant information, it is hereby found
that the amendment of the insheal wal­
nut import grade requirements, as
hereinafter set forth, will tend to ef­
flectuate the declared policy of the act.

It is hereby further found that it is
impracticable, unnecessary, and contrary
to the public interest to give preliminary notice and engage in public rulemaking
procedure, and that good cause exists
for making this action effective July 18, 1977, and for not postponing the effect­
tive time until 30 days after publication
in the Federal Register (5 U.S.C. 553(d))
in that: (1) The requirements of sec­tion 8e of the act make this action man­
datory; (2) this amendment merely
deletes an obsolete provision and thus
imposes no additional restrictions on
importers; (3) importers of walnuts
need no time for advance preparation to
comply with this action; and (4) no use­
ful purpose would be served by delaying the effective date of this action.

Therefore, § 999.100 is amended by re­
moving subparagraph (b) (1) to read as
follows:

§ 999.100 Regulation governing imports
of walnuts.

(b) ***

(1) Inshell walnuts. All inshell wal­
nuts shall be of a quality equal to or
better than the requirements of U.S. No.
2 and “baby” size as prescribed in the
United States Standards for Walnuts
(Julgen’s Regula) in the Shell (§§ 51.2945-
51.2956 of this title); or

(2) ***

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

Dated: July 1, 1977, to become effec­tive
July 18, 1977.

Charles R. Brader,
Deputy Director,
Fruit and Vegetable Division.

[FR Doc.77-19418 Filed 7-7-77; 8:45 am

Title 12—Banks and Banking

CHAPTER II—FEDERAL RESERVE SYSTEM
SUBCHAPTER A—BOARD OF GOVERNORS OF
THE FEDERAL RESERVE SYSTEM
[Reg. Z, PC-0083 through PC-0093]

PART 226—TRUTH IN LENDING

Official Staff Interpretations
AGENCY: Board of Governors of the Federal Reserve System.
ACTION: Official staff interpretation(s).

SUMMARY: The Board is publishing the following official staff interpretations of Regulation Z as to whether or not the requirements of the consumer leasing disclosure provisions of Regulation Z in the context of the lease disclosure form and agreement are satisfied. This is an official staff interpretation of Regulation Z, issued by a duly authorized official of the Division of Consumer Affairs, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 (202-452-2412).

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 to certain limitations stated in 12 CFR 261.6.
(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 Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

[12 CFR Part 226, FC-0083]

\(\text{\$226.8(b)}\) In simple interest loans, the continued accrual of interest on the unpaid balance after the date when an installment payment is due need not be disclosed as a "default, delinquency, or similar charge payable in the event of late payments." Similarly, interest accrued after the maturity date of the loan contract need not be disclosed if the interest rate after maturity is the same as the rate applicable after maturity is the same as the rate stated in the loan contract, or if the rate permitted by statute after the maturity date is lower than the stated rate. Where the interest on the unpaid balance after the maturity date is different from the rate stated in the loan contract, the Board believes disclosure is required by \(\text{\$226.8(b)}\) (4).

This is an official staff interpretation of Regulation Z, issued in accordance with \(\text{\$226.1(d)(3)\text{ of the regulation}}\), and limited in its application to the facts outlined herein. It is our opinion that this is responsive to your inquiry.

Sincerely,

[Signature]

[Name]
Associate Director.

[12 CFR Part 226, FC-0084]

\(\text{\$226.8(a)}\) Consumer leasing disclosures need not be more conspicuous than non-consumer leasing disclosures and the disclosures are combined. \(\text{\$226.8(a)}\) does not require use of any particular sequence of disclosures to comply with clear, conspicuous, and meaningful sequence requirements; disclosures need not be made in \(\text{\$226.15(b)}\) sequence. (See FC-0054.)

JUNE 20, 1977.

This is in reply to your letter of ** requesting an official staff interpretation of the requirements set forth in \(\text{\$226.8(a)}\) of the Regulation Z leasing disclosure provisions of Regulation Z in the context of the lease disclosure form and agreement which you signed in your letter. This letter is an official staff interpretation of the meaning of \(\text{\$226.8(a)}\) terms "clearly," "conspicuously," and "meaningful sequence" as applied to a consumer leasing disclosure. The letter considers the other questions raised in your letter to be inappropriate for an official staff interpretation as the positions in response thereto do not appear to be such that a lessor would wish to rely upon them in the event of controversy with the lessee. A response to those issues will, therefore, be provided in a separate unofficial letter to you.

In your letter inquires whether the regulation requires that the consumer leasing disclosures be more conspicuous than the required contract provisions where lease and lease contract are integrated. There is no requirement in the regulation that consumer disclosures be more conspicuous than other terms in a combined contract-disclosure statement. Since the remainder of the questions answered herein have been answered in the following subsections those questions as specified.

Although phrased in various manners, your questions 3 and 4 and the first part of questions 5, 7, 8, and 9 request an official staff interpretation regarding the requirement in \(\text{\$226.8(a)}\) of the regulation that "as applied to a consumer leasing disclosure, must be...sequence." If \(\text{\$226.6(a)}\) does not require the use of any particular sequential system or arithmetical progression in making the disclosures required in connection with a consumer leasing disclosure, such disclosures need not be made in the sequence of required disclosures set forth in \(\text{\$226.15(b)}\). We believe that the pattern of disclosures required by \(\text{\$226.6(a)}\) should 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-0054. Although framed in the context of a consumer credit transaction disclosure, it contains a discussion of the varying sequence requirements which may be helpful to you.

Unfortunately, staff cannot accommodate your request for a complete lease disclosure form enclosed with your letter. Limitations upon our resources and the marginal usefulness of such a specific sample has led staff to believe that a general policy or not undertaking this type of individual review. Staff, however, directs your attention to the Regulation Z pamphlet which sets forth the disclosures forms contained in the copy of the Regulation Z pamphlet enclosed with this letter. Although this sample form 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 \(\text{\$226.15(d)(3)}\) 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,

[Signature]

[Name]
Associate Director.

[12 CFR Part 226, FC-0085]

\(\text{\$226.15(a)}\) Two sides of a single page may be used when making consumer leasing disclosures in a combined lease-disclosure statement. The following disclosures are above the place for the lessee's signature.

JUNE 20, 1977.

This is in response to your letter of ** which requested an official staff interpretation of \(\text{\$226.15(a)}\) which pertains to the use of two sides of a single page when making consumer leasing disclosures required by \(\text{\$226.15(a)}\). That subparagraph states that "as applied to a consumer leasing disclosure statement. As you note, the finance charge and annual percentage rate that are initially disclosed if payments are received on other than the scheduled dates. A payment that is made by the borrower after its due date will result in the accrual of more interest, just as an installment made in advance of the due date reduces the accrual of less interest. As to successive payment cycles, interest accrues from the date of the immediately preceding payment.

The staff considers the other questions raised in your letter to be inappropriate for an official staff interpretation as the positions in response thereto do not appear to be such that a lessor would wish to rely upon them in the event of controversy with the lessee. A response to those issues will, therefore, be provided in a separate unofficial letter to you.

In your letter inquires whether the regulation requires that the consumer leasing disclosures be more conspicuous than the required contract provisions where lease and lease contract are integrated. There is no requirement in the regulation that consumer disclosures be more conspicuous than other terms in a combined contract-disclosure statement. Since the remainder of the questions answered herein have been answered in the following subsections those questions as specified.

Although phrased in various manners, your questions 3 and 4 and the first part of questions 5, 7, 8, and 9 request an official staff interpretation regarding the requirement in \(\text{\$226.8(a)}\) of the regulation that "as applied to a consumer leasing disclosure, must be...sequence." If \(\text{\$226.6(a)}\) does not require the use of any particular sequential system or arithmetical progression in making the disclosures required in connection with a consumer leasing disclosure, such disclosures need not be made in the sequence of required disclosures set forth in \(\text{\$226.15(b)}\). We believe that the pattern of disclosures required by \(\text{\$226.6(a)}\) should 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-0054. Although framed in the context of a consumer credit transaction disclosure, it contains a discussion of the varying sequence requirements which may be helpful to you.

Unfortunately, staff cannot accommodate your request for a complete lease disclosure form enclosed with your letter. Limitations upon our resources and the marginal usefulness of such a specific sample has led staff to believe that a general policy or not undertaking this type of individual review. Staff, however, directs your attention to the Regulation Z pamphlet which sets forth the disclosures forms contained in the copy of the Regulation Z pamphlet enclosed with this letter. Although this sample form 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 \(\text{\$226.15(d)(3)}\) 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,

[Signature]

[Name]
Associate Director.
be made together or * * * [the contract or other instrument evidencing the lease on the same page and above the place for the lessee's signature * * * *] (Emphasis added.)

It is the staff's opinion that the signature must be at the end of the second side, in order that the single page contain required disclosures, it is the staff's opinion that compliance with § 226.15(a)(1), which requires that all the required disclosures be made together, may also be achieved by placing the lessor's signature at the bottom of the first side, so long as all the required consumer leasing disclosures are mad together on the first side of the two-sided document. This would permit the placement of the signature on the first side of the page and the incorporation of other non-disclosure contract provisions from the second side into the body of the contract in those instances where operational limitations (e.g., the use of carbons to make multiple copies) would dictate the use of a signature on the bottom of the first side. It should be pointed out, however, that there is no signature requirement in the regulation and that the requirement that all the disclosures be made on the first side of the two-sided document as the applicable portions of the Truth in Lending Act, your may wish to contact the office of the Commissioner of the State of Connecticut, for his views. I trust this is responsive to your inquiry.

Sincerely,

JERALD C. KLUCKMAN, Associate Director.

[12 CFR Part 226, FC-0066]

§ 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 Information Letter 666 to the effect that § 226.7(b)(1)(iv) of Regulation Z (formerly § 226.7(b)(3)) does not require the elements of the account to be described and disclosed as a total on the periodic statement for an open end account credit. Although § 226.7(b)(3) requires disclosure of the date and identification of the amounts of any other finance charges you specifically asked whether 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.

It is the staff's opinion that the disclosure of the total periodic rate under the method outlined above meets the requirements of § 226.7(b)(1)(iv). There is no requirement under open end credit that these various elements be combined (e.g., total periodic rate) and the total finance charge be disclosed, as there is for credit other than open end.

This letter is an official staff interpretation of Regulation Z. You specifically ask whether Regulation Z requires your client to provide new disclosures under these circumstances.

The answer to this question, staff believes, depends on whether the adjustment could be considered a "refinancing" under § 226.8(j). Although the payment amounts and/or the number of payments remaining may be adjusted, staff believes that the adjustment does not constitute a refinancing as contemplated by § 226.8(j). Staff's opinion is based, to some extent, on the fact that, since the adjustment is made in order to charge the consumer a percentage rate higher than which had previously been charged, the situation is somewhat analogous to § 226.8(j). Staff notes, however, that § 226.817. Section 226.817 states that a reduction in the annual percentage rate applicable to an existing extension of credit does not constitute a refinancing as defined by § 226.8(j). It is not clear to staff whether the adjustment in the periodic rate in the next billing cycle or the annual percentage rates charged to that initially disclosed is similar to the situation contemplated by § 226.817. 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 § 226.15(a)(1), which states that date need not be described as the "transaction date," "posting date," etc.

JUNE 22, 1977

This is in reply to your letter of * * * * in which you request official confirmation of the periodic statement disclosure of § 226.7(b) that the periodic statement disclose:

"Each periodic rate, using the term "periodic rate" (or "rates"), that 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)(v) requires disclosure of the periodic rates or rates which would apply in the next billing cycle (i.e., the one in which the increased rates first take effect).

In staff's opinion, the only periodic rates which must be disclosed are those periodic rates which may be used during the billing cycle to which the particular periodic statement applies. The notice of change of terms required by § 226.7(f) has already notified the consumer that the periodic rates which will be applied to the balance due at the time of the periodic statement will be increased as shown by the periodic statement attached during the next billing cycle. Staff believes it unnecessary to notify the customer on the periodic statement for the last billing cycle prior to the one in which the rates are increased of periodic rates which
would only be applied during future billing cycles.

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. I trust that this is responsive to your inquiry.

Sincerely,

JERADO C. KLICKMAN
Associate Director.

[12 CFR Part 226, FC-0991]

§ 226.8(b) (c) 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).

This is in response to your letter of * * * requesting an official interpretation of Regulation Z. Your company services the (credit card) association's card (credit card) banks, and you ask staff's view about the application of §§ 226.6 and 226.7 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 an (credit card) account. For the applications so generated and approved by your company, you intend to specifically reference the savings and loan association's involvement in the following ways:

(1) The name of the savings and loan association will appear on the top front of the credit card;

(2) The name of the savings and loan association will appear at the top of the brochure which encloses the actual credit card;

(3) The name of the savings and loan association will appear on the front of the periodic billing statement; and

(4) The name of the savings and loan association will appear in the periodic statement for purposes of § 226.8(n).

As may be sent out a notice which tells the customer to "may wish to submit the difference indicated below along with your next regular payment in order to return to and to avoid a final payment higher than your normal payment." The current principal balance is set forth, the estimated principal balance is subtracted from it, and the regular payment is shown. The regular payment is shown and added to the difference figure, and the total is labeled "final payment (may be paid on same date)."

This is an official staff interpretation of Regulation Z. The notice is not mailed periodically, and it does not relate to any periodic statements. Therefore, it does not notify the customer or a payment which is due; on the contrary, it merely tells the customer that if he 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 regular payment if he does not make the additional principal payment, staff nevertheless believes that this would not trigger a notice of this type into a periodic statement.

The other type of notice which your client will send out is in connection with closed end loans and is a notice of final payment. The bank issues coupons to its borrowers and does not send out regular periodic notices of payments due. The last payment, however, is not covered by a coupon because it is usually not the same as the regular payments. Thus, a final payment notice is sent to the customer prior to the due date of the final payment advising him of the amount due.

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 not mailed periodically. That is, a notice of the final payment is mailed with respect to any one loan.

Your final question is whether it is necessary in making the initial disclosures to advise the customer that, if payments are not made on time, it is possible that the final payment will have to be made for amount more than twice the regular payment and, thus, be a "balloon payment." As may be shown in the definition of a simple interest installment loan that interest will be calculated on the loan balance when the loan and that late or early payments will thus affect the amount of the final payment.

Staff believes that, in the case of such installments, disclosures required under Regulation Z should

---

[12 CFR Part 226, FC-0990]
be made on the assumption that the loan payments would 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 no additional finance charge would amount to a “balloon payment.” This information may, however, be given as additional information pursuant to § 226.6(c). Of course, this view assumes that if payments were made on time, the final payment would not amount to a balloon payment. This is an official staff interpretation of Regulation Z, issued in accordance with § 226.1(d)(3) and (4) of the regulation. I trust that it is responsive to your inquiry.

Sincerely,

JERALD C. KLYCKMAN, Associate Director.

[12 CFR Part 226, PC-0093]

§ 226.3(g) Sale of cancellable credit life insurance on existing obligations subsequent to consummation, where premium amounts are remitted to creditor as part of increased monthly payment, and incur no finance charge, is not a credit transaction. Effective date: June 23, 1977.

This is in reply to your letter of requesting an official staff interpretation on 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 debt obligations to certify their credit life insurance on those obligations. Any sales of insurance would, therefore, be made separately from the underlying credit obligation. The insurance agreement would permit the customer to cancel the insurance coverage at any time. The customer’s monthly premium payments would be computed on the outstanding daily balance of the indebtedness and would be remitted to the original creditor as part of an increased monthly payment. You indicate that these insurance premium payments would incur no finance charge and would be made concurrently with monthly coverage. You state that, in your opinion, such sales of credit life insurance on existing obligations are not credit transactions subject to the Truth in Lending Act and Regulation Z for the reasons that no debtor-creditor relationship is created between the customer and the insurer that any finance charge is imposed. The staff agrees with your conclusion on the facts you present.

This staff has consistently taken the position that Truth in Lending disclosures are not required for installment insurance premium plans if there is no debtor-creditor relationship established between the insurer and the insured with respect to future premiums. (See Public Information Letter 205, 492 and 869.) Since the plan you describe calls for monthly payments coinciding with and since the customer can cancel the coverage at any time with no finance obligation, the staff is of the view that no debtor-creditor relationship is established and no disclosure will amount to a “balloon payment.” 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 facts and issues outlined herein. We trust it is responsive to your inquiry.

Sincerely,

JERALD C. KLYCKMAN, Associate Director.
under common control with another Subsection (b) Lender.

(12) Management and services. A Subsection (b) Lender may employ a manager or adviser, or may contract for managerial or advisory services, subject to prior written approval of the SBA and subject to the supervision of the Lender's Board of directors. The contract shall specify the services to be rendered to the Subsection (b) Lender and to its applicants and borrowers.

(13) Prohibited financing. A Subsection (b) Lender may not make a loan to a small business concern which has received financing (or commitment therefor) from a small business investment company licensed by SBA which is an "associate", as defined by § 120.1(d)(2), of the Subsection (b) Lender.

(14) Borrowed funds. Shareholders owning ten or more percent of any class of the stock of the Subsection (b) Lender may not use borrowed funds in purchasing such stock unless the net worth of such shareholders is at least twice the amount borrowed or unless such shareholders receive SBA's prior written approval of a lesser ratio on the basis that it is adequate in the light of all circumstances.

3. Section 120.6(d)(2)(v) is revised to add the following:

§ 120.6 Reports to SBA by Subsection (b) Lenders.

(d) Other reports to SBA.

(v) Whenever ten percent or more of the stock of the Subsection (b) Lender's stock is pledged by any person (or group of persons acting in concert) as collateral for indebtedness, and such pledge does not involve any transfer for which prior written approval of SBA is required under § 120.6(b)(9), written notice of the terms of such transaction shall be furnished to SBA by the pledgor within thirty days following the date of the transaction.

§ 120.7 [Amended]

4. In § 120.7, Examination of Subsection (b) Lenders, editorial changes are made so that the rate table reads as follows:

<table>
<thead>
<tr>
<th>Total assets</th>
<th>Base fee</th>
<th>Additional fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>$30,000 or less</td>
<td>$400 None</td>
<td></td>
</tr>
<tr>
<td>$500,001 to $5,000,000</td>
<td>400 0.01 pt over $500,000</td>
<td></td>
</tr>
<tr>
<td>$5,001 to $15,000,000</td>
<td>700 0.01 pt over $5,000,000</td>
<td></td>
</tr>
<tr>
<td>$15,001 to $50,000,000</td>
<td>1,000 0.01 pt over $15,000,000</td>
<td></td>
</tr>
<tr>
<td>$50,001 to $100,000,000</td>
<td>1,500 0.02 pt over $50,000,000</td>
<td></td>
</tr>
<tr>
<td>Over $100,000,000</td>
<td>2,000 0.03 pt over $100,000,000</td>
<td></td>
</tr>
</tbody>
</table>

(Catalog of Federal Domestic Assistance Program No. 59012, Small Business Loans.)


A. VERNON WEAVER, Administrator.

[FR Doc.77-19380 Filed 7-7-77; 7:7-77:8 45 am]
Effective date: This regulation becomes effective July 8, 1977.

Dated: June 29, 1977.

WILLIAM P. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 77-19234 Filed 7-7-77; 8:45 am]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 75N-0107]

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 these regulations. This revision provides that voluntary compliance may begin immediately and that products initially introduced into interstate commerce on or after July 1, 1978, 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 20392), 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, Ulman & 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 held and initially introduced into interstate commerce on or after July 1, 1978, shall fully comply. In the alternative, that the regulations be stayed without delay 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 of July 1, 1978. 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 should still be pending after July 1, 1978, the Commissioner will entertain applications for 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, 1978, shall fully comply.

Dated: June 24, 1977.

WILLIAM P. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 77-19234 Filed 7-7-77; 8:45 am]

[Docket No. 76F-0050]

PART 135—FROZEN DESSERTS

Standards of Identity for Frozen Desserts; Confirmation of Effective Date, Partial Confirmation of Effective Date, Stay of Certain Court Proceedings, 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 other portions of the ice cream, frozen custard, ice milk, and sherbet standards pending the receipt and receipt of 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 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, 1978. 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 should still be pending after July 1, 1978, the Commissioner will entertain applications for 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, 1978, shall fully comply.

Dated: June 24, 1977.

WILLIAM P. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 77-19234 Filed 7-7-77; 8:45 am]
It is the understanding of the Food and Drug Administration that Executive Order 11821, OMB Circular No. A-107, and Executive Order 11494 were published before November 27, 1974, are exempt from economic impact evaluation. Executive Order 11494, which was 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 in the production of ice cream, frozen custard, ice milk, and sherbet thereby having 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 were allowed to compete with historical ingredients in the production of ice cream, frozen custard, ice milk, and sherbert, there would be an economic impact on the producers, sellers, and buyers of these 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"

(Definaed in 21 CFR 150.3 (d) as utilized to provide for the use of other milk-derived ingredients alone or in combination with nonfat milk solids in ice cream and frozen custard § 135.110 (b) (1) ICE MILK § 135.200, and sherbert § 135.140 (b) (1) and (2)

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

The Commissioner, having reviewed the comments submitted to support this objection, does not find 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 amended regulations utilizing the "safe and suitable" concept would: (a) Remove the current restriction on the use of sweet cheese whey, (b) allow the use of acid cheese whey, (c) provide for the use of modified sweet and acid whey products such as concentrated whey proteins, delactosed whey, and de-mineralized whey, (d) remove the current restrictions on when casein and caseinates may be used, (e) provide for the use of coprecipitates of casein, lactalbumins, and lactoglobulins, (f) allow individual components derived from milk, nonfat milk, sweet or acid cheese whey, or milk fat, including milk fat from whey proteins, delactosed whey, and de-mineralized whey, (g) allow the use of any form of butterfat or milk fat, including milk fat from whey proteins, delactosed whey, and de-mineralized whey, (h) provide for the use of modified sweet and acid whey products such as concentrated whey proteins, delactosed whey, and de-mineralized whey, (i) provide for the use of modified sweet and acid whey products such as concentrated whey proteins, delactosed whey, and de-mineralized whey, (j) provide for the use of modified sweet and acid whey products such as concentrated whey proteins, delactosed whey, and de-mineralized whey.

2. The current regulations provide for the use of any form of (a) milk, nonfat milk, cream, butterfat, buttermilk (a by-product from the manufacture of butter from cream), (b) partially delactosed nonfat milk (an ingredient obtained by altering the chemical composition of nonfat milk), concentrated or dried skin milk that is reconstituted with milk, (c) whey products such as concentrated whey proteins, delactosed whey, and de-mineralized whey, (d) casein (a milk protein substance obtained from nonfat milk by treating nonfat milk with sodium hydroxide and disodium phosphate to manufacture an ingredient mentioned in 2(b) 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 what proportion is left up to the fabricator of the ice cream, frozen custard, ice milk or sherbert as long as the other minimum requirements of the applicable standards are met and the basic physical and nutritional characteristics are not altered.

4. The amended regulations also do not set specific limitations on 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 what proportion is left up to the fabricator of the ice cream, frozen custard, ice milk or sherbert as long as the other minimum requirements of the applicable standards are met and the basic physical and nutritional characteristics are not altered.

5. The current regulations would allow the nonfat milk solids to be obtained from buttermilk, delactosed nonfat milk, or nonfat milk treated with sodium hydroxide and disodium phosphate as long as the other minimum requirements of the applicable standard were met. While these practices are not restricted under the regulations, they may not be feasible or practical. The resulting ice cream, sherbert, and milk derived ingredients might not have the 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 utilize more cheese whey, (b) produce modified cheese whey products and (c) provide for the use of any form of milk fat or nonfat dry milk, and would allow the use of any form of butterfat or milk fat, including milk fat from whey proteins, delactosed whey, and de-mineralized whey.

7. Milk varies in composition and nutritional values. Therefore, depending on the attributes of the milk used, processing and capability of manufacturing procedures to produce a uniform product, temperature and duration of storage as well as other factors, ingredients obtained from milk vary in composition and nutritional values. Ingredients 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 sherbert vary depending on the ingredient or blend of ingredients used to fabricate a food meeting the minimum requirements of the applicable regulation. This would be so whether the minimum requirement of the current or the amended regulations were met.

9. The physical characteristics of ice cream, frozen custard, ice milk and sherbert include, but are not limited to, flavor, body, color, texture, appearance, freezing point, performance in the freezer, whippability, 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 (a) the asserted effect on the physical and nutritional characteristics of ice cream, frozen custard, ice milk and sherbert that would result from the amended regulations, (b) parameters of the new ingredients of milk-derived ingredients allowable under both the current and amended regulations for ice cream, frozen custard, ice milk and sherbert, (c) parameters of the nutritional value variations of ice cream, frozen custard, ice milk and sherbert.
made in accordance with the minimum requirements of the current and amended applicable regulations, (d) the feasible, practical and most commonly acceptable combinations or blends of nonfat milk solids and/or other milk-derived ingredients were used to fabricate ice cream, frozen custard, ice milk and sherbet meeting the applicable regulation, (e) nutritional value data and information specifically for calcium, phosphorus, zinc, sodium, protein, vitamins B₁₂, A, thiamine, riboflavin, and panthenic acid, and (f) any other pertinent data or information.

Upon receipt and review of 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. This objection is directly related to the objection discussed in III above. The use of the minimum 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 ingredients requirement of the amended regulations.

2. The minimum milk 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 the publication of the final regulations, 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 provided for a decrease in the milk solids content of ice milk when bulky flavors are added to the food in order to eliminate a manufacturing problem. Without this provision, in the production of ice milk with bulky flavors (nuts, macaroons, candies, etc.), an ice milk manufacturer must (a) formulate and process a different batch of ice milk mix for each variation in kind and quantity of bulky flavor used, or (b) formulate and process an ice milk mix high enough in milk solids so that in no case will the minimum milk solids requirement of the food not be met.

3. The current regulations for ice cream provide for a decrease in milk solids content when bulky flavors are added to characterize the food, and the amended regulation would make the ice milk and the ice cream standards uniform.

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 requests additional data and information about changes in 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 provisions of the amended regulation for ice milk are stayed.

VI. THE PROVISIONS FOR THE DECLARATION OF OPTIONAL INGREDIENTS ON THE LABEL OF ICE MILK § 135.140

The basis for this objection is an assumption that ingredients such as casein, caseinates, modified whey and “other milk-derived ingredients” would not have been declared as required in the amended regulation. 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 applicable provisions in the standards for ice milk and sherbet state that all of the optional ingredients used shall 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)(2) (skimmed milk, concentrated skimmed milk, reconstituted skimmed milk and nonfat dried milk), § 101.4(b)(4) (milk, concentrated milk, reconstituted milk and dry whole milk), § 101.4(b)(8) (cream, reconstituted cream, dried cream and plastic cream) and § 101.4(b)(9) (butteroil and anhydrous butterfat) are used they may be declared either in descending order of proportion or by the use of the term “milk fat and nonfat milk.” Since all ingredients in these standards are optional, all ingredients must be declared as set forth above. This would require that casein, 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
in the same ingredient categories as those listed in § 101.4(b) (1), (2), and (3) and (g) and (h), intentionally did not include them in the ingredients entitled to be declared as "milk fat and nonfat milk."

The Commissioner, therefore, concludes that the objection was based on a misunderstanding of the regulations and does not raise an issue of fact that warrants a hearing.

VII. 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 regulations.

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 since (a) this section is integral to the objection contained 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, the decision of the Commissioner deems essential to make a final decision on the merits of granting the 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 sherbet 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 (HFC-20), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, and identified with Docket No. 76P-0500.

Received data and information may be seen in the above office between 9 a.m. and 4 p.m. Monday through Friday.

PROVISIONS STAYED

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) (2) is stayed to the extent that it permits the use of safe and suitable milk-derived ingredients not specifically listed as permitted in former § 135.30 (c) and (e).

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 casein limitation requirements of paragraph (e) remain in effect. The provisions of former § 135.10 incorporating these requirements also remain in effect.

3. Section 135.120(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 permits the use of safe and suitable milk derived ingredients not specifically listed as permitted in former § 135.20 (c) and (e) (7) and former § 135.65 (c) and (e) (7).

Therefore, former § 135.20 (c) and (e) (7) and former § 135.65 (c) and (e) (7) remain in effect.

5. Section 135.140(a) (3) is stayed with respect to the provisions for "nonfat milk-derived 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, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))), and under authority delegated to the Commissioner (21 CFR 5.1), notice is given that objections raising substantial issues of fact which might require a hearing under section 701(e) of the act were received. Accordingly, except as to those provisions listed above as stayed, the effective date of §§ 135.3, 135.110, 135.120, 135.140 and 135.160 as published in the Federal Register of April 12, 1977 (42 FR 19127) is confirmed as follows:

Compliance with these regulations, in their entirety.

SUMMARY: This document corrects the section number of a final rule that was published in the Federal Register on Monday, May 10, 1977.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

John Richards, Federal Register Writer (HFC-11), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2084.

SUPPLEMENTARY INFORMATION:

In FR Doc. 77-13088 appearing at page 23772 in the Federal Register of Tuesday, May 10, 1977, on page 23772, in the center column, the preamble is corrected in the last paragraph by changing in the fourth line "§ 801.425 (21 CFR § 801.425) " to read "§ 801.427 (21 CFR § 801.427)," in the top of the right column at the end of paragraph "§ 801.425" is changed to read "§ 801.427;" on page 23777 in the center column, in the second line of the second full paragraph "§ 801.425" is changed to read "§ 801.427;" and on page 23780 in the center column, § 10.502 Intrauterine devices for human use 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:

§ 801.427 Professional and patient labeling for intrauterine contraceptive devices.

Dated: July 1, 1977.

WILLIAM F. RANDOLPH, Acting Associate Commissioner for Compliance.

In FR Doc. 77-19472, appearing at page 29939 in the issue for Friday, June 10, 1977, in § 555.116(a)(1) (ii), in the next to last line, the number now reading "No. 017039" should have read "No. 017030."

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 555—CHLORAMPHENICOL DRUGS FOR ANIMAL USE

Chloramphenicol Tablets

Correction

In FR Doc. 77-19472, appearing at page 29859 in the issue for Friday, June 10, 1977, in § 555.116(a)(1) (ii), in the next to last line, the number now reading "No. 017039" should have read "No. 017030."

[FR Doc. 77-19472 Filed 7-7-77; 8:45 am]

[FR Doc. 77-19432 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. 77-19472, appearing at page 29939 in the issue for Friday, June 10, 1977, in § 555.116(a)(1) (ii), in the next to last line, the number now reading "No. 017039" should have read "No. 017030."

[FR Doc. 77-19472 Filed 7-7-77; 8:45 am]

[FR Doc. 77-19432 Filed 7-7-77; 8:45 am]
RULES AND REGULATIONS

Effective July 8, 1977, 31 CFR 561.231 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 minimum 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 Operations 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.

FEDERAL REGISTER, VOL. 42, NO. 13—FRIDAY, JULY 8, 1977
SUMMARY: This amendment eliminates the June 30, 1977 deadline for use of the original version of the mobile home certification label. That deadline was established at the time the original language of the label was adopted. The amendment will permit the existing stack of labels to be exhausted.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

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 cost would be absorbed by 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 (PIPAs), 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 PIPA inventories after December 31, 1976. However, it now appears that some such labels, ordered before the January 12 rule, may have entered PIPA inventories as late as March 15, 1977.

Therefore, to assure that such labels need not be destroyed, and to avoid the cost of such destruction, the Department is changing the relevant rule. As of March 15, 1977, only labels containing the original language will be used. The Department believes that this amendment eliminates the economic and inflationary impacts of this amendment and is constructed 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 PIPAs as of March 15, 1977, are exhausted. After such inventories are exhausted, only labels containing the language stated above shall be used.


CORDER C. BARONE
Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection.

Title 32—National Defense
CHAPTER I—OFFICE OF SECRETARY OF DEFENSE
SUBCHAPTER F—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-
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 601.103), has been amended by the issuance of Transmittal Letter 24, dated June 10, 1977.

In accordance with 39 CFR 601.105 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 a cross-reference to new section 26.

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 FORMULARY ADVERTISING
2. Paragraph 2-203.3 has been revised to update the provisions on the place and method of delivery of supplies, and to aid in a cross-reference to new section 26.

SECTION 7—CONTRACT CLAUSES
3. Paragraph 7-203.3 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. Paragraph 26 has been revised to include the provisions 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


W. ALLEN SANDERS,  
Assistant General Counsel,  
Legislative Division.

[FR Doc.77-19465 Filed 7-7-77; 8:45 am]
D.C. 20460. Such objections should be submitted in quintuplicate and should specify both 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 grounds legally sufficient to justify the relief sought.

Part 180, Subpart D, § 180.1001 is amended by (1) revising the entry “Polyoxyethylated primary (C₈ -C₁₀) * * * in paragraph (d)” by amending the limits and (2) alphabetically inserting new items in paragraphs (c) and (d), to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

<table>
<thead>
<tr>
<th>Inert Ingredients</th>
<th>Limits</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monosodium phosphate</td>
<td>No more than 875 per by weight</td>
<td>Postharvest fumigation in formulation with aluminum phosphte.</td>
</tr>
<tr>
<td>Sodium alpha-olefin sulfonate (sodium (C₁₀-C₁₅) olefin sulfonate).</td>
<td>Surfactants, related adjuvants of surfactants.</td>
<td></td>
</tr>
</tbody>
</table>

(d) * * *

<table>
<thead>
<tr>
<th>Inert Ingredients</th>
<th>Limits</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha-sultan (C₈-C₁₀) omega-hydroxypropylene)</td>
<td>Surfactants, related adjuvants of surfactants.</td>
<td></td>
</tr>
<tr>
<td>Alkylation (polyoxypropylene-co-polymer; poly(oxyethylene) content is 11-15 mole; poly(oxypropylene) content is 1-5 mole).</td>
<td>When used as a colorant Coloring agent, pigment.</td>
<td></td>
</tr>
<tr>
<td>Polyvinylpyrrolidone (PVP)</td>
<td>Applied prior to planting Surfactant.</td>
<td></td>
</tr>
<tr>
<td>Polyoxyethylated primary amine (C₈-C₁₀), the fatty amine derived from an animal source and contains 3 pet water; the poly(oxyethylene) content averages 20 moles.</td>
<td>Placed in formulation. With aluminum phosphide.</td>
<td></td>
</tr>
</tbody>
</table>

[FR Doc.77-19372 Filed 7-7-77; 8:45 am]

SUBCHAPTER N—EFFLUENT LIMITATIONS AND GUIDANCE

PART 419—PETROLEUM REFINING POINT SOURCE CATEGORY PRETREATMENT STANDARDS FOR EXISTING SOURCES

Interim Final Rule; Extension of Comment Period

AGENCY: Environmental Protection Agency.

ACTION: Interim final rule.

SUMMARY: This action extends the deadline for the receipt of comments on the interim final rulemaking establishing pretreatment standards for existing sources for the petroleum refining point source category (42 FR 15664, March 23, 1977). The deadline is moved to August 15, 1977.

EFFECTIVE DATE: This extension becomes effective July 8, 1977.

FOR FURTHER INFORMATION CONTACT:


[FR Doc.77-19373 Filed 7-7-77; 8:45 am]

CHAPTER II—FEDERAL RAILROAD ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

PART 258—REGULATIONS GOVERNING SECTION 505 OF THE RAILROAD RETRIBUTION AND REGULATORY REFORM 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 for Monday, June 6, 1977, on page 28985, third column, in the first line of § 258.27(b) (1) (vi) 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, Car Utilization, Distribution, Rules and Practices

June 29, 1977.

AGENCY: Interstate Commerce Commission.

ACTION: Car service rule.

SUMMARY: This car service rule denies the petition of Construction Aggregate Rail Shippers Conference, Inc., to modify car service rules previously prescribed in this proceeding and to revise the endorsed adequacy of car ownership formula.


FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: Petitioner's proposal was designed to place the burden of car ownership and supply on the originating class I railroad; to expedite movement of freight cars back to the owning carrier's lines; and to give the freight car owner more control over the use of its cars by other railroads. The petition was denied on the grounds that petitioner had failed to provide a convincing argument for abandoning the present adequacy of freight car ownership formula which is based on the principal that freight car ownership is a joint duty of all carriers participating in interline movements, and that the restrictions on use permitted by the proposed car service rules could encourage empty mileage and result in less efficient utilization of the national fleet.
This document (order) also stated that no further action was contemplated with respect to the show cause order 346 I.C.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 directive 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 I.C.C. 284, in order that weaknesses in the prescribed car service rules and the car ownership formula might be exposed and corrected. The Commission reasoned that the rules and formula 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 and that the previous effect of the fleet adequacy reporting requirements imposed at 335 I.C.C. 309.

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 the same as a claim in accordance with the provisions of 49 CFR Part 1005 in the event the baggage is not recovered within 15 days after filing." The ten day period specified in the above-quoted phrase should have read "15 day period" so that, as corrected, paragraph (f)(1) reads as set forth below.

FOR FURTHER INFORMATION CONTACT:

Mr. Michael Erenberg, Assistant Deputy Director, Section of Operating Rights, Interstate Commerce Commission, 12th and Constitution Avenue NW., Washington, D.C. 20423 (202-275-7292).

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 upon which it 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 1005 in the event the baggage is not recovered within 15 days after filing.

* * *

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

[FR Doc. 77-19424 Filed 7-7-77; 8:45 am]

Title 10—Energy

PART 70—SPECIAL NUCLEAR MATERIAL

Export Requirement Exemption

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Final Rule.

SUMMARY: As a result of a request from the National Aeronautics and Space Administration to export special nuclear material to the Soviet Union for use in a joint space experiment, and in order to facilitate U.S. participation in international programs pursuant to intergovernmental cooperative agreements, NRC is amending its regulations to exempt U.S. government agencies from the requirements for an export license for small quantities of special nuclear material intended for use in U.S. Government sponsored or cooperative activities in foreign countries.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

Section 75.7 of the Atomic Energy Act, 42 U.S.C. 2092, authorizes the Commission to "exempt certain classes or quantities of special nuclear material or kinds of uses or users from the requirements for a license * * * when it makes a finding that the exemption * * * 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 0.65 gram of high-enriched 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. Under present regulations, the Commission is precluded from issuing an export license for this material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement material because there is no agreement
to section 123 of the Atomic Energy Act. Recently, another export by Energy Research Development Administration to the USSR of 2,400,000 liters of lactic acid 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 authority granted under sections 53, 54, and 57d. of the Act to facilitate United States participation in international programs pursuant to intergovernmental cooperative agreements.

In view of the urgency of the export proposed and the insignificant amounts of the material involved, and the international nature of the cooperative agreement under which this experiment and others will take place, the Commission has found that the customary 30-day notice of proposed rulemaking, and public hearings, are impracticable and unnecessary and good cause exists why 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 1974, as amended, and Sections 552 and 553 of Title 5, the United States Code, the amendments to Title 10, Chapter 1, Code of Federal Regulations, Part 70 is published as an amendment subject to codification and effective.

A new § 70.15 is added to read as follows:

§ 70.15 Intergovernmental cooperative activities.

Any United States Government agency is exempt from the regulations in this part and from the requirements for a 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 United States 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.


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

For the U.S. Nuclear Regulatory Commission.

SAML. J. CHILK.
Secretary of the Commission.

FR Doc. 77-19528 Filed 7-7-77; 8:45 am}

---

**RULES AND REGULATIONS**

**CHAPTER II—FEDERAL ENERGY ADMINISTRATION**

**PART 211—MANDATORY PETROLEUM ALLOCATION REGULATIONS**

**PART 212—MANDATORY PETROLEUM PRICE REGULATIONS**

**Treatment of Separate Reservoirs as Stripper Well Properties**

**AGENCY:** Federal Energy Administration.

**ACTION:** Ruling.

**SUMMARY:** The appended Ruling is issued by the Federal Energy Administration ("FEA") Office of General Counsel pursuant to 10 CFR 203.150 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 with the Office of General Counsel pursuant to the provisions of 10 CFR 203.183.

**DATES:** Not applicable.

**FOR FURTHER INFORMATION CONTACT:**


Denis M. Moore (Office of General Counsel), 12th and Pennsylvania Avenue, NW., Room 7132, Washington, D.C. 20461, (202) 568-2885.


**ERIE J. FYE,**

**Acting General Counsel,**

**Federal Energy Administration.**

---

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 distinct producing 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 governmental regulatory authority, and where production has been consistently and historically reported as such. The amended definition of "property" now requires producers to provide more realistic incentives under the two-tier price system over the longer term of prices controls on domestic crude oil. See 41 F.R 36172, August 26, 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 1975-15, 46 FR 40829, September 4, 1975.)

Subsequent to issuance of the amended definition of property, FEA received comments addressed to certain issues raised by the amendment (as well as other issues not relevant to this Ruling). FEA responded in "FEA Ruling 1977-3" (42 FR 4409, January 25, 1977). In "Ruling 1977-2," FEA determined that, with respect to separate reservoirs, a separate 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 exercised the option to treat such reservoirs as separate stripper well properties."

FEA also determined in "Ruling 1977-2" that, subject to certain exceptions not relevant in the context of this Ruling, once a producer has exercised the option to treat such reservoirs as separate properties, the producer of those separate reservoirs as a single property.

This Ruling is addressed only to those producers to whom FEA has issued a determination that has enabled them to retain revenues obtained as a result of improperly treated such separate reservoirs as stripper well properties. This producer of such separate reservoirs as a single property. Since the issuance of "Ruling 1977-2," FEA has learned that, with respect to certain properties, some producers elected to designate single properties as two or more separate reservoir-properties and, thereby to treat these producers to be placed in the same position that would have been otherwise permitted under the price regulations. Accordingly, FEA will permit to retain revenues obtained as a result of improper treatment of such a reservoir as a stripper well property.

**DISCUSSION**

Since the issuance of "Ruling 1977-2," FEA has learned that, with respect to certain properties, some producers elected to designate single properties as two or more separate reservoir-properties and, thereby to treat these producers to be placed in the same position that would have been otherwise permitted under the price regulations. Accordingly, FEA will permit to retain revenues obtained as a result of improper treatment of such a reservoir as a stripper well property. However, because of the restrictions contained in "Ruling 1977-2" which generally prohibit the redefinition of any two more separate reservoir-properties from being treated as a single property, these latter producers would be permitted to produce and sell greater quantities of new crude oil than previously permitted under the price regulations had they not erroneously treated such separate reservoirs as stripper well properties. In no case, however, will a producer be permitted to retain revenues obtained as a result of improper treatment of such a reservoir as a stripper well property.
EXAMPLE I

Facts. Producer X elected to treat a single property as three separate properties effective October 1, 1976, based upon the recognition by FEA that appropriate governmental regulatory authority of three separate reservoirs underlying the property. However, Producer X's decision to treat the separate properties as separate properties was based solely upon the mistaken assumption 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 reservoir properties than would have been produced and sold had Producer X continued to treat the single property as a PEA property. For the months of October 1976 through January 1977, Producer X elected to treat the three reservoirs as separate properties subject to the same right to produce crude oil as stripper well properties. However, as in Example I, the mistaken assumption that Reservoir A could be classified as a stripper well property was the basis for Producer X's decision to treat the three reservoirs as separate properties. For the months of October 1976 through January 1977, each separate reservoir was treated as a separate property. Where such mistake was not corrected within the appropriate time for the election to separate separate reservoirs, the aggregate volumes of new crude oil produced for the months of October 1976 through January 1977 will not include the volumes excluded by FEA in Example I. Accordingly, any revenues obtained by Producer X as a result of the mistaken assumption that Reservoir A could be classified as a stripper well property shall be returned to the purchaser of such volumes. FEA will not require any additional refunds, subject to the offsets provided for in Example I.

EXAMPLE II

Facts. Producer Y elected to treat a single property as three separate properties effective October 1, 1976, because to do so would have resulted in lower volumes of new crude oil produced and sold from the single property as stripper well properties. However, Producer Y's mistaken assumption that Reservoirs B and C could be classified as stripper well properties was the basis for Producer Y's decision to treat the single property as three separate properties. For the months of October 1976 through January 1977, Producer Y elected to treat the three reservoirs as separate properties subject to the same right to produce crude oil as stripper well properties. Where such mistake was not corrected within the appropriate time for the election to separate separate reservoirs, the aggregate volumes of new crude oil produced for the months of October 1976 through January 1977 will not include the volumes excluded by FEA in Example II. Accordingly, any revenues obtained by Producer Y as a result of the mistaken assumption that Reservoirs B and C could be classified as stripper well properties shall be returned to the purchaser of such volumes. FEA will not require any additional refunds, subject to the offsets provided for in Example II.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
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 have invested additional funds which cannot be recovered, even by the recertification permitted by this Ruling, FEA will consider relief, on a case-by-case basis through the FEA Office of Exceptions and Appeals, on grounds of gross inequity or serious hardship.

Reinstitution of Supplier/Purchaser Relationships

In situations similar to one of the examples above, a producer may have erroneously certified production from one or more reservoirs 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) (ii) or (iii). 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 § 211.63 would require prompt reinstatement of the supplier/purchaser relationship with the original purchaser.


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

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

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 to assist the establishment or operation of State offices of 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:

1. Introduction.

2. Statutory Requirements.

3. Eligible Consumer Groups.

4. Allowable Expenditures.

5. Minimum Program Requirements.

C. Application.

D. Selection of Grantees.

E. 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) (Public Law 94-163, 83 Stat. 1125 et seq., 42 U.S.C. 6801 et seq.)

The purpose of this program is to establish or operate a State office of consumer services (Office) to support consumer representation in proceedings before an electric utility regulatory commission (Commission). A consumer, for the purpose of the guidelines, is any 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 fund programs in a limited number of States if each grantee is to have a reasonable probability of providing effective assistance for consumers.

On May 16, 1977, FEA published an advance notice of program guidelines (Advance notice), 42 FR 24768, which described the program for State Offices being developed by FEA and solicited comments from interested persons. FEA received and considered thirty-nine 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 requirement of publishing a proposed rule, FEA is publishing this final rule because it considers that consumer interests will best be served by making grants to programs 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 Issues Raised by Intervenor Requests for Financial Assistance in NRC Proceedings," prepared by Beasberg, Hewes, Kiores and Kass ("The Board Report"); 1976; Federal Regulation and Regulatory Reform, Report by the Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce ("Committee Report") (1976); Crampton, "The Why, 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 1973," 16 William and Mary L. Rev. 215 (1975); Note, "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 make general factual assessments of the impacts of proposed electric utility rate changes and other proposed regulatory actions upon consumers; (B) to provide technical or financial assistance to eligible consumer groups in the decisions, administrative findings and determinations and executive orders and proclamations, as enforced by the State and its judicial system. This provision negates any implication that FEA requires specific legislative or executive act for reimbursement by intervenors in agency proceedings in the absence of a statutory or group has a sufficiently strong 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 participation by selling or taking out additional mortgages on their houses. Accordingly, a further purpose served by the reasonably obtainable test is to ensure that an applicant does not have to 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 provided from looking behind a consumer group to inquire into the wealth of its individual members regardless of whether the group is incorporated or an 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 participation are small in relation to the social, economic or environmental consequences for consumers of the outcome of the proceeding. In this situation, if the costs of participation for consumers are exceptionally important, 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 initial outlay (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 by achieving specific rate reductions for all consumers or altering the regulatory process or technical assistance irrespective of the extent of its financial resources. Where the cumulative consequences of the decisionmaking process. Thus, the necessity of consumer participation will provide a commission with access to the information it needs to identify and evaluate accurately and impartially the costs and benefits of substantive changes at 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. 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 required a consumer group to demonstrate that it lacked sufficient resources, whereas the guidelines require that the result only that 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 concluded for the facts that a group of consumers who own or have equity in their homes are ineligible for assistance on the theory that the consumers could obtain similar or additional assistance through their participation by selling or taking out additional mortgages on their houses. FEA did not propose a class action standard. Under this class action test, a Federal agency has implied authority to allow reimbursement to a consumer group as a necessary ancillary function of carrying out a regulatory or program. The necessity test appears unenforceable in light of Section 2903(a) statutory directive to encourage consumer participation.

For this reason, § 460.14 provides more flexible standards. FEA has decided to use a “fairness test.” This requires that a consumer group present a consumer interest, the representation of which would substantially contribute to a full and fair determination of the issues to be considered in the proceedings. FEA is convinced that the guidelines to decide class is reimbursement by intervenors in agency proceedings in the absence of a statutory directive authorizing broad consumer participation. Under the necessity test, an Office could not delegate the authority to allow reimbursement to a consumer group as a necessary ancillary function of carrying out a regulatory program. The necessity test appears unenforceable in light of Section 2903(a) statutory directive to encourage consumer participation.

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

The guidelines now permit a consumer group to inquire into the wealth of its individual members regardless of whether the group is incorporated or an ad hoc association.
allowing an Office to rely on outside experts on occasion, it should not propose. Another comment stated the contrary view that the 45 percent ceiling on expenditures incurred in hiring experts and consultants should be raised substantially. FEA considers that the 45 percent limit, which is provided in § 460.13(a) (3) is appropriate. It further the twin goals of an Office’s long term viability and improving its own expertise and operational capacity, and at the same time ensuring that it has access to additional manpower and expertise when needed for the effective performance of 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) (4). An Office’s 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 is authorized to make for attorneys’ and experts’ fees and other reasonable expenses incurred in participating in agency proceedings; and law review articles and Congressional committee reports considering the circumstances in which a party is or should be entitled to recover its costs of representation in administrative and judicial proceedings.

The ceilings on allowable expenditures for attorneys’ and experts’ fees and other out-of-pocket expenses adopted by the guidelines are intended to strike a balance. On the one hand, a substantial number of large eligible consumer groups will be able to receive financial assistance and, on the other, allowances are provided that are realistic in light of prevailing market rates for, and costs of, services necessary to a consumer group’s effective participation.

5. Minimum Program Requirements—FEA has established minimum program requirements in § 460.12(a) which call for compliance with the statutory requirements of the Act. In § 460.12(b), FEA has prescribed minimum program requirements for which a State must provide procedures. To comply with these requirements an Office must conceptualize its program for assisting consumers by developing procedures that are essential to its effective operation. A grantee or Office shall establish and publish these procedures within either six months of the date on which the requirements of § 460.12(a) are met, whichever occurs later. FEA may grant an extension of time to a grantee upon application, for good cause shown.

An Office must develop all of the enumerated procedures, regardless of whether they pertain to a function proposed for an Office in its application, because FEA believes that in the long run, an Office should have the capability to carry out all three functions. To be viable, an Office needs to be able to perform analyses, intervene in proceedings on its own behalf and assist eligible consumer groups. Only in this way will an Office be able to discharge fully its obligation to act effectively on behalf of consumers.

FEA received thirteen comments on the issue of whether or not an Office should be required to establish priorities among eligible consumer groups. Six comments objected to this requirement. Some comments endorsed the concept of priorities and suggested a variety of criteria upon which these priorities should be based. Two comments suggested that proven competence and experience in representing utility regulatory matters and making presentations to this commission would be the critical requirements. Two comments stated that the financial need and age of the consumer group were the most significant factors. Another comment suggested giving priority to certain classes of consumers such as residential users of electricity and to certain types of groups such as environmental, civic, or nonprofit organizations. The final comment focused on such factors as the group’s size, the importance of the interest it represented, and the amount of the expense incurred by an electric utility that would be at issue in the proceeding.

In § 460.12(b) (3), the guidelines provide criteria that an Office shall consider in establishing among eligible consumer groups but that also allow considerable latitude for each grantee to establish its own requirements. In general, the guidelines do not impose upon the grantee the criteria that will ensure that an Office will provide assistance to groups that represent large numbers of consumers with a substantial aggregate interest in the outcome of a particular proceeding. The criteria are also intended to ensure that direct assistance will be furnished to groups that are capable of effectively representing a consumer interest by presenting well-reasoned, well-organized testimony. At the same time, FEA has included as a consideration the uniqueness or novelty of a consumer group’s position, in order not to preclude an Office from assisting well-qualified advocates of unconventional and innovative approaches.

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

B. APPLICATIONS

Application procedures are set forth in § 460.11. To be eligible for a grant, a State must designate an Office to be administered by 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 statement of task sequence and a timetable. The application also shall include an analysis of how the proposed budget for the Office exceeds by the amount 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 is greater, to perform functions similar to those to be conducted for this program. A State must also provide information concerning any 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 GRANTEES

Grantees will be selected on the basis of FEA's evaluation of their applications through the use of the rating system set forth in § 460.13. An application may receive up to 100 points for the feasibility and quality of the proposed Office, taking into account the overall conceptualization of the proposal and the feasibility of its implementation. An application may receive up to 50 points for a State's demonstration of its need for an Office. Of this, up to 25 points will be awarded on the basis of the magnitude of need demonstrated with respect to the information provided in response to Section 460.12. The remaining 25 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 where the costs to consumers for a KWH of electricity are already high or likely to increase sharply; second, the percentage of per capita income of a State's residential consumers spent for electricity 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 uses natural gas to generate electricity, as an indication of where consumers are likely to experience sharp increases in the price of electricity due to increases in the price of natural gas or conversion to other electricity generating sources.

FEA has selected these three factors as ones which will provide comparable information concerning the current and anticipated electricity price and supply characteristics in each State. FEA already has the data needed to perform the analyses of these factors.

D. TERMINATION OF GRANTS

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

5. Environmental and Inflationary Reviews.

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 shall be submitted to 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 11821 and OMB Circular A-107, issued November 27, 1974, and has been determined not to be a major regulatory action involving an evaluation of its inflationary impact.


ERIC J. FYI
Acting General Counsel
Federal Energy Administration


Person" means an individual, partnership, corporation, unincorporated association, social security number, any other group, entity or organization.

"Proceeding" means a proceeding before a utility regulatory commission.

"State" means a State, the District of Columbia, 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 for the control, 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 a body of the authority, functions, organization, activities, budget and financial resources of a Consumer-Interest Office established in accordance with § 460.15, for the establishment or operation of an Office.

§ 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 on the basis of the evaluation made in accordance with § 460.11, for the establishment or operation of an Office.

§ 460.11 Applications.

(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 this regulation 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 a Consumer-Interest Office operating within the State;

(4) An assurance that the final proposed budget for the Office exceeds, by the amount of the grant award, the amount expended by the State, if any, in the prior fiscal year; and

§ 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—
(i) make general factual assessments of rate changes and other proposed regulatory actions upon consumers, including residential consumers;
(ii) provide technical or financial assistance to an eligible consumer group, including residential consumers, taking into account developments in electric utility rate design reform; and
(iii) advocate, on its own behalf, a position which it determines represents the position most advantageous to consumers, including residential consumers, taking into account developments in electric utility rate design reform; and
(iv) is independent of a commission with respect to the following—
(I) the Commission has no direct control over the Office's budget or its disbursement of funds;
(II) the Commission has no authority over the hiring, management, or dismissal of the personnel employed by an Office; and
(III) employees of the Office do not perform services for, report to, or act on behalf of, the commission.

(b) 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 FPA 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, including 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—
(i) consumer interests;
(ii) the composition, diversity and number of members of an eligible consumer group;
(iii) the relative effectiveness of an eligible consumer group's proposed presentation including the extent to which—
(A) the eligible consumer group is familiar with and understands the subject matter and issues involved in the proceeding;
(B) its proposed presentation is feasible and well-conceived; and
(C) the eligible consumer group can effectively represent a consumer interest in a proceeding;
(D) the uniqueness or novelty of an eligible consumer group's position or point of view; and
(E) 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 or consumer advisory committee, to ensure that the Office obtains and considers the broadest possible spectrum of consumer views;
(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) developing consumer groups and advising them with information concerning this program and its operation.

(c) After complying with the requirements of paragraph (b) of this section, an Office shall carry out activities for the functions prescribed in § 460.12(a)(1) or (a)(2) (i) or (ii). FPA may upon application by a grantee or Office and for good cause shown extend the time limit set forth in this section. (3) No more than 45 percent may be paid for the services of consultants, providers of personal services in which the consultant including employment by a corporation, partnership, consortium or other business enterprise engaged in performing personal services in which the consultant has a financial interest which is equal to or exceeds 10 percent.
(4) Any person which employs or otherwise uses the personal services of the consultant including employment by a corporation, partnership, consortium or other business enterprise engaged in performing personal services in which the consultant is an officer or director, partner or active principal, and
(5) Any business entity including a corporation, partnership, consortium or other business enterprise engaged in providing personal services in which the consultant participates in a profit-sharing program.
§ 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—
(1) Compensation of employees of the Office;
(2) 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;
(3) 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
(4) No more than 20 percent may be paid to contractors for the use of computers and similar equipment for the storage and analysis of data;
(5) Payments to sub-grantees to carry out the functions described in § 460.12(a) (2) (i) or (ii) 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;
(6) Payments to a consultant by an Office or sub-grantee shall not exceed the prevailing market rate for the level and quality of personal service but not to exceed 75 dollars per hour exclusive of reasonable costs for travel and incidental disbursements such as mailing and photocopying; and
(7) 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.
(b) No grant funds shall be expended until a State has established an Office which meets the requirements of § 460.12.
(c) For the purposes of paragraph (a) (3) of this section, a consultant shall include—
Any person which employs or otherwise uses the personal services of the consultant involving employment by a corporation, partnership, sole proprietorship, or other business enterprise engaged in performing personal services;
(2) Any person in which the consultant owns 10 percent or more of the stock, including options to purchase stock, or other securities issued by a corporation or any person engaged in performing personal services in which the consultant has a financial interest which is equal to or exceeds 10 percent;
(3) Any person, such as a parent company or affiliate, which owns 10 percent or more of the stock, including options to purchase stock, of the consultant, or other securities issued by the consultant;
(4) Any person engaging in activities which are of the same kind in the consultant which is equal to or exceeds 10 percent;
(5) Any business entity engaged in performing personal services including a corporation, partnership, consortium or other business enterprise in which the consultant is an officer, director, partner or active principal, and
(6) Any business entity including a corporation, partnership, consortium or other business enterprise engaged in providing personal services in which the consultant participates in a profit-sharing program.
§ 460.14 Eligible consumer group.
No consumer group shall receive financial or technical assistance from an Office unless—
(a) The consumer group's—
(1) Representation of a consumer interest would substantially contribute to a full and fair determination of the issues to be considered in the proceeding; and
(2) Participation in the proceeding is necessary to the effective representation of the consumer interest; and
(3) The consumer interest would not be effectively represented because—
(i) The consumer group does not have reasonably available and cannot reasonably obtain sufficient resources to participate effectively in the proceeding; or
(ii) 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
(iii) 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) FPA 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 up to
50 points may be scored for the quality of the proposed Office and up to 50 points may be scored for a State's need to establish and operate an Office.

(b) FEA shall evaluate the quality of a proposed Office on the basis of its conceptualization and the feasibility of its implementation taking into account—

(1) The precision with which goals and objectives for the Office are defined;

(2) Whether the activities proposed for the Office will effectively carry out the functions selected in accordance with §460.11(b)(5);

(3) The responsibilities, experience and competence of the key personnel and consultants proposed for the Office;

(4) The organizational structure of the Office including the extent of coordination proposed between the Office and other parts of the State government representing consumers or regulating electric utilities;

(5) The feasibility of the Office’s complying with the requirements of §460.12;

(6) The task sequence for activities and the likelihood that an Office can meet the schedule of the proposed timetable as required by §460.11(b)(10); and

(7) The adequacy of the budget required by §460.11(b)(7) in relationship to the proposed activities.

(c) FEA shall evaluate a State’s need for an Office based upon—

(i) The average revenue per KWH calculated for all electric utilities within the State;

(ii) The percentage of per capita income of residential consumers within the State which is spent for electricity for residential use; and

(iii) The extent to which the State uses natural gas to generate electricity.

§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 by each grantee and sub-grantee of the 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, after consideration of any response filed by the grantee, the Administrator shall determine whether or not to terminate the grant for failure 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 rule making 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 of 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 undenatured, 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 undenatured, 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.

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.

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, (Office of General Counsel), Federal Energy Administration, 12th and Pennsylvania Avenue, NW., Room 5138, Washington, D.C. 20461, 202-566-9567 or 566-2085.

SUPPLEMENTARY INFORMATION:
On May 26, 1977, FEA issued a Further Notice of Proposed Rulemaking and Public Hearing on the post-exemption monitoring of middle distillate prices (42 FR 27937, 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 past 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 30627, 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. FYOI, Acting General Counsel, Federal Energy Administration.

[10 CFR Part 430]
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


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 30633 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.

Ezra J. Pazer,
Acting General Counsel,
Federal Energy Administration.

Section 4.3.2 of Appendix I is deleted and sections 4.1.4, 4.2.1.2, 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-heating energy consumption of a basic model. Calculate the conventional oven annual self-heating energy consumption, Eo, as set forth below.

For conventional gas ovens:

\[ E_o = \frac{E_{t} + E_{i}}{S} \times C \]

where

- \( E_{t} \) = Energy consumption in cubic feet of gas per oven tested according to 3.2.1.
- \( E_{i} \) = Electrical energy consumed by an ignition device for the self-heating operation of a conventional gas oven.
- \( S \) = Conversion factor of watt-hours to Btu's (3.412 Btu/Watt-hour).
- \( C \) = Conversion factor of cubic feet to standard cubic feet.

4.1.5 Microwave oven annual self-heating energy consumption of a basic model. Calculate the microwave oven annual self-heating energy consumption, Epm, as set forth below.

\[ E_{pm} = \frac{E_{t} \times C_{m}}{S_{m}} \times C \]

where

- \( E_{t} \) = Energy consumption in cubic feet of gas per oven tested according to 3.2.1.
- \( C_{m} \) = Conversion factor of microwatts to Btu's (0.0002765 Btu/microwatt).
- \( S_{m} \) = Conversion factor of cubic feet to standard cubic feet.
- \( C \) = Conversion factor of cubic feet to standard cubic feet.

4.5.3 Specific microwave efficiency. Calculate the specific microwave efficiency, \( e_i \), for each test load (i), and defined as

\[ e_i = \frac{E_{pm} \times S_{m} \times C_{m}}{E_{t} \times C_{m}} \]

where

- \( E_{pm} \) = Specific microwave power out as defined in 3.2.2.
- \( S_{m} \) = Measured weight of the test block according to 3.3.2, in pounds.
- \( C_{m} \) = Specific heat of aluminum, 0.21 Btu/lb\(^\circ\)F.
- \( C \) = Conversion factor of microwatts to Btu's (0.0002765 Btu/microwatt).
- \( E_{t} \) = Energy consumption in cubic feet of gas per oven tested according to 3.2.1.

4.5.4 Specific microwave efficiency. Calculate the specific microwave efficiency, \( e_i \), for each test load (i), and defined as

\[ e_i = \frac{E_{pm} \times S_{m} \times C_{m}}{E_{t} \times C_{m}} \]

where

- \( E_{pm} \) = Specific microwave power out as defined in 3.2.2.
- \( S_{m} \) = Measured weight of the test block according to 3.3.2, in pounds.
- \( C_{m} \) = Specific heat of aluminum, 0.21 Btu/lb\(^\circ\)F.
- \( C \) = Conversion factor of microwatts to Btu's (0.0002765 Btu/microwatt).
- \( E_{t} \) = Energy consumption in cubic feet of gas per oven tested according to 3.2.1.

PROPOSED RULES

SUPPLEMENTARY INFORMATION: On June 22, 1973, the EPA published in the Federal Register (38 FR 16148) a notice that the United States Department of the Interior (USDI), Bureau of Reclamation, Washington, D.C. 20240, had submitted a petition (FAP 3H5030). This petition proposed that 21 CFR 193 be amended by the 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 to sodium-magnesium salt mixtures to irrigate, control, and fertilize rice fields.

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. The petition is in accordance with the label and labeling requirements of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (58 Stat. 1973, 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 rod-feeding study, and a rat teratology study. An adequate analytical method (gas chromatography) is available to enforce the proposed tolerance. Tolerance, however, has not been established for residues of dalapon from 75 ppm to 0.1 ppm (negligible residue) on a wide variety of crops and the data are not adequate to establish tolerances for residues of dalapon in or on a variety of crops and crop groupings appears elsewhere in this 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 this document. Thereby 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 Insecticide, Fungicide, 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 bear a notation indicating both the subject and the petition/document control number, "FAP3H5030/P7." 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. CAMPT
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) 881-2554.

SUPPLEMENTARY INFORMATION: On December 21, 1976, John Quarles, Acting Administrator of EPA, issued compliance date extensions (41 FR 55189) to the Savannah Electric and Power Company's Port Wentworth Generating Station for Units 1, 2, and 3. 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 control equipment 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 (vi) of § 55.570(a)(1) to read as follows:

Subpart L—Georgia

§ 55.570 Compliance date extensions.

(a) * * *

(1) * * *

(iii) August 1, 1977. Initiate site preparation toward 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.

(v) 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.

(vi) October 15, 1978 (Unit 1), November 15, 1978 (Unit 2), December 31, 1978 (Unit 3). Complete shakedown 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.

Dated: June 29, 1977.

John A. Little, Acting Regional Administrator.

[FR Doc. 77-19422 Filed 7-7-77; 8:45 am]

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

Proposed Amendment to Tolerance Regulation for Pesticide Chemical Naed

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

SUMMARY: This notice proposes that established tolerances for naldex 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 8, 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 reformulating the pesticide tolerance for naldex 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) § 180.215 be reformatted, (2) § 180.319 be amended to correct an error in the regulations, and (3) § 180.215 be amended to update the record.
In June 1974, the Agency amended 40 CFR 180.215 in response to a petition (1P1078) filed by Chevron Chemical Company, 94804 Interim tolerances for naled residues in or on certain raw agricultural commodities were established pending review and completion of toxicity data for naled. A petition for a permanent tolerance for naled was submitted to the Agency. In addition, the petition submitted by Chevron also included a proposal for a permanent tolerance for residues of naled in or on soybeans, which was 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 2423) by establishing permanent tolerances for residues of naled in or on the raw agricultural commodities beans (succulent) and peas (succulent) at 0.5 parts per million.

On January 29, 1975, the Agency amended 40 CFR 180.215 (40 FR 4273) in response to two petitions (PP0F00975 and PP1F111) also filed by Chevron Chemical Company. Permanent tolerances established for all remaining interim tolerances found in Section 180.319. However, amendments to 40 CFR 180-319 were once again overlooked. This rule 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 use of the pesticide for area pest (mosquito and fly) control. To make the minimum tolerance uniform for all uses of naled on growing crops, regardless which registered use of naled causes such residues, the established tolerances for almonds (hulls) and almonds (nuts) are being increased from 0.05 to 0.5 ppm to permit the use of the insecticide naled (1,2-dibromo-2, 2-dichlorovinyl 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 (succulent)</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>1</td>
</tr>
<tr>
<td>Brussels sprouts</td>
<td>1</td>
</tr>
<tr>
<td>Cabbage</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>0.5</td>
</tr>
<tr>
<td>Celery</td>
<td>3</td>
</tr>
<tr>
<td>Collards</td>
<td>3</td>
</tr>
<tr>
<td>Cucumber</td>
<td>0.5</td>
</tr>
<tr>
<td>Cucumbers</td>
<td>0.5</td>
</tr>
<tr>
<td>Eggplant</td>
<td>0.05</td>
</tr>
<tr>
<td>Eggs</td>
<td>0.05</td>
</tr>
<tr>
<td>Goats, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Goats, mbyp</td>
<td>0.05</td>
</tr>
<tr>
<td>Goats, meal</td>
<td>0.05</td>
</tr>
<tr>
<td>Grapefruit</td>
<td>3</td>
</tr>
<tr>
<td>Grapes</td>
<td>10</td>
</tr>
<tr>
<td>Grasses, forage</td>
<td>1</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>0.05</td>
</tr>
<tr>
<td>Horses, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Horses, mbyp</td>
<td>0.05</td>
</tr>
<tr>
<td>Horses, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Kale</td>
<td>3</td>
</tr>
<tr>
<td>Lemons</td>
<td>1</td>
</tr>
<tr>
<td>Lettuce</td>
<td>1</td>
</tr>
<tr>
<td>Melons</td>
<td>0.5</td>
</tr>
<tr>
<td>Mushrooms</td>
<td>0.05</td>
</tr>
<tr>
<td>Oranges</td>
<td>3</td>
</tr>
<tr>
<td>Peaches, fresh</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>0.65</td>
</tr>
</tbody>
</table>

Tolerances are established for residues of naled at 0.05 ppm for eggs, milk, and the fat, meat, and meat byproducts of livestock and poultry with respect to 40 CFR 180.6, 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 naled in or on raw agricultural commodities such as oranges, spinach, and turnips at 3 ppm, the negligible residue designator "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 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 along with copies of the petition submitted to facilitate the work of the Agency and of others interested in inspecting them. The comments should be a notation indicating the subject and document control number "CP(1078)". 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. Camp, 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-dibromo-2, 2-dichlorovinyl 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>Poultry, mbyp</td>
<td>0.05</td>
</tr>
<tr>
<td>Poultry, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Pigeons, mbyp</td>
<td>0.05</td>
</tr>
<tr>
<td>Rice</td>
<td>0.5</td>
</tr>
<tr>
<td>Saltwater, seed</td>
<td>0.5</td>
</tr>
<tr>
<td>Sheep, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Sheep, mbyp</td>
<td>0.05</td>
</tr>
<tr>
<td>Sheep, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Spinach</td>
<td>3</td>
</tr>
<tr>
<td>Squash</td>
<td>0.5</td>
</tr>
<tr>
<td>Squash, winter</td>
<td>0.5</td>
</tr>
<tr>
<td>Strawberries</td>
<td>3</td>
</tr>
<tr>
<td>Swiss chard</td>
<td>3</td>
</tr>
<tr>
<td>Tangerines</td>
<td>3</td>
</tr>
<tr>
<td>Tomatoes</td>
<td>0.5</td>
</tr>
<tr>
<td>Turnips, tops</td>
<td>3</td>
</tr>
<tr>
<td>Walnuts</td>
<td>0.5</td>
</tr>
</tbody>
</table>

A tolerance of 0.5 part per million is established for the pesticide naled in or on all raw agricultural commodities, except those otherwise listed in this section, from 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 naled and corresponding tabular material from the regulation.

[FR Doc.77-19415 Filed 7-7-77; 8:45 am]

[40 CFR Part 180 ]

PP321698 (PPS: PRL 788-81)

PESTICIDE PROGRAMS

Tolerances and Exemptions from 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 raw agricultural commodities. This proposal was submitted by the U.S. Department of the Interior. The 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 Critpichio, Registration Division (WH-569), Office of Pesticide Programs, EPA, (202-765-2516).

SUPPLEMENTARY INFORMATION:

The United States Department of the Interior (USDI), Bureau of Reclamation, Washington, DC 20440, has submitted a pesticide petition (PP 321698) to the EPA. This petition requests that the Administrator, pursuant to section 408(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 western United States, in programs of the USDI 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, and seed and pod vegetables 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.

The data submitted in the petition and all other relevant material having been evaluated, it has been concluded that the tolerances established by amending 40 CFR 180.150 will protect the public health. The toxicological data considered in support of the proposed tolerances 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 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 since long-term feeding studies are now available. Existing tolerances are adequate to cover residues which may result in the feed or meat and poultry consumed in 40 CFR 180 6(a)(2). (A related document proposing the establishment of a food additive tolerance for residues of dalapon in potable water appears under 21 CFR Part 186 in this Federal Register.) The EPA proposes, therefore, that the tolerances be established 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 the rulemaking as described in 40 CFR 180 6(a)(2) be revised. The EPA proposes that the rulemaking 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 to the Federal Register Section, Technical Services Division (WH-369), Office of Pesticide Programs, EPA, 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 of others interested in inspecting them. The comments must be received on or before August 8, 1977. And should bear a notation indicating both the subject and the petition/document control number, "FP3E1383/43". 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. CAMP, Acting Director, Registration Division.

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

It is proposed that Part 180, Subpart C, Section 180.150 be revised (1) by designating the existing tolerances as paragraph (a), (2) by deleting the negligible residue designation ("N"), (3) by establishing the new paragraph (b) containing tolerances for residues of dalapon resulting from application of dalapon sodium magnesium salt mixtures to irrigation ditch banks in the western United States in programs of the USDI Bureau of Reclamation, and (4) 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 magnesium salt mixtures to irrigation ditch banks in the western United States, in programs of the USDI Bureau of Reclamation, and on the following raw agricultural commodities:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almonds</td>
<td>10.0</td>
</tr>
<tr>
<td>Almonds, hulls</td>
<td>50.0</td>
</tr>
<tr>
<td>Apples</td>
<td>5.0</td>
</tr>
<tr>
<td>Asparagus</td>
<td>30.0</td>
</tr>
<tr>
<td>Bananas</td>
<td>5.0</td>
</tr>
<tr>
<td>Beans</td>
<td>5.0</td>
</tr>
<tr>
<td>Beans, straw</td>
<td>1.0</td>
</tr>
<tr>
<td>Beets, sugar (roots)</td>
<td>5.0</td>
</tr>
<tr>
<td>Beets, sugar (tops)</td>
<td>5.0</td>
</tr>
<tr>
<td>Cattle, mbyp</td>
<td>2.0</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, car. dried</td>
<td>10.0</td>
</tr>
<tr>
<td>Corn, fodder</td>
<td>5.0</td>
</tr>
<tr>
<td>Corn, forage</td>
<td>5.0</td>
</tr>
<tr>
<td>Cottonseed</td>
<td>5.0</td>
</tr>
<tr>
<td>Cotton, ginned</td>
<td>5.0</td>
</tr>
<tr>
<td>Cucurbita fresh</td>
<td>(including sweet</td>
</tr>
<tr>
<td>K &amp; CWHR)</td>
<td></td>
</tr>
<tr>
<td>Corn, grain</td>
<td>10.0</td>
</tr>
<tr>
<td>Cottonseed</td>
<td>35.0</td>
</tr>
<tr>
<td>Grapes, seed</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, mbyp</td>
<td>5.0</td>
</tr>
<tr>
<td>Goats, meat</td>
<td>2.0</td>
</tr>
<tr>
<td>Grapefruit</td>
<td>5.0</td>
</tr>
<tr>
<td>Grapes</td>
<td>3.0</td>
</tr>
<tr>
<td>Grapes, seed</td>
<td>5.0</td>
</tr>
<tr>
<td>Grasses, range</td>
<td>10.0</td>
</tr>
<tr>
<td>Hogs, mbyp</td>
<td>2.0</td>
</tr>
<tr>
<td>Hogs, meat</td>
<td>5.0</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>15.0</td>
</tr>
<tr>
<td>Oranges</td>
<td>5.0</td>
</tr>
<tr>
<td>Peaches</td>
<td>15.0</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 USDI Bureau of Reclamation, and 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>Pears</td>
<td>3.0</td>
</tr>
<tr>
<td>Pears, shell</td>
<td>15.0</td>
</tr>
<tr>
<td>Peas</td>
<td>15.0</td>
</tr>
<tr>
<td>Peas, wine, pod</td>
<td>15.0</td>
</tr>
<tr>
<td>Peas, wine, without pole</td>
<td>15.0</td>
</tr>
<tr>
<td>Pecans</td>
<td>1.0</td>
</tr>
<tr>
<td>Plums</td>
<td>3.0</td>
</tr>
<tr>
<td>Potatoes</td>
<td>10.0</td>
</tr>
<tr>
<td>Poultry, (excluding kidney)</td>
<td>7.0</td>
</tr>
<tr>
<td>Poultry, kidney</td>
<td>9.0</td>
</tr>
<tr>
<td>Sheep, mbyp</td>
<td>2.0</td>
</tr>
<tr>
<td>Sheep, meat</td>
<td>2.0</td>
</tr>
<tr>
<td>Sorghum</td>
<td>1.0</td>
</tr>
<tr>
<td>Sorghum, forage</td>
<td>5.0</td>
</tr>
<tr>
<td>Soybeans</td>
<td>1.0</td>
</tr>
<tr>
<td>Soybeans, pore</td>
<td>2.0</td>
</tr>
<tr>
<td>Sugarcane</td>
<td>1.0</td>
</tr>
<tr>
<td>Taigermes</td>
<td>8.0</td>
</tr>
<tr>
<td>Walnuts</td>
<td>5.0</td>
</tr>
</tbody>
</table>

[Dates: Comments must be received on or before September 7, 1977.]

INTERSTATE COMMERCE COMMISSION

[49 CFR Parts 1047, 1082]

[No. MC-C-3497, MC-C-4000]

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

Extension of Comment Period

AGENCY: Interstate Commerce Commission.

ACTION: Proposed rules.

SUMMARY: At the request of Todd A. Peterman, Representative of American Trucking Associations, Inc., the time for filing comments in the above-entitled 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. 131—FRIDAY, JULY 8, 1977
ADDRESSES: 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 Proceedings, (202-275-7292), H. J. Homme, Jr., Acting Secretary.

[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. The 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 5312, Interstate Commerce Commission, Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT:

Deputy Director Rosenak or Assistant Deputy Director Gobetz, Section of Rules, Office of Proceedings, 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 tariff, which rate, term or condition was a result of the exercise of independent action by a member of the rate bureau, unless that member has first notified that 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 illustrating this practice if the petition is granted and a proceeding instituted. This practice, petitioner argues, hinders a carrier's right of independent action recognized in section 5a(6) of the Interstate Commerce Act (49 U.S.C. 15b) and in Ex Parte 297, Rate Bureau Investigation, 351 F.T.C. 427 (1976). It maintains that the proposed rule is intended to curb the practice.

The matter submitted by petitioner has been variously raised in certain sections 5a amendatory agreement application proceedings presently pending before the Commission. Consideration and disposition of the matter in a single proceeding upon a full and complete record will avoid piecemeal litigation and avoid the expenditure of unnecessary time and expense to all parties concerned and the Commission.

Note.—This is not a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969.

By the Commission. (Commissioners Hardin and Christian were absent and did not participate.)

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

[FR Doc. 77-19865 Filed 7-7-77; 8:45 am]

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

[50 CFR Part 611]

FOREIGN FISHING VENTURES WITHIN U.S. FISHERY CONSERVATION ZONE

Advance Notice of Proposed Rulemaking


ACTION: Advance notice of proposed rulemaking.

SUMMARY: Announcement is made of six-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 by the National Marine Fisheries Service (NMFS). 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 8, 1977, at New England Aquarium, Central Wharf, Atlantic Avenue, Boston, Massachusetts 02110.

On August 9, 1977, at Recreation Hall, 30 Federal Street, Brunswick, Maine 04011.


On August 17, 1977, at King's Grant Motel (Conference Room to be posted), Route 70 and River Road, Point Pleasant, New Jersey 08742.

On August 18, 1977, at Southampton Inn (Conference Room to be posted), 91 Hill Street, Southampton, Long Island, New York 11968.


The hearings will begin at 7:30 p.m. and will continue until all testimony is received. The hearings will terminate, however, by 10:00 p.m.

In addition to oral testimony, written comments also are solicited. These may be submitted to the address shown below no later than August 29, 1977.

FOR FURTHER INFORMATION CONTACT:

Mr. William G. Gordon, Regional Director, Northeast Region, National Marine Fisheries Service, Room 214, 14 Elm Street, Gloucester, Massachusetts 01930. Telephone: (617) 281-3600.

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.

Winfried H. Meiborn, Associate Director, National Marine Fisheries Service.

[FR Doc. 77-19828 Filed 7-7-77; 8:45 am]

[50 CFR Part 611]

FOREIGN FISHING VENTURES WITHIN U.S. FISHERY CONSERVATION ZONE

Advance Notice of Proposed Rulemaking

PROPOSED RULES

PERIC Administration, U.S. Department of Commerce.

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), 17620 Pacific Highway, South, Seattle, Washington 98188.

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


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 Chitwood, 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.

WINTRED H. MEIBOHM, Associate Director, National Marine Fisheries Service

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

[Docket No. E77-125]

AMINOIL, U.S.A.

Emergency Order


PG&E provide the following information:

(1) The information necessary to establish a point of connection on PG&E's line in section 8, T. 2 N., R. 3 E., near the Union Scapesi 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, T. 6 N., R. 2 E.

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

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

This order is issued pursuant to the authority delegated to me by the President in Executive Order No. 11686 (February 2, 1977), and shall be served upon Aminoil, 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.


[FR Doc. 77-19469 Filed 7-7-77; 8:45 am]

Docket No. E77-121]

TUCO, INC., AND LLANO, INC.

Supplemental Emergency Order; Correction

In FR Doc. 77-17786, 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" to the delivery point on TUCO's line at Section 13, Township 18 South, Range 27 East, Eddy County, New Mexico.

RICHARD L. DUNHAM, Administrator.


[FR Doc. 77-19469 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, Washington, D.C., July 25, 1977, at 9:30 a.m. The meeting will re-Commence from 1:00 p.m. 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 nitrite and nitrosamines, (2) redetermination 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 202-447-6189.

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

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

[FR Doc. 77-19469 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 and the associated 230 kV transmission portion of the 1973 Final Environmental Impact 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 the 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, currently under construction in Luzerne County, Pennsylvania. These portions of the 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.

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. 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.

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. 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. Units No. 1 and No. 2, and for the 128 miles of 500 kV transmission facilities.

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

DAVID A. HAMIL, Administrator, Rural Electrification Administration.

ALLEUGHENY 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 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 42.3 miles of the 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, 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. Comment 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.

to be considered in connection with the proposed loan guarantee commitment.

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 South Agriculture 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. HAMIL, Administrator, Rural Electrification Administration.

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 the construction approval for the Rural Electric Cooperative Power Association for Cooperative Power Association of Minne­apolils, Minnesota, and United Power As­sociation of Elk River, Minnesota (CPA-U A), 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-U A 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 comments have been made by CPA-U A in consultation with 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 (15) 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 VELLORE, Acting Administrator, Rural Electrification Administration.

CIVIL SERVICE COMMISSION

DEPARTMENT OF LABOR

Revocation of Authority To Make Noncareer Executive Assignment
Under authority of § 320 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. SPRY, Executive Assistant to the Commissioners.

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., 1328 Willowbush 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. 93-418) and section 331.29 of the Adjustment Assistance Regulations for Firms and Communities (3 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.

[FED Doc. 77-19999 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 Ardmore 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 251 of the Trade Act of 1974 (Pub. L. 93-518 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 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.

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

National Oceanic and Atmospheric Administration

**PROPOSED ESTUARINE SANCTUARY, ROKCERY 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 Rokcery Bay.

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 26, 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 appropriate. Priority 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 staff may question 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:


Written comments may also be submitted by mail to the Office of Coastal Zone Management. Written 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 address above. 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. Gleiter, Assistant Administrator for Administration.

[FED Doc. 77-19386 Filed 7-7-77: 8:45 am]

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 for availability. (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 ten cents per page from the Environmental Protection Agency, 400 M Street, N.W., Washington, D.C. 20460.

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

DEPARTMENT OF AGRICULTURE


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 in South Dakota and Nebraska. Prairie dog colonies will be done with use of chemical toxicants. A key feature of the plan is to manage prairie dogs on a 32-square mile area in the Buffalo Gap National Grassland, primarily to enhance habitat for the black-footed ferret. Anticipated effects will be a reduction in habitat available for species associated with prairie dogs other than black-footed ferrets and a reduction in beef production by 186,750 lbs. per year. (ELR Order No. 78067).

**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 management practices will increase the wildlife use area to 49,440 acres and reduce the trail access area to 18,160. Socio-economic impacts will result due to the mix of user groups able to enter Little Kern. Comments made by: USDA, DOI, REW, EPA, DOT, COE, AHP, State and local agencies, and interested groups and persons. (ELR Order No. 78060).

Salmon River Wild and Scenic Rivers Proposal, 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 to Ironside Dam, to its confluence with the Snake River through Nencesee, Lewis, Idaho, and Lemhi Counties, Idaho. The purpose of the action is to continue the implementation of development and increased recreation use within the river corridor. There are approximately 6,680 acres of private lands involving 50 owners within the proposed boundary area. Comments made by: USDA, DOI, U.S.A., H.U.D., DOC, DOT, EPA, PPC, WRC, state and local agencies, and concerned citizens. (ELR Order No. 79086).

Proposed Pere Marquette Wild and Scenic River, Lake, and Mason Counties, Mich., June 29: Proposed is the legislative designation of 66.4 miles of the Pere Marquette River and 13,000 adjoining acres as
part of the National Wild and Scenic Rivers System. The system was designed to preserve the unique natural resource values of the area. Comments made by: DOI, USA, HUD, FPC, WRC, 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 includes the addition of one or two 246 MW each) steam generating units at the Reid Station. This supplement serves to complete BEA's and EPA's requirements under NEPA by presenting the environmental impacts associated with the discharge of effluents from the second unit, including the results of air quality modeling. (ELR Order No. 70803.)

**SOIL CONSERVATION SERVICE**

**Final**

Avery Brook Watershed, Hartford County, Connecticut, June 27: The proposed action is for construction of a watershed project for protection against flooding, soil erosion, and water pollution. The project includes: installation of riprap and vegetation to control erosion; improvement of stream channels for drainage; construction ofimprovement of roads; protection of scenic values; and the protection of wetlands. The direct and indirect environmental impacts of the action are described in the statement. (ELR Order No. 70801.)

**DEPARTMENT OF DEFENSE, ARMY CORPS**

**Contact:** Mr. Richard H. Broun, Director, Office of Federal Activities, Environmental Protection Agency, 382 East Main St., Columbus, Ohio 43216. Telephone number 614-469-6579.

**Draft**

East Oak Bayou, Harris County, Texas, July 1: The proposed action is the construction of a flood control system to reduce the risk of flooding in the upper East Oak Bayou area. The action includes the construction of a levee, spillway, and pump station. The environmental impacts of the action are described in the statement. (ELR Order No. 70802.)

**Bald Head Island (permit), Brunswick County, North Carolina, June 27: Proposed is the granting of a U.S. Army permit to the Bald Head Island Corporation for the construction of a boat marina and access facilities adjacent to the Bald Head Island, North Carolina. The project includes the construction of a marina basin, service facilities, and access ways. The direct and indirect impacts of project implementation will be filling of 2.5 acres of high marsh, and alteration of dune, marsh, stone and the aesthetics of the area. (Wilmington District) Comments made by: EPA, HUD, DOC, DOI, H E W, state and local agencies, and concerned citizens. (ELR Order No. 70804.)

**ENVIRONMENTAL PROTECTION AGENCY**

**Contact:** Ms. Rebecca W. Hammert, Director, Office of Federal Activities, Environmental Protection Agency, 337 W. Tower, Washington, D.C. 20463. Telephone number 202-773-0830.

**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 designed to provide wastewater treatment for a planned development. The project includes the construction of a wastewater treatment plant, a stormwater treatment plant, and a sludge transport pipeline. The direct and indirect environmental impacts are described in the statement. (ELR Order No. 70803.)

**FEDERAL POWER COMMISSION**

**Contact:** Mr. Jack M. Heimann, Acting Assistant Director for Environmental Quality, Federal Power Commission, 104 NE, Washington, D.C. 20428. Telephone number 202-775-4791.

**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 Natural Gas Co. to import LNG from Algeria to a terminal to be located in the vicinity of Port O'Connor, Texas on Matagorda Bay. Authorization for the construction of the terminal and pipeline facilities is subject to the completion of additional studies and reports. The direct and indirect environmental impacts are described in the statement. (ELR Order No. 70804.)

**DEPARTMENT OF HUD**

**Contact:** Mr. Richard M. Bruner, Director, Office of Environmental Quality, Department of Housing and Urban Development, 451 7th Street, SW., Washington, D.C. 20441. Telephone number 202-755-6086.

**Final**

Cape Cod Canal, Bourne and Sandwich, O & M, Bourne County, Mass., June 28: The proposed project is to construct a navigation channel of the Cape Cod Canal, including improved access to the main channel, mooring basins, and boat basins. In addition, the project includes maintenance and operation of a breakwater, a jetty, a railroad bridge, two highway bridges, three dikes, maintenance and administration buildings, and electric traffic control system. The environmental impacts of the project are described in the Final EIS. (ELR Order No. 70803.)

**Supplement**

Greenpeace and Bimmam Wood, Harris County, Texas, June 27: The proposed action is the approval of a U.S. Army permit to the Bald Head Island Corporation for the construction of a boat marina and access facilities adjacent to the Bald Head Island, North Carolina. The project includes the construction of a marina basin, service facilities, and access ways. The direct and indirect environmental impacts of project implementation are described in the Final EIS. (ELR Order No. 70803.)

**Final**

Bent Tree Planned Unit Development, Dade County, Fla., June 27: The proposed project is an undeveloped area consisting of 2,250 acres of land in Dade County, Florida. The project includes the construction of a planned unit development with residential, commercial, and recreational facilities. The environmental impacts of the project are described in the Final EIS. (ELR Order No. 70803.)

**NOTICE**

**NOTICE OF INTENT TO PROPOSE A NEW MAJOR PROPOSAL TO THE CENTER FOR CIVILIAN AND MILITARY APPLICATIONS OF NUCLEAR SCIENCE AND TECHNOLOGY**

The U.S. Department of Energy has been requested to prepare an Environmental Impact Statement for the proposed transfer of nuclear technology to the United Kingdom. The purpose of this action is to facilitate the development of nuclear energy in the United Kingdom. The environmental impacts of the proposed action are described in the Notice of Intent. (ELR Order No. 70804.)

**Indian Oaks Subdivision, Wil County, Ill., June 27: Proposed is the provision of FHA mortgage insurance for 315 single-family and multi-family apartment facilities that comprise 1,888 units and will eventually total 2,250 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 area is still wooded and will remain so even after development. Comments made by: DOI, DOC, EPA, state and local agencies, concerned citizens. (ELR Order No. 70804.)

**Memorial Parkway Subdivision, Harris County, Texas, June 29: Proposed is the development of a single-family and multi-family housing project consisting of 351 acres of land. The project includes the construction of 1,060 acres of housing units and 40 acres of commercial facilities. Adverse impacts will be removal of agricultural land from production and an increase in traffic congestion. (ELR Order No. 70804.)

**West Side Housing (S-1), Denver County, Colo., June 28: This statement supplements a Final EIS filed with CEQ in January 1973. The proposed project, the West Side Housing Development, was never approved due to lack of funds. The addition of an emergency and fire services building is subject to the completion of additional studies and reports. The direct and indirect environmental impacts are described in the Final EIS. (ELR Order No. 70804.)

**NOTICE OF INTENT TO PROPOSE A NEW MAJOR PROPOSAL TO THE CENTER FOR CIVILIAN AND MILITARY APPLICATIONS OF NUCLEAR SCIENCE AND TECHNOLOGY**

The U.S. Department of Energy has been requested to prepare an Environmental Impact Statement for the proposed transfer of nuclear technology to the United Kingdom. The purpose of this action is to facilitate the development of nuclear energy in the United Kingdom. The environmental impacts of the proposed action are described in the Notice of Intent. (ELR Order No. 70804.)

**Sectron 104 (b)**

**Draft**

Denver, Colo.—Slain Lake Sanitary Sewer, Denver County, Colo., June 27: Proposed are the plans for the development of the Slain Lake Sanitary Sewer System in Denver, Colorado. Plans call for the replacement of existing sanitary sewers located within the drainage basin. The direct and indirect environmental impacts are described in the EIR. (ELR Order No. 70804.)

**High Point, N.C.—Big Ditch, North Carolina, June 27: Proposed are the plans for the development of the Big Ditch Sanitary Sewer System in High Point, North Carolina. Plans call for the replacement of existing sanitary sewers located within the drainage basin. The direct and indirect environmental impacts are described in the EIR. (ELR Order No. 70804.)

**NOTICE**

**NOTICE OF INTENT TO PROPOSE A NEW MAJOR PROPOSAL TO THE CENTER FOR CIVILIAN AND MILITARY APPLICATIONS OF NUCLEAR SCIENCE AND TECHNOLOGY**

The U.S. Department of Energy has been requested to prepare an Environmental Impact Statement for the proposed transfer of nuclear technology to the United Kingdom. The purpose of this action is to facilitate the development of nuclear energy in the United Kingdom. The environmental impacts of the proposed action are described in the Notice of Intent. (ELR Order No. 70804.)

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

**NOTICE**

**NOTICE OF INTENT TO PROPOSE A NEW MAJOR PROPOSAL TO THE CENTER FOR CIVILIAN AND MILITARY APPLICATIONS OF NUCLEAR SCIENCE AND TECHNOLOGY**

The U.S. Department of Energy has been requested to prepare an Environmental Impact Statement for the proposed transfer of nuclear technology to the United Kingdom. The purpose of this action is to facilitate the development of nuclear energy in the United Kingdom. The environmental impacts of the proposed action are described in the Notice of Intent. (ELR Order No. 70804.)
ments to Big Ditch stream in High Point, North Carolina. Corrective methods proposed for the Big Ditch include: (1) piping the stream to the right of the Big Ditch comes 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 corrective action will result in increased erosion and stream sedimentation, removal of trees, and flooding of adjacent structures. 

Final
DeKalb County, Tenn.—3rd Year Water Line, June 27; Proposed is the installation of 18 miles of 6-inch, 4-inch, and 2-inch plastic pipe water line in DeKalb County, Tennessee. The project will provide potable water for 135 rural families who have been consuming well water that stands an 80 percent chance of being polluted. Water will also be available in adequate amounts for firefighting purposes. Temporary construction related impacts are expected. Comments made by: DOI, EPA, Interested parties. (ELR Order No. 70797.)

Final
Arkansas Nuclear One, Unit 2, Pope County, Arkansas, July 1; Proposed is issuance of a permit to construct a bridge across Shallotte Creek, Brunswick County, North Carolina. Plans call for the construction of a bridge approximately 90 feet in length and 15 feet in width to connect two parcels of property owned by the applicant. Adverse impacts will include pollution of the stream, and increased air and noise pollution. (ELR Order No. 70815.)

DEPARTMENT OF DEFENSE

Open Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-436), 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 being conducted pursuant to Public Laws 91-611, 92-231, and 94-547.

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 season extension on the 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 FX-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 of 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 prior to the meeting, but oral participation by the public is limited because of the time schedule.

Inquiries may be addressed to Mr. David Westheuser, U.S. Army Engineer District, Detroit, Corps of Engineers, P.O. Box 1027, Detroit, Michigan 48221, telephone (313) 226-6770.


By Authority of The Secretary of The Army.

Rome D. Smyth, Colonel, United States Army, Director, Admin. Mgt., TAGCEN.

FEDERAL HIGHWAY ADMINISTRATION

New System of Records

The Defense Mapping Agency systems of records notices as prescribed by the
Privacy Act of 1974 have been published in the Federal Register as follows:

FR Doc. 75-31675 (40 FR 35977) August 19, 1975.
FR Doc. 76-5066 (41 FR 5513) February 27, 1976.

Notice is hereby given that the Defense Mapping Agency submitted a proposed System of Records on June 19, 1977, pursuant to the provisions of Office of Management and Budget (OMB) Circular No. A-130, Transmittal Memorandum No. 1, dated September 30, 1975, and Transmittal Memorandum No. 3, dated May 17, 1976, which provide supplemental guidance to Federal agencies regarding the preparation and submission of reports required by 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 45877) 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 Headquartes, Defense Mapping Agency, Attn.: Counsel, Building 56, Naval Observatory, Washington, D.C. 20305, or before August 19, 1977. The system will become effective, within 30 days (August 19, 1977), as proposed without further notice unless comments are received which result in a contrary determination.

### B0601-03 HOTHASH

**System name:** Advanced Personnel Data System—Civilian (APDS-C).

**System location:**
- Director, Defense Mapping Agency, Bldg. 56, Naval Observatory, Attn.: Counsel, Building 56, Naval Observatory, Washington, D.C. 20305.
- Director, DMA Aerospace Center, Attn.: PO, St. Louis Air Force Station, Missouri 63118.
- Director, DMA Hydrographic Center, Attn.: PO, Washington, D.C. 20305.
- Director, DMA Topographic Center, Attn.: PO, Washington, D.C. 20305.
- Director, Inter American Geodetic Survey, Attn.: SD Drawer 534, Ft. Clayton, Canal Zone.

**Categories of individuals covered by the system:**
- Current and former DMA civilian employees.
- Categories of records in the system:
  - Civilian employment information including authorization for position, personnel data, suspense information; position control information; projected inactivation; personnel information; civilian education and training data; performance appraisal, ratings, evaluation of potential; civilian historical files covering job experience, training and transitions; 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, as for personal files, as for personnel files from which to produce statistical reports in hard copy, or for immediate access display on remote computer terminals; miscellaneous files.

**Temporary use 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 management and records keeping system that pertains to evaluation, authorizations and position control, position management, staffing, skills inventory, career management, training, retirement, employee services, rights and benefits, merit promotions, determinations, reductions in force, complaints resolution, labor management relations, and the suspending and processing of personnel actions; to provide for transmission of such records between employees or activities within the Defense Mapping Agency; to provide reports to the Civil Service Commission; to provide reports of military reserve status to other armed services for contingency planning; 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 civilian 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 offices to facilitate the assessment of the DMA Affirmative Action Plan; to obtain listings of employees by function or area for labor and inventory purposes; to disclose to officials of labor organizations recognized under Executive Order 11491, amended, when relevant and necessary, to their duties of exclusive representation concerning personnel policies and practices and matters affecting working conditions.

**Authority for maintenance of the system:**
- 5 U.S. Code 301 and 44 U.S. Code 3101.

**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 magnetic tapes.
  - Maintained on disks or drums.
  - Maintained on computer paper print-outs.
  - Maintained on microfiche.

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

**Safeguards:**
- Records are accessed by custodian(s) of the record system.
- Records are accessed by person(s) responsible for servicing the record system in performance of their official duties.
- Records are accessed by authorized personnel who are properly screened and cleared for need-to-know.
- Records are stored in security file containers/cabinets.
- 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, pulping, macerating, or burning. Data stored digitally within the 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.**

**Other**

- 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.
- Records are accessed by person(s) responsible for servicing the record system in performance of their official duties.
- Records are accessed by authorized personnel who are properly screened and cleared for need-to-know.
- Records are stored in security file containers/cabinets.
- 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.

**Safeguards:**
- Records are accessed by custodian(s) of the record system.
- Records are accessed by person(s) responsible for servicing the record system in performance of their official duties.
- Records are accessed by authorized personnel who are properly screened and cleared for need-to-know.
- Records are stored in security file containers/cabinets.
- 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, pulping, macerating, or burning. Data stored digitally within the 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.**

**Other**

- 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:
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, photograph and signature.

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/employee 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).


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 1E801, 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 9:45 a.m. in Room 1E801, The Pentagon, Washington, D.C.

The State Certification Program for Alaska 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. Edwin Coat
Acting Regional Administrator.
U.S. Environmental Protection Agency, Region X.

COMPUTER-READABLE CANDIDATE LISTS

Availability

An April 28, 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 (96 Stat. 2003, 15 USC 2601 et seq.).

This notice detailed, in part, the procedure for obtaining a copy of the candidate list on magnetic tape.

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)
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 U.S.C. 136a et seq., written request to: Computer List, OTS (TS-557), Attn: Kenneth Olsen, Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460. For additional information you may call Mr. Olsen (202) 426-9619.

Dated: June 20, 1977.

KENNETH L. JOHNSON
Acting Assistant Administrator
[FR Doc.77-19379 Filed 7-7-77:8:45 am]

NOTICES

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 5G167) submitted by Mobay Chemical Corp., Chemagro Agricultural Div., 500 Executive Blvd., Elmsford, NY 10523. 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 the Regional Administrator, EPA, the Food and Drug Administration.

The scientific data reported and all other relevant material have been evaluated, and it has been determined that a renewal of the temporary tolerance will protect the public health. A related document concerning the renewal of a temporary food additive regulation for residues of the fungicide on rice hulls appears elsewhere in today's Federal Register. Therefore, the temporary tolerance is renewed on condition that the pesticide is used in accordance with the experimental use permit with the following provisions:

1. The total amount of the pesticide to be used must not exceed the quantity authorized by the experimental use permit.

2. Mobay Chemical Corp., Chemagro Agricultural Div., must immediately notify the EPA of any findings from the experimental use that have a 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 the Food and Drug Administration.

This temporary tolerance expires June 20, 1978. Residues not in excess of 0.1 ppm remain registered for use on rice under this temporary tolerance. This expiration date 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 tolerance. This temporary tolerance may be revoked if the experimental use permit is revoked or if any scientific data or experience with this pesticide indicate such revocation is necessary to protect the public health. Inquiries concerning this notice may be directed to Special Registrations Section, Registration Division, WH-567, Office of Pesticide Programs, Room 315, East Tower, 401 M Street SW., Washington, D.C. 20460 (202-753-4851).

Dated: June 20, 1977.

DOUGLAS D. CAMPT
Director, Registration Division.
[FR Doc.77-19223 Filed 7-7-77:8:45 am]

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 (86 Stat. 973; 89 Stat. 973; 7 U.S.C. 136a et seq.). This application involves 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.

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 the plan attached thereto, may be examined during normal business hours at the following locations:

Department of Food and Agriculture, 1220 "N" Street, Room A170, Sacramento, CA 95815 (916-425-2742).

Date: June 28, 1977.

DOUGLAS D. CAMPT
Acting Director, Registration Division.

APPLICATION RECEIVED

EPA File Symbol 21137-4. EM Laboratories Inc., Pesticides Div., 14 Executive Blvd., Elmsford NY 10523. FUNGINEX. Active Ingredients: Triforine (N,N-(1,4-piperazine-diyldi)-2,2,2-trichlorovinylidene) bis (formamide) 18.9%. This application involves 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.

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.

Date: June 28, 1977.

[FR Doc.77-19378 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 5G167) submitted by Mobay Chemical Corp., Chemagro Agricultural Div., 500 Executive Blvd., Elmsford, NY 10523. 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 the Experimental Use Permit (FIFRA), as amended (86 Stat. 973; 7 U.S.C. 136a et seq.), and the regulations thereunder (48 CFR 182). Notice of receipt of this application was made in accordance with the provisions of Section 3(c) (4) of FIFRA (40 CFR 182.2(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-569), Office of Pesticide Programs, Environmental Protection Agency, Room 461, East Tower, 401 M St. SW., Washington DC 20460. Three copies of the comments should be submitted to the Agency and others interested in inspecting them. The comments must be received on or before August 8, 1977, and should bear a notation indicating the EPA File Symbol and 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) 426-2454.

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.

Date: June 28, 1977.

DOUGLAS D. CAMPT
Acting Director, Registration Division.

APPLICATION RECEIVED

EPA File Symbol 21137-4. EM Laboratories Inc., Pesticides Div., 14 Executive Blvd., Elmsford NY 10523. FUNGINEX. Active Ingredients: Triforine (N,N-(1,4-piperazine-diyldi)-2,2,2-trichlorovinylidene) bis (formamide) 18.9%. This application involves 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.

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.

Date: June 28, 1977.

DOUGLAS D. CAMPT
Acting Director, Registration Division.

APPLICATION RECEIVED

EPA File Symbol 21137-4. EM Laboratories Inc., Pesticides Div., 14 Executive Blvd., Elmsford NY 10523. FUNGINEX. Active Ingredients: Triforine (N,N-(1,4-piperazine-diyldi)-2,2,2-trichlorovinylidene) bis (formamide) 18.9%. This application involves 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.

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.

Date: June 28, 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 476—4787 and 4784—4787. The plan indicates that the State lead agency and cooperating agencies have sufficient qualified personnel and funds necessary to conduct the programs described in the State Plan. Certain EPA funds have been provided to the lead agency to support the certification program. In FY 1978—79 a grant of $235,000 was awarded to the Department of Food and Agriculture for this purpose. Additionally, the Cooperative Extension Service, University of California, has received applicant training monies during FY 1976 and FY 1977. The State lead agency will submit an annual report to EPA on or before March 30 of each year concerning the previous calendar year to include the information specified in 40 CFR 4788.

The certification requirements for private and commercial applicators will be met by the restricted materials control system, which requires applicants intending to use or possess 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. The oral interview will take place at the time a restricted materials permit is issued to the private applicator. Additionally, the County Agricultural Commissioner is required to consider the broad criteria specified in Section 14004.5 of the California Food and Agricultural Code. Permits may be issued for restricted pesticides for a season, but never in excess of twelve months. The private applicator, after issuance of the restricted materials permit, will be subject to pesticide use surveillance. The private applicator will be required to complete a prescribed refresher training course prior to or within six months following the date of expiration. Supervision of non-certified applicators by certified private applicators is discussed in the plan.

COMMERCIAL APPLICATOR CERTIFICATION

Commercial applicators fall into four identified groups. They are (a) agricultural pest control operators, (b) technicians employed by local public health vector control agencies, (c) structural pest control operators, and (d) all other commercial applicators. The standards of competency utilized for commercial applicators will be determined by the lead agency and will meet or exceed those in 40 CFR 171.4 and 171.6. All commercial applicators are determined competent by means of satisfactorily passing a written examination.

AGRICULTURAL PEST CONTROL APPLICATORS

The Agricultural Pest Control Operator 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 license. The training program for both apprentice and journeyman pilots is included in the plan.

During 1976, the lead agency issued over 1,800 agricultural pest control operator licenses. In that same year, 300 apprentice pilots and over 600 journeyman pilots were licensed by the Department of Agriculture.

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 chemical or biological agents to control vectors. This certification program meets or exceeds 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 invertebrate 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 appropriate 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 periodic training. Each certified technician certificate will expire two years after issuance. As a condition for renewal, the completion of a prescribed refresher training course will be required prior to or within 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.
Commercial applicators not included in the previous categories will be certificated under the following categories: Agricultural Pest Control, Forest Pest Control, Ornamental and Turf Pest Control, Right-of-Way Pest Control, Industrial and Institutional Pest Control, and the Regulatory Pest Control category.

In addition, other appropriate materials will be certificated as necessary to assure competence through frequent direct contact and observation of pesticide applications.

Interested persons are invited to submit written comments on this petition to the Chief, Pesticides Branch, 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 8, 1977, and should include the following information:

1. The total amount of the pesticide to be used must not exceed the quantity 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. This includes any reports of production, distribution and performance, and on request make the records available to any authorized official of the EPA or the Food and Drug Administration.

These temporary tolerances expire June 15, 1978. Residues not in excess of these temporary tolerances remaining in or on the above 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 shows that such residues are not 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 (202-755-4851).
NOTICES

FEDERAL ENERGY ADMINISTRATION

PETROLEUM COMPANY FINANCIAL REPORTING SYSTEM

Public Panel

AGENCY: Federal Energy Administration (FEA).

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

SUMMARY: The Federal Energy Administration (FEA) is required to obtain financial information concerning petroleum company operations to fulfill its responsibilities under the FEA Act of 1970. FEA's Petroleum Company Financial Reporting System (FRS) is designed to provide energy information from the petroleum industry that will enable more informed deliberation as to possible government actions with regard to the petroleum industry. The 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 production, etc.?

II. OBJECTIVES OF FRS

The information collected by FRS will enable more informed deliberation as to possible government 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 production, etc.?

The second area of responsibility constitutes the primary function of a financial reporting system. The second area of responsibility is the relationships between 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?

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 12 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(e)(5) of the FEA Act further states that the Administrator shall "promote stability in energy prices to the consumer, promote 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 18(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 506 of the Energy Policy and Conservation Act (EPCA), Public Law 94-163, as amended, which amends Section 11(c) of the Energy Supply and Environmental Coordination Act of 1974 (ESECA), Public Law 93-319, as amended, to require that the Administrator file quarterly reports with the President and the Congress presenting energy information as informed by Section 506(e) 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 preceding quarterly report was filed 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 separate calculation of capital, revenue, and operating costs; (b) the separate reporting of the financial results for domestic and foreign operations; (c) the separate reporting of the financial results for domestic and foreign operations; and (d) the separate reporting of the financial results for domestic and foreign operations.

III. PREVIOUSLY PUBLISHED VERSION OF FRS

IV. IMPLEMENTATION SCHEME

V. COMMENTS INVITED, PARTICULARLY ON CERTAIN ISSUES:

VI. PANEL DISCUSSION PROCEDURES

NOTICES 35187

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

35187
A proposed version of the FRS form and an October 14, 1975, public hearing concerning the design and implementation of the form has been the subject of a previous notice (40 FR 43612, September 22, 1975).

The present version of the FRS form responds to many of the comments made by interested parties at that previous public hearing and to comments received by mail. Specific comments regarding further elimination of parts or individual elements in the forms are solicited. At the same time, FEA solicits ideas for additional data requirements that will serve the public policy analysis process. In each case, supporting arguments should accompany comments.

In light of the data collected and the burden of preparing the form were the primary concerns expressed by companies which submitted comments. Many firms felt that their companies would be particularly burdened unless those parts of FRS which have changed since the earliest version of the form are considered. 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.

As a part of the forms clearance process the GAO will publish a Federal Register Notice with the proposed final version of the form, and all interested parties will again be invited to provide comments. That process is expected to take about 45 days and be complete at the end of November.

FEA plans to implement the FRS in phases. In the first phase, to be implemented this year, FEA plans to require only a sample of 35 to 50 large petroleum companies to complete and submit the form. This sample may include large integrated companies as well as large oil companies that have their own marketing functions. In subsequent phases, FEA plans to expand the reporting coverage to include a sample of smaller companies as well as the large petroleum companies, and may develop surveys of firms producing only other fuels such as coal or uranium.

Respondents will be required to submit the form by (a) 135 days after the close of each year, FEA's fiscal year, or (b) 100 days after receipt of the form, whichever is later. As a means of establishing a historical data base, FEA will require a condensed version of the form to be submitted indicating responses for the years 1972 through 1976.

The July 29, 1977, public panel discussion is for the purpose of discussing any issues and problems connected with the design and implementation of FRS. However, described below are some issues 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 injury.

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 commercial or financial information obtained from a person and privileged or confidential (5 U.S.C. 552(b)(4)), please so indicate. Such comment should include: (1) The information to which the exemption applies; (2) an explanation of the competitive injury to the submitting party which would result from public disclosure; (3) an indication whether and why 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. This modification of the earlier form is the requirement to report refining and marketing functions of integrated companies as separate business segments. In requiring the reporting of financial information by business segment, FEA has as its objective the determination of the return on investment achieved by each segment. FEA recognizes that many companies may not have accurate data 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.

3. 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 to the same company by the same product to third parties by the same company in the same locality in the same time period, etc., (2) establishing the price based upon some preset return over the energy field, and not just petroleum companies, file annual reports or form 10-Ks; (3) establishing a uniform detailed system of accounts to improve comparability between companies, and (4) the expansion of the form to include additional vertical and horizontal line of business segments. As to (3) the Financial Accounting Standards Board and the Securities and Exchange Commission, pursuant to Section 503 of EFPCA, as described in Section I of this Notice, are presently working to establish accounting standards for financial reporting in the extractive industries. As to (4) the form has been expanded to collect costs and revenues by vertical and horizontal business segment, adding separate segments for refining and marketing, for example.
The second area of desired comment concerns allocation of asset, liability, or income items not specific to a segment or operation, such as general corporate expenses, research and development, or other corporate service, to the separate business segments. Although such financial information cannot always be specifically associated with a particular segment on the basis of objective evidence, calculation of net income and investment information for each segment concerned, and (d) whether there are other indicators of segmental performance which can be used without the allocation of such items.

3. Use of nonconsolidated subsidiaries. FEA proposes to modify the 1975 FRS forms and instructions to show separately the operating data for consolidated and nonconsolidated affiliates. Data for nonconsolidated operations would reflect the company's equity share in its affiliates' operations. FEA believes that this form of reporting is already standard practice, but any comments on potential problems would be welcomed.

4. Prospective implementation of financial accounting standards. In response to Section 503 of EPCA, the Financial Accounting Standards Board (FASB) is expected to promulgate financial accounting standards for companies involved in the exploration, development and production of oil and natural gas by December 22, 1977. The SEC will determine whether to rely on these standards or to adopt different ones. The purpose of the panel discussion is to assist the FEA in its decision-making procedures.

VI. PANEL DISCUSSION PROCEDURES

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 4426, Washington, D.C. 20585. Written comments will be received either before or within 5 days before the meeting. Written comments may be submitted either before or within 5 days prior to the meeting.

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 9:30 a.m., Monday through Friday, except Federal holidays. Any person may purchase a copy of the transcript from the reporter.
### Certificate No. Owner/Operator and Vessels

<table>
<thead>
<tr>
<th>Certificate No.</th>
<th>Owner/Operator and Vessels</th>
</tr>
</thead>
<tbody>
<tr>
<td>12632</td>
<td>Southern Shipbuilding Corp.: Jeju I.</td>
</tr>
<tr>
<td>12633</td>
<td>Kabushiki Kaisha Utsukushu Hon-ten: Shofuku Maru No. 61.</td>
</tr>
<tr>
<td>12634</td>
<td>Kanji Seiyu: Kuya Maru No. 1.</td>
</tr>
<tr>
<td>12635</td>
<td>AS Vasa Shipping OT: Michael Andrew.</td>
</tr>
<tr>
<td>12636</td>
<td>Marconic Ocean Industries Ltd.: Allan Judith.</td>
</tr>
<tr>
<td>12637</td>
<td>Milan Sea Shipping Co. Ltd.: Mountpark.</td>
</tr>
<tr>
<td>12639</td>
<td>Fairmont Enterprises Ltd.: Thomas &amp; Williamson, Partner.</td>
</tr>
<tr>
<td>12640</td>
<td>Daeyang Shipping Corp. Ltd.: Daeyang Royalty.</td>
</tr>
<tr>
<td>12641</td>
<td>Yanagiya Goryo Kabushiki Kaisha: Hoku Maru No. 25.</td>
</tr>
<tr>
<td>12643</td>
<td>Empire Navigation, Ltd.: Enrius.</td>
</tr>
<tr>
<td>12644</td>
<td>Northshelf Shipping Co. S.A. Le- onis Halcoques.</td>
</tr>
<tr>
<td>12645</td>
<td>Kavos Maritime, Inc.: Silver Lady.</td>
</tr>
<tr>
<td>12646</td>
<td>Emperor Maritime, Inc.: Al Raouf.</td>
</tr>
<tr>
<td>12647</td>
<td>Samson Shipping, Ltd.: Al Rezak.</td>
</tr>
<tr>
<td>12648</td>
<td>Rederi M.S. Oceanic: Oceanic.</td>
</tr>
<tr>
<td>12649</td>
<td>Pinto Shipping Co. S.A.: Vincen­tius.</td>
</tr>
<tr>
<td>12650</td>
<td>F.B.V. Corp.: Cat No. 1.</td>
</tr>
<tr>
<td>12651</td>
<td>Partredetia Tegus: Tegus.</td>
</tr>
<tr>
<td>12652</td>
<td>Kommanditeitskapet A/S: Tibet.</td>
</tr>
<tr>
<td>12653</td>
<td>Eastport Shipping Co. Ltd.: East­port.</td>
</tr>
<tr>
<td>12654</td>
<td>Flower Marine Corp.: African Ad­daz, Arabian Addaz, Euro Pri­ority, Europe.</td>
</tr>
<tr>
<td>12655</td>
<td>Carib Compania Naviera, Ltd.: Carib.</td>
</tr>
<tr>
<td>12656</td>
<td>Theva Compania Maritima S.A.: The­flos J. Vatts.</td>
</tr>
<tr>
<td>12657</td>
<td>International Carriers Corp.: Amazonia.</td>
</tr>
<tr>
<td>12658</td>
<td>Apollo Shipping Ltd.: Ya­nias D.</td>
</tr>
<tr>
<td>12659</td>
<td>PASQUERA Intercontinental S.A.: Esperanza.</td>
</tr>
<tr>
<td>12660</td>
<td>Red Sea Saudite Maritime Co. Ltd.: Al Hada.</td>
</tr>
<tr>
<td>12661</td>
<td>Allied Trading Co. Ltd.: Linda.</td>
</tr>
<tr>
<td>12662</td>
<td>Bienf Onshore, Inc.: Bienf Trader, Bici­t Traveler.</td>
</tr>
<tr>
<td>12664</td>
<td>Bilton Shipping S.A.: Golden Star.</td>
</tr>
<tr>
<td>12665</td>
<td>Billi Compania Naviera S.A.: Baf­falo.</td>
</tr>
<tr>
<td>12666</td>
<td>Eviroze Maritime Co. S.A.: Stella C.</td>
</tr>
<tr>
<td>12667</td>
<td>Marigold Shipping Co. S.A.: Ti­bete Halcon.</td>
</tr>
<tr>
<td>12668</td>
<td>Comben Longstaff &amp; Co. Ltd.: Leis­terbrook, Lincolnbrook.</td>
</tr>
<tr>
<td>12669</td>
<td>Pacifica Shipping Inc.: Euro­transport.</td>
</tr>
<tr>
<td>12670</td>
<td>Agrangoli Maritime S.A. of Li­ma.</td>
</tr>
<tr>
<td>12671</td>
<td>Crystal Pinus Inc.: Crystal Cama­lila.</td>
</tr>
<tr>
<td>12672</td>
<td>Tevora Maritime S.A.: Tajima.</td>
</tr>
<tr>
<td>12673</td>
<td>Pacifica Marigoto S.A.: Areu, oro­st.</td>
</tr>
<tr>
<td>12675</td>
<td>Goonick Carriera Inc.: Yls. Trader.</td>
</tr>
<tr>
<td>12676</td>
<td>Chi Song Navigation Inc.: Chi­ho.</td>
</tr>
<tr>
<td>12677</td>
<td>Kommanditgesellschaft MS Bob­berg: Bobberg.</td>
</tr>
</tbody>
</table>
| 12678 | Dubai Maritime Mishref S.A.:
| 12679 | Cidar Maritime Inc.: Eu­ro­serve. |
| 12680 | K/S Mascot: Fetiche. |
| 12681 | Carina Navigation Corp.: Carina I. |

### Certificate No. Owner/Operator and Vessels

<table>
<thead>
<tr>
<th>Certificate No.</th>
<th>Owner/Operator and Vessels</th>
</tr>
</thead>
<tbody>
<tr>
<td>12682</td>
<td>Cedar Maritime Inc.: Ysisanla.</td>
</tr>
<tr>
<td>12683</td>
<td>Eastern Reaven Shipping S.A.: Eastern Bridge.</td>
</tr>
</tbody>
</table>

---

### By the Commission

**JOSEPH C. POLKING, Acting Secretary.**

[FR Doc.77-19492 Filed 7-7-77; 8:45 am]

**TRANS-ATLANTIC ASSOCIATED FREIGHT CONFERENCES (LONDON) Agreement Filed**

Notice is hereby given that the following agreement has been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1918, as amended (39 Stat. 733, 75 Stat. 783, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement at the Washington office of the Federal Maritime Commission, 1100 L Street NW., Room 1026, or may inspect the agreement at the Field Offices located at New York, N.Y., New Orleans, Louisiana, San Francisco, California, and San Juan, Puerto Rico. Comments on such agreements, including requests for hearing, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, on or before July 28, 1977. Any person desiring a hearing on the proposed agreement shall provide a clear and concise statement of the matters upon which they desire to adduce evidence. An allegation of discrimination or unfairness shall be accompanied by a statement describing the discrimination or unfairness with particularity. If a violation of the Act or detriment to the commerce of the United States is alleged,
the statement shall set forth with particular the acts and circumstances said to constitute such violation or detriment to commerce.

A copy of any such statement should also be forwarded to the party filing the agreement which is specified hereinafter and the statement should indicate that this has been done.

Notice of agreement filed by:

Agreement No. 10301, 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.

JOSPEH C. POLKING,
Acting Secretary.

[F.R. Doc. 77-19491 Filed 7-7-77:8:45 am]

[F.D.C. No. ER77-426]

FEDERAL POWER COMMISSION
APPALACHIAN 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. 23, service to Kingsport Power Company, an affiliate of APCO. The supplement would impose a surcharge of 0.33 mills/kWh on all energy billed to Kingsport 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 become uncollectable as a result of changes made in its fuel adjustment clause pursuant to Commission order No. 517.

Public notice of the filing was issued on June 16, 1977, with protests or petitions 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 submitted as part of its rate increase filing to Kingsport in Docket No. ER76-799. It was accepted by the Commission, suspended, and given an effective date of September 21, 1976. APCO has requested waiver of the Commission’s notice requirements so that the surcharge can become effective as of that date.

The alleged revenue deficiency that APCO proposes to recover involves the difference in the base cost of fuel between the old and the revised clauses.

APCO did not change its one-month lag billing provision but did update the base fuel cost level substantially in the revised clause.

over 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 lag provision) for that fiscal month. It now claims that it is entitled to recover 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.

In Public Service Company of New Hampshire (PSNH), Opinion No. 790 as well as in Virginia Electric and Power Company (VEPCO), Order Denying Proposed Fuel Adjustment Clause Surcharge, the Commission did not permit the fuel adjustment clause surcharges to become effective because they “would require that customers of * * * today pay for costs incurred previously.” APCO’s proposed surcharge is no exception.

As the Commission stated in the VEPCO case:

It is clear that the Commission never contemplated that these clauses should guarantee penny for penny recovery. Although these clauses are designed to reflect increased fuel costs they are not designed to relieve the utility of all the risks of doing business * * * The fuel adjustment clause is a part of the filed rate and although the monthly charge under the fuel adjustment clause may vary the formula used to compute that charge does not vary. The fuel adjustment formula, not the monthly fuel adjustment factors, constitute the rate [footnote omitted].

APCO will not be allowed to collect revenues under its suspended clause.

The Commission finds: (1) APCO’s filing presents no factual issues that require an evidentiary hearing and no legal justification for the imposition of a fuel adjustment clause surcharge to its customer, Kingsport Power Company. (2) Good cause exists to reject APCO’s filing for the fuel adjustment clause surcharge.

The Commission orders: (A) Appalachian Power Company's tender of a supplement to its Rate Schedule No. 23 in this docket for filing is hereby summarily disallowed. (B) The Secretary shall cause prompt publication of this order in the Federal Register.

By the Commission.

KENNETH F. PLUMS,
Secretary.

[F.R. Doc. 77-19494 Filed 7-7-77:8:45 am]

[F.D.C. No. CP75-56, et al.]

EL PASO ALASKA CO.
Availability of Alcan II Computerized Financial Documentation


The Federal Power Commission, Bureau of Natural Gas, Systems Analysis

Availability of Alcan II computerized financial documentation has been requested on a confidential basis.

The Federal Power Commission has requested that Alcan II computerized financial documentation be provided for the financial data shown in the Federal Power Commission's Recommendations to the President.

KENNETH F. PLUMS.
Secretary.

[F.R. Doc. 77-19450 Filed 7-7-77:8:45 am]

[F.D.C. No. E-9309]

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 204 of the Act, seeking authorization to extend the latest permissible issue date to December 31, 1978 and to extend the final maturity date to December 31, 1979, on $40 million of short-term promissory notes previously authorized; all other terms and conditions previously instituted shall remain in full force and effect.

The net proceeds to be derived from the notes will be used to provide additional funds for Applicant’s construction 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 Commission, Washington, D.C. 20426, petitions or protests in accordance with the requirements of the Commission’s Rules of Practice and Procedure (18 CFR 1.1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Persons wishing to become parties to 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. PLUMS.
Secretary.

[F.R. Doc. 77-19454 Filed 7-7-77:8:45 am]
**NOTICES**

**Order Approving Rate Increase and Modification of Tariff PGA Clause**


On April 29, 1977, Montana-Dakota Utilities Co. (Montana-Dakota) proposed for filing a proposed rate increase of $289,382 annually for jurisdictional natural gas sales and services. The increase is proposed to become effective on July 1, 1977. Montana-Dakota also proposes to modify its tariff PGA clause to recognize special circumstances affecting its sales to Northern Gas Company (Northern Gas).

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 L, M and N pursuant to Section 154.63 of the Commission's regulations and requested in lieu of the regulations so as not to be required to file statements A through K, O and P. In view of the relatively small amount of increase sought, the 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 much more stable and slowly fluctuating volume of sales to Northern Gas and shall accordingly be approved.

Public notice of Montana-Dakota's filing herein was issued on May 6, 1977, pursuant to Section 7(c) of the Natural Gas Act (18 CFR 157.14), have been published in the Federal Register, Volume No. 2.

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 data 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 included in this application and would be submitted in Phase II of this proceeding:

- Exhibit A—Gas Supply Data
- Exhibit I—Market Data
- Exhibit L—Construction, Operation and Management
- Exhibit O—Depreciation and Depletion
- Exhibit P—Tariff

Applicant states that Exhibit AA—Environmental Impact Assessment, being filed concurrently by NQP-LNG, Inc., covers the proposed pipeline and facilities 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 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 Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 154.63 and 154.64). 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 protested parties to the proceeding, Article(s), or other person party to the proceeding or to participate as a party in any hearing thereof must file a petition to intervene in accordance with the Commission's Rules. Any 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 for the hearing, 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.

**NATURAL GAS PIPELINE CO. OF AMERICA**

Application and Request for Phased Proceeding


Pursuant to a decision of the Commission, the above named Applicant is authorized to construct and operate the Gulf Coast LNG Terminal.

The application seeks authorization from the Commission in a two-phase proceeding to 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 contractual and procedural, to offset its declining supplies. Applicant states that it is currently negotiating for the purchase of LNG for several sources.

**ORDER**

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 data 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 included in this application and would be submitted in Phase II of this proceeding:

- Exhibit A—Gas Supply Data
- Exhibit I—Market Data
- Exhibit L—Construction, Operation and Management
- Exhibit O—Depreciation and Depletion
- Exhibit P—Tariff

Applicant states that Exhibit AA—Environmental Impact Assessment, being filed concurrently by NQP-LNG, Inc., covers the proposed pipeline and facilities 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 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 154.63 and 154.64). 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 protested parties to the proceeding, Article(s), or other person party to the proceeding or to participate as a party in any hearing thereof must file a petition to intervene in accordance with the Commission's Rules. Any 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 for the hearing, 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.

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

35193

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. Lamb,
Secretary,
[FR Doc. 77-19445 Filed 7-7-77: 8:45 am]

Docket No. CP77-448

NGP-LNG, INC.

Application and Request for Phased Proceeding


Take notice that on June 20, 1977, NGP-LNG, Inc. (Applicant), 122 South Michigan Avenue, Chicago, Illinois 60603, filed in the docket proceeding in this docket pursuant to Section 7(e) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of a facility in Ingleside in San Patricio County, Texas (Gulf Coast LNG Terminal), to receive, unload, store, and vaporize liquefied natural gas (LNG), and the delivery of such vaporized LNG in interstate commerce, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant, a wholly-owned subsidiary of Peoples Gas Company (Peoples) seeks authorization from the Commission in a two-phased proceeding. In Phase I of such proceeding, Applicant requests that the Commission evaluate the environmental and safety aspects of the proposed development of the Ingleside site as an LNG terminal 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 proposed facilities and for the delivery of the subject gas.

Applicant indicates that it proposes to construct and operate the Gulf Coast LNG Terminal in order to receive, unload, store, and vaporize LNG that would be transported for 0.9 mile by Applicant to the terminal property line and there would be delivered to Applicant's facilities. Natural Gas Pipeline Company of America (Natural), also a wholly-owned subsidiary of Peoples, Natural would transport the vaporized LNG to the proposed 27.6 mile, 30-inch pipeline to a point of interconnection with its existing main transmission system located 4 miles north of Sinton, Texas, in San Patricio County, it is stated. Applicant indicates that in an attempt to alleviate its critical gas supply shortage, Natural is exploring all reasonable avenues, both traditional and non-traditional, to offset its declining supplies.

Applicant states that the facilities at the proposed Gulf Coast LNG Terminal would be capable of receiving LNG tankers as large as 165,000 cubic meter capacity transporting LNG from foreign sources, and that the tankers would enter the Corpus Christi Ship Channel through the Aransas Pass jet­ties and proceed to a position at the tanker berth. It is indicated that the terminal facilities of the particular facilities 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 1,650 million barrels of LNG, (4) a system that would convert the LNG into gaseous form for transmission, (5) auxiliary support systems and (6) 0.9 mile of pipeline to transport the LNG to Natural's proposed 27.5-mile pipeline.

It is stated that all facilities which handle LNG would be constructed of cryogenic materials. On-shore ship unloading pumps would pump LNG into the ship's piping headers which provide ship-to-shore tie-in connections. On-shore piping would carry the LNG to a storage system. Each tank would be approximately 230 feet in diameter and 130 feet in height and would be capable of receiving 350,000 barrels of LNG it is said.

It is stated that the design 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 design fill rate of the storage system.

LNG pumps would supply LNG to the vaporizer system during onloadout. Applicant asserts that the vaporizer system would receive LNG at the pipeline pressure and vaporize the LNG for pipeline transmission.

Applicant indicates that the proposed facilities would be located on a 378-acre tract of undeveloped industrial property adjacent to the north shore of Corpus Christi Bay, in the southeast San Patricio County, Texas, and that the proposed site is immediately adjacent to the proposed location of the pipeline. It is 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 Commissions' commencement of evaluation of environmental and safety issues, as requested in Phase I of this proceeding, would aid 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:

Exhibits G-II—Flow diagram data
Exhibit H—Gas supply data
Exhibit I—Market data
Exhibit L—Financing
Exhibit M—Construction, operation and management
Exhibit N—Financials, expenses, income
Exhibit O—Depreciation and depletion
Exhibit P—Tariff

Applicant has submitted with the instant filing Exhibit AA—Environmental Impact Assessment and Exhibit Z—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 1.8 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 protest 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 the grant of the proceeding 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. 77-19446 Filed 7-7-77: 8:45 am]

Docket No. RP73-64 (PGA77-2) (DCA77-2)

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
NOTICES

June 29, 1977.

By the Commission.

Kenneth F. Plumbs,
Secretary.

[FR Doc. 77-19452 Filed 7-7-77; 8:45 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. CP77-446 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 6-inch line in Beauregard Parish, Louisiana, 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 deliveries 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 commence 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 80 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 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 Regu-
lations 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 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 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.

[Docket No. RP72-133 (PGA77-2)]

UNITED GAS PIPE LINE CO.

Order Accepting for Filing and Suspending Proposed PGA Rate Increase, Requiring Adjustments, and Directing the Submission of Additional Information


On May 16, 1977, United Gas Pipe Line Company (United) tendered for filing a proposed semi-annual PGA rate increase of $89.65 per Mcf † consisting of (1) an increase of 20.4 cents per Mcf or approximately $187 million-annually in the current cost of purchased gas and (2) an increase of 9.95 cents per Mcf in the charge to recover deferred purchased gas costs of $69.6 million. United requests that the proposed higher PGA rates be permitted to become effective on July 1, 1977. A review of United's filing reveals that it is predicated, in part upon 60-day emergency purchases at rates in excess of those established in Opinion No. 770-A and upon certain alleged non-jurisdictional purchases.

† Thirty-Seventh Revised Sheet No. 4 to United's FPC Gas Tariff, First Revised Volume November 16, 1974.

† Exclusive of 343 cents per Mcf special surcharge pursuant to Opinion No. 770-A.

United shall be entitled to include in its purchased gas costs those rates for emergency purchases which a reasonably prudent pipeline would pay for gas under 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.

The issue of whether purchased gas costs associated with United's alleged non-jurisdictional purchases should be included in its PGA 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 any non-jurisdictional purchases included in its present filing. No other information as to these purchases is available, inasmuch as the respective 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 PGA filing is required for proper determination of any emergency purchases at rates in excess of those established in Opinion 770-A.

If the Commission on its own motion be permitted to become effective subject to the outcome of proceedings then, if the Commission on its own motion be permitted to become effective on July 1, 1977, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

The necessity for United's higher PGA rates is based, in part, upon the anticipated purchase of 12,900,000 Mcf from Delhi Gas Pipeline Corporation (Delhi) in Sea Robin's Docket No. RP73-89 (PGA77-2). A review of Sea Robin's filing indicates that its rates may be predicated in part, on purchases which have not been accepted. Therefore, United's PGA rates shall be accepted subject to downward adjustment to track adjustments which may be required in Sea Robin's PGA rates.

It further appears that United's filing reflects increased PGA rates of Sea Robin Pipeline Company (Sea Robin). In Sea Robin's Docket No. RP73-89 (PGA77-2). A review of Sea Robin's filing indicates that its rates may be predicated in part, on purchases which have not been accepted. Therefore, United's PGA rates shall be accepted subject to downward adjustment to track adjustments which may be required in Sea Robin's PGA rates.

Finally, in the absence of information pertaining to the alleged non-jurisdictional purchases, it is not possible to verify that the effective dates of the claimed increases thereunder will occur prior to the proposed effective date of July 1, 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.

In light of the foregoing, the Commission finds that United's proposed PGA 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 PGA rates in Docket No. RP72-89 (PGA77-2).

(2) Claimed producer rate increases which are not 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.

(C) All amounts included in United's proposed PGA 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 for each alleged non-jurisdictional purchase:

(1) The pipeline's name 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;

(5) The relationship between the purchaser and the seller.

(E) 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 for each alleged non-jurisdictional purchase:

(1) producer name, (2) contract date, (3) location, (4) a statement of individual rate components including base rate, Btu adjustment, gathering or other charges, and taxes, and (5) total cost claimed (volume × total rate).


Copies of the filing were served upon the public utilities' jurisdictional customers and state public service commissions. Any person desiring to be heard or to protest said filing on whether the filing conforms to the Commission's decision approving the settlement agreement should file a petition to intervene or protest with the Federal Power Commission, 552 North Capitol Street NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before July 15, 1977. Protest will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMS,
Secretary.

[FR Doc. 77-19449 Filed 7-7-77;8:45 am]

[DOCKET NO. CP77-445]

COLORADO INTERSTATE GAS CO.

Application


Take notice that on June 16, 1977 Colorado Interstate Gas Company (Applicant), P. O. Box 1087, Colorado Springs, Colorado 80904, filed in Docket No. CP77-445 an application pursuant to Section 7 of the Natural Gas Act as more fully set forth in the application, for a certificate of public convenience and necessity authorizing the sale of up to 40,000 Mcf of gas per day to National Gas Pipeline Company of America (NGPL), during the period of July 1, 1977 through October 31, 1977, 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 the proposed short-term sale would be separate from and in addition to Applicant's historical, long-term sales to NGPL. Applicant also requests that the requested authorisation terminate on October 31, 1977.

Applicant indicates that it would deliver to NGPL the proposed volumes of gas by means of a commensurate reduction in the volumes of gas it would otherwise receive from Northwest Pipeline Corporation (NPC) under NPC's Rate Schedule PT-1 near Green River, Wyoming, and NPC would then deliver an equivalent quantity of gas to El Paso.

Natural Gas Company (El Paso) for transportation and delivery to Transwestern Pipeline Company (Transwestern) for ultimate delivery to (NGPL). Applicant also states that no additional facilities would be required to render the proposed service.

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 natural gas annual supply of 1.8, 1.10). All such petitions or protests should be filed on or before July 15, 1977. Protest will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMS,
Secretary.

[FR Doc. 77-19449 Filed 7-7-77;8:45 am]

[DOCKET NO. CP77-445]

COLORADO INTERSTATE GAS CO.

Application


Take notice that on June 16, 1977 Colorado Interstate Gas Company (Applicant), P. O. Box 1087, Colorado Springs, Colorado 80904, filed in Docket No. CP77-445 an application pursuant to Section 7 of the Natural Gas Act as more fully set forth in the application, for a certificate of public convenience and necessity authorizing the sale of up to 40,000 Mcf of gas per day to National Gas Pipeline Company of America (NGPL), during the period of July 1, 1977 through October 31, 1977, 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 the proposed short-term sale would be separate from and in addition to Applicant's historical, long-term sales to NGPL. Applicant also requests that the requested authorisation terminate on October 31, 1977.

Applicant indicates that it would deliver to NGPL the proposed volumes of gas by means of a commensurate reduction in the volumes of gas it would otherwise receive from Northwest Pipeline Corporation (NPC) under NPC's Rate Schedule PT-1 near Green River, Wyoming, and NPC would then deliver an equivalent quantity of gas to El Paso.

NOTICES

Natural Gas Company (El Paso) for transportation and delivery to Transwestern Pipeline Company (Transwestern) for ultimate delivery to (NGPL). Applicant also states that no additional facilities would be required to render the proposed service.

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 natural gas annual supply of 1.8, 1.10). All such petitions or protests should be filed on or before July 15, 1977. Protest will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMS,
Secretary.

[FR Doc. 77-19449 Filed 7-7-77;8:45 am]

[DOCKET NO. CP77-445]

COLORADO INTERSTATE GAS CO.

Application


Take notice that on June 16, 1977 Colorado Interstate Gas Company (Applicant), P. O. Box 1087, Colorado Springs, Colorado 80904, filed in Docket No. CP77-445 an application pursuant to Section 7 of the Natural Gas Act as more fully set forth in the application, for a certificate of public convenience and necessity authorizing the sale of up to 40,000 Mcf of gas per day to National Gas Pipeline Company of America (NGPL), during the period of July 1, 1977 through October 31, 1977, 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 the proposed short-term sale would be separate from and in addition to Applicant's historical, long-term sales to NGPL. Applicant also requests that the requested authorisation terminate on October 31, 1977.

Applicant indicates that it would deliver to NGPL the proposed volumes of gas by means of a commensurate reduction in the volumes of gas it would otherwise receive from Northwest Pipeline Corporation (NPC) under NPC's Rate Schedule PT-1 near Green River, Wyoming, and NPC would then deliver an equivalent quantity of gas to El Paso.
the provision that the amended certificate authorization and the rights granted thereunder were conditioned upon Petitioner obtaining the necessary storage rights on the acreage needed to extend the Artemas-B Storage Reservoir within one year from the issuance of the Order, which period would expire July 20, 1977. It is impractical for the areas of the lease acquisition that has not been completed as of June 3, 1977, are as follows:

(1) A modification of the present lease from the Commonwealth of Pennsylvania is required to include its 1/4 undivided interest in 60 acres situate within the extension herein applied for;

(2) 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, etc. 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, etc.

(3) A 1,363.1 acres owned by the State of Maryland. This lease has been approved by 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 (3) and (4) 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 or July 20, 1977, in the instant docket by deleting from ordering paragraph (D) the phrase, "within one year from the issuance of this order," and 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 acreage needed to extend the Artemas-B Storage Reservoir.

Any person desiring to be heard or to make any protest to or against these changes in rates, or on the denial of the petition to amend should on or before July 19, 1977, file with the Federal Power Commission, Washington, D.C. 20423, 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 while 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. PLUMS, Secretary.
utility has agreed to a fixed contract rate according less than a fair return, it would not be appropriate to use that higher standard in the case sub judice. 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 205, 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-7740."

(B) Ordering Paragraph (C) of the Order issued April 29, 1977 is hereby amended to read as follows:

"In all other respects, our Order of April 29, 1977 remains in full force and effect."

(C) 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.77-19438 Filed 7-7-77; 8:45 am]

ELMS BROTHERS & CO.
Settlement Proposal


Take notice that on June 22, 1977, Elms Brothers and Company filed a settlement proposal in the captioned proceeding offering to accept rates of $0.6290 and $1.49, respectively, for its Greene County and Washington County Wells that are the subject of this proceeding.

Any person desiring to be heard or to make any protest with reference to said proposal should on or before July 15, 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, an investigation is ordered to determine the just and reasonable rate to be charged to the Village 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.77-19438 Filed 7-7-77; 8:45 am]

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 79978, filed in Docket No. CP77-456 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction, extension, or modification of interstate facilities and for the sale of natural gas for resale pursuant to Section 7 of the Natural Gas Act. The application, along with the Environmental Impact Statement, is available for public inspection.

It is stated that Natural has asked Applicant and other entities to provide additional gas supplies which are available to Natural but not located in close proximity to its systems. Natural will 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 levels for the 1977-78 winter season, if it is issued.

Applicant indicates that Natural has contracted with Colorado Interstate Gas Company (Colorado) to supply volumes of gas purchased by Natural to Northwest Pipeline Corporation (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 quantities to Applicant 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 amount representing 10.0 cents 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 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 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]

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 79978, 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 sales lateral pipeline facilities and for a certificate of public convenience and necessity authorizing the relocation, and modification of cer-
tains facilities, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant seeks permission and approval to abandon and convey, without cost, to the City of Mesa, Arizona, certain minor sales lateral pipeline facilities and a certificate of public convenience and necessity authorizing the relocation and rebuilding of Applicant's existing Mesa No. 2 meter station facility all located on Applicant's interstate system in Maricopa County, Arizona.

It is indicated that on November 29, 1981, in Docket No. G-1345 (10 FPC 844), Applicant was authorized to construct and operate the Mesa No. 2 meter station and approximately 10 miles of 4½-inch O.D. sales lateral pipeline, all located in Maricopa County, Arizona, in order to provide natural gas service for the City of Mesa. It is further indicated that by order issued February 28, 1956, at Docket No. G-13107 (10 FPC 292), Applicant was authorized to construct and operate approximately 10.2 miles of 6%-inch O.D. pipeline looping and the 4½-inch O.D. sales lateral pipeline in order to provide Applicant with additional pipeline capacity to serve the increased natural gas requirements of the City of Mesa. The Mesa No. 2 meter station and the 4½-inch O.D. and 6%-inch O.D. lateral pipelines are currently utilized by Applicant in rendering gas service to the City of Mesa, it is said.

Applicant states that it is as a result of encroachment1 in the vicinity of the Mesa No. 2 meter station, such site has become increasingly congested and less suitable for location of gas measurement facilities. Applicant indicates that it is therefore necessary to relocate the existing Mesa No. 2 meter station to a site on the existing pipeline some 2,200 feet south of the present site, and also to rebuild the existing metering facilities when relocated in order to upgrade the measurement of deliveries and accommodate changes in operating conditions.

Applicant indicates that it and the City of Mesa have agreed to the relocation and the conveyance by Applicant to the City of Mesa of the subject pipeline facilities pursuant to a letter agreement dated January 7, 1977, between the two parties. It is stated that the City of Mesa would accept from Applicant, upon Applicant's relocation of the subject meter station facilities and approximately 0.42 mile of said 4½-inch O.D. pipe loop commencing at the proposed outlet of the relocated Mesa No. 2 station and terminating at the point of interconnection of such facilities with the City of Mesa's existing distribution system, the present site of the Mesa No. 2 meter station. These facilities would be operated and maintained by the City of Mesa, and would become a part of the City of Mesa's distribution system utilized in serving its customers requirements, it is said.

Applicant states that the realignment of facilities would permit a reduction in the current operating pressure of the segment of pipeline to be conveyed by the Natural Gas Act regulations required to accept such delivery pressures from Applicant and necessary for distribution system operation. It is said that no change in the contract demand quantity or daily volume deliveries to the City of Mesa would occur as a result of the proposed realignment of the facilities.

Applicant indicates that the original total cost of the facilities to be conveyed to the City of Mesa is $11,897.59, and that the total estimated cost of the relocation and rebuilding of the said facilities No. 2 meter station and approximately 10.42 mile of said 4½-inch O.D. and 6½-inch O.D. pipeline is $48,344. Applicant further states that it would finance the cost of the facilities relocated and rebuilt through use of internal 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 1.6 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 any question raised in the application to intervene in writing and filed. If a petition to intervene is filed within the time required therein, if the Commission on its own review of the matter finds that a grant of the certificate and permission and approval for the proposed abandonment are 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, 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 F. PLUMB, Secretary.

[FRC Doc 77-19933 Filed 7-7-77 8:45 am]

[Docket No. RI77-64]

FRIO PRODUCTION CO.

Petition for Special Relief


Take notice that on May 5, 1977, Frio Production Company (Frio), P.O. Box 1890, Alice, Texas, filed a petition for special relief in Docket No. RI77-04, pursuant to Section 276 of the Commission's General Policy and Interpretations (16 CFR 2.76), a small producer, seeks authorization to charge $1.60 per Mcf at 14.65 psia for gas produced from three wells in the Ramerino Field in Live Oak County, Texas. The gas underlying these wells is dedicated to United Gas Pipe Line Company (United) as a result of a contract between Frio and United dated August 24, 1972. Applicant reworked and added compression to one of these wells in consideration of a rate increase to 55 cents per Mcf, pursuant to 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.

According to the application, production from these wells has ceased due to a compressor failure. Applicant seeks authorization based on the work previously done under the 1974 contract amendment, anticipated work to repair the compressor, construction of an access road, and other items. Frio estimates that $0.060 Mcf of gas could be produced from these wells. United has agreed to pay a higher special relief rate up to $1.60 per Mcf.

Any person desiring to be heard or to make any protest with reference to said petition 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 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 any question raised in the application to intervene in writing and filed. If a petition to intervene is filed within the time required therein, if the Commission on its own review of the matter finds that a grant of the certificate and permission and approval for the proposed abandonment are 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, 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 F. PLUMB, Secretary.
tions to intervene in accordance with the Commission's Rules.

KENNETH F. PLUMB, Secretary.

[F.R. Doc. 77-19444 Filed 7-7-77; 8:45 am]

[Docket No. R177-85]

GOLDKING PRODUCTION CO.

Petition for Special Relief


Take notice that on May 11, 1977, Goldkings Production Company (Petitioner), 200 First City National Bank Bldg., Houston, Texas, filed in Docket No. R177-85 a petition for special relief pursuant to Section 2.76 of the Commission's Rules and Practice and Procedure.

Petitioner during October, 1976 re-entered and re-completed the Ballard and Cardella #1 Krenek well at a depth between 7485 and 7491 feet involving expenditures for surface equipment and delivery facilities together with other items representing an aggregate investment of $68,986 to recover estimated reserves 174,000 Mcf of natural gas located in the Bonus Field, Wharton County, Texas. Such property was acquired by assignment of an oil and gas lease dated August 26, 1975 from Brown & McKenzie, which lease expired and thereafter was renewed by Petitioner. Petitioner seeks a rate of approximately $1.16 per Mcf and requests that such rate be made effective subject to refund. Such rates when commenced are pursuant to a contract dated April 19, 1977 between Petitioner and Texas Eastern Transmission Corporation.

It appears reasonable and consistent with the public interest in this case to prescribe a period shorter than 15 days for filing of protests and petitions to intervene. Therefore, any person desiring to become a party to any protest with reference to said application should file a protest on or before May 31, 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 C.F.R. 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protest 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.

[F.R. Doc. 77-19444 Filed 7-7-77; 8:45 am]

NOTICES

[Docket No. ER76-715]

INDIANA & MICHIGAN ELECTRIC CO.

Order Approving Settlement Agreement


On May 28, 1976, Indiana and Michigan Electric Company (I&E) filed a proposed settlement agreement for approval based on a settlement with Northern Indiana Public Service Company (NIPSCO). By Order dated June 25, 1976, the Commission accepted the proposed settlement agreement. The proposed rate increase and the proposed settlement agreement itself, the filing, 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 agreement between I&M and NIPSCO filed 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 § 32.19 (a) within 30 days of the date of 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 February 17, 1977 at an agreed upon interest rate of 9 percent per annum.

(C) The Commission hereby orders that Section 35.3 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 this order to show monthly billing determinants and the effect of the proposed settlement agreement and the loss of revenues under prior, present, and settlement rates. The report should show the monthly bill changes, in both dollars and as a percentage of the total bill, and the monthly interest computation together with a summary of such information for the total refund period. A copy of such report should be due by I&M to each Staff within whose jurisdiction the wholesale customers and end customers are affected by the Order against I&M or any party or persons affected by the Order against I&M or any party or persons affected by the Order against I&M.

1 The filing in Docket No. ER76-714 involves a rate increase filing for service to Michigan Power Company.

2 The filing in Docket No. ER76-716 involves a rate increase application for service to I&M Cooperative and Municipal resale customers.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
I&ME's resale services in the consolidated proceedings. During the settlement conference held on November 10, 1976, Staff requested additional information from I&ME to complete its evaluation of I&ME's filing which was subsequently provided. On December 8, 1976 Staff filed revised Settlement Cost of Service Top Sheets. The proposed settlement hereinafter approved by this Order provides for an increase in rates less than the amount 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&ME 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 reasonableness of the proposed settlement agreement.

On March 16, 1977, the Michigan Public Service Commission approved a rate filing for service to Michigan Electric Company (I&ME) filed proposed increased rates for service to Michigan Power Company (MPCO) a wholly-owned subsidiary. By Order dated June 25, 1976, the Commission ordered 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 proceedings in docket Nos. ER76-715 and ER76-716.


The Settlement Agreement proposes certain changes to I&ME's rate filing as originally submitted on May 28, 1976. Inasmuch as it provides for (1) a reducton in the rate to be charged for service to 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 proceedings in docket Nos. ER76-715 and ER76-716.


The Settlement Agreement proposes certain changes to I&ME's rate filing as originally submitted on May 28, 1976, inasmuch as it provides for (1) a reduction in the rate to be charged for service to 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; (2) an effective date of July 27, 1976 (the date I&ME's increases were permitted to become effective subject to refund); (3) reduction in the original proposed demand charge of $8.17 per KW to $6.95 per KW; (4) refund of a rate increase not permitted to become effective subject to refund; (5) refund of a rate increase interpreted in excess of settlement rates at 9 percent in I&ME's rate filing; (6) requests waiver of 33.13 of the Commission's regulations to the extent necessary to effect all provisions of the proposed settlement; and (5) the inclusion of a provision dealing with mutually agreed upon procedures for the curtailment of power and energy deliveries to MPCO in the event that there should be a shortage of capacity and or energy requiring I&ME to curtail power and energy delivery to its own customers.

The proposed settlement rate would reduce the amount of previously requested increase from $7,254,000 to approximately $5,939,000. On November 1, 1976, Staff filed Settlement Cost of Service Top Sheets for approximately $5,939,000. On November 1, 1976, Staff filed Settlement Cost of Service Top Sheets for

The filing in Docket No. ER76-715 involves a rate increase filing for service to Northern Indiana Public Service Company. The filing in Docket No. ER76-716 involves a rate increase filing for service to I&ME Cooperative and Municipal resale customers.
NOTICES

[NORHERN NATURAL GAS CO. Application]


Take notice that on June 16, 1977, Northern Natural Gas Company (Applicant), 2325 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, all 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 1, 1976, in Docket No. CP76-265 (F.P.C. 1977), 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). It is also stated 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.

[F.R. Doc. 77-19443 Filed 7-7-77; 8:45 a.m.]

[Docket No. CP77-443]

NORTHEAST PIPELINE CORP. Application


Take notice that on June 22, 1977, Northeast 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 best efforts basis for Natural Gas Pipeline Company (Natural) for a period commencing on the date of any authorization issued herein and continuing through October 31, 1977, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

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 15, 1977, between Applicant and Natural. Applicant indicates that Natural and Colorado Interstate Gas Company (CIG) have entered into an agreement dated June 13, 1977, which provides that CIG would 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 ultimately to make approximately equivalent 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 deliver to CIG pursuant to Applicant's and El Paso in the vicinity of Ignacio, Colorado.

Applicant states that it would charge Natural 8 cents per billion Btu's for the proposed volume of natural gas it would otherwise deliver to El Paso, for Natural's account, at the point of interconnection between Applicant and El Paso. Applicant would not require any additional facilities to effectuate the proposal, it is said.

It is stated that deliveries by CIG to Applicant for the account of Natural would be made by Applicant reducing the volumes, adjusted for heating value, to El Paso, from volumes of natural gas at an existing point of interconnection between the facilities of Applicant and El Paso in the vicinity of Green River, Wyoming, and that Applicant would re-deliver 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 indicated 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 1.3 cents at the end of each one-year period.
(ii) $0.689 for gas from a well or wells commenced on or after 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 742, it is said. It is stated that 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, at a point 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 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 any party to appear or be represented at the hearing.

KENNETH F. PLUMS, Secretary.

[FPR Doc. 77-19502 Filed 7-7-77: 45 am]

[Docket No. CP77-447]

NORTHWEST PIPELINE CORP.

Application


Take notice that on June 17, 1977, Northwest Pipeline Corporation (Applicant), P.O. Box 1526, Salt Lake City, Utah 84110, filed in Docket No. CP77-447 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the transportation of up to 5,000 Mcf of natural gas 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 Piceance Creek lateral located in Rio Blanco County, Colorado, and Applicant would receive for transportation such volumes as are delivered by IGC and would re-deliver equivalent volumes, subject to Applicant's right to purchase up to 40 percent of the volumes delivered for transportation, at an existing point of interconnection between the facilities of Applicant and Intermountain near Pocatello, Idaho.

It is indicated 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 1.3 cents at the end of each one-year period.
(ii) $0.689 for gas from a well or wells commenced on or after 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 742, it is said. It is stated that 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, at an existing point of interconnection between Applicant's and IGC facilities in Rio Blanco County, Colorado, for the receipt or the re-delivery of such volumes, subject to 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.
NOTICES

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. ERT7-42]

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 FCC 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 (PSCO), and Oklahoma Gas and Electric Company (OG&E). PSCO states that the rate schedules expire by their terms at midnight 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. Municipal states 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 PSCO, OG&E, and SWPA. The Municipal therefore seek a Commission order continuing the terms of the present contract until a new contractual arrangement may be accepted by the Commission. Municipal states 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, PSCO filed an answer to the petition to intervene and protest contending that Municipal were not totally dependent upon SPA since two of the cities receive a portion of their power 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 205(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 PSCO'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 Municipal 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 PSCO's service termination.

(B) Pending a hearing and final decision hereon, PSCO's submittals are hereby accepted for filing and suspended for five months, until December 1, 1977.

(C) Municipal hereby agreed 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. ERT7-87]

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 representing a settlement of the issues between the Commission, the Sierra Pacific Power Company (Sierra), and certain customers of Sierra.

The Sierra Pacific Power Company (Sierra), the Truckee-Donner Public Utility District (Truckee-Donner), and the Public Service Commission of Nevada (Fallon) have filed a proposed Settlement Agreement that is too narrowly drawn. Mt. Wheeler: Pacific Gas and Electric Company (PG&E); the City of Fallon, Nevada (Fallon); the Truckee-Donner Public Utility District (Truckee-Donner); and the Sierra Pacific Power Company (Sierra) have filed an answer to the proposed Settlement Agreement, together with a Statement of Position submitted in furtherance of the matters of the record.

The Sierra Pacific Power Company (Sierra) has filed a Statement of Position, together with a Portion of the Record, in furtherance of the matters of the record.

The proposed Settlement Agreement does not resolve the issue of whether it is proper for Sierra to transfer Mt. Wheeler to Rate Schedule R. The order then set the entire filing for hearing. In addition, the order permitted the intervention 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-Donner); and the Public Service Commission of Nevada (Fallon) to file a statement of position. A joint order of the Secretary of the Navy was granted by order issued June 8, 1975.

As a result of informal settlement conferences among the parties, a proposed Settlement Agreement was submitted and received into evidence at a hearing held December 20, 1976 (Tr. 4:109-110). The proposed Agreement would modify Mt. Wheeler'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 subject to refund. Notion of issues at bar forth Schedule R. The order then set the entire filing for hearing. In addition, the order permitted the intervention 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-Donner); and the Public Service Commission of Nevada (Fallon) to file a statement of position. A joint order of the Secretary of the Navy was granted by order issued June 8, 1975.

The proposed Agreement does not resolve the issue of whether it is proper for Sierra to transfer Mt. Wheeler to Rate Schedule R. The order then set the entire filing for hearing. In addition, the order permitted the intervention 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-Donner); and the Public Service Commission of Nevada (Fallon) to file a statement of position. A joint order of the Secretary of the Navy was granted by order issued June 8, 1975.

As a result of informal settlement conferences among the parties, a proposed Settlement Agreement was submitted and received into evidence at a hearing held December 20, 1976 (Tr. 4:109-110). The proposed Agreement would modify Mt. Wheeler'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 subject to refund. Notion of issues at bar forth Schedule R. The order then set the entire filing for hearing. In addition, the order permitted the intervention 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-Donner); and the Public Service Commission of Nevada (Fallon) to file a statement of position. A joint order of the Secretary of the Navy was granted by order issued June 8, 1975.
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 any party. The investigation of this type was in fact the subject of a hearing in this docket, and the initial decision therein, issued March 28, 1977, is currently pending review by the Commission.

On the same date on which the proposed Settlement Agreement was submitted for inclusion in the record, Sierra circulated a modification to its fuel adjustment clause. (Docket No. 2623, pp. 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. 4109, 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 Mt. Wheeler 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 that period. Also attached to Sierra's Statement of Position was a letter from Mt. Wheeler submitting four separate proposals for pricing fuel costs: (1) a base price based on a twelve-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 its settlement offer; (3) the one month operating period alternative which Sierra's earlier proffering of alternate proposals for pricing fuel costs: (1) a base price based on a twelve-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 its settlement offer; (3) the one month operating period alternative which Sierra subsequently submitted as its settlement offer; (4) the one month operating period alternative which Sierra subsequently submitted as its 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 the period covered by Sierra's filing in this docket and provided for a hearing, permitted service to Mt. Wheeler to be placed under Schedule R, subject to refund. The proposed Agreement would keep Mt. Wheeler under Schedule R. At least until the Commission issues its opinion reviewing the Initial Decision, therefore, service to Mt. Wheeler remains under Schedule R. Accordingly, the base energy cost in the proposed fuel clause to be applied to Mt. Wheeler is correctly derived. Should the Commission ultimately decide to restore Mt. Wheeler's separate R-2 rate schedule, then the fuel clause applicable to Mt. Wheeler, including the base energy cost and the factor components, would be coordinated with the underlying R-2 rate.

Mt. Wheeler's objection to this application to its service at 230 kV line was subsequently placed into service the 230 kV transmission line which would keep Mt. Wheeler under Schedule R or Schedule R-2. Mt. Wheeler's objection to its loss factor assignment is also tied to the determination of the applicable rate schedule. Sierra's premise in placing Mt. Wheeler on Schedule R is that construction of the 230 kV transmission line served to integrate Mt. Wheeler's electric utility, we must expect ripples in the billings to a non-intermittent customer. In both instances, the actual average per-kwh fuel cost for the month will not necessarily be equivalent to the per-kwh fuel cost billed in the same month. Any increase or decrease (or termination) in the kwhs purchased by a customer from month to month will prevent the recovery from that customer of the precise amount of past fuel costs which the customer caused the company to incur. As has been reiterated in Opinion No. 790, this imprecision is not fatal to the propriety of the fuel clause.

Sierra is of course free to file in some future proceeding a fuel clause modified along the lines recommended by Mt. Wheeler. In this proceeding, however, the proposed Settlement Agreement submitted by Sierra contains a fuel adjustment clause which would be designed to produce as nearly as practicable a mirror image of the rate of cost of fuel upon the price of energy which is delivered by an electric utility, we must expect ripples in that reflection. Because of the time factor involved in gathering and assimilating data, expressing the number of dollars spent for gallons of oil or tons of coal in terms of dollars per kilowatt hour, and mailing and collecting the resulting billings, there must be some imprecision in matching fuel expense with delivery of electricity. The resulting imprecision is not fatal to the propriety of the fuel clause.

* In Sierra Pacific Power Company, 52 FPC 385 (1974) (Opinion No. 702), the Commission held that Sierra had placed into service the 230 kV transmission line which would connect Mt. Wheeler with Sierra's main system, and that the case was before the Commission. Mt. Wheeler's counsel to Judge Kanell, at page 111.

1 We find that the settlement fuel clause is in conformity with Order No. 517, and we have found unpersuasive its argument that the settlement fuel clause would keep Mt. Wheeler under Schedule R or Schedule R-2.

2 We would observe in this connection that while every fuel adjustment clause should be designed to produce as nearly as practicable a mirror image of the cost of fuel upon the price of energy which is delivered by an electric utility, we must expect ripples in that reflection. The settlement fuel clause is in conformity with Order No. 517, and we have found unpersuasive its argument that the settlement fuel clause would keep Mt. Wheeler under Schedule R or Schedule R-2.

3 Sierra is of course free to file in some future proceeding a fuel clause modified along the lines recommended by Mt. Wheeler. In this proceeding, however, the proposed Settlement Agreement submitted by Sierra contains a fuel adjustment clause which would be designed to produce as nearly as practicable a mirror image of the rate of cost of fuel upon the price of energy which is delivered by an electric utility, we must expect ripples in that reflection. Because of the time factor involved in gathering and assimilating data, expressing the number of dollars spent for gallons of oil or tons of coal in terms of dollars per kilowatt hour, and mailing and collecting the resulting billings, there must be some imprecision in matching fuel expense with delivery of electricity. The resulting imprecision is not fatal to the propriety of the fuel clause.

Sierra is of course free to file in some future proceeding a fuel clause modified along the lines recommended by Mt. Wheeler. In this proceeding, however, the proposed Settlement Agreement submitted by Sierra contains a fuel adjustment clause which would be designed to produce as nearly as practicable a mirror image of the rate of cost of fuel upon the price of energy which is delivered by an electric utility, we must expect ripples in that reflection. Because of the time factor involved in gathering and assimilating data, expressing the number of dollars spent for gallons of oil or tons of coal in terms of dollars per kilowatt hour, and mailing and collecting the resulting billings, there must be some imprecision in matching fuel expense with delivery of electricity. The resulting imprecision is not fatal to the propriety of the fuel clause.

Sierra is of course free to file in some future proceeding a fuel clause modified along the lines recommended by Mt. Wheeler. In this proceeding, however, the proposed Settlement Agreement submitted by Sierra contains a fuel adjustment clause which would be designed to produce as nearly as practicable a mirror image of the rate of cost of fuel upon the price of energy which is delivered by an electric utility, we must expect ripples in that reflection. Because of the time factor involved in gathering and assimilating data, expressing the number of dollars spent for gallons of oil or tons of coal in terms of dollars per kilowatt hour, and mailing and collecting the resulting billings, there must be some imprecision in matching fuel expense with delivery of electricity. The resulting imprecision is not fatal to the propriety of the fuel clause.

Sierra is of course free to file in some future proceeding a fuel clause modified along the lines recommended by Mt. Wheeler. In this proceeding, however, the proposed Settlement Agreement submitted by Sierra contains a fuel adjustment clause which would be designed to produce as nearly as practicable a mirror image of the rate of cost of fuel upon the price of energy which is delivered by an electric utility, we must expect ripples in that reflection. Because of the time factor involved in gathering and assimilating data, expressing the number of dollars spent for gallons of oil or tons of coal in terms of dollars per kilowatt hour, and mailing and collecting the resulting billings, there must be some imprecision in matching fuel expense with delivery of electricity. The resulting imprecision is not fatal to the propriety of the fuel clause.

Sierra is of course free to file in some future proceeding a fuel clause modified along the lines recommended by Mt. Wheeler. In this proceeding, however, the proposed Settlement Agreement submitted by Sierra contains a fuel adjustment clause which would be designed to produce as nearly as practicable a mirror image of the rate of cost of fuel upon the price of energy which is delivered by an electric utility, we must expect ripples in that reflection. Because of the time factor involved in gathering and assimilating data, expressing the number of dollars spent for gallons of oil or tons of coal in terms of dollars per kilowatt hour, and mailing and collecting the resulting billings, there must be some imprecision in matching fuel expense with delivery of electricity. The resulting imprecision is not fatal to the propriety of the fuel clause.
all the parties except PG&E and Mt. Wheeler is in conformance with Order No. 517 and should be approved. We further find that the settlement fuel clause is applicable to Mt. Wheeler as well as to the other wholesale customers. As we have stated, supra, Mt. Wheeler's argument regarding the synchronization problem is unpersuasive, and its objections concerning the proper base energy cost and the proper loss factor are moot for so long as Mt. Wheeler is served under Schedule R.

Public notice of the filing and certification of the proposed Settlement Agreement was issued on March 18, 1977, with comments thereon due on or before April 9, 1977. On April 7, 1977, the Department of the Navy filed comments in support of the settlement and the alternative fuel clause proposed by Sierra. In comments filed April 6, 1977, the Commission Staff supported the settlement and the alternative fuel clause and agreed that the fuel clause should apply to Mt. Wheeler. Late comments filed on April 12, 1977, by Truckee-Donner called attention to a typographical error in the Settlement Agreement.

Based on our review of the record in these proceedings, including the Settlement Agreement itself and Sierra's Statement of Position on the fuel clause (with attached comments of the other parties), we conclude that the Settlement Agreement represents a reasonable resolution, in the public interest, of the issues in the proceeding (with the exceptions of the reserved issues), and that accordingly the settlement should be approved.

The Commission finds: The proposed Settlement Agreement submitted to the Commission in this docket should be approved and made effective, as hereinafter ordered.

The Commission orders: (A) The Settlement Agreement certified to the Commission on March 7, 1977, by the Presiding Administrative Judge in the proceedings is hereby approved, incorporated herein by reference and approved subject to the conditions specified.

(B) Sierra shall file within 30 days of the issuance of this order revised tariff sheets in conformance with the settlement agreement and the revised fuel clause included as Attachment B to Sierra's Statement of Position filed February 28, 1977.

(C) Within 30 days after the settlement tariff sheets are accepted for filing, Sierra shall refund amounts collected in excess of the settlement rates with interest computed at 9% per annum.

(D) Within 15 days after refunds have been made, Sierra shall file with the Commission a report describing monthly billing determinants and revenues under prior, present and settlement rates; 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 each State Commission within whose jurisdiction the wholesale customers distribute and sell electric energy at retail.

(E) This order is without prejudice to any findings or orders which have been made or which will hereafter be made by the Commission, and is without prejudice to any claims or contentions which may be made by the Commission, its staff, or any party or person affected by this order, in any proceeding now pending or hereafter instituted by or against Sierra or any person or party.

(F) The Secretary shall cause prompt publication of this order in the Federal Register.

By the Commission.

KENNETH F. PLUMB, Secretary.

[FR Doc. 77-19499 Filed 7-7-77; 8:45 am]

[TENNESSEE GAS PIPELINE CO.]

Order Accepting Rate Filing Under Tariff Rate Adjustment Provisions


On May 16, 1977, Tennessee Gas Pipeline Company, 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) provisions in the General Terms and Conditions of its 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 collected subject to refund, as provided in Tennessee's tariff, and subject to the outcome of the proceedings in Docket Nos. RP75-13, RP75-113, and RP77-82.

The proposed rate filings include three separate tracking adjustments: (1) a PGA rate increase of $0.44 per Mcf to track both increased gas costs of $0.71 per Mcf for the 1976-77 period 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 track decreased gas costs and an increase of 0.08 cents per Mcf or $921,060 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) 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. This filing, filed as its purchases under the Emergency Act are less than two percent of its total purchases, is 18 CFR 1000.9(e)(1). The Commission will grant this request and permit recovery in the PGA surcharge as accepted here for.

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 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, as proposed.

The Commission finds that: (B) To the extent that the rates accepted here reflect charges attributable to R&D expenditures by Tennessee, these rates shall be collected subject to refund, with interest, upon conclusion of the proceedings in Docket Nos. RP75-13, RP75-113, or RP77-62. (C) The Secretary shall cause prompt publication of this order to be made in the Federal Register.

By the Commission.

KENNETH F. PLUMB, Secretary.

[Docket No. RI77-48]

TEXAS ENERGY, Inc.

Petition for Special Relief


Take notice that on May 23, 1977, Texas Energy, Inc. (Texas Energy), P.O. Box 817, Amarillo, Texas, filed a petition pursuant to Section 7(c) of the Natural Gas Act and Section 2.76 of the Commission's General Policy and Interpretation (18 CFR 2.76) for a certificate of public convenience and necessity. Petitioner seeks authorization to transport up to 2,304 MCF 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 fully set forth in the application which is on file with the Commission and open to public inspection.

It is indicated that all of the volumes of gas proposed to be transported to Western Kentucky for delivery to Martin-Marietta at its Lowsport, 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 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 167.10). 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 to the 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.

Under the procedure herein provided for, unless otherwise advised, it will be

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

35207
NOTICES

TRANSCONTINENTAL GAS PIPE LINE CORP.

Application

June 29, 1977.

Take notice that on June 21, 1977, Transcontinental Gas Pipe Line Corporation (Applicant), P.O. Box 1396, Houston, Texas 77201, 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 CFR 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 United States & Alaska Douglas, Inc. (Crown) and Davasco, 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 at the rates specified, which would be in effect and applicable only for the period of time covered by this application.

It is stated that Collins, Crown and Davasco have purchased from Samedan Oil Corporation (Samedan) up to 750 Mcf of natural gas per day (at 15.65 psia basis) of gas to be produced from the Carl Unit No. 1, Bee County, Texas. It is indicated that Collins, Crown and Davasco would pay Samedan for all gas delivered $2.25 per million Btu’s (at 14.65 psia) and that they would also pay Samedan 8.4 cents per Mcf for gathering and transporting gas to delivery point.

Applicant states that Collins, Crown and Davasco would arrange to have such quantities delivered to United Gas Pipe Line Company (United) and United would deliver the gas to Applicant at mutually agreed-upon rates of exchange with Applicant and others, the United System, and related systems. Applicant further states that it would receive the transportation volumes existing points of delivery to PSNC for the accounts of Collins, Crown and Davasco, and that PSNC would transport the subject gas to Collins’ and Crown’s Roxboro, North Carolina plants and to Davasco’s Gastonia, North Carolina plant.

It is indicated that the volumes of gas proposed to be transported and delivered to Collins, Crown and Davasco would be used for Priority 2 use and that there is no other alternate fuel for use at these plants.

Applicant states that it would charge Collins, Crown and Davasco 29.8 cents per Dekatherm (dt) 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, 3.8 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 “common 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 do so before July 11, 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 18 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 an application in accordance with the Commission’s Rules.

Take further notice that, pursuant to the jurisdiction 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 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.77-19435 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 CFR, §§ 1.7 and 5.7, for leave to intervene or a protest in accordance with the Commission’s Rules of Practice and Procedure, requesting the Commission to issue a notice of proposed rulemaking concerning 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 formulating 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 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 potential customers from making efforts to overcome gas shortages. By establishing uniform rules governing pipeline transportation service of non-system gas, it is alleged that pipeline customers will be enabled to secure supplemental supplies of gas, thereby increasing the general interstate 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

Federal Register, Vol. 42, No. 131—Friday, July 8, 1977
petition should on or before July 15, 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 manner for public inspection. A party to a proceeding or to participate in the proceedings as a protestant must file a protest with 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 manner for public inspection. A party to a proceeding or to participate in the proceedings as a protestant must file a protest with the Commission. Washington, D.C. 20426, a petition to intervene in accordance with the Commission's order of April 25, 1977, approving Panhandle's rate settlement in the captioned 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 (PGA) of Panhandle's tariff and revisions in Panhandle's Rate Schedules TT-1, TSIE-1 and TSE-1. The proposed changes in Panhandle's PGA relate to the determination of the base cost of gas from suppliers, the allocation factors from pipeline suppliers, and the use of reserves. The proposed changes to Colorado Interstate Gas Company and Kansas Nebraska Natural Gas Company from the calculation of the current average cost of purchased gas. The PGA revisions in 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 PGA 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 payments and a reduction in the DCA surcharge. This sheet reflects rate levels approved in First Substitute Nineteenth Revised Sheet No. 3-A could be considered as a result of Panhandle's rate settlement during the pendency of the settlement approved by the Commission on April 25, 1977. Under the agreement, First Substitute Nineteenth Revised Sheet No. 3-A could be considered as effective April 1, 1977, prior to approval of the settlement. (Article II, Section 2 and Article VII), 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. The refund is available to refund. Hearing procedures shall be instituted to determine the lawfulness of the proposed increase. Panhandle's tendered settlement rates in Docket Nos. RP75-102 has been ad-

**NOTICES**

**[Docket No. RP75-102]**

**PANHANDLE EASTERN PIPE LINE CO.**

Order Accepting for Filing and Approving Tariff Revisions, Including Suspended Proposed Advance Payment Rate Sheet No. 3-A, Eliminating Hearing, Establishing Procedures, and Requiring Submission of Revised Settlement Rates

**JUNE 30, 1977.**

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 captioned 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 (PGA) of Panhandle's tariff and revisions in Panhandle's Rate Schedules TT-1, TSIE-1 and TSE-1. The proposed changes in Panhandle's PGA relate to the determination of the base cost of gas from suppliers, the allocation factors from pipeline suppliers, and the use of reserves. The proposed changes to Colorado Interstate Gas Company and Kansas Nebraska Natural Gas Company from the calculation of the current average cost of purchased gas. The PGA revisions in 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 PGA 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 payments and a reduction in the DCA surcharge. This sheet reflects rate levels approved in First Substitute Nineteenth Revised Sheet No. 3-A could be considered as a result of Panhandle's rate settlement during the pendency of the settlement approved by the Commission on April 25, 1977. Under the agreement, First Substitute Nineteenth Revised Sheet No. 3-A could be considered as effective April 1, 1977, prior to approval of the settlement. (Article II, Section 2 and Article VII), 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. The refund is available to refund. Hearing procedures shall be instituted to determine the lawfulness of the proposed increase. Panhandle's tendered settlement rates in Docket Nos. RP75-102 has been ad-

**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.  
Delmarva Power & Light Co.  
Elizabethtown Gas Co.  
Long Island Lighting Co.  
Lynxburg Gas Co.  
New Jersey Natural Gas Co.  
New York State Electric & Gas Corp.  
Philadelphia Electric Co.  
Philadelphia Gas Works  
Public Service Company of North Carolina, Inc.  
Public Service Electric & Gas Co.  
South Jersey Gas Co.  
TGI Corporation  
Washington Gas Light Co.

[FR Doc.77-19456 Filed 7-7-77;8:45 am]

**MICHIGAN WISCONSIN PIPE LINE CO., ET AL.**

Settlement Proposal

**JULY 1, 1977.**

Take notice that on March 6, 1977, Michigan Consolidated Gas Company (MCG) filed with the Commission in Docket No. CP76-254, one of the above-captioned dockets in this consolidated proceeding, a settlement proposal which purports to resolve MCG's rates in this proceeding.

The settlement was certified to the Commission by the Presiding Administrative Law Judge on March 22, 1977. Any person wishing to do so may submit comments in writing concerning MCG'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. MCG's settlement proposal is on file with the Commission and available for public inspection.

**KENNETH F. PLUMB, Secretary.**

[FN Doc.77-19505 Filed 7-7-77;8:45 am]

**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
may be unjust, unreasonable, unduly discriminatory or otherwise unlawful. Accordingly, the Commission shall accept for filing those rates proposed to become effective on July 1, 1977, but shall suspend their effect until December 1, 1977, when they shall be permitted to become effective, 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. The Commission finds that the increased need for depreciation rates of 5.75 percent for production, gathering, storage and offshore plant and 8 percent for all offshore property, 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 need for suspension of its proposed rate 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 in December 1, 1976, together with appropriate adjustments to the claimed allowances for return and income taxes. Natural shall file with such revised tariff sheets, supplemental constant and revenue data reflecting the adjusted reserve for depreciation.

The revised tariff sheet and supplemental data shall reflect the actual advance payment balance in Account No. 166 as of November 30, 1977.

Public notice of Natural's filing was issued on June 10, 1977, with comments and petitions to intervene due on or before December 22, 1977. Petitions to intervene were filed by the parties listed in Appendix B. The Commission believes that intervention of such petitioners may be in the public interest, and accordingly, grants the petitions to intervene in the proceedings hereinafter ordered.

The Commission finds: (1) It is necessary and proper in the public interest and in carrying out the provisions of the Natural Gas Act that the Commission order upon a hearing concerning the lawfulness of the rates proposed by Natural to become effective on July 1, 1977, and that the same be accepted for filing and suspended as hereinafter ordered.

(2) Good cause exists to deny 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 thereof.

(3) Good cause exists to grant waiver of Section 154.63(e) (2) (II) of the Regulations, subject to the condition hereinafter ordered.

(4) Good cause exists to order Natural to file revised tariff sheets and supplemental constant 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. 166 as of November 30, 1977.

(5) Good cause exists to permit the intervention of the petitioners listed in Appendix B.

NOTICES

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

---


See: Appendix A.

Appendix A

PANHANDLE EASTERN PIPE LINE COMPANY

(Docket No. AP75-102)

SHEETS PROPOSED TO BE EFFECTIVE DECEMBER 1, 1976

F.P.C. Gas Tariff, Original Volume No. 1—Substitute Third Revised Sheet No. 42-2, Fourth Revised Sheet No. 43-3, Second Substitute Fourth Revised Sheet No. 45-1, First Substitute Fourth Revised Sheet No. 2—Substitute First Revised Sheet No. 93, First Substitute First Revised Sheet No. 135, Substitute First Revised Sheet No. 211.

[FR Doc. 77-19458 Filed 7-7-77; 8:45 am]

[Docket No. RP77-98]

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 Hearing and Establishing Procedures


On May 31, 1977, Natural Gas Pipeline Company of America (Natural) tendered changes through November 30, 1977. The Docket No. AP75-102, based on the data which reflect the elimination of 1978. For the reasons stated below, the Commission finds: (1) It is necessary and proper in the public interest and in carrying out the provisions of the Natural Gas Act that the Commission order upon a hearing concerning the lawfulness of the rates proposed by Natural to become effective on July 1, 1977, and that the same be accepted for filing and suspended as hereinafter ordered.

(2) Good cause exists to deny 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 thereof.

(3) Good cause exists to grant waiver of Section 154.63(e) (2) (II) of the Regulations, subject to the condition hereinafter ordered.

(4) Good cause exists to order Natural to file revised tariff sheets and supplemental constant 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. 166 as of November 30, 1977.

(5) Good cause exists to permit the intervention of the petitioners listed in Appendix B.

---

1See: Appendix A.
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 schedules and complete any portions of Form No. for reconsideration by the Commission, not later than 11, 1977, these dates were uncontested until June 30, 1977, and September 30, 1977, respectively.

The Commission orders: The above-mentioned dates are further postponed until further notice.

By the Commission.

KENNETH E. PLUMB, Secretary.

[Note filed on December 20, 1987.]
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 the State Regulatory Commissions of Ohio, Michigan, Missouri, Indiana, Kansas and Illinois. On June 13, 1977, the Commission held oral argument 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, Eascoagas, PSE&G, Southern MRTC and the Commission, whose 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, however, that whereas Opinion No. 796 would provide 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 on the basis of their ability 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 where LNG was also recommended, (4) is improper where LNG is used for base load, high priority supplies, (5) is inconsistent with the goal of encouraging all forms of supplemental supplies in times of energy shortages, (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 load factor customers of Trunkline, Panhandle and MRT who won't be able to contract to purchase LNG because of the Trunkline's incremental pricing method including use of increasing block rates, with entitlements to low cost conventional source domestic gas in the initial tariff block and the higher priced LNG in the tail block which is the most "price elastic range" of the rate structure, and the high priority customers will be taken (1) if it is more costly than the alternatives, such as conservation or other energy sources, or (2) in the event of warm weather or a slackening of demand due to other factors. Staff also stated that under its pricing plan the probable "confrontation" with incremental pricing would occur at the distribution level, i.e. distributor-customers of LNG, to be faced with the ultimate consumers or put in storage. As an example, Staff notes that certain proposed short-term emergency supplies of gas, amounting to 11 out of 13 Bcf of gas offered at an incremental price of $3 per Mcf, were rejected by gas consumers last winter in Ohio as too expensive. Staff similarly rejects the argument that distributors, with low load factors (with high winter peaks) will be unable to contract for LNG stating that in the off-peak summer period can be sold by the pipeline to other customers with no storage problems.

Staff also argues that the Commission's Alaska recommendations, which included a rolled-in pricing proposal for Alaskan gas, is distinguishable from the incremental pricing case because in Nebraska and Kansas, the Alaska project is much greater ($10 billion) than the investment in the Trunkline LNG project ($93 million) and the market far smaller. Staff also notes that its filed comments show the price of LNG in the Sonatrach contract has now escalated from a base price of $1.30 to $1.64, a figure in excess of the $1.47 figure included in the Commission's certificate initial rate of $3.37 per MMBtu.

Staff supported an incremental pricing method including use of increasing block rates, with entitlements to low cost conventional source domestic gas in the initial tariff block and the higher priced LNG in the tail block which is the most "price elastic range" of the rate structure, and the high priority customers will be taken (1) if it is more costly than the alternatives, such as conservation or other energy sources, or (2) in the event of warm weather or a slackening of demand due to other factors. Staff also noted that under its pricing plan the probable "confrontation" with incremental pricing would occur at the distribution level, i.e. distributor-customers of LNG, to be faced with the ultimate consumers or put in storage. As an example, Staff notes that certain proposed short-term emergency supplies of gas, amounting to 11 out of 13 Bcf of gas offered at an incremental price of $3 per Mcf, were rejected by gas consumers last winter in Ohio as too expensive. Staff similarly rejects the argument that distributors, with low load factors (with high winter peaks) will be unable to contract for LNG stating that in the off-peak summer period can be sold by the pipeline to other customers with no storage problems.

Staff also argues that the Commission's Alaska recommendations, which included a rolled-in pricing proposal for Alaskan gas, is distinguishable from the incremental pricing case because in Nebraska and Kansas, the Alaska project is much greater ($10 billion) than the investment in the Trunkline LNG project ($93 million) and the market far smaller. Staff also notes that its filed comments show the price of LNG in the Sonatrach contract has now escalated from a base price of $1.30 to $1.64, a figure in excess of the $1.47 figure included in the Commission's certificate initial rate of $3.37 per MMBtu.

Staff supported an incremental pricing method including use of increasing block rates, with entitlements to low cost conventional source domestic gas in the initial tariff block and the higher priced LNG in the tail block which is the most "price elastic range" of the rate structure, and the high priority customers will be taken (1) if it is more costly than the alternatives, such as conservation or other energy sources, or (2) in the event of warm weather or a slackening of demand due to other factors. Staff also noted that under its pricing plan the probable "confrontation" with incremental pricing would occur at the distribution level, i.e. distributor-customers of LNG, to be faced with the ultimate consumers or put in storage. As an example, Staff notes that certain proposed short-term emergency supplies of gas, amounting to 11 out of 13 Bcf of gas offered at an incremental price of $3 per Mcf, were rejected by gas consumers last winter in Ohio as too expensive. Staff similarly rejects the argument that distributors, with low load factors (with high winter peaks) will be unable to contract for LNG stating that in the off-peak summer period can be sold by the pipeline to other customers with no storage problems.

Staff also argues that the Commission's Alaska recommendations, which included a rolled-in pricing proposal for Alaskan gas, is distinguishable from the incremental pricing case because in Nebraska and Kansas, the Alaska project is much greater ($10 billion) than the investment in the Trunkline LNG project ($93 million) and the market far smaller. Staff also notes that its filed comments show the price of LNG in the Sonatrach contract has now escalated from a base price of $1.30 to $1.64, a figure in excess of the $1.47 figure included in the Commission's certificate initial rate of $3.37 per MMBtu.

Staff supported an incremental pricing method including use of increasing block rates, with entitlements to low cost conventional source domestic gas in the initial tariff block and the higher priced LNG in the tail block which is the most "price elastic range" of the rate structure, and the high priority customers will be taken (1) if it is more costly than the alternatives, such as conservation or other energy sources, or (2) in the event of warm weather or a slackening of demand due to other factors. Staff also noted that under its pricing plan the probable "confrontation" with incremental pricing would occur at the distribution level, i.e. distributor-customers of LNG, to be faced with the ultimate consumers or put in storage. As an example, Staff notes that certain proposed short-term emergency supplies of gas, amounting to 11 out of 13 Bcf of gas offered at an incremental price of $3 per Mcf, were rejected by gas consumers last winter in Ohio as too expensive. Staff similarly rejects the argument that distributors, with low load factors (with high winter peaks) will be unable to contract for LNG stating that in the off-peak summer period can be sold by the pipeline to other customers with no storage problems.

Staff also argues that the Commission's Alaska recommendations, which included a rolled-in pricing proposal for Alaskan gas, is distinguishable from the incremental pricing case because in Nebraska and Kansas, the Alaska project is much greater ($10 billion) than the investment in the Trunkline LNG project ($93 million) and the market far smaller. Staff also notes that its filed comments show the price of LNG in the Sonatrach contract has now escalated from a base price of $1.30 to $1.64, a figure in excess of the $1.47 figure included in the Commission's certificate initial rate of $3.37 per MMBtu.

Staff supported an incremental pricing method including use of increasing block rates, with entitlements to low cost conventional source domestic gas in the initial tariff block and the higher priced LNG in the tail block which is the most "price elastic range" of the rate structure, and the high priority customers will be taken (1) if it is more costly than the alternatives, such as conservation or other energy sources, or (2) in the event of warm weather or a slackening of demand due to other factors. Staff also noted that under its pricing plan the probable "confrontation" with incremental pricing would occur at the distribution level, i.e. distributor-customers of LNG, to be faced with the ultimate consumers or put in storage. As an example, Staff notes that certain proposed short-term emergency supplies of gas, amounting to 11 out of 13 Bcf of gas offered at an incremental price of $3 per Mcf, were rejected by gas consumers last winter in Ohio as too expensive. Staff similarly rejects the argument that distributors, with low load factors (with high winter peaks) will be unable to contract for LNG stating that in the off-peak summer period can be sold by the pipeline to other customers with no storage problems.

Staff also argues that the Commission's Alaska recommendations, which included a rolled-in pricing proposal for Alaskan gas, is distinguishable from the incremental pricing case because in Nebraska and Kansas, the Alaska project is much greater ($10 billion) than the investment in the Trunkline LNG project ($93 million) and the market far smaller. Staff also notes that its filed comments show the price of LNG in the Sonatrach contract has now escalated from a base price of $1.30 to $1.64, a figure in excess of the $1.47 figure included in the Commission's certificate initial rate of $3.37 per MMBtu.
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, the Commission is of the opinion that the incremental pricing method should be used in its stead. One of the reasons made available to the Trunkline Gas system as insurance to protect Priority 1 loads and Priority 2 plant protection requirements. To ensure that this supply is made available to the LNG system, as stated above, rolled-in pricing is required 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 (or 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 Trunkline Gas has a base load is projected to be LNG by the mid-1980's (I.D., p. 23), at which time Trunkline Gas will be meeting 75 percent of its Priority 1 requirements, even with imported LNG, with no gas left over for lower priorities (I.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 lower priority users, rolled-in 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 from the LNG.

With respect to the availability of alternate fuels, the Commission agrees with and adopts the Presiding Judge's findings (I.D., p. 30):

* that alternate fuels are not available in the vicinity or within a comparable price range to offset the need for imported LNG, for the reasons set forth in his Initial Decision.

In related matter, the Commission agrees that it cannot in this proceeding, ensure that future commissions or successor regulatory authorities, would never curtail the gas sold under separate incremental rate schedules. We also agree that the eventual curtailability 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 recommendation and with our decision in Columbia LNG, Opinion No. 786 to use rolled-in pricing. Once we have determined that the LNG supply project is in the public interest, the Commission agrees that it cannot in this proceeding, require incremental or rolled-in pricing, but rather whether to certify this project with incremental or rolled-in pricing, or to, in effect, kill the project by using incremental pricing, an action tantamount 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 (or 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 Trunkline Gas has a base load is projected to be LNG by the mid-1980's (I.D., p. 23), at which time Trunkline Gas will be meeting 75 percent of its Priority 1 requirements, even with imported LNG, with no gas left over for lower priorities (I.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 lower priority users, rolled-in 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 from the LNG.

With respect to the availability of alternate fuels, the Commission agrees with and adopts the Presiding Judge's findings (I.D., p. 30):

* that alternate fuels are not available in the vicinity or within a comparable price range to offset the need for imported LNG, for the reasons set forth in his Initial Decision.

In related matter, the Commission agrees that it cannot in this proceeding, ensure that future commissions or successor regulatory authorities, would never curtail the gas sold under separate incremental rate schedules. We also agree that the eventual curtailability 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 recommendation and with our decision in Columbia LNG, Opinion No. 786 to use rolled-in pricing. Once we have determined that the LNG supply project is in the public interest, the Commission agrees that it cannot in this proceeding, require incremental or rolled-in pricing, but rather whether to certify this project with incremental or rolled-in pricing, or to, in effect, kill the project by using incremental pricing, an action tantamount 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 (or 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 Trunkline Gas has a base load is projected to be LNG by the mid-1980's (I.D., p. 23), at which time Trunkline Gas will be meeting 75 percent of its Priority 1 requirements, even with imported LNG, with no gas left over for lower priorities (I.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 lower priority users, rolled-in 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 from the LNG.

With respect to the availability of alternate fuels, the Commission agrees with and adopts the Presiding Judge's findings (I.D., p. 30):

* that alternate fuels are not available in the vicinity or within a comparable price range to offset the need for imported LNG, for the reasons set forth in his Initial Decision.

In related matter, the Commission agrees that it cannot in this proceeding, ensure that future commissions or successor regulatory authorities, would never curtail the gas sold under separate incremental rate schedules. We also agree that the eventual curtailability 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 recommendation and with our decision in Columbia LNG, Opinion No. 786 to use rolled-in pricing. Once we have determined that the LNG supply project is in the public interest, the Commission agrees that it cannot in this proceeding, require incremental or rolled-in pricing, but rather whether to certify this project with incremental or rolled-in pricing, or to, in effect, kill the project by using incremental pricing, an action tantamount 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 (or 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 Trunkline Gas has a base load is projected to be LNG by the mid-1980's (I.D., p. 23), at which time Trunkline Gas will be meeting 75 percent of its Priority 1 requirements, even with imported LNG, with no gas left over for lower priorities (I.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 lower priority users, rolled-in 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 from the LNG.

With respect to the availability of alternate fuels, the Commission agrees with and adopts the Presiding Judge's findings (I.D., p. 30):

* that alternate fuels are not available in the vicinity or within a comparable price range to offset the need for imported LNG, for the reasons set forth in his Initial Decision.
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 oil price index in the supply contract was analogous to 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 excess terminal costs, Staff argues that, despite the track excess record in this case, these costs are unknown and 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 LNG to the price of #2 and #6 oils, Commission Staff emphasizes, however, that the review of the escalation provision in the Panhhandle-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 Trunkline's proposals 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 occurring twice a year, we find it appropriate to permit this escalator to operate as set forth above. Upon reconsideration, we affirm our position that the Pacific Gas case is applicable to the instant case based upon the record in this proceeding. With regard to the renegotiation provision, the Commission concurs with the statement of Trunkline's Counsel that Section 4 procedures should be followed with respect to this provision.

With regard to the shipping contracts, we are not persuaded by any change in Opinion No. 796 is necessary with regard thereto. As Staff correctly notes, the costs for this portion of this project are not known and are subject to changes due to cost overruns and other cost increases. Accordingly, any change in the $3.37 per MMBTU rate necessitated by changes in the shipping arrangements shall continue to be subject to review and approval 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 our 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 rate applications 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 it is willing to accept the general outline of the minimum bill provisions as made by the Commission. We find that: (1) permit calculation related to the minimum bill on an annual (rather than daily) basis; (2) impose no penalty (i.e., loss of return on or return of equity) if LNG is delivered at contractual volumes during a given year but not more than 90% of the contractual 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 than that the minimum bill should permit recovery of equity in the event of service interruption and further that Trunkline should not be penalized by 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 interruption recognizes the risk between consumers and stockholders. Accordingly, the Commission reaffirms its position herein.

In response to a request for clarification by Seller, the Commission notes that Trunkline LNG will be permitted to recover costs actually incurred during the locked-in period, except that capital costs (e.g., 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 then appropriate refunds made at the end of the year. However, because the Commission has rejected Trunkline's request for a cost of service tariff as set forth above, a different method of calculating the 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 share-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 facilities and related facilities;
(d) The requirements for repayment of such debt;
(e) Amounts, if any, Seller shall be obligated to pay for LNG supplies and (or) LNG services, if any, under the LNG supply and shipping contract; (f) All return of and return on equity in the event Seller has delivered at least 90 percent of the contractual volumes calculated on a monthly basis.
(g) On an annual basis, the minimum bill shall be recomputed according to the above formula and an appropriate refund made, or surcharge collected, as appropriate;

Provided, however, that Buyer's obligation to pay for nondelivered amounts shall not extend beyond the time at which Seller is able to avoid such costs under its supply and shipping contracts. Upon review, the Commission shall similarly reject Trunkline's proposal that a "swing" provision not as a "guarantee" of minimum bill formula. We view the 10% "swing" provision not as a "guarantee" of minimum bill formula, 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.\(^\text{a}\)

\(^{\text{a}}\) Opinion No. 796 (mimeo, pp. 20-21) citing Pacific Indonesia LNG Co. et al., — FPC —, issued April 2, 1976, in Docket No. CP74-160, paragraphs (a) through (c) of the minimum bill formula. We view the 10% "swing" provision not as a "guarantee" of minimum bill formula, 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.


FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
The reason for the monthly formula, which is eventually adjusted to reflect the calculation of the minimum bill on an annual basis, is to permit monthly bills to be charged on 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 under the minimum bill which might occur if recovery were delayed until the end of the year.

**MISCELLANEOUS**

Algonquin, Eascom and Public Service Electric & Gas urge deletion of Ordering Paragraph (L). 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 required 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 obey all applicable laws and regulations so that compliance with such provisions is not made a condition by deletion of Ordering Paragraph (L). Trunkline LNG does not specifically object to the conditions set forth below. It reserves in the body of this Opinion its right to modify 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 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 has been made aware of these risks 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. Later petitions to intervene were filed by Pertamina, Southeastern and NIPSCO. For good cause shown, the Commission shall grant the petitions subject to the conditions set forth below. The Commission finds:

1. Application processed on behalf of the Board of Governors under delegated authority.

**FEDERAL RESERVE SYSTEM**

**NOTICES**

**35215**

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

**ACTIONS OF THE BOARD; APPLICATIONS AND REPORTS RECEIVED DURING THE WEEK ENDING JUNE 18, 1977**

**Regulation J amendment, by adding a new section concerning the wire transfer of funds between member banks (Docket No. R-0013).**

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.

**Letter to Chairman William Proxmire, Senator Committee on Banking, Housing and Urban Affairs on H.R. 5675, which permits the payment of interest on Treasury accounts.**

**Statement by Governor J. Charles Partee before the Senate Committee on Banking, Housing and Urban Affairs on H.R. 5675, which permits the payment of interest on Treasury accounts.**

**To Establish a Domestic Branch Pursuant to Section 9 of the Federal Reserve Act.**


**To Establish a Domestic Branch Pursuant to Section 25 of the Federal Reserve Act.**

**Chase Manhattan Bank, N.A.: Branch—Manila, Philippines.**

**Citiwide National Bank: Branch—Manila, Philippines.**

**Security Pacific National Bank: Branch—Manama, Bahrain.**

**The Bank of California, N.A.: Branch—Manila, Philippines.**

**International Investments and Other Actions Pursuant to Sections 25 and 23(a) of the Federal Reserve Act and Sections 4(c)(9) and 4(c)(13) of the Bank Holding Company Act of 1956, as amended.**
NOTICES

APPROVED


To Expand a Bank Holding Company Pursuant to Section 3(a) (3) of the Bank Holding Company Act of 1956. APPROVED

Hawkeye Bancorporation, Des Moines, Iowa, for approval to acquire 60 percent or more of the voting shares of Commercial State Bank of Des Moines, Iowa. First City Bancorporation of Texas, Inc., Houston, Texas, for approval to acquire 100 percent (less directors' qualifying shares) of the voting shares of City National Bank of Austin, Austin, Texas. First Interstate Bancrares, Inc., Dallas, Texas, for approval to acquire 100 percent 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 acquire 100 percent of the voting shares of Riffe Bank Agency, Inc., Riffe, Colorado and to indirectly acquire 95.6 percent or more of the voting shares of The First National Bank in Riffe, Riffe, Colorado.

To Expand a Bank Holding Company Pursuant to Section 4(c)(8) of the Bank Holding Company Act of 1956

DELAYED

Union Trust Bancorp, Baltimore, Maryland, notification of intent to engage in de novo activities (as agent in the sale of insurance and leasing collateral held against its extensions of credit) at 119 East Inner Harbor Drive, Baltimore, Maryland, through its subsidiaries, Landmark Financial Corporation of North Carolina and Landmark Mortgage Corporation (wholly-owned subsidiaries of Landmark Financial Services, Inc.) (6-19-77). 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 1443 West Schaumburg Road, Schaumburg, 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 (servicing and processing customer servicing 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 guaranteed merchant) at 172 Court Street, Auburn, Maine, through its subsidiary, Northeast Community Services Corp. (6-19-77).

Chemical New York Corporation, New York, New York, notification of intent to engage in de novo activities (the origination and sale of mortgage real estate; the servicing of mortgage loans owned by the Galbreath Mortgage Company and owned by others) in the vicinity of Elrey Parkway and Murfreesboro Pike, Nashville, Tennessee.

1 Application processed by the Reserve Bank on behalf of the Board of Governors under delegated authority.

2 Application processed by the Reserve Bank on behalf of the Board of Governors under delegated authority.

3 Merchants National Corporation, Indianapolis, Indiana, notification of intent to relocate de novo activities (leasing of capital goods and equipment to industry; and bank or other financial intermediary, or to advise in leasing such personal property where at the inception of the lease the effect of the transaction will be to yield a return that will compensate the lessor for not less than the lessor's full investment in the property plus the estimated total cost of financing the property over the term of the lease) from 3110 S. Washington, Denver, Colorado to 12000 East 47th Avenue, Denver, Colorado, through its direct subsidiary, Circle Leasing of Colorado Corp. (6-17-77).

4 BankAmerica Corporation, San Francisco, California, notification of intent to engage in de novo activities (making or acquiring, for its own account and other extensions of credit such as would be made or acquired by a finance company and servicing loans and other extensions of credit such as would be made or acquired by a finance company) in connection with the extensions of credit made or acquired by the corporation at 2001 Van Ness Avenue, San Francisco, California, through its subsidiary, Financial America Corporation (an affiliate of a Colorado Corporation) (6-16-77).

Security Pacific Corporation, Los Angeles, California, notification of intent to engage in de novo activities (the origination and acquisition of mortgage loans including development and construction loans on multifamily and commercial properties, for its own account or for the sale to others and the servicing of such loans for others) at 1700 West Loop South, Houston, Texas, 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

Permitted

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).

Certifications Issued Pursuant to the Bank Holding Company Tax Act of 1961

First Missouri Banks, Inc., Creve Coeur, Missouri, prior certification pursuant to § 6160(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 Buick, Inc., St. Louis, Missouri, was necessary or appropriate to effectuate § 4 of the Bank Holding Company Act (Legal Division Docket TCR 76-104).

4 Processed on behalf of the Board of Governors under delegated authority.
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 538 West Diversey, Chicago.

To Establish an Overseas Branch of a Member Bank Pursuant to Section 35 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.

First Bankers Corporation, Inc., Huntington, West Virginia, notification of intent to engage in de novo activities (leasing personal property and the leasing of such property; and acting as agent or broker for the sale of credit related life/accident and health insurance) at Centre 71, 71st Street and Memorial Drive, Tulsa, Oklahoma and Southroads Shopping Center, 4945 E. 41st Street, Tulsa, Oklahoma, through its subsidiary, Firstcor Person-to-Person Financial Services, Inc.

Citicorp, New York, New York, notification of intent to relocate de novo activities (making consumer installment sales finance contracts; sale of credit related life/accident and health insurance; sale by a licensed agent of insurance which protects personal property) from 5525 E. Admiral Place, Tulsa, Oklahoma, to Main Park Financial, Grand, Dunia, a subsidiary, Nationwide Financial Services Corporation (6-13-77).

Citicorp, New York, New York, notification of intent to relocate de novo activities (purchasing consumer installment sales finance contracts for its own account; sale of credit related life/accident and health insurance; sale by a licensed agent of insurance which protects personal property) from 5525 E. Admiral Place, Tulsa, Oklahoma, to Main Park Financial, Grand, Dunia, a subsidiary, Nationwide Financial Services Corporation (6-13-77).

Citicorp, New York, New York, notification of intent to relocate de novo activities (purchasing consumer installment sales finance contracts for its own account; sale of credit related life/accident and health insurance; sale by a licensed agent of insurance which protects personal property) from 5525 E. Admiral Place, Tulsa, Oklahoma, to Main Park Financial, Grand, Dunia, a subsidiary, Nationwide Financial Services Corporation (6-13-77).

To Form a Bank Holding Company Pursuant to Section 3(a) (1) of the Bank Holding Company Act of 1956.

Citizens Bancorp, Inc., Hartford City, Indiana, for approval to acquire 100 percent of the voting shares of Citizens Bank, Hartford City, Indiana, and the subsidiaries of the Citizens Bank, Hartford City, Indiana, and the subsidiaries of the Citizens Bank, Hartford City, Indiana, and the subsidiaries of the Citizens Bank, Hartford City, Indiana.

Banco Corporacion, New York, New York, notification of intent to engage in de novo activities (leasing personal property and the leasing of such property; and acting as agent or broker for the sale of credit related life/accident and health insurance) at Centre 71, 71st Street and Memorial Drive, Tulsa, Oklahoma and Southroads Shopping Center, 4945 E. 41st Street, Tulsa, Oklahoma, through its wholly owned subsidiary, Pittsburgh National Leasing Corporation, 6-10-77.

Security Pacific Corporation, Los Angeles, California, notification of intent to engage in de novo activities (the financing of personal property and equipment related to the financing of sales to individuals for personal, family or household purposes; purchasing sales finance contracts executed in connection with the sale of personal, family or household goods or services; acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered, whether for personal, family or household purposes; or acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered) at 700 North Market Street, San Francisco, California.

Security Pacific Corporation, Los Angeles, California, notification of intent to engage in de novo activities (the financing of personal property and equipment related to the financing of sales to individuals for personal, family or household purposes; purchasing sales finance contracts executed in connection with the sale of personal, family or household goods or services; acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered, whether for personal, family or household purposes; or acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered) at 700 North Market Street, San Francisco, California.

Security Pacific Corporation, Los Angeles, California, notification of intent to engage in de novo activities (the financing of personal property and equipment related to the financing of sales to individuals for personal, family or household purposes; purchasing sales finance contracts executed in connection with the sale of personal, family or household goods or services; acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered, whether for personal, family or household purposes; or acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered) at 700 North Market Street, San Francisco, California.

Security Pacific Corporation, Los Angeles, California, notification of intent to engage in de novo activities (the financing of personal property and equipment related to the financing of sales to individuals for personal, family or household purposes; purchasing sales finance contracts executed in connection with the sale of personal, family or household goods or services; acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered, whether for personal, family or household purposes; or acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered) at 700 North Market Street, San Francisco, California.

Security Pacific Corporation, Los Angeles, California, notification of intent to engage in de novo activities (the financing of personal property and equipment related to the financing of sales to individuals for personal, family or household purposes; purchasing sales finance contracts executed in connection with the sale of personal, family or household goods or services; acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered, whether for personal, family or household purposes; or acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered) at 700 North Market Street, San Francisco, California.

Security Pacific Corporation, Los Angeles, California, notification of intent to engage in de novo activities (the financing of personal property and equipment related to the financing of sales to individuals for personal, family or household purposes; purchasing sales finance contracts executed in connection with the sale of personal, family or household goods or services; acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered, whether for personal, family or household purposes; or acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered) at 700 North Market Street, San Francisco, California.

Security Pacific Corporation, Los Angeles, California, notification of intent to engage in de novo activities (the financing of personal property and equipment related to the financing of sales to individuals for personal, family or household purposes; purchasing sales finance contracts executed in connection with the sale of personal, family or household goods or services; acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered, whether for personal, family or household purposes; or acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered) at 700 North Market Street, San Francisco, California.

Security Pacific Corporation, Los Angeles, California, notification of intent to engage in de novo activities (the financing of personal property and equipment related to the financing of sales to individuals for personal, family or household purposes; purchasing sales finance contracts executed in connection with the sale of personal, family or household goods or services; acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered, whether for personal, family or household purposes; or acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered) at 700 North Market Street, San Francisco, California.

Security Pacific Corporation, Los Angeles, California, notification of intent to engage in de novo activities (the financing of personal property and equipment related to the financing of sales to individuals for personal, family or household purposes; purchasing sales finance contracts executed in connection with the sale of personal, family or household goods or services; acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered, whether for personal, family or household purposes; or acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered) at 700 North Market Street, San Francisco, California.

Security Pacific Corporation, Los Angeles, California, notification of intent to engage in de novo activities (the financing of personal property and equipment related to the financing of sales to individuals for personal, family or household purposes; purchasing sales finance contracts executed in connection with the sale of personal, family or household goods or services; acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered, whether for personal, family or household purposes; or acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered) at 700 North Market Street, San Francisco, California.

Security Pacific Corporation, Los Angeles, California, notification of intent to engage in de novo activities (the financing of personal property and equipment related to the financing of sales to individuals for personal, family or household purposes; purchasing sales finance contracts executed in connection with the sale of personal, family or household goods or services; acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered, whether for personal, family or household purposes; or acting as agent in the sale of such personal property and the financing of such personal property by such other persons or entities as the nature of such sales or services rendered) at 700 North Market Street, San Francisco, California.
NOTICES

The Sylvania Savings Bank Company, Sylvas, has applied for the Board's approval for its own account or for the sale to and acquisition of mortgage loans included in the de novo activities (the origination and acquisition of mortgage loans including development and construction loans on multi-family and commercial properties for the specific purpose of the old account or for the sale to others) from 8316 Claremont Mesa Boulevard to 691 Camino de la Reina, San Diego, California, through its subsidiary, Security Pacific Leasing Company (6-13-77).

Wells Fargo & Company, San Francisco, California, a national bank, has applied for the Board's approval to relocate de novo activities (the origination and acquisition of mortgage loans including the servicing of such financings and/or a servicing business) in the greater Los Angeles, California, area to 591 Camino de la Reina, San Diego, California, through its subsidiary, Security Pacific Mortgage Company (6-13-77).

Wells Fargo & Company, San Francisco, California, has applied for the Board's approval to relocate de novo activities (making or acquiring, for its own account or for the account of others, loans and other extensions of credit; servicing loans and other extensions of credit for other persons, acting as an insurance agency or broker, and underwriting and selling certain types of insurance that are directly related to the extension of credit by Wells Fargo & Company or its subsidiaries), credit life and credit accident insurance, property and casualty insurance, and group life insurance and group mortgage life insurance (from 100 West First Street to 1135 Terminal Way, Reno, Nevada, through its subsidiaries, Wells Fargo Mortgage Company and WPMC Corporation (6-14-77).

Wells Fargo & Company, San Francisco, California, notification of intent to engage in the business of credit life and credit accident insurance, property and casualty insurance, and group life insurance and group mortgage life insurance, from the offices of the Board of Governors or the Reserve Bank to be relocated at the Federal Reserve Bank of Kansas City, Kansas City, Missouri, pursuant to § 4(c)(8) of the Act (FR Doc. 77-19404 Filed 7-7-77; 8:45 am).

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 percent of the voting shares of Lake View Trust Company and Lake View Bank, through acquisition of Midland Mortgage Company (6-14-77).

The application may be inspected at the offices of the Board of Governors of the Federal Reserve System, June 30, 1977.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 77-19405 Filed 7-7-77; 7:45 am]

MIDLAND CAPITAL CO.

Order Approving Formation of Bank Holding 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 formation of a bank holding company through acquisition of 100 percent of the voting shares of Midland Mortgage Co., Oklahoma City, Oklahoma ("Midland 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 residential and commercial mortgages. The mortgage banking operations of Midland Mortgage, affording opportunity for interested persons to submit comments and views, has been given in accordance with § 3 and 4 of the Act (42 FR 26247). 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(c)(8) of the Act.

Applicant is a non-operating corporation organized for the purposes 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, holds approximately 0.2 percent of total commercial and savings deposits in the Oklahoma City market, controlling 0.7 percent of the total deposits therein. Inasmuch as Applicant has no existing operations, consideration of the proposal inter se as it relates to the acquisition of Bank would have no adverse effects on existing or potential competition. Accordingly, the Board concludes that the competitive factors are consistent with approval of the application to become a bank holding company.

The financial and managerial resources and future prospects of Applicant, which are dependent upon those of Bank and Mortgage, are considered satisfactory and consistent with approval of the application to become a bank holding company. The debt to be incurred by the debt to be incurred by the proposed acquisition of Bank is payable primarily from dividends to be derived from Bank and Mortgage without having adverse effects on the financial condition of either Bank or Mortgage. Therefore, the Board concludes that the competitive factors are consistent with approval.

Consummation of the proposed transaction would result in an organization that appears capable of enhancing Bank's ability to improve its operating efficiency and thereby become a stronger

1. Mortgage also currently owns 100 percent of Midland Property Management Co. and Midland Center Co. These corporations exist solely for the purpose of owning Midland Realty Co., a general partnership that holds title to and operates Midland Center, an existing apartment complex in the Oklahoma City in which Mortgage's head office is located. Discussion of the acquisition of Midland Center Center appears infra.

2. The relevant market for both banking and the origination of mortgage loans is approximated by the Metropolitan Statistical Area of Oklahoma City, Oklahoma SMSA. Within this market there are 76 banks, 15 savings and loan associations, and some of the largest mortgage companies in the country.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
competitor within the market. Accordingly, considerations relating to convenience and needs are consistent with approval. It is the Board's position that the proper disposition of Bank would be in the public interest and that the application to become a bank holding company should be approved.

In connection with the application to become a bank holding company, Applicant has also applied for approval to acquire 75 per cent of the outstanding voting shares of Mortgage, a company that, along with its wholly owned subsidiary, Johnston-Records Co., engages in the general business of mortgage banking, as described above, at four locations in the Oklahoma City area and in Lawrence, 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 58th largest mortgage servicer in the United States, with a mortgage loan servicing portfolio of $757.5 million. During 1976, it originated in excess of $152 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 on 1-4 family residential properties. During 1976, Mortgage originated $19.5 million of such mortgages while Bank originated $0.4 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 originations) and the degree of segmentation of the market. On the other hand, consummation of the proposal whereby Applicant will acquire Bank and Mortgage will result in a well-managed and financially strong organization with resources 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 concerns involved, the Board finds no evidence in the record that consummation of the proposal would result in an undue concentration of resources, conflicts of interest, or other adverse effects upon the public interest.

In connection with the application to acquire Mortgage, the Board has 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 occupies 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 $600,000. 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 space in Bank's headquarters building during the latter half of 1976. 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 "incidental activities... necessary to carry on the activities" of Mortgage, within the meaning of § 252.4(a) of Regulation Y. Accordingly, under § 4(a)(2) of the Act, Applicant 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)(2) of the Act and the balance of the factors set forth in § 4(c) 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. 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.

As required by the Bank Merger Act, notice of proposed merger, in form approved by the board of directors, has been published and reports on competitive factors have been requested from the Attorney General, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation. The Reserve Bank has considered the application and all comments and reports received in light of the factors set forth in the Act.

Based on the record in this case, the application is approved for the reasons summarized in the Reserve Bank’s Order of this date relating to the application of Piedmont Bank grup Incorporato to acquire the successor by merger to the Piedmont Trust Bank. 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 or by the Federal Reserve Bank of Richmond (Reserve Bank) under authority delegated by the Board of Governors (12 CFR 265).

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 P. BLACK, President.

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

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 received by


GRIFFITH L. GARWOOD, Deputy Secretary of the Board.
[FR Doc. 77-19412 Filed 7-7-77; 8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration
ADVISORY COMMITTEES

Notice of Meetings; Correction
In FR Doc. 77-16858 appearing on page 30898 in the Federal Register of Friday, June 17, 1977: On page 30891, 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 a.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.77-19401 Filed 7-7-77; 8:45 am]

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

SIERRA PETROLEUM CO., INC.
Acquisition of Bank
Sierra Petroleum Co., Inc., 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 26, 1977.


GRIFFITH L. GARWOOD, Deputy Secretary of the Board.
[FR Doc.77-19411 Filed 7-7-77; 8:45 am]

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 successor by merger to the People's 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 except as a means to facilitate the acquisition of the voting shares of the two banks. Accordingly, the proposed acquisition of the shares 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 31st calendar day following the effective date of 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 53.8 percent of deposits in Henry County and the City of Martinsville while Carroll ranks fourth with 6.9 percent of deposits in Henry County and the City of Galax. These relative positions will not be influenced by holding company affiliation, and, under State law, neither bank may 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 any 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 should 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 thirty-third 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' qualifying shares, of the voting shares of First Bank & Trust, Carrollton, Texas. 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 Dallas. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than July 29, 1977.


GRIFFITH L. GARWOOD, Deputy Secretary of the Board.
[FR Doc.77-19410 Filed 7-7-77; 8:45 am]

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

SIERRA PETROLEUM CO., INC.
Acquisition of Bank
Sierra Petroleum Co., Inc., 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 26, 1977.


GRIFFITH L. GARWOOD, Deputy Secretary of the Board.
[FR Doc.77-19411 Filed 7-7-77; 8:45 am]
FOR FURTHER INFORMATION CONTACT:

Donald Gable, Bureau of Veterinary Medicine (HFV-100), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857.

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 notice of opportunity for hearing, 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 premixes.

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, 82 Stat. 343–351 (21 U.S.C. 360b)) and under authority delegated to the Commissioner (21 CFR 5.1) and redelegated to the Director, the Bureau of Veterinary Medicine (21 CFR 5.29) (formerly 21 CFR 5.29 prior to recodification published in the Federal Register of March 23, 1977 (42 FR 15553)), the time for filing data to support a request for hearing on the subject notice is extended to August 10, 1977.

Dated: July 1, 1977.

C. D. Van Houweling, Director, Bureau of Veterinary Medicine.

GEORGIA-PACIFIC CORP.

Notice of Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Georgia-Pacific Corporation has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a certain polyamidol-epichlorohydrin resin in the manufacture of paper and paperboard for food-contact use.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 343(b)(5))) notice is given that a petition (FAP 633196) has been filed by Schuyler, Birch, Swindler, McKee & Beckett, 1000 Connecticut Avenue NW., Washington, D.C. 20036, on behalf of Georgia-Pacific Corp., proposing that § 176.170 Components of paper and paperboard in contact with aqueous and fatty foods (21 CFR 176.170, formerly § 123.230) 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 report may be seen in the office of the Hearing Clerk (HPC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20677, 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.

Food and Drug Administration

LIBBY, McNEILL & LIBBY, INC.

Canned Pears Deviating From Identity Standards; Temporary Permit for Market Testing.

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces the proposed market testing of foods deviating from the standard of identity prescribed in § 145.17 (21 CFR 145.17, formerly § 10.5, prior to recodification published in the Federal Register of March 15, 1977 (42 FR 14302) concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity promulgated under section 401 of Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

This permit allows the company to conduct interstate market testing of canned pears that deviate from the standard of identity prescribed in § 145.17(a) (formerly § 27.29, 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 flavoring. 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, McNeill & 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 Monroe and Rock Island.

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 Part 101 (21 CFR Part 101, formerly 21 CFR Part 1 prior to recodification published in the Federal Register of March 15, 1977 (42 FR 14302)).

This permit is effective for a period of 15 months beginning no later than October 6, 1977.

Dated: June 29, 1977.

WILLIAM F. RANDOLPH, Acting Associate Commissioner for Compliance.

METABOLIC, INC.


AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces a formal evidentiary public hearing, and a prehearing conference, on the factual issue relating to the Bureau of Biologies’ proposed revocation of U.S. License No. 415 issued to Metabolic, Inc., 4520 Yoakum 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. 4A-35, 5600 Fishers Lane, Rockville, MD, 20857; 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 CONTACT:
John F. Harty, Jr., Compliance Regulations Policy Staff (HFC-10), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD, 20857, 301-443-3480.

SUPPLEMENTARY INFORMATION: A notice of opportunity for a hearing was published in the Federal Register of May 13, 1977 (42 FR 24328), on the Bureau of Biologics' proposal to revoke U.S. License No. 001/77 to the licensee, Metabolic, Inc., pursuant to 21 CFR 601.6, of the terms of its license, including Metabolic's failure to submit a report within 4 days of the occurrence of any failure which, if continued or repeated, would jeopardize the safety of the establishment to assure compliance with the requirements prescribed by FDA for Source Plasma (Human). Metabolic's objection to this item in its request for a hearing was based on a claim that the requirement was invalid on its face, and that the results of the testing were not required to be submitted within the time limit specified by FDA.

4. Whether equipment was properly standardized and/or performing in the manner for which it was designed so as to assure compliance with the requirements prescribed by FDA for Source Plasma (Human). (Metabolic's objection to this item in its request for a hearing was based on the requirement that equipment be calibrated with a refractometer in testing protein control values.) The Hearing Examiner will consider whether deviations from the specified tolerances for plasma separation, trip scales used to control plasma donations, and hematocrit centrifuges are significant.

5. Whether Source Plasma (Human) was stored at a temperature of -20° C or colder.

6. Whether there were adequate procedures for notifying collection facilities and donors of a reactive test for hepatitis B surface antigen (HBAg).

7. Whether records of each step in the manufacture and distribution of products 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 storage, location, and shipment of plasma received from the collections locations.

On May 3, 1977, the licensee, Metabolic, Inc., filed suit in the United States District Court for the Southern District of Texas to enjoin the Food and Drug Administration to release the suspension. Metabolic, Inc., et al. v. Joseph Califano, et al. (Civil No. H77CA676). On May 23, 1977, the Court directed that Metabolic, Inc., continue to produce plasma to assure compliance with the requirements prescribed by FDA for Source Plasma (Human). Under the Court's order, the licensee submitted written notice of each deviation which occurred from January 1, 1977, to May 13, 1977, and notified the Bureau of its intention to appeal the order. The licensee was given until July 12, 1977 to submit comments on the proposed revocation.

In an effort to comply with the time limitations suggested by the District Court's decision, and pursuant to 21 CFR 10.19, the following modifications in the procedures, which may be further amended at the prehearing conference, are adopted to expedite the hearing:

1. Section 12.45(a) (21 CFR 12.45(a)) is modified to provide for the filing of written notices of participation by or before July 12, 1977.

2. Section 12.35(b) (21 CFR 12.35(b)) is modified to provide that § 12.85(a) (21 CFR 12.85(a)) submissions by participants other than the Bureau and objections to the completeness of the administrative record be submitted by or before July 22, 1977. In view of the detailed suspension letters, the issuance of Lists of Observations (FD Form 483), the correspondence between the Bureau and Metabolic, and pleadings and other documents filed in the District Court, § 12.85(a)(4) is waived.

In its request for a hearing, Metabolic objected to each of the grounds for revocation. Almost every objection included an assertion (1) that since improvements had been made, the deficiency had been or would be corrected, (2) that the deficiency was the result of human error, and (3) that it occurred without intent. These are not questions of fact on whether or not grounds exist for revocation. Similarly, Metabolic contended that the problems identified in the Notice of Opportunity for Hearing existed because of the suspended the lots. The Commissioner has reviewed the issues of fact on which a hearing has been requested and concludes that a hearing will be granted as to the following:

1. Whether more than the maximum permissible 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 plasmapherased more than twice within 7 days.

3a. Whether plasma samples for the serologic protein electrophoresis test were drawn at least every 4 months, or at the earliest opportunity thereafter or whether, if drawn, the results were in the donor record file and available for physician review and, in each case, donors continued to be plasmapherased.

b. Whether donors were plasmapherased 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 requirements prescribed by FDA for Source Plasma (Human). (Metabolic's objection to this item in its request for a hearing was based on a claim that the requirement was invalid on its face, and that the results of the testing were not required to be submitted within the time limit specified by FDA."

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
license or from published biologies regu- lations need not be shown to have re- sulted in some demonstrable public harm; improper manufacturing practices must be shown 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. 576 (E.D. N.Y., 1968); United States v. Med- wick Laboratories, Inc., 416 F. Supp. 832 (M.D. Ill., 1976); United States v. An article of drug.” * * * White Quadriscet, 484 F.2d 148 (C.A. 7, 1973.).) The Commission points out that the terms of biologies licenses and the published biologies regulations embody requirements designed to protect the public from harm. Thus, any demonstration of significant deviations from such terms or regulations can be viewed as presenting a danger to public health. However, the Notice of Opportunity for Hearing announced FDA’s intention to revoke Metabolic’s license, which does not require an independent showing of danger to health. The issues for the hearing, therefore, relate solely to the existence of facts revealing deviations from the license terms or regulations sufficient to justify revocation.

At this time, however, the Com- missioner is denying Metabolic’s request that he lift the suspension and stay or abate the revocation proceedings. Metabolic contends that the deviations from standards designed to protect donors were minor, infrequent, and inad- vertent. These considerations are not necessarily determinative on the ques- tion of a danger to health. The issue is not documentation of adversely affected donors in Metabolic collection facilities, but practices deviating from the terms of the license or the biologies regulations that by hypothesis create that potential. Metabolic requested that the suspension be lifted so that it could begin operations on the ground that it is impossible to comply with all regulations and make corrections while suspended. Post-reinstatement inspections were welcomed by Metabolic. The Com- missioner reiterates a point of which Metabolic has already been advised, i.e., that a mechanism does exist for re- censure or reinstatement from under suspension. That procedure includes the following basic requirements:

1. The license application, particu- larly standard operating procedures, is revised as necessary;
2. The applicant begins operation on a pilot basis; and
3. An inspection is conducted to de- termine whether the applicant appears to be operating in compliance with the license, the standard operating proce- dures, and all applicable regulations. Re- reinstatement without prior inspection would be contrary to the obligation of FDA to enforce the premarket licensure scheme established by section 351 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 Biologies 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 ques- tions 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 ques- tion of the release of products now on hand.

Metabolic objected to that portion of the Notice of Opportunity for Hearing which incorporated by reference defici- encies noted in the February and April suspension letters on the grounds that this constituted inadequate specification of the bases for the hearing. Metabolic also contended that these letters had been “sufficiently and properly” an- swered. The Commissioner believes in- corporation by reference is proper. Metabolic’s objections to that the hearing be held in Houston, Texas, is denied. The Administrative Law Judge and all Bu- reau of Biologies personnel are in Rock- ville and/or Bethesda, MD.

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 Ad- ministrative Law Judge will be Daniel J. Davison.

Any participant may appear in person, or with counsel or other qualified repre- sentative, and may be heard with respect to matters relevant to the issues under consid­ eration. Nonparty participants shall disclose data and information pur­ suant to § 12.85 by 5 days after the last day of the hearing.

Dated: July 6, 1977.

SHERWIN GARDNER, Acting Commissioner of Food and Drugs.

[FR Doc. 77-16269 Filed 7-7-77; 8:45 am]

Health Resources Administration
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 bod- lees scheduled to meet during the months of July and August 1977:

Name: United States National Committee on Vital and Health Statistics.

Date and Time: July 25-27, 1977, 9 a.m.


Open for entire meeting.

Purpose. The Secretary and by delega- tion the Assistant Secretary for Health and Human Services, Center for Health Statistics (NCHS) are charged under section 306 of the Public Health Service Act, as amended, (42 U.S.C. 242k), with the responsibility to collect, analyze and disseminate national health statistics on vital events and health ac-

activities, including the physical, mental, and physiological characteristics of the population, illness, injury, impairment, the supply and utilization of health care facil- ities and manpower, the operation of the health services system, health eco- nomic expenditures, and changes in the health status of the population. The Secretary, through the National Center for Health Statistics System; stimulate and conduct basic and applied research in health data systems and sta- tistical methodology; coordinate the overall health statistical activities of the Secretary and agencies of the Health Re- sources Administration and provide technical assistance in the management of statistical information; maintain op- erational liaison with statistical gather- ing and informatic service of other health agencies, public and private, and provide technical assistance within the limitations of staff resources, research, consultation and training programs in international statistical activities; and participate in the development of national health policy with Federal agencies.

The meeting is open to the public for observation and participation. Anyone wishing to participate, obtain a roster of members, minutes of meeting, or other material, should contact Mr. Harold E. Such, National Center for Health Statistics, Room 2-21, Parkdawn Building, 5000 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-4100. The meeting will begin on July 31, 1977, at 8 a.m.

Name: Health Services Developmental Grants Study Section.

Date and Time: July 31-August 1, 1977, 8 a.m., Place: Fairchild Conference Room, O'Hare Internation Airport, Chicago, Illinois.

Open July 31, 8 a.m.—Adjournment.

Closed for remainder of meeting.

Purpose. The Committee is charged with the initial review of applications for Federal assistance in the program areas administered by the National Center for Health Service Research.

Agenda. The open session of the meet- ing on July 31, 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 ex- isting and proposed national policies that are designed to improve the per- formance of the health care system. The closing is in accordance with provision set forth in section 552(b)(6), Title 5
NOTICES


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.

Agenda items are subject to change as priorities dictate.

Dated: June 29, 1977.

JAMES A. WALSH,
Associate Administrator for Operations and Management.

[FR Doc. 77–19210 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. 89–463), 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

Date and Time: August 29–31, 1977, 8:30 a.m. to 12:15 p.m.

Place: Center Building, Room 7–32, 3700 East-West Highway, Hyattsville, Maryland 20782.

Open August 29, 8:30 a.m.–12:30 p.m. (10:30 a.m.–12:30 p.m. will be structured study for Council members)

Closed remainder of meeting.

Purpose. The Council advises the Secretary with respect to the preparation of general regulations and with respect to policy matters in the administration of programs of financial assistance for the health professions and makes recommendations based on its review of applications requesting such assistance.

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 77–15851 appearing at page 28936 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 will 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. 77–19212 Filed 7–7–77; 8:45 am]

National Institutes of Health
ADVISORY COMMITTEES
Open Meetings

Pursuant to Public Law 92–443, notices are hereby given of the meetings of committee 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 by the public 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, Operations and Management.
Executive Secretary: J. Dan Recer, Ph.D.,

Agenda: To consider chemicals for bioassay

Place: Building 31C, Conference Room 10,

Times: Open for the entire meeting. "

Other information pertaining to the
meeting can be obtained from the Exec-utive Secretary indicated.

EXECUTIVE SUBGROUP OF THE CLEARINGHOUSE ON ENVIRONMENTAL CARCINOGENS

Dates: August 9, 1977; 9:30 a.m.-adjournment.

Place: Building 31C, Conference Room 7,

National Institutes of Health.

Times: Open for the entire meeting.

Agenda: To discuss related matters.

Executive Secretary: Dr. James M. Sontag,

Dated: June 24, 1977.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc.77-19259 Filed 7-7-77;8:45 am]

CARCINOGENESIS SCIENTIFIC ADVISORY COMMITTEE

Cancellation of Meeting

Notice is hereby given of the can-
cellation of the meeting of the Carcinogens Scientific Advisory Committee, Di-
vision of Cancer Cause and Prevention, National Cancer Institute, National In-
stitutes of Health, July 10-19, 1977,

which was published in the Federal Reg-
ister on May 25, 1977 (42 FR 28703).

Dated: June 29, 1977.

SUZANNE L. FREMEAU,
Committee Management Officer,
NIH.

[FR Doc.77-19260 Filed 7-7-77;8:45 am]

COMMITTEE ON CANCER IMMUNOTHERAPY

Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Committee on Cancer Immunotherapy, National Cancer Institute, August 18, 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 552(b)(4) and 552(b)(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 18, 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 personal information concerning individuals associated with the proposals.

Dated: June 27, 1977.

SUZANNE L FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc.77-19258 Filed 7-7-77;8:45 am]

REVIEW OF CONTRACT PROPOSALS

Meetings

Pursuant to Public Law 92-463, notice is hereby given of the meetings of com-
mittees advisory to the National Cancer Institute.

These meetings will be open to the public to discuss administrative details or other issues relating to committee business as indicated in the notice. Attended by the public will be limited to space available.

These meetings will be closed to the public as indicated below in accordance with the provisions set forth in Sections 552(b)(4) and 552(b)(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.

Dated: June 27, 1977.

SUZANNE L FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc.77-19265 Filed 7-7-77;8:45 am]

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Cardiology Advisory Committee, National Heart, Lung, and Blood Institute, Building 31, Conference Room S.

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 Connen, Chief, Public Inquiries and Reports Branch, National Heart, Lung, and Blood Institute, Federal Building, 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.

PLANNING AND AGENDA WORK GROUP OF THE NATIONAL ADVISORY RESEARCH RESOURCES COUNCIL

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 2:00 p.m., in Room 5103, 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.

Mr. James Augustine, Information Officer, National Institutes of Health, Room 5B13, Building 31, Bethesda, Maryland 20014 (301) 496-5167, will provide summaries of the meeting and rosters of the Work Group members, and Dr. James P. O'Donnell, Deputy Director, Division of Research Resources, National Institutes of Health, Room 5B03, Building 31, Bethesda, Maryland 20014 (301) 496-6023, will furnish substantive program information.


Suzanne L. Fremau,
Committee Management Officer,
National Institutes of Health.
SUPPLEMENTARY INFORMATION: Section 20(a) (3) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 658(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 22(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 develop employer environmental limits for all products or intermediates involved in commercial scale coal gasification. Because of the vast number of chemical species, their varying toxicities, the unique safety hazards, and the potential for exposure to suspected chemical carcinogens is an exceedingly important consideration, work practices and engineering controls designed to limit occupational exposure, methods to educate the employees, and methods of biological and 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 in coal gasification facilities is requested to submit such information, with accompanying documentation:

1. 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.

2. Engineering controls, including ventilation, environmental temperature, humidity, and housekeeping and sanitation procedures, with attention to the technological feasibility of such controls.

3. Specifications for the conditions under which personal protective devices should be required.

4. 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.

5. 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.

6. The types of records concerning occupational exposure to such agents that employers should be required to maintain.

7. Warning devices and labels which should be required for the prevention of occupational diseases and hazards caused by such agents.

All information received concerning coal gasification, 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. EISER,
Acting Director, National Institute for Occupational Safety and Health.
[FR Doc.77-19328 Filed 7-7-77; 8:45 am]

VINYL

Request for Information

AGENCY: National Institute for Occupational Safety and Health, Center for Disease Control, Public Health Service, HEW.

ACTION: Notice of request for information.

SUMMARY: This notice solicits information concerning direct contact with such substances which may be present within man.

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 Development 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:

Dr. Irwin Baumen, Chief, Criteria Development Branch, NIOSH, 301-443-5230.

SUPPLEMENTARY INFORMATION: Section 20(a) (3) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 658(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 22(c) of the Act authorizes the National Institute for Occupational Safety and Health (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. NIOSH is proposing to develop a criteria document concerning direct contact with recommended occupational health standard for vinyls (to include Vinyl acetate, Vinyl chloride, Vinyl fluoride, Vinylidene chloride, Vinylidene fluoride, and Polyvinylidene chloride). 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.

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

Social Security Administration

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. 75-12 pursuant to section 1116(a)(2) of the Social Security Act, 42 U.S.C. 1316(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 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 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, 92nd Congress, 85 Stat. 888-716), 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 2653.6 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 filed with the Director, Juneau Area Office, Bureau of Indian Affairs, Post Office Box 3-8000, Juneau, Alaska 99802.

RAYMOND V. BUTLER,
Acting Deputy Commissioner of Indian Affairs.

Bureau of Land Management

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

DAVID V. BUTLER
Acting Deputy Commissioner of Indian Affairs.

Bureau of Land Management

FILOPRIA

Proposed Withdrawal and Reservation of Land; Correction

In FR Doc. 77-18136, appearing at page 32232 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, 1979.

LAWRENCE J. HUDY,
Director, Eastern States.

[FR Doc. 77-18485 Filed 7-7-77; 8:46 am]
NOTICES

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

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, 600 Camp Street/Suite 641, 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 8, 1972 will be considered.

HAROLD P. SHEVERDING,
Acting Manager.

JUNE 20, 1977.

[FR Doc.77-19426 Filed 7-7-77;8:45 am]

MONTANA

Opportunity for Public Hearing and Republication 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 MERRIDIAN, MONTANA

BEAVERHEAD NATIONAL FOREST

TRAPPER CREEK CHARCOAL KILN AREA

T. 2 S., R. 10 W., Sec. 6, W¹/2 of Lot 1.
Total area—21.85 acres.

CANYON CREEK CHARCOAL KILN AREA

T. 2 S., R. 10 W., Sec. 8, 1/4 SE¹/4 NW¹/4.
Total area—50 acres.

The areas described aggregate 41.85 acres in Beaverhead County, Montana.

The applicant desires that the lands be reserved as they 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. 35229, Document No. 86-2829.

Notice is hereby given that, pursuant to section 204(h) of the Federal Land Policy and Management Act of 1976, 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 36157, Billings, Montana 59107.

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. 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. 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 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, 1981, 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.

[FR Doc.77-19427 Filed 7-7-77;8:45 am]

MONTANA

Opportunity for Public Hearing and Republication 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 MERRIDIAN, MONTANA

LOLO NATIONAL FOREST

SAVENAC NURSERY, BIG CREEK ADDITION

T. 19 N., R. 30 W., Sec. 27, 1/4 NE¹/4, 1/4 SW¹/4, and SW¹/4.

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, 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 36157, 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. 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 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, 1981, 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.

[FR Doc.77-19428 Filed 7-7-77;8:45 am]

NEW MEXICO

Applications


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 (78 Stat. 476), Transwestern Pipeline Company has applied for three 4-inch and one 6-inch natural gas pipeline rights-of-way across the following lands:

New Mexico Principal Meridian, New Mexico

T. 18 S., R. 25 E., Sec. 6, SW¹/4 SE¹/4; Sec. 8, NW¹/4 NE¹/4; T. 20 S., R. 30 E., Sec. 12, SE¹/4 NE¹/4; Sec. 13, NE¹/4 SW¹/4; T. 22 S., R. 29 E., Sec. 7, lots 1 and 3 NE¹/4 SW¹/4; Sec. 18, lots 1 and 2.

T. 25 S., R. 25 E., Sec. 12, SW¹/4 SE¹/4.
NOTICES

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 39 N., R. 8 W.,
Sec. 26, S3/4 W1/4 and NW1/4 SW1/4;
Sec. 27, SW1/4 NE1/4, S1/2 SW1/4, SE1/4 SW1/4 and NW1/4 SE1/4;
Sec. 34, N1/2 NW1/4;
Sec. 28, S1/2 SE1/4;
Sec. 29, N1/2 SW1/4;
Sec. 31, N1/2 W1/2;
Sec. 32, S1/2 SE1/4.

T. 39 N., R. 9 W.,
Sec. 15, W1/2 SW1/4, SE1/2 SW1/4, E1/2 SE1/4 and SW1/4 SE1/4;
Sec. 12, N1/2 NW1/4;
Sec. 14, N1/2 NW1/4;
Sec. 30, N1/2 E1/2.

T. 39 N., R. 10 W.,
Sec. 1, lot 11;
Sec. 12, lots 3 and 4.

These pipelines will convey natural gas across 3,658 miles of public lands in San Juan 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 6770, Albuquerque, New Mexico 87107.

FRED E. PADILLA, Chief, Branch of Lands and Minerals Operations.

[FR Doc. 77-19488 Filed 7-7-77; 7:78:45 am]

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 4 1/2-inch natural gas pipeline rights-of-way across the following lands:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 19 S., R. 28 E.,
Sec. 31: W1/4 SE1/4;
T. 20 S., R. 28 E.,
Sec. 6, lot 2 and SW1/4 NE1/4.

These pipelines will convey natural gas across 0,916 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.

[FR Doc. 77-19487 Filed 7-7-77; 8:45 am]

WYOMING

Application


Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920, 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 6 inch O.D. and 8 inch O.D. pipelines, a 1 inch "sweet" gas line, 8 inch "pig" launching facilities, an electric control launching facility, and 6 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:

SIXTH PRINCIPAL MERIDIAN, RIO BLANCO COUNTY, COLORADO

T. 4 S., R. 101 W.,
Sec. 1: N1/2 NE1/4, SW1/2 NE1/4, NW1/2 SE1/4, E1/2 SW1/4;
Sec. 11: S1/2 SE1/4;
Sec. 12: NW1/4 NE1/4, NE1/4 NW1/4, SW1/4 NW1/4, NW1/4 SE1/4;
Sec. 34: Lot 4, NE1/4 SE1/4;
Sec. 35: Lots 1 and 2, SE1/4 NE1/4, NE1/4 SE1/4;
Sec. 36: Lots 2, 3, 4 and 5, NW1/4, N1/2 SE1/4;

SIXTH PRINCIPAL MERIDIAN, GARFIELD COUNTY, COLORADO

T. 5 S., R. 100 W.,
Sec. 6: Lots 9 and 10.
T. 5 S., R. 101 W.,
Sec. 1: Lot 8;
Sec. 2: Lots 6 and 8;
Sec. 3: Lot 6;
Sec. 11: SE1/4 NE1/4, NW1/4 NW1/4, NE1/4 SE1/4;
Sec. 12: W1/4 W1/4.

The above-named gathering system will enable the applicant to collect natural gas in the area through which the pipelines will pass and to convey it to the applicant's customers.

The purpose of this notice is: (1) To inform the public that the Bureau of Land Management is proceeding with the preparation of environmental and other analytic reports, necessary for determining whether or not the application should be approved and if approved, under what terms and conditions. (2) To give all interested parties the opportunity to file objections to the proposed gathering system to file its claim or objections in the Colorado State Office. Any party so filing must include evidence that a copy thereof has been served on North-West Pipeline Corporation.

Any comment, claim, or objections must be filed with the Chief, Branch of Adjudication, Bureau of Land Management, Colorado State Office, Room 700, Colorado State Bank Building, 1600 Broadway, Denver, Colorado 80202, as promptly as possible after publication of this notice.

THOMAS HARDIN, Chief, Branch of Adjudication.

[FR Doc. 77-19427 Filed 7-7-77; 8:45 am]

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

SIXTH PRINCIPAL MERIDIAN, WYOMING
T. 18 N., R. 98 W., Sec. 26 N.W. 1/4, NE 1/4, SW 1/4, and NW 1/4 SW 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. 21, T. 18 N., R. 98 W. The related facilities will 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.

Department of the Interior proposes to acquire salt ponds to be reserved to provide opportunities for wildlife oriented recreation within the open space. As part of this proposal certain salt ponds will be included in a National Wildlife Refuge established to protect Fish and Wildlife Service, Department of the Interior, Washington, D.C. 20240.

Dated: June 29, 1977.

HEATHER L. ROSS,
Deputy Assistant Secretary of the Interior.

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 357 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. 20248. Notice of the institution of the investigation was published in the Federal Register on July 1, 1976 (41 FR 27134).

Issued: July 1, 1977.

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 United States 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). We have determined that an industry in the United States is likely to be injured by reason of the importation of such merchandise into the United States.

Notice of the institution of the investigation and of a public hearing to be held in connection therewith was duly given by posting copies thereof in the Office of the Secretary, United States International Trade Commission, Washington, D.C., and at the Commission’s New York Office, and by publishing the notice in the Federal Register of April 11, 1977 (42 FR 18906). On May 12, 1977, a hearing was held in accordance with the notice, and all persons requesting the opportunity were permitted to appear by counsel or in person.

In arriving at its determination, the Commission gave due consideration to all written submissions from interested parties and information adduced at the hearing as well as information obtained by the Commission’s staff from questionnaires, personnel interviews, and other sources.

On the basis of the investigation, the Commission (Chairman Minchew and Commissioner Abondi dissenting) has 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 that 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.

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 which the Department of the Treasury has determined are being, or are likely to be sold in the United States are likely to be sold at less than fair value (LTFV) within the meaning 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).

We have determined that an industry in the United States is likely to be injured by reason of the importation of such merchandise into the United States.

LTFV SALES

The Department of the Treasury investigated U.S. imports of metal-walled above-ground swimming pools from...
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 the Treasury. The LTFV import category made up almost all sales of the subject merchandise sold in the United States by Asahi during the period of investigation. Treasury found margins on Asahi's sales in the United States ranging from 1 percent to 32 percent on approximately 47 percent of the sales compared. The weighted average margin on all sales was 3.5 percent. 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 can be taken apart and reassembled above-ground pools exported by sales compared. The weighted average sales from 1 foot to 3 feet in depth. Family pools, which are noninflatable and transportable, are normally categorized into two groups: Splasher and family pools. Splashes, which are circular, range from 6 to 12 feet in diameter, and from 1 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 8 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 90 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 metal-walled above-ground pools have accounted for over 90 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 1972-76 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 splasher pools 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 80 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 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 Asahi 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 decreased from 246,000 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 above-ground pools, declined from 123,000 pools in 1974 to 45,000 pools in 1975, and then increased to 76,000 pools in 1976—38 percent below the 1974 level.

The average number of production and related workers engaged in the manufacture of family pools followed a trend similar to that for producers' shipments, declining from 811 in 1974 to 346 in 1975 and then increasing slightly to 418 in 1976—32 percent below the 1974 level.

The LTFV 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 domestic shipments, declined from $3.6 million in 1974 to $2.7 million in 1975. In 1976, despite an increase in net sales and related income to $3.5 million, the ratio of net operating profit to net sales for the 3 firms on their above-ground swimming pool operations declined from 12.7 percent in 1974 to 7.5 percent in 1975 and to 7.5 percent in 1976.

There is additional evidence that the domestic producers lost sales to LTFV imports from Japan and, if such imports continue, it is likely that they will injure the domestic industry. U.S. producers advised the Commission that sales lost to LTFV imports totaled $2.3 million in 1975 and $4.4 million in 1976. Officials of several of the firms listed by U.S. producers as having reduced purchases of domestically produced pools because of increased purchases of Japanese pools stated that price was the determinative factor in their decisions to begin importing pools from Japan or increase their imports. Fifteen U.S. purchasers of above-ground pools reported data to the Commission showing a displacement of purchases of U.S.-made pools by imports of Japanese pools during the period 1975 and 1976.

Price data collected by the Commission indicate that all sizes of above-ground pools imported from Japan undersell the domestic product, but that the margin of underselling is more pronounced with respect to family pools. Since 1975, when imports of family pools from Japan first entered the United States, such pools have been sold at prices averaging from 24 to 41 percent below those of U.S.-made pools. However, at the Commission's public hearing, the domestic industry maintained, and counsel for Asahi agreed, that the practical price advantage is much less. This is because U.S. producers provide their customers with numerous services that are not available from Japanese manufacturers. Such services include a form of easy financing that is written into the contract allowing the pool dealer to pay for pools to July or August, although actual delivery may have taken place up to 7 months earlier. Furthermore, often pool producers do not force dealers to take family pools when previously ordered. The financing and flexibility in delivery provided by U.S. producers are not available for imports from Japan, which are purchased only through irrevocable letters of credit and require lengthy lead times. Taking such factors into consideration, it is believed that the real price advantage of imports from Japan is less than 10 percent. Consequently, the 3.5 percent average dumping margin found by Treasury is a significant factor in causing likelihood of injury to the domestic industry.

As noted above, it is evident that Japanese imports of splasher pools new to the market for these articles and the LTFV imports from Japan have also made significant inroads into the U.S. market for family pools. Information obtained in the investigation indicates that Asahi is capable of significantly increasing its share of the U.S. family pool market by reason of its ability to expand production of metal-walled above-ground pools with existing equipment. In view of these considerations, the U.S. industry is likely to be injured if LTFV imports continue unabated.

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 EMILIO MACHADO, MINISTER TO THE COMMISSION AND COMMISSIONER ITALO H. ABLONDI

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 6, 1977, the Commission instituted investigation No. AA1921-165 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; 
(2) The requisite injury must be by reason of importation into the United States of the merchandise which the Treasury has determined is being, or is likely to be, sold at LTFV 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 as a 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 this investigation, are reproduced in an area of relative insignificance in terms of sales, employment, and profitability. Thus, they are essentially a non-inflatable unlike many children's pools, and are portable as opposed to the larger in-and-ground pools. The above-ground pools involved in this investigation are normally categorized as "splashers," which are smaller units, and the larger "family pools," generally having a diameter of 15 feet and over.

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 60 percent of the 1971 U.S. production of the pools in question.

Prevention of the establishment of an industry is not an issue in the instant investigation and will not be discussed further.

NOTICES

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 decline occurred during the first quarter of 1977 for all pool sizes. Of particular importance is the marked decline in imports of family pools, for which the ratio decreased by more than 50 percent from that in the first quarter of 1977. This sharp decline has special significance because family pools constitute the vast bulk of the value of all above-ground swimming pools sold in this country.

In addition, the Commission has received assurances from the Secretary of Commerce that import penetration into the United States is likely to continue at the rate at which it is currently decreasing.

In some cases, the prices at which the pools are being sold in the United States are not being injured 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 decline occurred during the first quarter of 1977 for all pool sizes. Of particular importance is the marked decline in imports of family pools, for which the ratio decreased by more than 50 percent from that in the first quarter of 1977. This sharp decline has special significance because family pools constitute the vast bulk of the value of all above-ground swimming pools sold in this country.

Further decline occurred during the first quarter of 1977 for all pool sizes. Of particular importance is the marked decline in imports of family pools, for which the ratio decreased by more than 50 percent from that in the first quarter of 1977. This sharp decline has special significance because family pools constitute the vast bulk of the value of all above-ground swimming pools sold in this country.

In addition, the Commission has received assurances from the Secretary of Commerce that import penetration into the United States is likely to continue at the rate at which it is currently decreasing.

In some cases, the prices at which the pools are being sold in the United States are not being injured by reason of LTFV imports.

U.S. PRODUCERS' SHIPMENTS, EMPLOYMENT, AND PROFITABILITY

The declines experienced by the domestic industry during 1976 in the areas of shipments, employment, and profitability must be viewed within the context of the generally poor economic conditions existing at that time. In 1974 in response to a strong and increasing demand, shipments were at their highest level during the 1973-76 period. In 1975, however, total apparent U.S. consumption of swimming 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 138,000 pools in 1976, an increase of 46 percent over the previous year.

Employment followed a similar upward course in 1976, and the figures for the first quarter of 1977, 1977, showed a 17 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 $4.9 million from $8.5 million from the previous year, net operating profits soared to $11.8 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 9.2 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 imports, but rather because of the prevailing domestic market patterns during the period in question. One additional factor which may have 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 strong post-recession surge 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 found in other cases 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 more than 50 percent in that same period.

CONCLUSION

On the basis of the facts 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
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 § 0.100 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 quotas 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. The Administrator has decided that the legitimate need of this substance for 1977, the Drug Enforcement Administration hereby establishes an interim 1977 aggregate production quota for ecgonine for conversion of 700 kilograms expressed as anhydrous base.

The establishment of the interim aggregate production quota for ecgonine for conversion is effective on July 6, 1977.

Dated: July 1, 1977.

Peter B. Beningo, Administrator.

DEPARTMENT OF JUSTICE
Drug Enforcement Administration

NOTICES

In the event that comments or objections to this proposal raise one or more issues which the Administrator finds, in his sole discretion, warrants a full adversary-type hearing, the Administrator 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 6, 1977.

The making of a written finding that a State plan reflects a determined effort to improve the quality of law enforcement and criminal justice throughout the State and make a significant and effective contribution to the State's efforts to deal with crime if, on the basis of the evaluation for effectiveness and impact, LEAA finds that:

(a) There is clear and explicit evidence that the plan follows a logical progression from crime analysis and problem analysis to the development of programs where the plan features either an in-depth examination in which each of the components of the plan builds upon each of the previous steps in the plan development;

(b) Quantifiable goals have been realistically set and are related to identified problems;

(c) Standards have been realistically set, and are related to goals to be achieved.

The plans for 1977 aggregate production quota for ecgonine for conversion are summarized in Policy Letter 156 and are published in the Federal Register.

JAMES M. H. GREGG, Assistant Administrator, OFM.
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 upon the 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, 601 D Street NW, Washington, D.C. 20213.

Signed at Washington, D.C., this 5th day of July 1977.

ERNEST O. 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>Quality Box Co., Inc.</td>
<td>Natchez, Miss.</td>
<td>Manufacture of paper boxes</td>
</tr>
<tr>
<td>Commer Manufacturing Co., Inc.</td>
<td>Dayton, O.</td>
<td>Manufacture of paperboard and paper products</td>
</tr>
<tr>
<td>Trooper, Inc.</td>
<td>Wadley, Ga.</td>
<td>Manufacture of women's and men's work clothing</td>
</tr>
<tr>
<td>Judy's Automotive Service, Inc.</td>
<td>Atlanta, Ga.</td>
<td>Sweet potato storage and processing warehouses</td>
</tr>
<tr>
<td>Holiday Holter Mills, Inc.</td>
<td>Cambridge, N.Y.</td>
<td>Manufacturing and packaging of hose products</td>
</tr>
<tr>
<td>Davis Wood Products, Inc.</td>
<td>New York, N.Y.</td>
<td>Manufacture of plywood and furniture parts</td>
</tr>
<tr>
<td>Judy Branch, O.</td>
<td>Columbus, O.</td>
<td>Night club with food and dancing</td>
</tr>
<tr>
<td>C &amp; H Industries, Inc.</td>
<td>Dallas, Tex.</td>
<td>Manufacturing of women's and men's work clothing</td>
</tr>
<tr>
<td>E. H. &amp;. Industries, Inc.</td>
<td>Miami, Fla.</td>
<td>Manufacturing of women's and men's work clothing</td>
</tr>
<tr>
<td>Assurance Manufacturing Corp.</td>
<td>Palm Springs, Calif.</td>
<td>Manufacturing of mobile homes and modular homes</td>
</tr>
</tbody>
</table>

PENSION AND WELFARE BENEFIT PROGRAMS

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[Prohibited Transaction Exemption 77-8; Application No. D-381]

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 31974 in the issue for Tuesday, June 21, 1977, in the first line, middle column, page 31974, "C.B. 72" should read "C.B. 722"; and in the last line of the paragraph titled "Exemption," middle column, page 31975, "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.


TYPE OF MEETING: Partially open. July 26—9 a.m.—3 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:

Gerald B. Devey, Executive Secretary, Science Applications Task Force, National Science Foundation, Telephone 202-634-6608. 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 assistance to the NSF Director on science applications programs and related organizational and management issues.


REASON FOR CLOSING: The denial 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. 92-463.

M. REBECCA WINKLER,
Acting Committee, Management Officer.

July 1, 1977.

RENEGOTIATION BOARD

EXCESSIVE PROFITS AND REFUNDS

Interest Rate

Correction

In FR Doc. 77-18075 appearing on page 32339 in the issue for Friday, June 24, 1977, in the ninth line, "7%" should be corrected to read "7.5%.

EXEMPTION OF FOREIGN MILITARY SALES

Rescission 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(k) 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 such amendments to CBOE rules that are presently applicable only to trading of options on underlying stocks, so as to make these 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 that the Government securities market is largely an institutional market in which the average trade size is $1,000,000 and the securities options trading is a small percentage of the underlying Government securities market. In view of this large average trade size, it is necessary 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. The position limit applies to exercise limits (Rule 4.12).

Rule 4.17, which currently imposes a restriction on certain out-of-the-money options on underlying stocks, was developed only after considerable trading experience. In view of 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 problem with Rule 4.17.

The purpose of Rules 5.3 and 5.4, in establishing criteria for the listing and delisting of options covering particular underlying securities, is to ensure that the underlying Government securities chosen for options trading are widely held and actively traded. For this reason, it is proposed that only the larger Government issues be listed as underlying securities and that these will ordinarily remain as underlying securities only for one year following their original selection, since CBOE will ordinarily not introduce 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, the Government security on which the option is based will be the subject of an additional series of options covering a particular underlying Government security at one percentage point intervals whenever the quoted 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 102½ or above, or 103½ 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 obtaining the bidder's and offer's prices promptly. 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.

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. 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 the delivery and payment provisions of recommendations, and 1933 Act disclosures (Rules 7.9, 9.9, and 9.15) to provide separate account approval and disclosure requirements for options on Government securities, including that it is a dealer market, and that Government securities are less volatile than stocks.

Rule 11.3 (Delivery and Payment) will be amended to make it explicit that, in accordance with the standards 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 assigned 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 the date of the exercise settlement date.

It is proposed to amend Rule 12.3 to provide minimum margin requirements for option contracts on Government se-
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 (2)(vi)(A) of the CBOE's Statement of Basis and Purpose. The purposes of CBOE, as set forth in the Statement of Basis and Purpose, are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and the development of aARNet market and 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 section 6(b)(5) since it expects such a market 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 further secure the risks and opportunities of investing in securities, and to redistribute those risks and opportunities between the holder and writer of the option, CBOE expects that Government securities options will be used primarily to hedge against adverse price fluctuations in Government securities resulting from changes in interest rates and other economic developments which affect the money and capital markets.

In January 1976, CBOE established a Fixed Income Securities Task Force consisting of CBOE members and commercial banks experienced in the options market or in the market for fixed income securities to assess 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 selecting Government notes and bonds as the underlying fixed income securities, as reflected in the proposed rule change. For that reason, neither CBOE nor the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number 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 delegated authority.

George A. Fitzsimmons, Secretary.

June 29, 1977.

[FR Doc. 77-19610 Filed 7-7-77; 8:45 am]

DEPARTMENT OF STATE

[Public Notice CM-7/88]

STUDY GROUP 5 OF THE U.S. NATIONAL COMMITTEE, INTERNATIONAL TELEGRAPH 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 5011 of the Department of Commerce, 1325 G Street, N.W., Washington, D.C. This Study Group deals with matters in telecommunication services relating to the development of the international digital data transmission services.

The agenda for the July 26 meeting will include consideration of the following:


2. Approval of draft Provisional Recommendations as recommended by CCITT Study Groups VII and XVII.

3. Identification of subjects for U.S. contributions to December 1977 Working Party meeting of CCITT Study Group XVII and to the April 1978 meeting of Study Group VII.

4. Consideration of the following principles for interworking of data networks with telephone/telex networks: and Other.

All participants are invited to submit written data, views and arguments concerning the foregoing. Persons desiring to make written submissions should file 6 copies thereof with the Secretary of the Commission, CBOE, D.C. 20549. Copies of the filing with respect to the foregoing and all written submissions will be available for inspection and copying in the Public Reference Room, 1100 L Street NW., Washington, D.C. on request. No filing is required.

Dated: June 20, 1977.

Arthur L. Freeman,
Chairman,
U.S. National Committee.

[FR Doc. 77-19604 Filed 7-7-77; 8:45 am]

[Public Notice CM-7/97]

SHIPPING COORDINATING COMMITTEE, SUBCOMMITTEE ON SAFETY OF LIFE AT SEA

Meeting

The working group on standards of training and watchkeeping of the Subcommittee 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 Seventh 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 to develop the US position on watchkeeping requirements in the annex to the draft convention.

For further information, contact Capt. J. P. Dowley, United States Coast Guard, G-MVP/82. Washington, D.C. 20590, (area code 202) 426-1500.

The Chairman will entertain comments from the public as time permits.

Richard K. Bank, Chairman.

Shipping Coordinating Committee.


[FR Doc. 77-19993 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

Pursuant to the authority delegated to me by AID Delegations of Authority No. 164-10, dated December 29, 1961 (27 FR 449), as amended, with respect to Loan Agreements; No. 38, dated April 16, 1964 (29 FR 5280), and as amended, with respect to Project Agreements, Trust Fund Agreements, and Grants to International Organizations; No. 99, dated April 27, 1973 (38 FR 12834), with respect to Contracting and Related Functions; and No. 119, dated October 12, 1976 (41 FR 48655), with respect to other authorities and functions delegated to me, I hereby redelege 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 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, 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 Bangladesh.

This Redelegation of Authority is effective immediately.


Michael H. B. Adler,
Acting Assistant Administrator,
Bureau for Asia.

[FR Doc. 77-19389 Filed 7-7-77; 8:45 am]

MISSION DIRECTOR AND DEPUTY MISSION DIRECTOR, USAID PHILIPPINES

Redelegation of Authority No. 164-12 (Revised)

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 5280), as amended, with respect to Project Agreements, Trust Fund Agreements, and Grants to International Organizations; No. 112, dated October 12, 1975 (40 FR 48955), 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;

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, 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 Bangladesh.

This Redelegation of Authority is effective immediately.


Michael H. B. Adler,
Acting Assistant Administrator,
Bureau for Asia.
tracts, amendments and modifications thereof, 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.

Redelegation 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 (Revised)

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 5280), as amended, with respect to Project Agreements, Trust Fund Agreements, and Grants to International Organizations: No. 89, dated April 27, 1973 (38 FR 12834), with respect to Contracting and Related Functions; and No. 112, dated October 12, 1975 (40 FR 48955), 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 (FIO/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 190, (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 officials and
organizational entities indicated thereunder:

Assistant Secretary (International Affairs)
Deputy Assistant Secretary for Trade and Investment Policy
Deputy Assistant Secretary for 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
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
Deputy 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 Assistant 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
Senior Adviser (Debt Research)
Office of Government Finacing
Office of Agency Finance and Market Policies
Office of Revenue Sharing
Assistant Secretary (Public Affairs)
Deputy Assistant Secretary (Public Affairs)
Office of Public Affairs
Fiscal Assistant Secretary
Deputy Fiscal Assistant Secretary
Bureau of Government Financial Operations
Bureau of the Public Debt
Commissioner of Internal Revenue
Deputy Commissioner
Internal Revenue Service
Comptroller of the Currency
First Deputy Comptroller
Office of the Comptroller of the Currency

6. The Deputy Secretary, the Under Secretary for Monetary Affairs, the Under Secretary, the General Counsel, and the Assistant Secretaries are authorized to perform any functions 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 hereetofore 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 Orders No. 190 (Revision 13) and No. 199 (Revision 13—Amendment 1) are rescinded effective this date.

Dated: July 1, 1977.

W. MICHAEL BLUMENTHAL,
Secretary of the Treasury.

[FR Doc. 77-19493 Filed 7-7-77; 8:45 am]
NOTICES

INTERSTATE COMMERCE COMMISSION

[Notice No. 431]

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 ensure their attendance. Cancellation or postponement of hearings in which they are interested.


MC 142152 (Sub-1), N.A.T. Transportation, Inc. now being assigned September 18, 1977 (1 day) at Chicago, Illinois, in a hearing room to be later designated.

MC 30255 (Sub-1), K & R Delivery, Inc., now assigned September 17, 1977 at Chicago, Illinois, has been postponed indefinitely.

MC 142747, David L. Tate, Hamer L. Tate, Albert E. Tate & Gerald Ross, d/b/a/ Tate Cheese Company, now being assigned September 14, 1977 (1 day) at Chicago, Illinois, in a hearing room to be later designated.

MC 120873 (Sub-161), K.T. Carrier Corp., now being assigned September 15, 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 144705, Frather Auto Sales, Inc., now being assigned September 21, 1977 (3 days) at Chicago, Illinois, in a hearing room to be later designated.

MC 53378 (Sub No. 14), McVey Trucking, Inc. now assigned August 3, 1977 at Chicago, Illinois in Room 348, 230 South Dearborn Street, Chicago, Illinois, in a hearing room to be later designated.

MC 140654 Sub 20, Lester Coggins Trucking Inc. now assigned August 9, 1977 at Lexington, Kentucky and will be held at the Holiday Inn North, 1000 Newtom 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, 1000 Newtom Pike.

AB 8 Sub No. 16 Burlington Northern, Inc., Abandoned Branch Line—Barnard, in Nodaway County Missouri, now being assigned September 13, 1977 (2 days) for hearing in Maryville, Missouri, in a hearing room to be later designated.

MC 108277 Sub No. 456 Frozen Food Express, Inc. now being assigned September 15, 1977 at Kansas City, Kansas, in a hearing room to be later designated.

MC-F-19129 Kaw Transport Company—Control—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.

ChICAGO AND NORTH WESTERN TRANSPORTATION CO.

Abandonment Between Marshall Junction and Vesta, in Lyon and Redwood Counties, Minn.


The Interstate Commerce Commission hereby gives notice that its Section of Energy and Environment has concluded that the proposed abandonment by the Chicago and North Western Transportation Company of its branch line between Marshall Junction and Vesta, a distance of 37.3 miles, all in Lyon and Redwood Counties, Minn., if approved by the Commission, does not constitute a major Federal action significantly affecting the quality of the human environment within the meaning of section 1508.27, Environmental Policy Act of 1969 (NEPA). 42 U.S.C. 4321 et seq., and that preparation of a detailed environmental impact statement will not be required under section 432(2) (C).

It was concluded, among other things, that the associated environmental impacts are not considered significant because the involved traffic could be diverted to heavy motor vehicles with only minor alterations in highway traffic volume, safety hazards, fuel consumption, intrusive noise incidents, and ambient air quality. In addition, no definitive developmental plans are dependent on the continuation of the subject line.

This conclusion is contained in a staff-prepared environmental threshold assessment survey, which is available on request to the Interstate Commerce Commission, Office of Proceedings, Washington, D.C. 20423; telephone 202-275-2011.

Interested persons may comment on this matter by filing their statements in writing with the Interstate Commerce Commission, Washington, D.C. 20423, on or before August 10, 1977.

It should be emphasized that the environmental threshold assessment survey represents an evaluation of the environmental issues associated with an application for abandonment. The Commission does not purport to resolve the issue of whether the present or future public convenience and necessity permit discontinuance of the line proposed for abandonment. Consequently, comments on the environmental study should be limited to discussion of the presence or absence of environmental impacts and reasonable alternatives.

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

[FR Doc.77-19514 Filed 7-7-77; 8:45 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, maintain, cancel, or impose and charge at intermediate points that are 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-883), 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 of the reverse direction. Grounds for relief—Market competition and return shipments. Tariff—Supplement 16 to Southwestern Freight Bureau, Agent, tariff 127-G, I.C.C. No. 5128. Rates have been published to become effective on August 5, 1977.

By the Commission.

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

[FR Doc.77-19512 Filed 7-7-77; 8:45 am]
which may be examined at the field office named below. Send protests to: Director, Interstate Commerce Commission, 9 Clinton Street, Newark, N.J. 07102.

No. MC 59204 (Sub-No. 62TA), filed June 21, 1977. Applicant: SMITH & SOLOMON TRUCK CO., How Lake, New Brunswick, N.J. 08902. Applicant's representative: Herbert Burstein, 2575 Orange St., New York, N.Y. 10048. 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 plants to site of Carling 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 shipping: 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 102367 (Sub-No. 199TA), filed June 22, 1977. Applicant: McNAIR TRANSPORT, INC., 4229 Meadow Lane, P.O. Drawer 5337, Bossier City, La. 71110. Applicant's representative: Joe C. Day, 4240 N. Loco West, Suite 208, Houston, Tex. 77018. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Soda soft solutions, in bulk, in tank truck vehicles, from plant sites of Merichem Co. and/or storage facilities of Merichem Co. in Houston, Tex., to all points in Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, and Oklahoma, for 180 days. Supporting shipping: Merichem Co., 1914 Haden Road, Houston, Tex. 77015. Send protests to: District Supervisor Ray C. Armstrong, Jr., 701 Loyola Ave., 4838 Federal Bldg., New Orleans, La. 70118.

No. MC 160988 (Sub-No. 779TA), filed June 21, 1977. Applicant: NATIONAL TRAILER CONVOY, INC., 525 S. Main, P.O. Box 3329, Tulsa, Okla. 74103. Applicant's representative: Irvin Tull (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. Dakota 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 shipping: Associated Contractors of America, Inc., 224 6th Avenue SE., Aberdeen, S. Dak. 57401. Send protests to: District Supervisor Joe Green, Rm. 240, One World Trade Center, New York, N.Y. 10048.

No. MC 107452 (Sub-No. 11TA), filed June 16, 1977. Applicant: R. D. BROWN (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Limestone, in bulk, in pneumatic tank vehicles, from the plant site and/or warehouse facilities of Wvo-Ben Products located at or near Lovell and Greybull, Wyo., to points in Washington and Oregon, for 180 days. Supporting shipping: Materials Supply Division, Wyo-Ben Products, 5304 Hooper Road, Billings, Mont. 59104. Send protests to: District Supervisor Paul A. Naughton, Interstate Commerce Commission, Rm. 105, Federal Bldg., and Court House, 111 South Wolcott, Casper, Wyo. 82601.

No. MC 107515 (Sub-No. 1053TA), filed June 20, 1977. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, 3901 Jonesboro Road SE., Forest Park, Ga. 30293. Applicant's representative: Alan E. Serby, 3379 Peachtree Road NE., Suite 225, Atlanta, Ga. 30326. Authority sought to operate as a common carrier, by motor vehicle, over regular routes, transporting: Magazines, periodicals and parts and sections thereof, from the plant site of R. R. Donnelly & Sons, Chicago, Ill., to Memmis, 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 shipping: U.S. News and World Report, Inc., 350 E. 22nd Street, Chicago, Ill. 60616. Send protests to: E. A. Bryant, District Supervisor, Interstate Commerce Commission, Room 300, 1252 West Peachtree Street NW., Atlanta, Ga. 30309.

No. MC 107515 (Sub-No. 1684TA), filed June 20, 1977. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, 3901 Jonesboro Road SE., Forest Park, Ga. 30293. Applicant's representative: Alan E. Serby, 3379 Peachtree Road NE., Suite 225, Atlanta, Ga. 30326. Authority sought to operate as a common carrier, by motor vehicle, over regular routes, transporting: Meat by-products, with mechanical refrigeration from the plant site and/or warehouse facilities of Dixie Packer, Inc., at or near 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 shipping: Dixie Packers, Inc., P.O. Box 622, Madison, Fla. 32340. Send protests to: E. A. Bryant, District Supervisor, Interstate Commerce Commission, Room 300, 1252 West Peachtree Street, Atlanta, Ga. 30309.

No. MC 113235 (Sub-No. 1487TA), filed June 23, 1977. Applicant: SLAY TRANSPORTATION CO., INC., 3001 S. 7th Street, St. Louis, Mo. 63104. Applicant's representative: T. M. Tahan (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over regular routes, transporting: Limestone, in bulk, in pneumatic tank vehicles, from the plant site of Ash Grove at or near Sequoia, Mo., to Bayway, N.J., GREYHULF Heights, Greyluff, Wy., 82426. Applicant's representative: James M. Hoyland, P.O. Box 118, Interstate Commerce Building, Big Pine, N. Dak. 58202. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Bentonite clay, in bulk, in pneumatic tank vehicles, from the facilities of Wvo-Ben Products located at or near Lovell and Greybull, Wyo., to points in Washington and Oregon, for 180 days. Supporting shipping: Materials Supply Division, Wyo-Ben Products, 5304 Hooper Road, Billings, Mont. 59104. Send protests to: District Supervisor Paul A. Naughton, Interstate Commerce Commission, Rm. 105, Federal Bldg., and Court House, 111 South Wolcott, Casper, Wyo. 82601.

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

Authorities sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: CIGAR, 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: Ray F. Barlow, P.O. Drawer S, Cortez, Colo. 81419. Send protests to: Robert A. Radler, District Supervisor, P.O. Box 1167, Albany, N.Y. 12201.

No MC 119670 (Sub-No. 327TA), filed June 22, 1977. Applicant: THE VICTOR TRANSIT CORPORATION, 5250 Este Avenue, Cincinnati, Ohio 45232. Applicant's representative: Robert H. Kinker, 314 W. Main St., P.O. Box 466, Franklin, Ky. 40061. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Paper, from Teniente, Nev., to the facilities of Union Carbide Corporation at or near Tempe, Ariz., for 180 days.

Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Herb. G. Garner, 3000 E. Main St., P.O. Box 308, Denver, Colo. 80206. Authority sought to operate as a common carrier, by motor vehicle, other than corrugated, from Belchertown, 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, 63 William St., Wellesley, Mass. 02181. Send protests to: Robert A. Radler, District Supervisor, P.O. Box 1167, Albany, N.Y. 12201.

No MC 119599 (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. Siton (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Malt beverages, in containers, from Ft. Worth, Tex., to the commercial zone, for 180 days.

Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Ed Role­sen, Jr., Inc., P.O. Box 47, Pottsville, Pa. 17901. Send protests to: John V. Barry, District Supervisor, Interstate Commerce Commission—B0, 600 Federal Building, 911 Walnut Street, Kansas City, Mo. 64106.

No MC 119670 (Sub-No. 327TA), filed June 22, 1977. Applicant: THE VICTOR TRANSIT CORPORATION, 5250 Este Avenue, Cincinnati, Ohio 45232. Applicant's representative: Robert H. Kinker, 314 W. Main St., P.O. Box 466, Franklin, Ky. 40061. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Paper, from Teniente, Nev., to the facilities of Union Carbide Corporation at or near Tempe, Ariz., for 180 days.

Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Herb. G. Garner, 3000 E. Main St., P.O. Box 308, Denver, Colo. 80206. Authority sought to operate as a common carrier, by motor vehicle, other than corrugated, from Belchertown, 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, 63 William St., Wellesley, Mass. 02181. Send protests to: Robert A. Radler, District Supervisor, P.O. Box 1167, Albany, N.Y. 12201.

No MC 119599 (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. Siton (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Malt beverages, in containers, from Ft. Worth, Tex., to the commercial zone, for 180 days.

Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Ed Role­sen, Jr., Inc., P.O. Box 47, Pottsville, Pa. 17901. Send protests to: John V. Barry, District Supervisor, Interstate Commerce Commission—B0, 600 Federal Building, 911 Walnut Street, Kansas City, Mo. 64106.

No MC 119599 (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. Siton (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Malt beverages, in containers, from Ft. Worth, Tex., to the commercial zone, for 180 days.

Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Ed Role­sen, Jr., Inc., P.O. Box 47, Pottsville, Pa. 17901. Send protests to: John V. Barry, District Supervisor, Interstate Commerce Commission—B0, 600 Federal Building, 911 Walnut Street, Kansas City, Mo. 64106.
NOTICES

No. MC 124511 (Sub-No. 37TA), filed June 17, 1977. Applicant: JOHN F. OLIVER, P.O. Box 223, E. Highway No. 257, Meridian, Miss. 39301. Applicant's representative: Leonard R. Kofkin, 38 South LaSalle Street, Chicago, Ill. 60603. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Steel reinforcing bars, from the plant sites and facilities of Ceco Corporation at Chicago, Ill. to points in Culloway County, Mo., for 180 days. Supporting shipper: Daniel International, P.O. Box 108, Fulton, Mo. 65251. Send protests to: Vernon V. Coble, District Supervisor, Interstate Commerce Commission, 600 Federal Building, 511 Walnut Street, Kansas City, Mo. 64106.

No. MC 134145 (Sub-No. 85TA), filed June 20, 1977. Applicant: NORTH STAR TRANSPORT, INC., Route 1 Highway 1 and 59 West, Thief River Falls, Minn. 56715. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Glass, from Fargo, N. Dak. 58102, to points in Washington, Idaho, Montana, Utah, Arizona, 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: Computer Peripherals, Inc., 201 Wilshire Blvd., Suite 908, Los Angeles, Calif. 90071. Applicant's representative:challenge A. C. van Zandt, 6401 Old Highway 90, Okeechobee, Fla. 33474. Send protests to: Ronald A. Mau, District Supervisor, Interstate Commerce Commission, P.O. Box 22302, Fargo, N. Dak. 58102.

No. MC 133953 (Sub-No. 1TA), filed June 21, 1977. Applicant: CHEROKEE LINES, INC., P.O. Box 152, 695 E. Moses Cushing, Okla. 74432. Applicant's representative: Donald L. Stern, Suite 530, Univec Bldg., 7100 W. Center Rd., Omaha, Nebr. 68104. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Cured, preserved meats, in packages, from the plant sites and facilities of Land O' Frost, Inc., at Seary, Ark., to Detroit Metropolitan Airport, Terminal 1, and 59 West, Thief River Falls, Minn. 55118. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Portable wheel crushers, from the plant site of the La Font Corporation 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, 100 S. Wacker Drive, Chicago, Ill. 60606. Send protests to: Alphonse J. Begon, Jr., 1500 Deposit Guaranty Plaza, P.O. Box 22623, Jackson, Miss. 39263. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Block ice, from Adams, N.Y. 10017, to Westbrook, Me., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Pfizer, Inc., P.O. Box 3380, Springfield, Mass. 01103. Send protests to: Max Gorenstein, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 150 Causeway Street, Boston, Mass. 02114.


No. MC 143778 (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 South St. Paul, Minn., and Dubuque, Iowa to facilities of the State of Wisconsin Electric Power Co., at Eau Claire, Madison, Menomonie, Platteville, River Falls and Whitewater, Wis., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: The C. Reiss Coal Company, Sheboygan, Wis. 53081, (E. R. Knauk. Apply protests to: Gail Daugherty, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, U.S. Federal Building & Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, Wis. 53202.

No. MC 141546 (Sub-No. 22TA), filed June 20, 1977. Applicant: BULK TRANSPORT SERVICE, INC., P.O. Box 322, McLeansboro, Ill. 62859. Applicant's representative: Kenneth B. Williams, 84 State St., Boston, Mass. 02109. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Cement, in bulk, in tank trucks: From all Quebec-U.S. border points to points in Connecticut, Rhode Island, and Massachusetts, 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 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.
Saline, Franklin, Jefferson, Williamson, Gallatin, Marion, Hamilton, Hardin, Pope, Johnson, Union, and Jackson Counties in Illinois; to points south of State Route 32 in Indiana, for 180 days. 
Supporting shipper: John P. Masselink, Fuel Manager, Public Service Company of Indiana, Inc., 106 E. Main Street, Plainfield, Ind. 46168. Send protests to: Harold C. Jolliff, District Supervisor, Interstate Commerce Commission, P.O. Box 2418, Springfield, Ill. 62705.

No. MC 143311 (Sub-No. 1TA), filed June 22, 1977. Applicant: FAMCO TRANSPORT CORP., P.O. Box 80907, Seattle, Wash. 98110. Applicant's representative: James T. Johnson, 1200 Fifth Avenue, Seattle, Wash. 98101. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Shakes, stumps and trim, from points in Stagg County, Wash., to points in California under contract with Supreme Cedar Products, Inc., of Oakland, Calif., for 180 days. 
Supporting shipper: Supreme Cedar Products, Inc., Route 1, Box 140, Concrete, Wash. Send protests to: L. D. Boone, Transportation Specialist, Bureau of Transportation Operations, Interstate Commerce Commission, 858 Federal Building, Seattle, Wash. 98174.

No. MC 143402TA, filed June 21, 1977. Applicant: JOHN HENSAL TRUCKING, INC., Box 621, Woodward, Okla. 73801. Applicant's representative: C. L. Phillips, Rm. 244, Clasen Terrace Bldgs., Classen, Oklahoma City, Okla. 73104. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Drilling rigs, used in the discovery of natural gas and petroleum (from and to jobsite locations), between points in Kansas, Oklahoma, and Texas, for 180 days. 
Supporting shipper(s): There are approximately six (6) statements of support attached to the application, of which five (5) were examined at the Interstate Commerce Commission in Washington, D.C., or copies thereof which may be examined at the field office named below. Send protests to: District Supervisor lazy J. Jolliff, Bureau of Transportation Operations, Interstate Commerce Commission, P.O. Box 2418, Old Post Office Bldgs., 215 Northwest Third St., Oklahoma City, Okla. 73102.

No. MC 143403TA, filed June 20, 1977. Applicant: MADISON COAL & SUPPLY COMPANY, Port Amherst, Charleston, W. Va. 25506. Applicant's representative: John M. Friedman, 2930 Putnam Avenue, Hurricane, W. Va. 25526. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Coal, in bulk, in dump vehicles, from points in Lee, Owosy, Rockcastle, Jackson, Breathitt, Leslie, Perry, Morgan, Magoffin, Clay, Wolfe, Johnson, and Pike Counties, Ky., to points in Hamilton County, Ohio, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. 
Supporting shipper: R. L. Hartman, Jr., VP, Hatfield Coal Division of Amherst Industries, Inc., P.O. Box 14118, Cincinnati, Ohio 45214. Send protests to: H. R. White, District Supervisor, Interstate Commerce Commission, 3108 Federal Office Building, 200 Quadrant Street, Charleston, W. Va. 25301.

No. MC 143413TA, filed June 22, 1977. Applicant: A. & B. Morrows, Interstate Commerce Commission, P.O. Box 80007, Seattle, Wash. 98110. Applicant's representative: Edward L. Neele, 167 Fairfield Road (F-O Box 1490), Fairfield, N.J. 07006. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Flee goods, in individual rolls, and materials and supplies used in the dyeing or finishing of piece goods, between the plant sites of Braendly-Fiskill, 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: Braendly-Fiskill, Inc., 10 East Main Street, Beacon, N.Y. 12508. Send protests to: District Supervisor's Office, Morgans, Interstate Commerce Commission, 9 Clinton Street, Newark, N.J. 07102.

WATER APPLICATION

W-776 (Sub-No. 2TA), filed June 17, 1977. Applicant: LYKES BROS. STEAMSHIP CO., INC., 300 Poydras Street, New Orleans, La. 70113. Applicant's representative: A. F. Babin (same address as applicant). Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Five (5) pieces Nuclear Reactor Components consisting of two (2) reactors each 35' 2" x 23' 4" x 23' 4"; 784,000 lbs.; One (1) Service Support x 15' 7"; 600,000 lbs.; Two (2) Closure Heads each 19' 6" x 10' 8"/209,200 lbs. 
From: Port of New Orleans, La. To: Port of Longview, Wash., via the Panama Canal by Steamship, for 90 days. 

By the Commission.

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

PETITIONS, APPLICATIONS, FINANCE MATTERS (INCLUDING TEMPORARY SUSPENSION, ALTERATION OF ROUTE DESIGNATIONS, ALTERNATE ROUTE DEVIA- TIONS, AND INTRASTATE APPLICATIONS)

PETITIONS FOR MODIFICATION, INTERPRETA- TION, OR RESTATEMENT OF OPERATING RIGHTS AUTHORITY

The following petitions seek modification or interpretation of existing operating rights authority, or restateinent 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) numbering 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. (See notice issued May 13, 1977, Petitioner: PACIFIC INTERMOUNTAIN EXPRESS CO., a corporation, 1417 Clay Street, P.O. Box 958, Oakland, Calif. 94604. Petitioner's representative: Alfred G. Krebs (same address as petitioner). Petitioner holds an operating authority certificate in No. MC 730 (Sub-No. 149, issued July 31, 1959, authorizing transportion, as pertinent, over regular routes, of general commodities (except those of unusual value), household goods, as defined by the Commission, commodities in bulk, and those requiring special equipment) 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 Burley), for pick-up and delivery, and those in Idaho west of Burley, Idaho, and those in Oregon and Washington restricted to delivery only as follows: (A) from Salt Lake City over the above-described routes covering the transportation of fish, frozen fruits, cheese, horticultural goods, and those requiring special equipment, from Salt Lake City via La Grande to Walla Walla, Wash., for 180 days. 
(B) from La Grande to Walla Walla, for U.S. Highway 410 to Wallula, Wash.; and (3) from Walla Walla, Wash., for U.S. Highway 410 to Wallula, Wash.; and hence over Washington Highway 12 via 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, to Seattle, Wash., on a motor common carrier 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

1Copies of Special Rule 247 (as amended) can be obtained by writing to the Secretary, Interstate Commerce Commission, Washington, D.C. 20443.
the following described routes: (2) from Quincy, Wash., over Washington Highway 10 to Wenatchee, Wash., and thence over Wenatchee Highway 102 to Wenatchee, Wash.; (b) from Walla Walla, Wash., over U.S. Highway 410 to Wallula, Wash.; and (c) from Fall City, 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 1, 1977. Petitioner: FRANK MARTZ COACH COMPANY, a corporation, 908 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-No. 4 and 5) (M1) (notice of filing of petition to delete restriction), filed May 25, 1977. Petitioner: JALT CORP., doing business as United Newspaper Delivery Service, 5 Cutters Dock Road, P.O. Box 398, Woodbridge, N.J. 07095. Petitioner's representative: Morton E. Kiel, Suite 6103, 5 World Trade Center, New York, N.Y. 10048. Petitioner holds motor contract carrier permits in No. MC 123778 (Sub-Nos. 1, 16, 21, and 23), issued April 13, 1977, July 1, 1976, October 7, 1976, and December 6, 1976, respectively, authorizing generally, as pertinent, the transportation of magazines and similar products over regular routes, from 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 Edison, N.J., or, in the alternative, seeks to modify the permits which sought in the application, and de-scribing in detail the method—whether by tender, 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, data, and information on which such protest is based. Protests not in reasonable compliance with the requirements of the rules may be rejected. The original and one copy of the protest shall be filed with the Commission, and a copy shall be served concurrently upon 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) (g) 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 after procedures ordered by the Commission will result in dismissal of the application.

Further processing steps will be in accordance with procedures ordered by the Commission which will result in dismissal of the application.

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 seasonally file a protest will be construed as a waiver of opposition to the application. 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 Intermountain Express Co., A Corporation, 1417 Clay Street, P.O. Box 958, Oakland, California 94612. Applicant's representative: M. J. Cottle, Newspaper Delivery Service, 75 Cutters Dock Road, P.O. Box 39, Woodbridge, N.J. 07095. Petitioner's representative: Edward G. Bazelon, 39 South LaSalle St., Chicago, IL 60603. Authority to serve Edison, N.J., or, in the alternative, seeks to modify the permits which sought in the application. 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 seasonally file a protest will be construed as a waiver of opposition to the application. Each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application.
modities requiring special equipment): (1) Between Richmond, Va., and Junction U.S. Highway 460 and Virginia Highway 44; (2) From Richmond over U.S. Highway 60 to junction Virginia Highway 24, thence over Virginia Highway 24 to junction U.S. Highway 460, and return over the same route; (3) Between Richmond, Va., and Blacksburg, Va.; From Blacksburg over Virginia Highway 460 and Virginia Highway 24 to junction U.S. Highway 60 at or near Roanoke, Va.; (4) From Martinsville over U.S. Highway 220 to Roanoke, and return over the same route; (5) Between Danville over Virginia Highway 460 and Virginia Highway 24; From Danville over U.S. Highway 29 to junction Virginia Highway 24, and return over the same route; (6) Between Burkeville, Va., and Junction U.S. Highway 460 and Virginia Highway 24: From Burkeville over U.S. Highway 460 to junction Virginia Highway 24, and return over the same route; (7) Between South Boston, Va., and Emporia, Va.: From South Boston over U.S. Highway 501 to Junction Virginia Highway 24, and return over the same route; (8) Between Lynchburg over U.S. Highway 460 and Virginia Highway 24 to junction U.S. Highways 29 and 460 at or near Lunenburg, Va., and junction U.S. Highway 460 and U.S. Highway 49 at or near Amherst, thence over U.S. Highway 29 to Lynchburg, and return through (15) above and, as off-route points in connection with routes (1) through (15) above in part of Virginia located on and east of a line beginning at the Virginia-North Carolina state line, and extending along U.S. Highway 220 to Roanoke; thence on and south of a line extending from Roanoke over Virginia Highway 24 to its junction with U.S. Highway 60; thence over U.S. Highway 60 to its junction with Virginia Highway 188; thence southeast over Virginia Highway 188 to its junction with Colonial National Parkway; thence over Colonial National Parkway to the Chesapeake Bay Bridge at or near Yorktown, Va., with service authorized at all points on the highways specified and Salem, Va.

Note.—In routes (1) through (15) above, applicant seeks authority to convert its existing irregular-route authority to regular-route authority, its existing irregular-route authority as follows: Between points in part of Virginia located on and east of a line beginning at the Virginia-North Carolina state line, and extending along U.S. Highway 220 to Roanoke, thence on and south of a line extending from Roanoke over Virginia Highway 24 to its junction with U.S. Highway 60; thence over U.S. Highway 60 to its junction with Virginia Highway 188; thence along Colonial National Parkway to the Chesapeake Bay Bridge at or near Yorktown, Va., with service authorized at all points on the highways specified and Salem, Va. Route requests that it be held at Kansas City, Mo., or Chicago, Ill. Common control may be involved.

No. MC 2908 (Sub-No. 365), filed May 28, 1977. Applicant: RYDER TRUCK LINES, INC., 2050 Kings Road, P.O. Drawer 630, Mount Holly, N.J. 08060. Applicant's representative: T. C. Mader, Jr., Overlook Building, 6121 Lincolnia Road, Suite 400, Alexandria, Va. 22312. The purpose of this partial republication is to include an applicant's request that it be held in Mt. Holly, N.J.
NOTICES

CO. doing business as THE WAGGONERS, P.O. Box 980, Livingston, Mont. 59047. Applicant's representative: Jacob P. Billig, 2033 K Street NW, Washington, D.C. 20555. Application is filed to operate as a common carrier, by motor vehicle, over irregular routes, transporting agricultural 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 in Dallas, Texas.

No. MC 30644 (Sub-No. 591), filed May 31, 1977. Applicant: KROBLIN REFRIGERATED XPRESS, INC., P.O. Box 5000, Waterloo, Iowa 50704. Applicant's representative: John P. Rhodes (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes transporting: (a) doors; (b) windows, in and east of Ohio, Pennsylvania, Rhode Island, and distribution of doors, except commodities in bulk, from points in the District of Columbia, restricted to shipments originating at and destined to the above origins and destinations.

Note.—If a hearing is deemed necessary, the applicant requests that it be held in Dallas, Texas.

No. MC 30551 (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, N.C. 27802. 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: (a) Materials, supplies and equipment (except commodities in bulk, in tank vehicles) used in the processing, packing, storing, handling products, and supplies, materials and equipment used in the manufacture of aluminum and aluminum products (except in bulk), between the plants and facilities of Alumax, Inc., at or near Casa Grande, Ariz.; Long Beach, N.Y.; and Woodside, Cal.; Loveland, Colo.; Boise and Twin Falls, Idaho; and on the other, points in Arizona, California, Colorado, Idaho, Montana, Nevada, New Mexico, Oklahoma, Oregon, Texas, Utah, Washington and Wyoming.


No. MC 35000 (Sub-No. 28) filed May 31, 1977. Applicant: LOOMIS ARMORED CAR SERVICE, INC., 621 Sansome 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, in and east of Ohio, Pennsylvania, Rhode Island, and, on the other, points in Minnesota, the one hand, and, on the other, Superior, Wisconsin; (2) between Minneapolis, 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 it be held at Atlanta, Ga. 30315. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: General commodities, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment, 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, except those of unusual value, Classes A and B explosives, and those requiring special equipment, except those of unusual value.

Note.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Springfield, Ill. or St. Louis, Mo.

Note.—If a hearing is deemed necessary, the applicant requests it be held at either New York, N.Y. or Newark, N.J.

Note.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held in Kansas City, Missouri.
NOTICES

Tennessee, serving no intermediate points, but serving the terminal of Chattanooga, Tennessee, and Knoxville, Tennessee, and all points within their respective commercial zones. From Chattanooga, Tennessee, to Knoxville, Tennessee, over Interstate Highway 75, and return over the same route. (11) Serving Huntsville, Alabama, as an off-route point in connection with carrier's regular route operations described above between Atlanta and Cartersville, and between Cartersville, Georgia and Chattanooga, Tennessee (12) Serving Polkston, Georgia; Hake City, Florida, as off-route points in connection with carrier's regular route operations described in Docket MC-86697 Sub 41.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests that it be held at either Chattanooga, Tenn. or Atlanta, Ga.

No. MC 59367 (Sub-No. 108), filed May 27, 1977. Applicant: DECKER TRUCK LINE, INC., P.O. Box 915, Fort Dodge, Iowa 50501. Applicant's Representative: Mr. William L. Fairbank, 1980 Financial Center, Des Moines, Iowa 50309. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: general commodities, meat packinghouses, and those requiring special equipment (except hides and commodities in bulk), (1) from Fremont, Nebr., to points in Illinois, Indiana, Iowa, Michigan, Minnesota, and Wisconsin; (2) from Fort Dodge, Iowa, to points in Illinois, Indiana, Michigan, and Minnesota; and (4) from Fort Dodge, Iowa, to points in Illinois, Indiana, Michigan, and Minnesota, restricted to the transportation of traffic originating at the plant sites and storage facilities of Spencer Foods, Inc., and destined to points in the respective above-named destination states.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests that it be held at either Minneapolis, Minn., or Omaha, Nebr.

No. MC 61403 (Sub-No. 244), filed May 31, 1977. Applicant: THE MASON AND DIXON TANK LINES, INC., Highway 11-W, P.O. Box 969, Kingsport, Tennessee 37662. Name of Representative: Mr. W. C. Mitchell, Suite 1201, 370 Lexington Avenue, New York, N.Y. 10017. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Acids, Chemicals, Explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment. Between the following points and states: Western New York (except in bulk) (1) From the facilities of the Aluminum Company of America, located at or near Ochlocknee, Ga., to points in Arkansas, Colorado, Delaware, Illinois, Iowa, Indiana (except Richmond, Gary, and Hammond points in their respective commercial zones), Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, New Hampshire, New Jersey, New York, Ohio, Oklahoma, Pennsylvania, Texas, Vermont, West Virginia, and Wisconsin.

NOTE.—If a hearing is deemed necessary, the applicant requests that it be held at Tulsa, Okla.

No. MC 62162 (Sub-No. 8), filed May 25, 1977. Applicant: Dave Campbell, d/b/a Campbell Truck Line, Lake City, Iowa 51434. Applicant's representative: Larry D. Knox, 600 Rubbly Building, Des Moines, Iowa 50309. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: detasseling machines, loading equipment and harvesting machines on shippers' owned trailers, between Iowa, Illinois, Kansas, Missouri, Nebraska, and Texas.

NOTE.—If a hearing is deemed necessary, the applicant requests that it be held at Des Moines, Iowa or Omaha, Nebraska.

No. MC 67121 (Sub-No. 9) filed May 18, 1977. Applicant: HARP TRANSPORTATION LINE, a Corporation, P.O. Box 1159, St. Joseph, Missouri 64502. Applicant's Representative: Mr. H. H. Lewis, The 1560 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, commodities in bulk, and those requiring special equipment). Between the following points and states: Western Nebraska, South Dakota, and North Dakota; and (2) from Denver, Colo., and Minneapolis, Minn., to points in the United States in commerce originating at Blue Mountain and Nepton, Ontario, Canada.

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at Detroit, Mich., or Washington, D.C.


NOTE.—If a hearing is deemed necessary, applicant requests it be held at New York, N.Y.

No. MC 95640 (Sub-No. 982), filed May 23, 1977. Applicant: WATKINS MOTOR LINES, INC., 114 West Griffin Road, P.O. Box 1836, Lakeland, Florida 33802. Applicant's representative: Ben W. Fincher (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Floor covering, common carrier (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, 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 (2) from the facilities of the Oil-Dri Corporation of America, located at or near Ochlocknee, Ga., to points in Arkansas, Colorado, Delaware, Illinois, Iowa, Indiana (except Richmond, Gary, and Hammond points in their respective commercial zones), Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, New Hampshire, New Jersey, New York, Ohio, Oklahoma, Pennsylvania, Texas, Vermont, West Virginia, and Wisconsin.

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

Federal Register
VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
35251

35251

applicant requests it be held at Washington, D.C.

Docket No. MC 95876 (Sub-No. 200), filed May 26, 1977. Applicant: ANDERSON TRUCKING SERVICE, INC., 203 Cooper Ave. North, St. Cloud, Minn. 56301. Applicant’s representative: Donald A. Morken, 1000 First National Bank Bldg., Minneapolis, Minn. 55402. 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 Winnecoo and Neenah, Wis., on the one hand, and points in the United States (except Alaska and Hawaii), on the other.

NOTE—Common control may be involved if a hearing is deemed necessary, applicant requests it be held at Washington, D.C., or Minneapolis, Minn.

Docket No. MC 95876 (Sub-No. 201), filed May 31, 1977. Name of carrier: ANDERSON TRUCKING SERVICE, INC., 203 Cooper Avenue North, St. Cloud, Minn. 56301. Applicant’s representative: Donald A. Morken, 1000 First National Bank Bldg., Minneapolis, Minn. 55402. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, in the transportation of: Pipe, cable, conduit, wire, and strip steel and attachments therefor, from Glendale (Marshall County), W. Va., to points in Illinois, Indiana, Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, Oklahoma, South Dakota, Texas, and Wisconsin.

NOTE—Common control may be involved if a hearing is deemed necessary, applicant requests it be held at Chicago, Ill., or Tampa, Fla.

Docket No. MC 95876 (Sub-No. 200), filed May 26, 1977. Applicant: ANDERSON TRUCKING SERVICE, INC., 203 Cooper Ave. North, St. Cloud, Minn. 56301. Applicant’s representative: Donald A. Morken, 1000 First National Bank Bldg., Minneapolis, Minn. 55402. 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 Winnecoo and Neenah, Wis., on the one hand, and points in the United States (except Alaska and Hawaii), on the other.

NOTE—Common control may be involved if a hearing is deemed necessary, applicant requests it be held at Washington, D.C., or Minneapolis, Minn.

Docket No. MC 95876 (Sub-No. 201), filed May 31, 1977. Name of carrier: ANDERSON TRUCKING SERVICE, INC., 203 Cooper Avenue North, St. Cloud, Minn. 56301. Applicant’s representative: Donald A. Morken, 1000 First National Bank Bldg., Minneapolis, Minn. 55402. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, in the transportation of: Pipe, cable, conduit, wire, and strip steel and attachments therefor, from Glendale (Marshall County), W. Va., to points in Illinois, Indiana, Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, Oklahoma, South Dakota, Texas, and Wisconsin.

NOTE—Common control may be involved if a hearing is deemed necessary, applicant requests it be held at Washington, D.C.

No. MC 99488 (Sub 5), filed May 4, 1977. Applicant: JIMMY STEIN MOTOR LINES, INC., P.O. Box 2286, Mobile, Ala. 36601. Applicant’s representative: J. Douglas Harris, 1406 Union Bank Tower, Montgomery, Ala. 36104. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, in the transportation of general commodities (except commodities in bulk, explosives and household goods as defined by the Commission); (1) Between the plant site of MacMillan Bloedel, Inc., near Pine Hill, Ala., and Meridian, Miss., over Alabama State Highway No. 10 and Mississippi State Highway No. 19, serving all intermediate points and the off-route point of Naheola, Ala. Restricted against shipments of less than 5,000 pounds, and against shipments of general commodities (except those of unusual value, Class A and B explosives, household goods as defined by the Commission, and those requiring special equipment) serving Mole Lake, Wis., and points in the towns of Nashville, Lincoln, and Crandon, Forest County, Wis., 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. 38 and return serving all intermediate points. (11) Between Silas, Ala., and Grove Hill, Ala., over U.S. Highway 84 and return serving all intermediate points. (12) Between Chatom, Ala., and the plant site of Phillips Petroleum Co., Chatom Plant, over Alabama Highway No. 56 approximately 9 miles west of Chatom, to Chatom with existing authority. Irregular routes: (16) Voting machines between points in Mobile County, Ala.

NOTE—This application is made to convert Certificate of Registration No. MC 99488—Common control may be involved— militants 2 Sub-No. 1, 2, 3, and 4 now held by applicant, Jimmy Stein Motor Lines, Inc., to a certificate of public convenience and necessity and in the public interest. Applicant: JIMMY STEIN MOTOR LINES, INC., P.O. Box 2286, Mobile, Ala. 36601. Applicant’s representative: J. Douglas Harris, 1406 Union Bank Tower, Montgomery, Ala. 36104.

Docket Number MC 99555 (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., 306 S. Bills Street, Waushau, Wis. 54401. Applicant’s representative: Nancy J. Johnson, 4505 Regent Street, Suite 190, Madison, Wis. 53705. Authority sought to operate as a common 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 Commission, commodities in bulk, and those requiring special equipment) serving Mole Lake, Wis., and points in the towns of Nashville, Lincoln, and Crandon, Forest County, Wis., and the site of the Jackson Lock and Dam located near U.S. Highway No. 84 and return.

NOTE—The purpose of this republication is to correct the territorial description. If a hearing is deemed necessary, the applicant requests it be held at Milwaukee or Madison, Wis., or Minneapolis or St. Paul, Minn.


to its junction with U.S. Highway 97, thence over U.S. Highway 97 to Klamath Falls and return over the same route, as alternate routes for operating convenience only, serving no intermediate points.

NOTE—Common control may be involved if a hearing is deemed necessary, the applicant requests it be held at either San Francisco, Calif., or Eugene and return over the same route. If a hearing is deemed necessary, the applicant requests it be held at either Chicago, Ill., or Tampa, Fla.
NOTICES


No. MC 108258 (Sub-No. 11), filed June 2, 1977. Applicant: MASHKIN FREIGHT LINES, INC., 64 Oakland Avenue, East Hartford, Conn. 06108. Applicant’s representative: Gerald A. Joseloff, 80 State Street, Hartford, Conn. Authority sought to operate as a common carrier by motor vehicle, over irregular routes, transporting: Bakery products, from the facilities of First National Stores, Inc., located at East Hartford, Conn., to points in New Hampshire, New Jersey, New York, North Carolina, and Vermont.

No. MC 111401 (Sub-No. 488) (partial correction). filed May 10, 1977, published in the FEDERAL REGISTER issue of June 16, 1977, as No. MC 111401 (Sub-No. 448), and republished as corrected this issue. Applicant: GROENDYKE TRANSPORT, INC., 2510 Rock Island Boulevard, P.O. Box 832, Enid, Okla. 73703. Applicant’s representative: Alvin L. Hamilton (same address as applicant). The purpose for this partial correction is to indicate the correct docket number as No. MC 111401 (Sub-No. 488). The rest of the publication remains the same.

No. MC 111545 (Sub-No. 237), filed May 31, 1977. Applicant: HOME TRANSPORTATION CO., INC., P.O. Box 6216, Station A, Marietta, Ga. 30067. Applicant’s representative: Robert E. Born (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Heat exchangers or coolers for air, gas, or liquids; (2) machinery and equipment for heating, cooling, conditioning, humidifying, dehumidifying, and rooming of air, gas, or liquids; and (3) parts, attachments, and accessories for use in the installation and operation of (1) and (2) above, from the plant and warehouse facilities of Trane Co., in or near Fayette County, Ky., to points in Alabama, Georgia, Illinois, Iowa, Kansas, Louisiana, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, Oklahoma, South Carolina, Texas, and Wisconsin.

No. MC 111729 (Sub-No. 704), filed May 23, 1977. Applicant: PUROLATOR COURIER CORP., 3333 New Hyde Park Road, New Hyde Park, N.Y. 11430. Applicant’s representative: Elizabeth L. Henoch (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Cardiac pacemakers, related accessories, instruction booklets, specifications sheets and identification charts: Between Freeport and Houston, Tex., on traffic having an immediately prior or subsequent movement by air.

—Applicant holds contract carrier authority in No. MC 112750 and subtherunder, and therefore dual operations

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
may be involved. Common control may also be involved. If a hearing is deemed necessary, applicant requests it be held at Houston, Texas or Washington, D.C.

No. MC 112184 (Sub-No. 54), filed May 31, 1977. Applicant: THE MANFREDI MOTORMANUFACTURING COMPANY, 206 S. Second St., Newbury, Ohio 44065. Applicant's representative: John P. McMahon, 100 East Broad Street, Columbus, Ohio 43215. Authority sought to operate as a contract 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 limited line no. or contracts with PPG Industries, Inc.

Note.—Applicant holds common carrier authority in No. MC 128002 and subs 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 112520 (Sub-No. 340), filed June 1, 1977. Applicant: MCKENZIE TANK LINES, INC., Post Office Drawer 305, 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 112558 (Sub-No. 24), filed May 23, 1977. Applicant: RUSSELL TRUCKING LINE, INC., Post Office Drawer 100, Tallahassee, Fla. 32302. 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 or near the River Rouge, Michigan, on the one hand, and, on the other, points in Illinois, Indiana, Kentucky, Ohio, Pennsylvania, West Virginia and Wisconsin.

Note.—If a hearing is deemed necessary, applicant requests it be held at 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, by motor vehicle, transporting: Treated lumber mill products from Jefferson County, Arkansas to points in Minnesota, Iowa, Kansas, 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.

No. MC 114533 (Sub-No. 359), filed May 23, 1977. Applicant: BANKERS DISPATCH CORPORATION, 1106 West 35th St., Chicago, Illinois 60616. Applicant's Representative: Warren W. Wallin, 1106 West 35th St., Chicago, Illinois 60609. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Exposed and processed film and prints, complimentary replacement film and incidental dealer handling supplies (except motion picture film and materials and supplies used in storage of film, television motion pictures), between points in Salt Lake, Davis, and Weber Counties, Utah, on the one hand, and, on the other, points in Idaho, Colorado, Oregon and Washington.

Note.—Applicant holds contract carrier authority in No. MC 128616 and subs 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. 170), filed May 18, 1977. Applicant: SHAFFER TRUCKING, INC., P.O. Box 418, New Kingsport, 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 plants of Benefic Foods Co., located at or near Menomonee, Wisc., and Menomonee and Milwaukee, Wisconsin, and the storage facilities of Sanna Division, Beatrice Foods Co., located at or near Eau Claire and Wiconsin 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 Sanna 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 115182 (Sub-No. 367), filed May 26, 1977. Applicant: POOLE TRUCKING LINE, INC., Post Office Drawer 506, 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 points 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 South Dakota, 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 115182 (Sub-No. 368), filed May 23, 1977. Applicant: POOLE TRUCKING LINE, INC., Post Office Drawer 506, 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 Richey, 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.
No. MC 116648 (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 668, Cheyenne, Wyoming 82001. Authority sought to operate as a motor 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 80 (Interstate Highway 40), and (b) on and north of U.S. Highway 60 (Interstate Highway 20), and (c) north of U.S. Highway 75 (Interstate Highway 45), and (d) on and west of U.S. Highway 80 (Interstate Highway 45) and Texas which are (a) on and west of U.S. Highway 80 (Interstate Highway 40), and (b) on and north of U.S. Highway 60 (Interstate Highway 20), and (c) north 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 115826 (Sub-No. 266), filed May 31, 1977. Applicant: W. J. DIGBY, INC., P.O. Box 6508 Terminal Annex, Denver, Colorado 80217. Applicant's representative: Charles J. Kimball, 350 Capital Life Center, 1600 Sherman Street, Denver, Colorado 80202. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Meats, meat products, meat by-products and articles distributed by meat packfshouses (except hides and commodities in bulk), as defined in Section A and C of Appendix I to the report in Descriptions in Motor Carrier Certificates 61 M.C.C. 209 and 766. From the plant site and warehouse from Lee of 1953, Fred H. 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 116014 (Sub-No. 82), filed May 27, 1977. Applicant: STAFFORD TRUCKING, INC., 2155 Bldg., Indianapolis, Ind. 46204. 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 vehicle at the same time with the commodities described above, between points in Florida, Georgia, Kentucky Maryland, Missouri, North Carolina, New Jersey, Ohio, South Carolina, Tennessee, Virginia, and West Virginia. (2) Homogenized tobacco from Kentucky Tobacco and Peterboro, Virginia and Macon, Georgia. (3) From Hopewell, Virginia, to Louisville, Kentucky. (4) From Spotswood, New Jersey to Petersburg, Virginia and Macon, Georgia.

Note.—If a hearing is deemed necessary, applicant requests it be held with similar applications at either Raleigh, N.C., or Washington, D.C.

No. MC 116725 (Sub-No. 23), filed June 1, 1977. Applicant: INDIAN VALLEY ENTERPRISES, INC., 855 Maple Avenue, Harleysville, Pa., 19438. Applicant's representative: Edward J. F. Frazier, P.O. Box 626, 2207 Old Gettysburg Road, Camp Hill, Pa. 17011. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Foodstuffs, between the plaintiff's facilities or facilities of Keller Creamery Co. (a division of Beatrice Foods Co.) located at or near Somerset, 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.

No. MC 116849 (Sub-No. 4), filed June 1, 1977. Applicant: ISLAND TRANSPORTATION CORP., 209 Main Street, Westbury, N.Y. 11590. Applicant's representative: John W. Frame, P.O. Box 626, 2207 Old Gettysburg Road, Camp Hill, Pa. 17011. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Meats, meat products, meat by-products and articles distributed by meat packfshouses (except hides and commodities in bulk), as defined in Section A and C of Appendix I to the report in Descriptions in Motor Carrier Certificates 61 M.C.C. 209 and 766. From the plant site and warehouse from Lee of 1953, Fred H. 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.

No. MC 116922 (correction) (Sub-No. 99), filed May 5, 1977, published in the Federal Register of June 16, 1977, republished as correction in this issue of June 18, 1977. Applicant: LIQUID TRANSPORT CORP., 3901 Madison Avenue, Indianapolis, Ind. 46227. Applicant's representative: Robert W. Loser, 1008 Chamber of Commerce Building, Indianapolis, Ind. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Corn products and blends thereof, in bulk from the facilities of Island Foods, Inc. located at or near Indianapolis, Ind. to points in Illinois, Indiana, Kentucky, Michigan, Ohio, Pennsylvania, Tennessee, Wisconsin, and West Virginia, restricted against the transportation of traffic originating at the facilities of National Starch and Chemical Corporation, at Indianapolis, Indiana.

Note.—The purpose of this re-publication is to correct the territorial description in this proceeding. Applicant: LIQUID Trucking, Inc., who holds contract carrier authority under Docket No. MC-128161 (Sub-No. 1), therefor dual operations may be involved. Common control may also be involved. If a hearing is deemed necessary, applicant requests it be held in either Indianapolis, Ind. or Chicago, Ill.

No. MC 116819 (Sub-No. 219), filed June 1, 1977. Applicant: NATIONAL REFRIGERATED TRANSPORT INC., P.O. Box 51966, Dawson Station, Tulsa, Okl. 74151. Applicant's representative: Warren Taylor (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Picture frames, plastic products, and related advertising materials and supplies, from Worcester, Mass. to points in the United States (except Alaska, Connecticut, Hawaii, Maine, Massachusetts, New Jersey, New York, Rhode Island, and Vermont).

Note.—Common control may be involved.


Note.—Applicant states this application is filed solely to add this commodity to their
existing pertinent Certificate issued in MC-110819 (Sub-No. 25), if a hearing is deemed necessary, the applicant requests it be held at Chicago, Ill.

No. MC 119726 (Sub-No. 92), filed May 19, 1977. Applicant: N.A.B. TRUCKING CO., INC., 1644 W. Edgewood Avenue, Indianapolis, Ind. 46217. Applicant's representative: James L. Beatley, 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: (1) Books and paper products, (2) textile goods and parts, attachments, and accessories thereof, and (3) materials utilized in the manufacture and distribution thereof (except in bulk), from the plantsite of Oil-Dri Corp. of America, located at or near Ripley, Miss., and Ochlocknee, Ga., (1) from Ripley, Miss., to Hopkins, Minn., and (2) from Ochlocknee, Ga., to points in Florida, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Ohio, and Wisconsin.

Note.—If a hearing is deemed necessary, the applicant requests it be held at either Chicago, Ill., or Omaha, Neb.

No. MC 119888 (Sub-No. 113), filed May 20, 1977. Applicant: GREAT WESTERN TRUCKING CO., INC., P.O. Box 1384, Highway 103 East, Gulfport, Tex. 75901. Applicant's representative: Hugh T. Matthews, 2340 Pecos Street, Dallas, Texas 75201. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Hardware, conveyors and conveyer equipment, furniture, power equipment, and wheel goods and parts, attachments, and accessories thereof, and materials, equipment, and supplies, utilized in the manufacture and distribution thereof (except in bulk), between Indianola, Iowa, and Ochlocknee, Ga., (1) from Indianola, Iowa, to Kansas City and St. Louis, Mo., or Indianapolis, Ind., and (2) from Ochlocknee, Ga., to points in Florida, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Ohio, and Wisconsin.

Note.—If a hearing is deemed necessary, the applicant requests it be held at either Chicago, Ill., or Peoria, Ill.

No. MC 123407 (Sub-No. 381), filed May 31, 1977. Applicant: SAWYER TRANSPORT, INC., South Haven Square, U.S. Highway 6, Valparaiso, Ind. 46383. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Milk and milk products, and by-products, in bulk (except in bulk), from the plantsite and warehouse of Allied Chemical Corp., located at or near Durant, Iowa, to points in Arkansas, Illinois (except points in the St. Louis, Mo.-St. Louis, Ill., common carrier point), Kansas (except points in Kansas City, Mo.), Kentucky, Minnesota, Missouri, Nebraska, South Dakota, Tennessee, and Wisconsin.

Note.—If a hearing is deemed necessary, the applicant requests it to be held at Chicago, Ill., or Omaha, Neb.

No. MC 123948 (Sub-No. 358), filed May 23, 1977. Applicant: DIAMOND TRANSPORTATION SYSTEM, INC., 5021 21st Street, Racine, Wis. 53406. Applicant's representative: Paul C. Gartzke, 12 1st Ave., Dri Corp. of America, located at or near Durant, Iowa, to points in Florida, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Ohio, and Wisconsin.

Note.—If a hearing is deemed necessary, the applicant requests it to be held at Chicago, Ill., or Omaha, Neb.

No. MC 123819 (Sub-No. 43), filed May 25, 1977. Applicant: ACE FREIGHT LINE, INC., P.O. Box 16568, Memphis, Tenn. 38119. Applicant's representative: Bill R. Davis, Suite 101, Emerson Center, 2814 New Spring Rd., Atlanta, Ga. 30339. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Paper bags, (2) textile bags, when moving in mixed loads with paper bags, from Memphis, Tenn., to points in Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Missouri, Mississippi, Nebraska, New Mexico, New York, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, Texas, and Virginia; and (3) materials and supplies used in the manufacture, processing, and distribution of the commodities in (1) and (2) above, from points in Alabama, Arkansas, Florida, Georgia, Illinois, Louisiana, Mississippi, South Carolina, Texas, and Virginia to Memphis, Tenn.

Note.—If the hearing is deemed necessary, the applicant requests it be held at Memphis, Tenn.

No. MC 124306 (Sub-No. 29), filed May 27, 1977. Applicant: KENAN TRANS­ FORT CO., INC., P.O. Box 2729, Chapel Hill, N.C. 27514. Applicant's representative: Richard A. Gehley, 1000 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, and by-products, in bulk (except such commodities which are chemical), 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: WIKEL BULK TRANSPORT, INC., P.O. Box 2513, Dumas, Tex. 79327. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Milk and milk products, and by-products, in bulk (except in bulk), from points in Texas to South Dakota, Nebraska, Kansas, and Oklahoma.

Note.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Dallas, Tex.

No. MC 132407 (Sub-No. 382), filed June 1, 1977. Applicant: SAWYER TRANSPORT, INC., South Haven Square, U.S. Highway 6, Valparaiso, Ind. 46383. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Food and food covering, and products and supplies utilized in the manufacture, transportation, installation, maintenance, removal, and sale of the above commodities (except in bulk), from points in Texas to and through the United States, and in and east of North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, and Texas.

Note.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Dallas, Tex.

No. MC 121669 (Sub-No. 1), filed May 27, 1977. Applicant: MACFARLAND TRANSPORT, INC., Clay Street, Muscatine, Iowa 52761. Applicant's representative: William L. Fairbank, 1989 Financial Center, Des Moines, Iowa 50306. Authority sought 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 Durant, Iowa, to points in Arkansas, Illinois (except points in the St. Louis, Mo.-St. Louis, Ill., common carrier point), Kansas (except points in Kansas City, Mo.), Kentucky, Minnesota, Missouri, Nebraska, South Dakota, Tennessee, and Wisconsin.

Note.—If a hearing is deemed necessary, the applicant requests that it be held at Washington, D.C.
NOTICES

No. MC 124579 (Sub-No. 19), filed May 31, 1977. Applicant: WIKEL BULK EXPRESS, INC., Route 2, Huron, Ohio. Applicant's representative: James Duval, Post Office Box 797, West Carrollton, Ohio 45401. 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 Findlay, Ohio, and shipping facilities of Tyler Pipe Co., located at or near Tyler, Tex., to locations near Apex, N.C., to points in Virginia east of U.S. Highway 29 and north of U.S. Highway 60, and (2) from Norfolk, Va., to points in Virginia.

Note.—If a hearing is deemed necessary, applicant requests it be held at Washington, D.C.

No. MC 128802 (Sub-No. 4), filed May 31, 1977. Applicant: ARDEN E. OLSEN, Route No. 1, Kailspell, Mont. 59901. Applicant's representative: Joe Gerbase, 220 West Bridge Street, Dublin, Ohio 43017. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Beer and empty containers between Keiser, Mont., on the one hand, and, on the other, the various cities and points in Montana, Idaho, Washington, Oregon, and California, to points in Idaho, Montana, and Washington.

Note.—Common control may be involved. If a hearing is deemed necessary, applicant requests that it be held at Washington, D.C.

No. MC 128883 (Sub-No. 16), filed May 28, 1977. Applicant: ROBERT H. DITTRICH, doing business as Bob Dittrich Trucking, 1000 North Front Street, New Ulm, Minn. 56073. Applicant's representative: James W. Hightower, 136 Prairie, Texas 75050. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Liquid fertilizer, beer, and empty containers between New Ulm, Minn., to points in Iowa, South Dakota, North Dakota, and Wisconsin.

Note.—If a hearing is deemed necessary, applicant requests it be held at either Minneapolis or Mankato, Minn.

No. MC 128635 (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, 136 Prairie, Texas 75050. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Tractors (except truck tractors); and attachments, parts and accessories for tractors. Authority sought to operate in the same equipment with tractors, from the rail rams located at or near Huntington, Tex., to points in Louisiana and points in Wilkinson, Amite, and Pike Counties, Miss.; and (2) from the rail rams located at or near Houston, Tex., to points that are part of Texas located in and south of Interstate Highway 61 and on and south of Interstate Highway 68, restricted to traffic having a prior movement by rail.

Note.—If a hearing is deemed necessary, applicant requests it be held at Dallas, Texas.

No. MC 133095 (Sub 161), filed May 26, 1977. Applicant: TEXAS-CONTINENTAL LONG DISTANCE CO., P.O. Box 434, Dallas, Texas 75201. Applicant's representative: Hugh T. Matthews, 2340 Fifth Street, Dallas, Texas 75201. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Refrigerated intercommunication systems, refrigerators.
frosting boxes, imitation fireplaces and logs, heaters, range hoods, lighting fixtures, exhaust systems, and splash plates and parts, attachments and accessories thereof and materials, equipment and articles used in the manufacture and distribution thereof (except commodities in bulk), between Cleburne, Illinois and West, Tex., on the one hand, and, on the other, points in the United States (except Alaska and Hawaii).

Note.—Applicant holds motor contract carrier authority in No. MC 136032, and, subsection thereunder, therefore dual operations may be involved. If a hearing is deemed necessary, applicant requests it be held at Dallas, Tex.

No. MC 133590 (Sub-No. 10), filed May 23, 1977. Applicant: WESTERN CARRIERS, INC., 268 Franklin Street, Worcester, Massachusetts 01604. Applicant's representative: David D. Marr, 130 State Street, Suite 200, Springfield, Massachusetts 01103. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: (1) Foodstuffs (except commodities in bulk) from the facilities of John Morrell & Company located at or near McAllen, Tex., or Chicago, 111., or consolidation warehouses for the commodities as are dealt in by wholesale, retail and chain grocery and food business dealers; (2) equipment, materials, and supplies (except in bulk) used in the manufacture of truck and trailer suspension systems and parts, and 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 Hartford, Conn., Boston, Mass., or Washington, D.C.

No. MC 133589 (Sub-No. 131), filed May 23, 1977. Applicant: OVERLAND EXPRESS, INC., 719 First St., S.W., New Brighton, Minnesota 55112. Applicant's representative: David L. Knox, 600 Hubbell Building, Des Moines, Iowa 50309. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Foodstuffs (except commodities in bulk) from the facilities of John Morrell & Company located at or near McAllen, Tex., or Chicago, 111., or consolidation warehouses for the commodities as is dealt in by wholesale, retail and chain grocery and food business dealers; (2) equipment, materials, and supplies (except in bulk) used in the manufacture of truck and trailer suspension systems and parts, and 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).

No. MC 134286 (Sub-No. 26), filed May 31, 1977. Applicant: FININI EXPRESS, INC., P.O. Box 1564, Sioux City, Iowa 51102. Applicant's representative: Charles J. Kimball, 350 Capitol Life 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); (8) exempt commodities when moving with regulated commodities, (A) from Denver, Colo., to points in the United States in and west of Minnesota, Iowa, Missouri, Arkansas and Louisiana; (B) to Denver, Colo., from New Orleans, La., in 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 Denver, Colo. Common control may be involved.

No. MC 134755 (Sub-No. 106), 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 suspension systems and parts, and 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.—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 136005 (Sub-No. 3), filed May 18, 1977. Applicant: JACK D WHATELEY AND ROBERT T. CALHOUN, d/b/a MAGIC VALLEY REFRIGERATED EXPRESS, 1400 Whitewing, P.O. Box 2191, McAllen, Tex. 78501. Applicant's representative: Charles M. Williams, 350 Capitol Life Center, 1600 Sherman Street, Denver, Colo. 80203. Authority sought to operate as a common carrier by motor vehicle, over irregular routes, transporting: (1) Citrus fruits (except commodities in bulk), 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 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 citrus juice, from the facilities of Texas Citrus Exchange located at Harlingen, Tex., and from the storage facilities of Texas Citrus Exchange at Brownsville, and McAllen, Tex., to points in Oklahoma, Arkansas, 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, with Radio Shack, Division of Tandy Corpora­tion.

NOTE.—If a hearing is deemed necessary, applicant requests that it be held at Columbus, Ohio.

No. MC 136904 (Sub-No. 20), filed May 31, 1977. Applicant: WORSTER-MICH­IGAN, INC., R.D. No. 1, Gay Road, North East, Pennsylvania 16428. Applicant's representative: Joseph P. MacKrell, 29 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 Washington, D.C. Common control may be involved.

No. MC 136905 (Sub-No. 8), filed May 31, 1977. Applicant: PAPER TRA­NSPORT, Inc., P.O. Box 86, Stephens City, Va. 22655. Applicant's representative: Charles E. Cresger, 1339 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 New York, New Hampshire, Vermont, Massachusetts, Connect­icut, Rhode Island, Pennsylvania and New Jersey.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Washington, D.C.

No. MC 136906 (Sub-No. 1), filed May 17, 1977. Applicant: LEE P. WEGNER, Sr., d.b.a. WEGNER TRUCKING COM­PANY, W390 S629 Holiday Road Wau­kesha, Wis. 53186. Applicant's representative David V. Purcell, 111 East Wis­consin Avenue, Milwaukee, Wis. 53202. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Materials, equipment, and supplies (except com­modities in bulk), used in the manufac­turing, production, and distribution of refrigerated display coolers and freezers and refrigerated, sectional, walk-in cool­ing and freezing rooms, knocked down, from points in Indiana, Kansas, and Missouri, to Genesee, Wisc., under a con­tinuing contract or contracts with Zero Zone Refrigeration Manufacturing Company, Inc., located at Genesee, Wisc.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at St. Mary's, or Madison, Wis.

No. MC 136514 (Sub-No. 10), filed May 23, 1977. Applicant: ARCTICARE TRANSPORT, INC., P.O. Box 356, 47 East St., Rockville, Conn. 06066. Applicant's representative: Edward G. Villalon, 1331 Pennsylvania Building, Pennsylvania Avenue and 15th St. NW., Washington, D.C. 20004. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting Food­stuffs in vehicles equipped with mechanical refrigeration, from Baltimore, Md., and points in its Commercial Zone to points in New York, Maine, New Hamp­shire, Vermont, Massachusetts, Connect­icut, Rhode Island, Pennsylvania and New Jersey.

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at Washington, D.C.

No. MC 136534 (Sub-No. 2), filed June 1, 1977. Applicant: BAKER TRUCK SERVICE, INC., P.O. Box 535, Lew­iston, Idaho 83501. Applicant's representative: William L. Fairbank, 1339 Pennsylvania Avenue, Post Office Box 1417, Hagerstown, Md. 21740. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Meat, meat products, and meat by-products, and articles distributed by meat pack­inghouses, as described in Sections A and C of Appendix I to the report in Descrip­tions in Motor Carrier Certificates, 61 M.C.C. 209 and 766 (except commodities in bulk), from Marshalltown, Iowa, to points in Illinois, Indiana, and Wiscon­sin, restricted to traffic originating at the named origin and destined to the named destination states.

NOTE.—If a hearing is deemed necessary, applicant requests that it be held at Chicago, Ill.

No. MC 136966 (Sub-No. 1), filed May 20, 1977. Applicant: BAKER TRUCK SERVICE, INC., P.O. Box 535, Lew­iston, Idaho 83501. Applicant's representative: George R. LaBissoniere, 1100 North Capitol Street, Washington, D.C. 20006. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Particles, from the plantsite of Boise-Cascade located at Missoula, Mont., to Redwood, Ore., on the one hand, and, on the other, Tacoma, Wash.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Spokane, Wash.


NOTE.—If a hearing is deemed necessary, the applicant requests it be held at St. Paul, Minnesota.

No. MC 136585 (Sub-No. 49), filed May 31, 1977. Applicant: ABT PAPE TRANS­FER, INC., 100 East 12th Street, Du­buque, Iowa 52001. Applicant's representative: William L. Fairbank, 1339 Pennsylvania 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, Missouri, Wisconsin, and Wisconsin, restricted to traffic originating at the named origin and destined to the named destination states.

NOTE.—If a hearing is deemed necessary, applicant requests that it be held at St. Paul, Minnesota.

No. MC 136586 (Sub-No. 9), filed May 29, 1977. Applicant: ENDICOTT TRUCKING CO., A Corporation, P.O. Box 705, Columbus, Ohio 43216. Applicant's representative, Richard G. McComb, 220 West Bridge Street, P.O. Box 97, Dublin, Ohio 43017. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transport­ing: Such commodities as are dealt in by common carriers, transportation time in bulk, from Plymouth Meeting, Pa., to points in North Carolina and South Carolina.

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicants requests it be held at Philadelphia, Pa.

No. MC 136587 (Sub-No. 9), filed May 23, 1977. Applicant: REBER CORPORA­TION, 2216 Old Arch Road, Norristown, Pa. 19401. Applicant's representative: Roland Morris, 1650 Land Title Bldg., 100 S. Broad St., Philadelphia, Pa. 19110. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Foodstuffs, from points in Indiana, Kansas, 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.
by motor vehicle, over irregular routes, transporting: (1) Cigars from Dothan and Selma, Ala, to points in Delaware, Illinois, Indiana, Iowa, Kansas, Michigan, Missouri, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Virginia, and the District of Columbia; and (2) packaging material and tobacco blends and agricultural commodities, the transportation of which is otherwise exempt from economic regulation pursuant to section 203(b) (6) of the Interstate Commerce Act in mixed loads with packaging materials and tobacco blends and agricultural commodities, the transportation of which is otherwise exempt from economic regulation pursuant to section 203(b) (6) of the Interstate Commerce Act in mixed loads with packaging materials and tobacco blends and agricultural commodities, the transportation of which is otherwise exempt from economic regulation.

Note.—If a hearing is deemed necessary, applicant requests it be held at Columbus, Ohio.

No. MC 141177 (Sub-No. 4), filed May 26, 1977. Applicant: RICK'S DELIVERY SERVICE, INC., 6 West Alexandria Avenue, Staunton, Va. Applicant's representative: Patrick McElligot, 700 World Center Building, 916 16th St., NW., Washington, D.C. 20006. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Drugs, and related supplies and accessories, between the Baltimore-Washington International Airport located at or near Baltimore, Md., on the one hand, and, on the other, points in Maryland, Virginia, and the District of Columbia. Restricted against the transportation of shipments having an immediately prior or subsequent movement by air.

Note.—If a hearing is deemed necessary, the applicant requests that it be held in Washington, D.C. or Baltimore, Md.

No. MC 141410 (Sub-No. 41), filed May 31, 1977. Applicant: BLACK ANGUS, INC., P.O. Box 8789, Jackson, Miss. 32332. Applicant's representative: Morton E. Kiel, Suite 6193, 5 World Trade Center, New York, N.Y. 10048. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Agricultural insecticides or fungicides, organic phosphate compound mixtures, and weed killing compounds (except in bulk in tank vehicles) between Leland, Miss. and McIntosh, Ala., on the one hand, and, on the other, points in the United States (except Hawaii and Alaska), under contract with Olin Corporation located at Little Rock, Ark.

Note.—If a hearing is deemed necessary, applicant requests it be held at Little Rock, Ark.

No. MC 141618 (Sub-No. 3), filed May 23, 1977. Applicant: DAVID C. BURNS TRUCKING, 1146 East Main St., Casa Grande, Ariz. 85222. Applicant’s representative: Donald E. Ferns, Suite 320, 4040 East McDowell Road, Phoenix, Arizona 85060. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Glass or ceramic bottles, from the plant sites and facilities of Columbus Insulation Company, Inc. at Glendale and Tolleson, Arizona to points in that part of California, in and south of the counties of San Francisco, Contra Costa, San Joaquin, Tulalums and Mono, under a continuing contract, or contracts, with Cellier Insulation Company.

Note.—If a hearing is deemed necessary, the applicant requests it be held at Phoenix, Ariz.

No. MC 142343 (correction), (Sub-No. 1), filed April 25, 1977, published in the Federal Register Issue of May 19, 1977, republished as corrected this issue. Applicant: JOSEPH MACRI doing business as J & M TRUCKING, 8237 West Mexico, Lakewood, Colorado 80226. Applicant's representative: John T. Wirth, 2310 Colorado State Bank Building, 1600 Broadway, Denver, Colo. 80202. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Offal in bulk; and dead animals, hides, fats, bones, grease, and prepared blood. From points in Arizona, Colorado, Idaho, Kansas, Nebraska, New Mexico, Oklahoma, South Dakota, Texas, Utah and Wyoming, to Denver, Colo. Restricted to traffic originating at or destined to the facilities utilized by Denver Recycling Co., and under a continuing contract or contracts with Denver Recycling Co.

Note.—The purpose of this republication is to correct the commodity description in this proceeding. If a hearing is deemed necessary, the applicant requests that it be held at Denver, Colo.

No. MC 142476 (Sub-No. 1), filed May 26, 1977. Applicant: INDUSTRIES, INC., NATIONAL COURIER & EXPEDITING SERVICE, 282 South Potomac Street, Hagerstown, Md. 21740. Applicant's representative: Edward N. Butten, 1206 Pennsylvania Avenue, Post Office Box 1417, Hagerstown, Md. 21740. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: General commodities (except classes A and B explosives, commodities in bulk and commodities requiring special equipment), between Hagerstown, Md., on the one hand, and, on the other, points in New York, New Jersey, Pennsylvania, Virginia, Ohio, Maryland, West Virginia, and the District of Columbia, restricted against the transportation of shipments having an immediately prior or subsequent movement by air.

Note.—If a hearing is deemed necessary, the applicant requests that it be held at either Hagerstown, Md. or the District of Columbia.

No. MC 142811 (Sub-No. 1), filed May 23, 1977. Applicant: S. R. I. EXPRESS, INC., P.O. Drawer L, Petal, Miss. 39465. Applicant's representative: R. W. Schumaker, 1545 Wilshire Boulevard, Los Angeles, California 90017. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting restaurant supplies, foodstuffs and accessories, between the warehouse facilities of Sambo's Restaurants, Inc. in Florence, Kentucky, under a continuing contract, or contracts, with Sambo's Restaurants, Inc.
operate as a common carrier by motor vehicle, over irregular routes and in bulk, in dumps, from the plantsite and storage facilities of Carpenter Sales, Inc., located at Lakewood, N.J.

Note.—If a hearing is deemed necessary, the applicant requests it be held at Lakewood, N.J.

No. MC 134094 (Sub-No. 2), filed May 27, 1977. Applicant: GERALD E. CARPENTER, Rural Route No. 2, Box 241, Maxwell, Iowa 50616. Applicant's representative: Thomas E. Leathy, Jr., 1920 Financial Center, Des Moines, Iowa 50309. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Liquid soil conditioners and liquid fertilizers in bulk, from the plantsite and storage facilities of Carpenter Sales, Inc., located at Bon Durant, Iowa, to points in Alabama, Arkansas, California, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, and Wisconsin, under a continuing contract or contracts with Carpenter Sales, Inc.

Note.—If a hearing is deemed necessary, the applicant requests it be held at Bon Durant, Iowa.

No. MC 142857 (Sub-No. 2), filed May 31, 1977. Applicant: MCC TRANSPORTATION COMPANY, INC., 1311 West Seventh Street, Little Rock, Arkansas 72201. Applicant's representative: Eugene T. Lüpfer, Suite 1000, 1600 L Street NW., Washington, D.C. 20036. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Unfrozen bakery products, and equipment, materials and supplies used in the manufacture or distribution of unfrozen bakery products, from the plantsite of Meyer's Bakeries, Inc., at or near Orlando, Fla., on the one hand, and, on the other hand, points in Alabama, Arkansas, California, Florida, Georgia, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, and Wisconsin, under a continuing contract or contracts with Carpenter Sales, Inc.

No. MC 143068 (Sub-No. 1), filed May 26, 1977. Applicant: ROBERT TARBOX, d.b.a. TARBOX TRUCKING, Johnson Heights, Pa. 16912. Applicant's representative: S. Berne Smith, 180 Pine Street, P.O. Box 1148, Harrisburg, Pa. 17108. Authority is sought to operate as a common carrier, by motor vehicle over irregular routes, transporting: Aged and dried ingredients, from New York, N.Y., to plants in Delaware, Maryland, New Jersey, New York, and Pennsylvania.

Note.—If a hearing is deemed necessary, the applicant requests it be held at either Little Rock, Ark., or Washington, D.C.

Notices

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

Published by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408

July 8, 1977

NOTICES

35261

May 27, 1977. Applicant: GERALD E. CARPENTER, Rural Route No. 2, Box 241, Maxwell, Iowa 50616. Applicant's representative: Thomas E. Leathy, Jr., 1920 Financial Center, Des Moines, Iowa 50309. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Liquid soil conditioners and liquid fertilizers in bulk, from the plantsite and storage facilities of Carpenter Sales, Inc., located at Bon Durant, Iowa, to points in Alabama, Arkansas, California, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, and Wisconsin, under a continuing contract or contracts with Carpenter Sales, Inc.

Note.—If a hearing is deemed necessary, the applicant requests it be held at either Little Rock, Ark., or Washington, D.C.

No. MC 142971 (Sub-No. 1), filed May 26, 1977. Applicant: F & W TRANSPORT CO., INC., 37 River Road, Camden, N.J. 08105. Applicant's representative: Robert D. Popper, 166 Woodbridge Avenue, Highland Park, N.J. 08904. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting Wooden and Plastic Containers, and materials and supplies used in the manufacturing, sale, and distribution of Wooden and Plastic Containers, from the plantsite and storage facilities of Carpenter Sales, Inc., located at Little Rock, Ark.

Note.—If a hearing is deemed necessary, the applicant requests it be held at either Little Rock, Ark., or Washington, D.C.

No. MC 143105 (Sub-No. 1), filed May 27, 1977. Applicant: CHEROKEE LINES, INC., P.O. Box 152, Cushing, Okla. 74023. Applicant's representative: Donald S. Stern, Suite 530 Univar Building, 7100 West Center Road, Omaha, Nebr. 68106. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Cured, preserved meats, in packages, from the plantsite and storage facilities of Land O'Frost, Inc., located at Searcy, Ark., to points in California, Oregon, Washington, Idaho, Montana, Wyoming, Arizona, and Nevada, under a continuing contract or contracts with Land O'Frost, Inc.

Note.—If a hearing is deemed necessary, the applicant requests it be held at Chicago, Ill.

No. MC 143183 (Sub-No. 2), filed May 26, 1977. Applicant: L. M. ROACH, d.b.a. DEL TRUCKING COMPANY, Post Office Box 1741, Wilmington, N.C. 28401. Applicant's representative: Ralph T. McDonald, Post Office Box 2246, Raleigh, N.C. 27602. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting dry fertilizer and fertilizer materials, in bulk, in dump vehicles: from points in New Hanover, Columbus, and Brunswick counties, N.C., to points in South Carolina.

Note.—If a hearing is deemed necessary, the applicant requests it be held at Wilmington, N.C.

No. MC 143222 (Sub-No. 2), filed May 27, 1977. Applicant: W. S. McFADDEN, d.b.a. SHIFLET TRUCKING, INC., P.O. Box 1741, Wilmington, N.C. 28401. Applicant's representative: Fritz R. Kahn, 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 and liquors, in containers, from ports in the New York City Commercial Zone, 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 (2) wines 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., with unlimited intermediate stop-offs, under a continuing contract or contracts with Banfi Products, Inc., located at Farmingdale, N.Y.

Note.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at either Farmingdale, N.Y., (2) wines and liquors in vehicles equipped with mechanical refrigeration, from 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 (2) wines 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., with unlimited intermediate stop-offs, under a continuing contract or contracts with Banfi Products, Corp., located at Farmingdale, N.Y.

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 626, 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) advertising matter, premiums, catalogs, sales brochures, printed matter, and materials and supplies used in the manufacture and distribution of the above-named commodities; in bulk, in dump vehicles: from the facilities of Jewelcor, Inc. and Suburban Publishers, a subsidiary of Jewelcor, Inc., at or near Exeter, Pa.

Note.—Applicant has contract carrier authority pending in No. MC 140777; therefore, dual operations may be involved. If a hearing is deemed necessary, applicant requests it be held at Harrisburg, Pa.

No. MC 143242 (Sub-No. 1), filed May 10, 1977. Applicant: MART LINES, INC., 311 17th Street, Jersey City, N.J. 07306. Applicant's representative: John P. Tynan, P.O. Box 1469, 167 Fairfield Road, Fairfield, N.J. 07006. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Such Commodities as is dealt in by retail department stores, (1) between the Distribution Center of Mammoth Mart at Somerville, Mass. and New York, N.Y. and its Commercial Zone and Jersey City, N.J.; (2) between the Distribution Center of Mammoth Mart, Somerville, Mass. and stores of Mam-
NOTICES

No. MC 143316 (Sub-No. 4), filed May 25, 1977. Applicant: SUMNER STROYMAN and RENEE RICHMOND, a partnership, doing business as COMFORT TRANSPORTATION CO., 30 Howard Street, Somerville, Mass. 02144. Applicant's representative: Henry U. Snavely, 410 Pine Street, Vienna, Va. 22180. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: (1) bedding, mattresses, and (2) commodities used in the manufacture and distribution of the commodities in (1) above (except in bulk), between the facilities of Comfort Pillow & Feather Co., located in Middlesex County, Mass., on the one hand, and, on the other, points in the United States (except Alaska and Hawaii), under a continuing contract with Comfort Pillow & Feather Co., located at Somerville, Mass.

Note.—If a hearing is deemed necessary, applicant requests that it be held at Boston, Mass.

No. MC 143331 (Sub-No. ...), filed June 2, 1977. Applicant: FREIGHT TRAIN TRUCKING, INC., 4906 E. Compton Blvd., P.O. Box 817, Paramount, Calif. 90723. Applicant's representative: William J. Molheim 15942 Whittier Blvd., Suite 186, P.O. Box 1756, Whittier, Calif. 90609. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Plastic bottle or can carriers, from Fullerton, Calif., to Casa Grande, Phoenix and Tucson, Ariz., and Portales, N.M., under a continuing contract, or contracts, with Hi-Cone Division, Illinois Tool Works, Inc., located at Fullerton, Calif.

Note.—If a hearing is deemed necessary, applicant requests that it be held at Los Angeles, Calif.

No. MC 143338, filed May 17, 1977. Applicant: MAURICE GUILLÈMETTE, INC., St. Gregoire, Nicolet County, Quebec, Canada. Applicant's representative: Robert D. Schuler, 100 West Long Lake Road, Suite 102, Bloomfield Hills, Mich. 48013. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: (1) Dog or cat food, in cans or packages, from ports of entry on the International Boundary line between the United States and Canada located on the St. Clair River, restricted in (1) and (2) above to shipments originating at or destined to points in Michigan, to ports of entry on the International Boundary line between the United States and Canada located on the St. Clair River, restricted in (1) and (2) above to shipments originating at or destined to points in Quebec, Canada, under a continuing contract, or contracts, with Jean Demeure, Inc. of Gentilly, Quebec, Canada.

Note.—If a hearing is deemed necessary, the applicant requests it be held at Washington, D.C.

No. MC 14940 (Sub-No. 43), filed May 13, 1977. Applicant: TRAILWAYS OF NEW ENGLAND, INC., 1200 Eye Street, North West, Washington, D.C. 20005. Applicant's representative: D. Paul Stafford, 1500 Jackson Street, Suite 429, Dallas, Texas 75201. Authority sought to operate as a common carrier, by motor vehicle, over regular route, transporting: Passengers and their baggage in the vehicle with passengers, in special operations, beginning and ending: (1) in Alameda County on, north and east of points within 3 miles of said highways: in Contra Costa County and those points on Interstate Highway 80 between the Verrazano Narrows Bridge and the Alameda-San Joaquin County Boundary Line and junction with Interstate Highway 95, thence over Interstate Highway 95, to junction Interstate Highway 278, thence over Interstate Highway 78 toward Wallingford, Conn., and return over the same route, serving: Those points within the boundaries of the District of Columbia, and the District of Columbia, and return. If a hearing is deemed necessary, applicant requests it be held at New York, New York.

No. MC 47786 (Sub-No. 8), filed April 27, 1977. Applicant: ROBSSMEYER & WEBER, INC., doing business as RARITAN VALLEY BUS SERVICE, P.O. Box 312, Metuchen, New Jersey 08840. Applicant's representative: Robert E. Stein, 8 West 49th Street, New York, New York 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, in special operations, beginning and ending at points in Lebanon, New Jersey, and return, in charter operations.

No. MC 61016 (Sub-No. 46), filed May 23, 1977. Applicant: PETER PAN BUS LINES, INC., 6101 East 11th Street, Springfield, Mass. 01103. Applicant's representative: Frank Daniels, 15 Court Sq., Boston, Mass. 02108. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Passengers and their baggage in the vehicle with passengers, in special operations, beginning and ending at points in Hampden, Hampshire and Berkshire Counties, Mass., and extending to Atlantic City, N.J.

Note.—If a hearing is deemed necessary, applicant requests it be held at Springfield, Mass.

No. MC 99581 (Sub-No. 4), Correction, filed May 5, 1977, published in the Federal Register issue of June 16, 1977 republished as corrected this issue. Applicant: R. K. WEBER, INC., doing business as VACA VALLEY BUS LINES, 321 State St., Fairfield, Calif. 94533. Applicant's representative: Daniel W. Baker, 100 Pine St., San Francisco, Calif. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Passengers and baggage of passengers in the 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 those points on the following highways, including all points within 3 miles of said highways: Interstate Highway 680 between the Alameda-Contra Costa County Boundary Line and the Verrazano Narrows Bridge; State Highway 84, between junctions with Interstate Highway 680 and junction with Tesla Road, Tesla Road, between junction with State Highway 84 and the Alameda-Contra Costa 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

Harris (same address as applicant). Authorize amendment to territorial description in this proceeding. If a hearing is deemed necessary, applicant requests it be held at San Francisco, Calif.

Applicant: CALIFORNIA AMMONIA TRANSPORT, INC., 4980 Aloma Ave., No. Hampton, N.H. 03862. Applicant's representative: Thaddeus T. O'Sullivan, P.O. Box 2184, Mont. or Fargo, N.Dak.

Amendment to territorial description in the transportation of liquefied petroleum gas in tank trucks, over irregular routes, in the transportation of passengers and baggage in the same vehicle with passengers, in round trip charter operations, beginning and ending at points on and east of Route 128 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.

Hearing is deemed necessary. Applicant requests it be held at either Portsmouth, N.H., Exeter, N.H., or Concord, N.H.

Applicant: CONCORD COACH LINES LTD., 4706 50th St., Lloydminster, Sask.

Applicant's representative: Ronald Carlyle Harris (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 round trip charter operations, beginning and ending at points on and east of Route 128 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.

Hearing is deemed necessary. Applicant requests it be held at either Portsmouth, N.H., Exeter, N.H., or Concord, N.H.

FINANCE APPLICATIONS

NOTICE

The following applications seek approval to consolidate, purchase, merge, lease operating rights, and properties, or acquire control through ownership of stock, or rail carriers or motor carriers pursuant to Sections 51(3) and 510(a)(5) of the Interstate Commerce Act.

An original and two copies of protests against the granting of the requested authority must be filed with the Commission within 30 days after the date of this Federal Register notice. Such protests shall comply with Special Rules 240(c) or 240(d) of the Commission's General Rules of Practice (49 CFR 1100.240) and include a concise statement of protestant's interest in the proceeding. A copy of the protest shall be served currently upon applicant's representative, or applicant, if no representative is named.

NO. MC-F-132218. Authority sought for purchase of 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., 227 Circuit Street, West Hanover, PA 02339, and for acquisition by E. Virginia Beckstrom, RD No. 1, Ashville, NY 14710, W. M. Beckstrom, Sundell, Knowlton Avenue, Pittsburgh, PA., and control of such rights through purchase. Applicant's attorney: Frederick T. O'Sullivan, P.O. Box 2184, Peabody, MA 01960. Operating rights sought to be purchased: Household goods as defined by the Department of Transportation, 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 99, then over U.S. Highway 99 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.

Liquefied petroleum gas in minimum quantity of 2,000 gallons, in tank trucks, from points in Hobbs, New Mexico and points in New Mexico and Texas within 25 miles thereof, to points in Arizona with no transportation for compensation except as otherwise authorized; Liquefied petroleum gases, in bulk, in tank trucks, in minimum quantities of 2,500 gallons to points in Los Angeles, Orange, Ventura, San Bernardino, Kern, Kings, Tulare, and Fresno Counties, Calif., to points in Arizona, with no transportation for compensation on return except as otherwise authorized. Natural and casinghead gasoline and liquified petroleum gases, in bulk, in tank vehicles from Farmington, New Mexico, and points in New Mexico within 60 miles of Farmington to points in California and vice versa. No transportation for compensation except as otherwise authorized. The Certificate of Public Convenience and Necessity was served May 24, 1977 in No. MC 152515.

NOTICES

INC.—Purchase (portion)—Ally Transporation Company, published in the May 26, 1977 issue of the Federal Register, pages 27104 and 27105. Previous notice included a portion of the operating authority to be transferred which is Liquefied petroleum gas in tank trucks, over irregular routes from Kingsman, Arizona, to Flagstaff, Arizona, serving all intermediate points and off-route points within ten miles of the specified highway, restricted to delivery only; From King- man over U.S. Highway 66 to Flagstaff, and return over the same route; From Wickenburg, Arizona, to Flagstaff, Arizona, serving all intermediate points and off-route points within ten miles of the specified highways restricted to delivery only; From Wickenburg over U.S. High- way 99 to Prescott, Arizona and thence over Alternate U.S. Highway 89 to Flag- staff, and return over the same route, with no transportation for compensation except as otherwise authorized; Liquefied petroleum gases, in minimum quantities of 2,500 gallons, in tank trucks, in minimum quantities of 2,500 gallons to points in Los Angeles, Orange, Ventura, San Bernardino, Kern, Kings, Tulare, and Fresno Counties, Calif., to points in Arizona, with no transportation for compensation on return except as otherwise authorized. Natural and casinghead gasoline and liquified petroleum gases, in bulk, in tank vehicles from Farmington, New Mexico, and points in New Mexico within 60 miles of Farmington to points in California and vice versa. No transportation for compensation except as otherwise authorized. The Certificate of Public Convenience and Necessity was served May 24, 1977 in No. MC 152515.

NO. MC-F-132218. Authority sought for purchase of 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., 227 Circuit Street, West Hanover, PA 02339, and for acquisition by E. Virginia Beckstrom, RD No. 1, Ashville, NY 14710, W. M. Beckstrom, Sundell, Knowlton Avenue, Pittsburgh, PA., and control of such rights through purchase. Applicant's attorney: Frederick T. O'Sullivan, P.O. Box 2184, Peabody, MA 01960. Operating rights sought to be purchased: Household goods as defined by the Department of Transportation, 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 99, then over U.S. Highway 99 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.
NOTICES

Allegany, Broom, Cattaraugus, Chautauqua, Erie, Genesee, Chemung, Livingston, Niagara, Orleans, Steuben, Tioga, and Wyoming Counties, N.Y., with no transportation for compensation on return as otherwise authorized. Vendee is authorized to operate as a common carrier over irregular routes, from Red Lion and Stewartstown, Pa., to points in Pennsylvania, West Virginia, and Ohio; and for acquisition by Vernon O. Fritz, Clara M., 56222, of control of such rights through the purchase. Applicant's attorneys: Samuel Rubenstein, 301 North Madison Street, Silver Spring, Md. 20910.

No. MC-F—13247. Authority sought for purchase by FRITZ TRUCKING, INC., East Highway 7, Clara City, MN., 56222, of the operating rights of Krouch Truck Lines, Inc., 517 Tenth Street SW., P.O. Box 603, Watertown, SD., 57201, and for acquisition by GATEWAY TRANSPORTATION CO., Inc., 455 Park Plaza Drive, La Crosse, WI. 54601, of a portion of the operating rights of Warners Motor Express, Inc., West Country Club Road, Red Lion, PA., 17356, and for acquisition by estate of W. Leo Murphy, Sr., Indianapolis, IN, 46204, and Anthony M. Russell, both of 9A Commercial Avenue, Carlstadt, NJ. 07072, of control of such rights through the purchase. Applicant's attorneys: James J. Buechert, 345 South Main Street, Sturgis, SD. 57785, and A. Jaskiewicz, 1730 M Street, N.W., Washington, D.C. 20036, of control of such rights through the purchase.

No. MC—F—13250. Authority sought for purchase by AERO MAYFLOWER PA., to points in Connecticut, New Jersey, New York, Ohio, Box 107B, Indianapolis, IN., 46206, of a portion of the operating rights of Warners Motor Express, Inc., West Country Club Road, Red Lion, PA., 17356, and for acquisition by Joseph F. Russell, jr., 300 South Ocean Blvd., Palm Beach, FL., John A. Murphy, 300 North Ocean Blvd., Palm Beach, FL., 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, 100 North avenue, Orlando, Fl., 32812, of control of such rights through the purchase. Applicant's attorneys: Leonard A. Jaskiewicz, 1730 M Street, N.W., Washington, D.C. 20036, of control of such rights through the purchase. Applicant's attorneys: Maxwell A. Howell, 1511 K Street NW., Washington, D.C. 20005, and F. Holmes Satterfield, Jr., 1730 M Street, N.W., Washington, D.C. 20036, 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 exception as a common carrier over irregular routes between Sewell, N.J., and points in Gloucester and Camden Counties, Pa., on the one hand, and, Philadelphia, PA. Vendee is authorized to operate as a common carrier in Alabama, Arkansas, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Kansas, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Virginia, West Virginia, and Wisconsin. Application has not been filed for temporary authority under section 310(a).

South Carolina, Georgia, and Florida, from points in York County, Pa., to points in Maryland, to points in Delaware, North Carolina. South Carolina, Georgia, and Florida, from points in North Carolina, to points in South Carolina, Georgia, and Florida, and the District of Columbia; from points in North Carolina, South Carolina, Georgia, and Florida, and the District of Columbia; from points in Maryland, to points in South Carolina, Georgia, and Florida, and the District of Columbia; from points in South Carolina, Georgia, and Florida, and the District of Columbia; from points in Maryland, to points in Delaware, North Carolina, South Carolina, Georgia, and Florida, and the District of Columbia; from points in South Carolina, Georgia, and Florida, and the District of Columbia; from points in Maryland, to points in Delaware, North Carolina. Application has not been filed for temporary authority under section 310(a).

No. MC-F—13254. Authority sought for purchase by UNION CARTAGE COMPANY, 6A Southwest Cutoff, Worcester, MA 01604. Application for Elimination of Route of Oneida Motor Freight, Inc., Commercial Avenue, Carlstadt, NJ 07072, and for acquisition by Joseph F. Russell, jr., and Anthony M. Russell, both of 6A Southwest Cutoff, Worcester, MA 01604, of control of such rights through the purchase. Applicant's attorneys: Leonard A. Jaskiewicz, 1730 M Street, N.W., Washington, D.C. 20036, of control of such rights through the purchase. General commodities, with exception as a common carrier over regular routes between Albany, N.Y., and Buffalo, N.Y., and the District of Columbia. Rejected shipments of new furniture, uncrated, from points in Pennsylvania, to points in Maryland, to points in Ohio, and for acquisition by Joseph F. Russell, jr., of Washington, D.C. Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Maryland, Wisconsin, Michigan, and to points in Illinois, Indiana, Ohio, and West Virginia, points in Virginia (except those within 15 miles of Washington, D.C.); and from Dallastown, Pa., to points in Washington, Pa., and the District of Columbia; from Philadelphia, Pa., on the one hand, and, on the other, points in New Jersey, Delaware, and Maryland. New furniture, between points in Philadelphia, Pa., on the one hand, and, on the other, points in Pennsylvania; new furniture, between Philadelphia, Pa., on the one hand, and, on the other, points in New Jersey, Delaware, and Maryland. New furniture, between points in Philadelphia, Pa., on the one hand, and, on the other, points in Pennsylvania; new furniture, between Philadelphia, Pa., on the one hand, and, on the other, points in New Jersey, Delaware, and Maryland. New furniture, between points in Philadelphia, Pa., on the one hand, and, on the other, points in Pennsylvania; new furniture, between Philadelphia, Pa., on the one hand, and, on the other, points in New Jersey, Delaware, and Maryland. New furniture, between points in Philadelphia, Pa., on the one hand, and, on the other, points in Pennsylvania; new furniture, between Philadelphia, Pa., on the one hand, and, on the other, points in New Jersey, Delaware, and Maryland.

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

From Albany over New York Highway 5 to Vernon, New York, thence over New York Highway 254 to junction New York Highway 31, thence over New York Highways 31 to Rochester, New York, thence over U.S. Highway 104 to Niagara Falls, New York, and thence over New York Highway 384 to Buffalo, and return over the same route. Vendee is authorized to operate as a common carrier in Missouri, Kansas, Nebraska, and Minnesota, inclusive, and to operate as a common carrier between Kansas City, Mo., and Richland, Mo., serving the intermediate points of Crocker, Missouri, with no restrictions.

No. MC-F-13261. Authority sought for purchase by THE MICKOW CORP., P.O. Box 1774, Des Moines, IA., 50306 of the operating rights of Romans Drywall Co., 1716 Pennsylvania, Dallas, TX., 75202, and for acquisition by Double-D Systems Corporation, P.O. Box 1774, Des Moines, IA., 50306 of control of such rights through the purchase. Vendee is authorized to operate as a common carrier in Missouri, Illinois, Kansas, and Iowa, and to operate over unspecified points in Kansas, Missouri, and Illinois. Vendee is authorized to operate under section 210a(b). The operating rights sought to be transferred: General commodities, with exceptions as a common carrier over regular routes between Kansas City, Mo., and Richland, Mo., serving the intermediate points of Crocker, Missouri, with no restrictions.

No. MC-F-13263. Authority sought for purchase by BEAUFORT TRANSFER COMPANY, Box 151, Gerald, MO., 63037, of the operating rights of Steve J. Termolin, 108 Morgan St., Des Moines, IA., 50309, in Iowa, and for acquisition by THE MICKOW CORP., Box 151, Gerald, MO., 63037, of control of such rights through the purchase. Vendee is authorized to operate as a common carrier over regular routes between Kansas City, Mo., and Richland, Mo., serving the intermediate points of Crocker, Missouri, with no restrictions.

No. MC-F-13265. Authority sought for purchase by EAST TEXAS MOTOR FREIGHT LINES, INC., d.b.a. ETMF FREIGHT SYSTEM, 2355 Stemmons Freeway, Dallas, TX., 75207, of a portion of the operating rights of Hensmon-Richard, Inc., d.b.a. Hensmon-Richard Trucking, 4750 North White Oak Lane, New Bedford, MA., 02740, and for acquisition by H. R. Bright, individually, and as executor and trustee of the estate of Mary Frances Smith, Bright, deceased, and H. G. Schiff, both of 2355 Stemmons Freeway, Dallas, TX., 75207, of control of such rights through the purchase. Vendee is authorized to operate as a common carrier over regular routes between Kansas City, Mo., and Richland, Mo., serving the intermediate points of Crocker, Missouri, with no restrictions.

S.C.; between Darlington, S.C., and Cam-
451 (1976), any protests may include a statement indicating the presence or absence of any effect of the requested Commission action on the quality of the human environment. If any such effect is alleged to be present, the statement shall indicate with specific data the exact nature and degree of the anticipated impact. See Implementation—National Environmental Policy Act, 1969, supra, at p. 487.

Interested persons may participate formally in a proceeding by submitting written comments regarding the application. Such submissions shall indicate in the proceeding designation Finance Docket No. 281490 and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than 45 days after the date notice of the filing of the application is published in the Federal Register. Such written comments shall include the following: the person's position, e.g., party, protestant or party in support, regarding the proposed transaction; specific reasons why approval would or would not be in the public interest; and a request for oral argument. Additionally, interested persons who do not intend to formally participate in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of written comments to the Commission and to those interested persons who have filed written comments in the proceeding that are being served concurrently upon the applicant, the Secretary of Transportation and the Attorney General.

ATLANTIC RICHFIELD CO., ANADONIA CO. OPERATING RIGHTS APPLICATION (S) DIRECTLY RELATED TO FINANCE PROCEEDINGS

NOTICE

The following operating rights application(s) are filed in connection with pending finance applications under Section 5(2) of the Interstate Commerce Act, or seek tacking and/or gateway elimination in connection with transfer applications under Section 212(b) of the Interstate Commerce Act.

An original and two copies of protests to the granting of the authorities must be filed with the Commission 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 1100.247) and include a concise statement of protestant's interest in the proceeding and copies of its conflicting authorities. Verifiable statements in opposition should not be tendered at this time. A copy of this notice is devoted entirely to served concurrently upon applicant's representative, or applicant if no representative is named.

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 121420 (Sub-No. S), filed June 13, 1977. Applicant: DART TRUCKING CO., P.O. Box 188, Canfield, Ohio 44406. Applicant's representative: Paul F. Beery, Paul F. Beery, L.P.A., 275 East State Street, Columbus, Ohio 43215. Authority sought to transport in bulk, and over irregular routes, transporting: (1) General commodities, between Atwater, Ohio, on the one hand, and, on the other, points in Ohio; (2) coal, builder's supplies, farm equipment, farm 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, within 50 miles of Toronto, Ohio, on the one hand, and, on the other, points in Ohio; and, (4) such explosives, in gaseous form, as defined by the Commission, commodities in bulk, and those requiring special equipment, between points in York County, S. C., and, on the one hand, and, and 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-P-13266. By this application, Mason and Dixon seeks to convert the certificate of registration issued Ohio Transfer & Storage Co. in MC 120165 (Sub-No. 1) to one of public convenience and necessity. If a hearing is deemed necessary, applicant requests that the application be held at Columbia, S.C. Notice of the hearing will be issued in the Federal Register.

No. MC 121420 (Sub-No. B), filed June 13, 1977. Applicant: DART TRUCKING CO., P.O. Box 188, Canfield, Ohio 44406. Applicant's representative: Paul F. Beery, Paul F. Beery, L.P.A., 275 East State Street, Columbus, Ohio 43215. Authority sought to transport in bulk, and over irregular routes, transporting: (1) General commodities, between Atwater, Ohio, on the one hand, and, on the other, points in Ohio; (2) coal, builder's supplies, farm equipment, farm 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, within 50 miles of Toronto, Ohio, on the one hand, and, on the other, points in Ohio; and, (4) such explosives, in gaseous form, as defined by the Commission, commodities in bulk, and those requiring special equipment, between points in York County, S. C., and, on the one hand, and, and 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-P-13266. By this application, Mason and Dixon seeks to convert the certificate of registration issued Ohio Transfer & Storage Co. in MC 120165 (Sub-No. 1) to one of public convenience and necessity. If a hearing is deemed necessary, applicant requests that the application be held at Columbia, S.C. Notice of the hearing will be issued in the Federal Register.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
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 Portage Counties, Ohio, to points in the lower peninsula of Michigan, (d) from points in Mercer County, Pa.; and points in Ashtabula, Mahoning, Trumbull, Columbiana, and Portage Counties, Ohio, to points in Pennsylvania (except points in Butler, Crawford, Venango, Armstrong, Jefferson, Warren, 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 part (5) of Ohio gateways);

(10) Coal, builders supplies, farm supplies, farm, consumer goods, lumber and logs, as are usually transported in dump trucks, (a) between points in Ohio, on the one hand, and, on the other, points in Ohio, Pennsylvania, and West Virginia, within 5 miles of Toronto, Ohio, including Toronto, and (b) between points in Ohio, on the one hand, and, on the other, points in Mercer County, and points in Ashtabula, Trumbull, Columbiana, and Portage Counties, Ohio (elimination in (10) of Atwater, Ohio gateway).

No.—The purpose of parts (1), (2), and (3) is to convert a certificate of registration issued by motor vehicle, of general commodities, with certain exceptions, over a deviation route as follows: From Michigan City, Ind., over U.S. Highway 421 to junction U.S. Highway 231, thence over U.S. Highway 231 to junction Interstate Highway 74, thence over Interstate Highway 74 to junction U.S. Highway 63, thence over Interstate Highway 80 to junction U.S. Highway 63, thence over U.S. Highway 63 to junction U.S. Highway 30 near Tama, Iowa, and return over the same route for operating convenience only. The notice indicates that the carrier is presently authorized to transport the same commodities over a pertinent service route as follows: From Michigan City, Ind., over U.S. Highway 20 to junction U.S. Highway 66, thence over U.S. Highway 66 to junction Illinois Highway 53, thence over Illinois Highway 53 (formerly Alternate U.S. Highway 66) to junction U.S. Highway 66, thence over U.S. Highway 66 to junction Interstate Highway 70, thence over Interstate Highway 70 to junction U.S. Highway 61, thence over U.S. Highway 61, thence over U.S. Highway 218, thence over U.S. Highway 218 to junction U.S. Highway 30, thence over U.S. Highway 30 to junction Iowa Highway 14, thence over Iowa Highway 14, thence over North Main, Iowa, and return over the same route.

No. MC 52752 (Deviation No. 4), WESTERN TRANSPORTATION CO., 1380 W. 35th Street, Chicago, Ill. 60609, filed June 27, 1977. Carrier's representative: Edward Baselon, 39 S. LaSalle St., Chicago, Ill. 60603. Carrier proposes to operate as a common carrier, by motor vehicle, of general commodities, with certain exceptions, over a deviation route as follows: From Cedar Rapids, Iowa, over Iowa Highway 146 to Homestead, Iowa, and return over the same route for operating convenience only. The notice indicates that the carrier is presently authorized to transport the same commodities over a pertinent service route as follows: From Cedar Rapids, Iowa, over U.S. Highway 218 to Iowa City, Iowa, thence over U.S. Highway 6 to Homestead, Iowa, and return over the same route.


CARRIERS OF PROPERTY

No. MC 3054 (Deviation No. 17), TUCKER FREIGHT LINES, INC., P.O. Box 3144, South Bend, Ind. 46619, filed June 23, 1977. Carrier proposes to operate as a common carrier, by motor vehicle, of general commodities, with certain exceptions, over a deviation route as follows: From El Dorado, Ark., over U.S. Highway 62 to junction U.S. Highway 61 near Texarkana, Tex., over U.S. Highway 61 to junction U.S. Highway 80 and Interstate Highway 20 By-Pass, and return over the same route.

Motor Carrier Intersate Application (s)

(1) The following application(s) for motor carrier authority to transport general commodities as a common carrier by motor vehicle as a permissible service route, would result in the 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 245 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 charges for the services of court reporters, and other related matters shall be directed to the State Commission with which the application is filed and shall not be addressed to or filed with the Interstate Commerce Commission.

California Docket No. A 57336, application filed June 3, 1977. Applicant: MERRILL E. WOLKINS, doing business as California Mall Delivery Service, P.O. Box 1949, San Francisco, Calif. 94111. Application's representative: Raymond A. Greene, Jr., 100 Pine St., Suite 2550, San Francisco, Calif. 94111. Certificate of public convenience and necessity sought to operate a freight service as follows: Transportation of 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 sections of Interstate Highway 101, between San Francisco and Sausalito, inclusive; (2) Interstate Highway 80, between San Pablo and Crockett, inclusive; (3) the route between Martinez and Pittsburg, inclusive; (4) the route between Crockett and Martinez, inclusive; (5) the route between the intersection of Interstate Highway 880 and Interstate Highway 405, inclusive; (6) the route between the intersection of Interstate Highway 4 and the intersection of Interstate Highway 880, inclusive; (7) the route between the intersection of Interstate Highway 880 and Interstate Highway 405, inclusive; (8) the route between the intersection of Interstate Highway 4 and Interstate Highway 880, inclusive; (9) the route between the intersection of Interstate Highway 4 and Interstate Highway 880, inclusive; (10) the route between the intersection of Interstate Highway 4 and Interstate Highway 880, inclusive; (11) the route between the intersection of Interstate Highway 4 and Interstate Highway 880, inclusive; (12) Interstate Highway 880 between its intersections with State Highway 24 and its intersection with State Highway 24, inclusive.
580 at Dublin; (13) Interstate 680 between its intersection with Interstate Highway 580 at Dublin and its intersection with Bernal Ave., inclusive; (14) Bernal Avenue between its intersection with Interstate Highway 680 and the City of Pleasanton, inclusive; and (15) Interstate Highway 680 between its intersection with Interstate Highway 680 at Dublin and its intersection with State Highway 238 at Mission San Jose, inclusive; (16) Used Deer Creek and its intersection with State Highway 238 at Mission San Jose, inclusive; (17) Through routes and rates may be established between any and all points specified in paragraphs A and B, above, and all off-route points within the outer perimeters of the routes designated herein may be served. (E) From all points and places within the San Francisco Territory (See Note A), on the one hand, to all points and places on or within 10 lateral miles of the following routes, on the other hand: (1) Interstate Highway 80 between Sacramento and San Francisco, inclusive; (2) Interstate Highway 680 between its junction with Interstate Highway 80 near Pinole and Stockton, inclusive; (3) Interstate Highway 680 between its intersection with State Highway 99 near Visalia, inclusive; (4) State Highway 120 between its intersection with Interstate Highway 5 and its intersection with State Highway 99, inclusive; (5) State Highway 120 between its intersection with Interstate Highway 5 and its intersection with State Highway 99, inclusive; (6) State Highway 156 between its intersection with Interstate Highway 5 and its intersection with State Highway 99 near Visalia, inclusive; (7) State Highway 99 between Sacramento and Tulare, inclusive; (8) Highway 152 between its intersection with Interstate Highway 5 and its intersection with State Highway 99, inclusive; (9) State Highway 33 between its intersection with State Highway 152 at the Dogpatch County Line and its intersection with Interstate Highway 5, via Firebaugh, inclusive; (10) State Highway 130 between its intersection with State Highway 99, inclusive; (11) U.S. Highway 101 between its intersection with Interstate Highway 5 and State Highway 99, inclusive; (12) U.S. Highway 101 between its intersection with State Highway 99 at Santa Cruz, inclusive; (13) State Highway 17 between its intersection with Los Gatos—San Jose Road at Los Gatos and its intersection with State Highway 1 at Santa Cruz, inclusive; (14) State Highway 1 between its intersection with State Highway 17 at Santa Cruz and its intersection with State Highway 68 at Monterey, inclusive; (15) State Highway 10 West from its intersection with the San Francisco City Line at Castroville to its intersection with U.S. Highway 101, inclusive; (16) State Highway 68 between its intersection with State Highway 1 at Monterey and its intersection with U.S. Highway 101 at Salinas, inclusive; and (17) State Highway 182 between its intersection with State Highway 1 at Gilroy and its intersection with State Highway 1 at Watsonville, inclusive. In performing the service herein authorized, applicant may make use of any and all streets, roads, highways and bridges necessary or convenient for the performance of said service, except that pursuant to the authority herein granted carrier shall not transport any shipments of (a) live animals, including persons, (b) highly finished, viz.: passenger automobiles, ambulances, hearses, limousines, tank trucks, tank trailers, tank semitrailers or a combination of such highway vehicles; (c) livestock, viz.: barrows, boars, bulls, butcher hogs, calves, cattle, cows, dairy cattle, ewes, feeder pigs, goats, sheep, hogs, sheep, sheep, sheep, sheep, steers, tramps, swine or wethers; (d) Liquids, compressed gases, commodities in semisolid form and commodities in suspension in tank trucks, tank trailers, tank semitrailers or a combination of such highway vehicles. (2) Commodity requiring the use of special refrigeration or temperature control in specially designed and equipped refrigerator equipment, and (3) Explosives subject to U.S. Department of Transportation Regulations governing the Transportation of Hazardous Materials. In performing the service herein authorized, carrier may make use of any and all streets, roads, highways and bridges necessary or convenient for the performance of said service.

NOTES

1. San Francisco Territory includes all of that area embraced by the following boundary: Beginning at the point San Francisco—San Mateo County boundary line is inclosed; thence easterly along said County line to a point one mile west of State Highway 88; southerly along an imaginary line one mile west of and paralleling State Highway 88 to its intersection with Southern Pacific Company right-of-way at Ararat Road, thence southeasterly along the Southern Pacific Company right-of-way to Pollard Road, thence southeasterly along Pollard Road and thence eastward along Pollard Road to the City of San Bruno, thence northerly along the City of San Bruno and the South Bay Beltline to the outer perimeter of the City of San Bruno. In performing the service herein granted carrier shall not transport any shipments of: (a) Live animals, including persons; (b) Liquids and compressed gases, commodities in semisolid form and commodities in suspension; (c) Explosives subject to U.S. Department of Transportation Regulations governing the Transportation of Hazardous Materials.

Hearing.—Date, time and place not yet fixed. Requests for procedural information should be addressed to the Public Utilities Commission, State of California, State Building, Civic Center, 455 Golden Gate Ave., San Francisco, Calif. 94102, and shall not be directed to the Interstate Commerce Commission. California Docket No. A 55339, 2nd Amendment filed June 30, 1977. Applicant: WEBSTER DELIVERY SERVICE, INC., 6360 S. Greenwood, City of Commerce, Calif. 90022. Applicant's representative: Levin & Oberman Incorporated, 3550 Wilshire Blvd., No. 1420 Los Angeles, Calif. 90010. Certificate of Public Convenience and Necessity sought to operate a freight service as follows: (a) Household goods and personal effects not to exceed 100 pounds, in packages not exceeding 12 cubic feet, in jute, cotton, burlap, gunny, fibreboard, or bundles (completely wrapped and sealed, except for security); (b) Liquids, compressed gases, commodities in semisolid form and commodities in suspension in tank trucks, tank trailers, tank semitrailers or a combination of such highway vehicles. (c) Livestock, viz.: barrows, boars, bulls, butcher hogs, calves, cattle, cows, dairy cattle, ewes, feeder pigs, goats, sheep, hogs, sheep, sheep, sheep, sheep, steers, tramps, swine or wethers; (d) Liquids, compressed gases, commodities in semisolid form and commodities in suspension in tank trucks, tank trailers, tank semitrailers or a combination of such highway vehicles; (e) Explosives subject to U.S. Department of Transportation Regulations governing the Transportation of Hazardous Materials. In performing the service herein authorized, carrier may make use of any and all streets, roads, highways and bridges necessary or convenient for the performance of said service.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
Los Angeles Basin Territory includes that area embraced by the following boundary: Beginning at the point Ventura County-Los Angeles County boundary line intersects the Pacific Ocean; thence north easterly along said county line to the point it intersects State Highway No. 118, approximately two miles west of Chatsworth; easterly along Highway No. 118 to Sepulveda Boulevard; northerly along Sepulveda Boulevard to Chatsworth Drive; northeasterly along Chatsworth Drive to the corporate boundary of the City of San Fernando; westerly and northerly along said corporate boundary to McCloy Avenue; and its prolongation to the Angeles National Forest Boundary; southeasterly and easterly along the Angeles National Forest and San Bernardino National Forest boundary to the county road known as Mill Creek Road; westerly along Mill Creek Road to the county road 3.8 miles north of Yucaipa; southerly along said county road to and including the unincorporated community of Yucaipa; westerly along Redlands Boulevard to U.S. Highway No. 99; northwesterly along U.S. Highway 99 to the corporate boundary of the City of Redlands; westerly and northerly along said corporate boundary to Brookside Avenue; westerly along Brookside Avenue; to Barion Avenue; westerly along Barton Avenue; and its prolongation to Palm Avenue; westerly along Palm Avenue; to La Cadena Drive; southwesterly along La Cadena Drive to Iowa Avenue; southerly along Iowa Avenue; 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 Avenue; southerly along San Jacinto Avenue; to State Highway No. 74.

Westerly along State Highway No. 74, to the corporate boundary of the City of Hemet; southerly, westerly and northwesterly along said corporate boundary to the right of way of the Atchison, Topeka & Santa Fe Railway Company; southwesterly along said right of way to Washington Avenue; southerly Washington Avenue; 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.

Hearing.—Date, time and place not yet fixed. Requests for procedural information should be addressed to the Public Utilities Commission, State of California, State Building, Civic Center, 455 Golden Gate Avenue, San Francisco, California 94102 and should not be directed to the Interstate Commerce Commission.


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, Florida 32304 and should not be directed to the Interstate Commerce Commission.

By the Commission.

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

FEDERAL REGISTER, VOL. 42, NO. 137—FRIDAY, JULY 8, 1977
CONTENTS

<table>
<thead>
<tr>
<th>Item</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Civil Rights Commission</td>
</tr>
<tr>
<td>2</td>
<td>Equal Employment Opportunity Commission</td>
</tr>
<tr>
<td>3</td>
<td>Federal Election Commission</td>
</tr>
<tr>
<td>4</td>
<td>Federal Maritime Commission</td>
</tr>
<tr>
<td>5</td>
<td>Securities and Exchange Commission</td>
</tr>
</tbody>
</table>

1

AGENCY HOLDING THE MEETING:
Commission on Civil Rights.


PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: July 8, 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).

[8-834-77 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, 3401 E Street NW., Washington, D.C. 20506.

STATUS: Open.

MATTERS TO BE CONSIDERED: Portions closed to the public.

3

AGENCY HOLDING THE MEETING:
Federal Election Commission.

DATE AND TIME: Wednesday, July 13, 1977, at 10 a.m.

PLACE: 1325 K Street NW., Washington, D.C.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Compliance.

PERSON TO CONTACT FOR INFORMATION:
Mr. David Fiske, Press Officer, telephone 202-523-4065.

MARJORIE W. EMMONS, Secretary to the Commission.
[8-830-77 Filed 7-6-77; 4:22 pm]

4

AGENCY HOLDING THE MEETING:
Federal Maritime Commission.

TIME AND DATE: July 13, 1977, 10 a.m.

PLACE: Room 12126, 1100 L Street NW., Washington, D.C. 20573.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agreements.

5

AGENCY HOLDING THE MEETING:
Securities and Exchange Commission.

TIME AND DATE: Tuesday, July 12, 1977, at 10 a.m.


STATUS: Open.

MATTERS TO BE CONSIDERED: Agreements.

4. Agreement No. 10032-5—Pooling and sailing agreement in the northbound trade from Brazilian ports to U.S. Atlantic ports—Proposed extension and miscellaneous amendments.

5. 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).


5. Sergio E. Vasquez (FMC License No. 1835) —Qualification for license as independent ocean freight forwarder.


9. Contact person for more information: Joseph C. Polking, Acting Secretary (202-523-5727).

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

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409).
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 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 (202-376-8025).

JULY 5, 1977.
[5-632-77 Filed 7-5-77; 4:22 pm]
Applications for Permits To Fish Off the Coasts of the United States
DEPARTMENT OF STATE

[Public Notice 558]

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)

Permit Period
Applied For: __________

State: ITALY

1. Name of Vessel: GABRIELLA C

2. Vessel No.: __________
   Hull Ho. __________
   Registration Ho. ______

3. Name and Address of Owner:
   Name: F.LLI CEFALU' FRANCESCO
   Address: via Onorato, 4,
   90139 Palermo
   Cable Address: ____________

4. Homeport and State of Registry: Palermo

5. Type of Vessel: Stern Trawler

6. Tonnage (Gross): 1325.98
   (Net): 651.24

7. Length: 31.15 M.
   Breadth: 11.52 M.
   Draft: 6.02 M.

   Maximum Speed: ________ kt.

9. Propulsion: Diesel (X), Steam (), Diesel/Electric (), Other

10. Date Built: 1971

11. Number and Nationality of Personnel: 32 persons, Italy
   Officers: 10
   Crew: 22
   Other (Specify): __________

12. Communications: VHF-FM (X), AM/SSB, Voice (X), Telegraphy (), Other
   International Radio Call Sign: 1KUJ
   Radio Frequencies Monitored: 24, 77
   Other Working Frequencies: ________

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
16. Navigation Equipment: Loran C (X), Loran A ( ), Omega ( ), Decca ( ), NavaSat ( ), Radar (X), Fathometer (X).

17. Cargo Capacity (NT) | 18. Cargo Space
--- | ---
600 TONS | Number
Salted Fish | Freezer
Fresh Fish | Dry Hold
Frozen Fish | 600 Tanks
Fish Meal | Other
Other | Other

19. Processing Equipment (Indicate daily capacity, NT)

20. Fisheries 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>1977</td>
<td>Squid, Butterfish</td>
<td>Bottom and mid-water trawls</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
16. Navigation Equipment: Loran C (X), Loran A ( ), Omega ( ),
Becca (x), Navsat ( ), Radar (x), Fathometer (x).
Other

17. Cargo Capacity (NT)

<table>
<thead>
<tr>
<th>Cargo Space</th>
<th>Number</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 tons</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salted Fish</td>
<td></td>
<td>Freezer</td>
</tr>
<tr>
<td>Fresh Fish</td>
<td></td>
<td>Dry Hold</td>
</tr>
<tr>
<td>Frozen Fish 500</td>
<td></td>
<td>Tanks</td>
</tr>
<tr>
<td>Fish Meal</td>
<td></td>
<td>Other</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

18. Cargo Space Number

19. Processing Equipment (Indicate daily capacity, NT)

20. Fisheries 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>
<th>Catch (MT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atlantic</td>
<td>1977</td>
<td>Squids, Mackerel,</td>
<td>Bottom and mid-</td>
<td>400</td>
</tr>
<tr>
<td></td>
<td>(5 and 6)</td>
<td>Other finfish</td>
<td>water trawls</td>
<td></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
ENVIRONMENTAL 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 a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. 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 only 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 useful 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 prepared 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 identified as significant photochemical oxidant sources.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are a constituent in the formation of photochemical oxidants (smog). This notice does not place any requirement on States; State Implementation Plan (SIP) provisions which offer reasonable alternatives to this policy will be approvable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.
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 selective 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 is limited by the need to produce low-reactive solvents. Some of the negligible or slowly reactive solvents currently are under intensive investigation and have been identified as potential substitutes for Freon 113 since they are potential substitutes for Freon 11, Freon 12, Freon 114, and Freon 115.

Available data suggest that none of the listed compounds contribute significant oxidant even during extended irradiation under multiday stagnation conditions. Following their release to the atmosphere, the broad group "halogenated paraffins" includes important industrial solvents, most of which are chlorinated methanes and ethanes and chlorofluorocarbons. They are nonvolatile organic compounds—particularly nonhalogenated VOC—yield appreciable ozone when irradiated in smog chambers designed to simulate the urban atmosphere. The only in-depth analysis available at this time concerns acute toxicity. Threshold limit values (TLV's) have been developed for many VOC. 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. Adverse health effects of the VOC could 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 ozone. Since 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 atmospheric stability and widespread use in aerosol 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 new controls to prohibit nonessential usage of fully halogenated chlorofluorocarbons as aerosol propellants. The restrictions were applied to all members of this class including Freon 113 since there 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 chlorofluoromethanes 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 coatings 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 NOx (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. TUREK, Acting Assistant Administrator for Air and Waste Management.
DEPARTMENT OF LABOR
Office of the Secretary

COMPREHENSIVE MANPOWER PROGRAMS AND GRANTS TO AREAS OF HIGH UNEMPLOYMENT

Proposed Rulemaking
COMPREHENSIVE MANPOWER PROGRAMS AND GRANTS TO AREAS OF HIGH UNEMPLOYMENT

PROPOSED RULES

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 existing grant application and closeout process. The new process would necessitate changes in the following sections:

Sections 95.14; 95.16; 95.18; 95.21; 95.52; 95.53; 95.54; 96.14; 96.48; 98.17.

A new paragraph (a) (4) (ii) in § 95.3, Eligibility for funds, would automatically extend eligibility as exceptional circumstance prime sponsors to: (a) A unit of local government which was a prime sponsor in the previous fiscal year, had a population of at least 100,000 persons and a poverty level of less than 20% of the poverty level in the previous year; and (b) a consortium where the independently eligible general local government from the previous fiscal year has decreased below 100,000 (but not below 90,000) in population.

A new paragraph (d) in § 95.13, Planning process; advisory councils, would incorporate the provisions, required by the recent Vocational Education Act amendments, for coordination efforts between the State Advisory Council on Vocational Education and the State Manpower Plan.

A new paragraph (e) in § 95.31, Baseline responsibilities of prime sponsors, and a revised § 96.28, Equitable service to the unemployed population; serving significant segments, would permit prime sponsors to provide equitable service to the unemployed population in terms of age, race, and sex; identify the significant segments to be served; and justify where service 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.

New paragraphs (b) and (c) in § 98.12, Allowable Federal costs, clarify the use of funds for construction and for repairs, maintenance, and capital improvements to existing facilities.

Because of the proposed changes to simplify the grant process, in reading all the changes in conjunction with the revised portions of Parts 95, 96, and 98, Community and Regional Planning, the "Comprehensive Employment Plan" or "plan" appear in the revised portions, the terms "grant application" or "grant", as appropriate, shall be substituted; except that in revised portions of Parts 95, 96, and 98 are proposed to be amended as follows:

PART 95—GENERAL PROVISIONS FOR PROGRAMS UNDER THE COMPREHENSIVE EMPLOYMENT AND TRAINING ACT

§ 95.4 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 the Office of Management and Budget or 70% of the lower living standard income level, whichever is higher. Family income shall be determined by:

(i) Annualizing all monies received from sources during the 3 months preceding the assignment of the economically disadvantaged classification, except for the monies excluded from family income as indicated in the Forms Preparation Handbook.

(ii) If, due to seasonal unemployment (e.g., teachers, seasonal employment, summer employment for youth, or other circumstances, the 3 month period is unacceptable, all monies received from all sources during the 12 months preceding the assignment of the economically disadvantaged classification, except for the monies excluded from family income as indicated in the Forms Preparation Handbook.

(b) "Family" shall mean one or more persons living in a single household who are related to each other by blood, marriage or adoption. A stepchild who receives at least 50% of his/her support from the stepparent shall be counted as a member of the stepparent's family. A member of a household:

(1) Who is 10 or older;

(2) Who receives less than 50% of his/her maintenance from the family; and

(3) Who is not the head of the household or the spouse of the head of the household, shall not be considered a member of the family. Such an individual shall be considered a family residing alone or in group quarters.

(c) "Participant" shall mean an individual who is eligible for and takes part in activities under provisions of the Act or receives services funded under the Act, except for an individual who receives only outreach and intake services. An individual applicant becomes a participant when:

The individual is declared eligible upon intake; and

(2) The individual receives employment, training or services funded under the Act following intake, except for an individual who receives only outreach and intake services.

(d) "Underemployed person" shall mean:

(1) A person who is working part-time but has been seeking full-time work, and who is a member of a family whose total family income (as defined in paragraphs (a) (2) (i) and (ii) of this section) in relation to his or her family size, does not exceed the poverty level determined in accordance with criteria established by CMB, and

(2) A person who is working full-time and who is a member of a family whose total family income (as defined in paragraphs (a) (2) (i) and (ii) of this section) in relation to his or her family size, does not exceed the poverty level determined in accordance with criteria established by CMB.

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 due 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...
a functioning labor market area or to be a rural area with a high level of unem­ployment, to have determined that (A) it has the capability for effectively carrying out a comprehensive manpower program under the Act, evidenced by its effective operation of programs such as CEP or other manpower programs; and (B) there is a special need for services provided by the Act (e.g., the area has a high proportion of such groups within the labor market as older workers, high school dropouts who have a high unemployment rate, substantial outmigration or unique commuting problems, and (C) it will afford administrative and program­matic advantages over other methods of delivering services under the Act; (ii) The following units of general local government or combination of such units shall automatically be considered as exceptional circumstance prime sponsors since such unit(s) have been deter­mined by the Secretary to meet the re­quirements of paragraph (a) (4) (i) of this section: (A) A combination of units of general local government which was a prime sponsor in the previous fiscal year, had a population of 100,000 or more persons according to the previous year's census update estimate, and has since decreased below 100,000 (but not below 90,000) in population; and (B) A combination of units of general local government which meet the re­quirements of paragraph (a) (3) (i) (A), (B) and (C) of this section, which were members of the same consortium in the previous fiscal year, and which contain at least one unit which had a population of 100,000 or more persons according to the previous year's census update estimate, but has since decreased below 100,000 (but not below 90,000) in popu­lation; and

§ 95.13 Planning process: advisory councils.

(d) * * *

(ii) One representative shall be ap­pointed from each of the following: The State Board of Vocational Education, the State Advisory Council on Vocational Education, the State employment service, and any State agency the Governor believes has an interest in manpower or manpower-related services within the area (Sec. 203 of the Vocational Education Act of 1973, as amended (Pub. L. 94-482)); and

(vii) Commenting at least once an­nually on the reports of the State Advisory Council on Vocational Education and incorporating those comments in the Annual Report to the Governor (Sec. 203 of the Vocational Education Act of 1973, as amended (Pub. L. 94-482)); and

§ 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 (PSA) 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 PSA. 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 PSA remains the same or that it is revised as described in attachments to the certification. The initial submission and subsequent certification of the PSA shall include the comment and pub­lication procedures of § 95.15 (c), (d), and (e) of this part. The PSA shall consist of the Signatory Page, the Narrative De­scription of General Information, Assur­ances and Certifications, and, for con­sortia, the approved consortium agree­ment.

(i) Signatory page. The Signatory Page, when signed by the designated prime sponsor and the authorized re­presentative of the RA, shall constitute a legal and binding document by which the designated prime sponsor agrees that all work performed under its Annual Plan will be in accordance with the Act, the assurances and certifications and the regulations of 29 CFR Parts 94, 95, 96 and 98.

(2) 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.

(B) A description of the special con­sideration that will be given to the needs of eligible disabled veterans, special vet­erans, and veterans who served in the Armed Forces and received other than a dishonorable discharge within the four years prior to the date of their appli­cation.

(C) A description of the placement and follow-up mechanisms and procedures to be used.

(iii) Delivery agents. (A) An explana­tion of the methods and criteria to be used in the selection of deliverers of services.

(B) 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 areas centers.

(D) A description of efforts to utilize apprenticeship or other on-the-job training opportunities available under Section 1787 of Title 38, United States Code.

(v) 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 organization and groups in the program plan.

(vi) 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;
order to obtain funds under Title I. The Annual Plan shall consist of the following statement of the following items:

(1) Application for Federal assistance. The Application for Federal Assistance shall identify each 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. Standard Form 424 contained in FMC 74-1 shall be used.

(B) A description of determination 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 opportunities. A description of the mechanisms which will be used to assure nondiscrimination and equal employment opportunities.

(vi) Additional assurance for Title II programs:

(A) For those Title II applicants who have received a discharge within four years prior to application, the participant to be served by each program shall be a veteran, one who has received a honorable discharge, in addition to any other requirements.

(B) A description of the linkage established.

(2) Description of programs if any, designed for persons of limited English-speaking ability.

(4) For those applicants intending to request funds under section 303 of the Act, a discussion of how migrants and seasonal farmworkers will be served.

(B) A statement of the significant segments of the unemployed population.

(ii) Approach.—(A) Program activities and services. (1) A description of the activities and services to be provided.

(B) A description of the linkage established.

(3) An explanation for non-use or duplication of existing services and facilities programs of demonstrated effectiveness listed in § 95.14(b) (iv) (B).

(C) Discussion of program planning summary (PPS) and budget information summary (BIS). 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 price.

(iv) Public service employment program. (A) For those Title II applicants whose geographic area differs from the Title I area described in the PPA, 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 employment program described in paragraph (c) (iv) (B) of this section.

(2) A description of determination of rates of compensation when they differ from what is normally paid by the employing agency.

(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.

(A) 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 public service job opportunities statement of planned enrollment levels, the participants to be served by each program activity (classroom training, on-the-job training, public service employment, and other activities) and planned outcomes for program participants. It shall also include an identification of the 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 the proposed public service job opportunities, occupations and wages, including a comparison of such wages for similar unsubsidized unsubsidized jobs in the area, 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 60 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 simultaneously 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 PSA 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.
copy of the signatory page will be provided to the designated prime sponsor by the Regional Office at such time as this approval will be submitted by the designated prime sponsor of its Annual Plan.

§ 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 (d) of this section, if an Annual Plan is approved, the RA shall provide the prime sponsor with a letter indicating approval.

(e) Funding authority will be issued by a Notice of Fund Availability.

§ 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 paragraphs (a)(1), (a)(2) (1), and (ii)(A) of this section without prior regional office approval, but must notify the RA of these changes in writing by the end of the quarter in which the change occurs. Revised portions of the PSA need not be submitted with the notice.

(2) Annual Plan modifications will not be initiated solely to adjust planned performance to meet actual performance.

(3) A-95 Clearance. (i) Modifications required by the A-95 clearance regulations for the current program year and/or; the designated prime sponsor to review the completed modification, the prime sponsor shall so indicate in the appropriate item on the revised Standard Form 424, noting clearances which were not requested before receiving the modification and clearances which did not request to review the completed modification after being notified of the prime sponsor’s intent to modify.

(ii) 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 Summary and Financial Status Report, and the clearinghouses to which the change has been made. At the same time this report is submitted, an updated Program Planning Summary, Budget Information Summary, or narrative description which, 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).

(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 paragraph (d) have been complied with.

(v) A copy of the newspaper announcement required in paragraph (c).

(vi) Revised Version of the program narrative description, if appropriate.

(vii) Revised Occupational Summary, if appropriate.

(b) 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

35321

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
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 granted the privilege of residing in the United States as lawful permanent residents or are refugees.

§ 95.33 Types of manpower program activities available.

(d) * * *

(ii) Inducements to employers. Prime sponsors may provide payments or other inducements to public or private employers for the bona fide training and related costs of enrolling individuals in the program; provided that payments to employers organized for profit are only made for the costs of recruiting, training, supportive services which are over and above those normally provided by the employer. Use of a formula which incorporates the trainee's wage as a factor and fixed unit cost contracting are acceptable methods of reimbursement to private-for-profit employers for extraordinary training costs associated with providing on-the-job training. When using a formula, the prime sponsor can reimburse the employer for extraordinary training costs associated with training on the job, up to a level not to exceed 50 percent of participant wages. Prime sponsors may design other methods of cost reimbursement provided that payments reflect only extraordinary training costs.

(iv) Labor organization consultation. Appropriate labor organizations shall be consulted in the design and conduct of any employment training programs where collective bargaining agreements exist with the employer. Prime sponsors shall consider the advice and comments of such labor organizations, when designing OJT programs and negotiating OJT contract provisions and shall ensure that wages for covered positions conform with collective bargaining agreements.

§ 95.34 Training allowances.

(1) Dependents allowances. (1) Dependents allowances of $5 per week for each dependent in excess of two dependents, and to a maximum of $20 for six or more dependents shall be provided to participants receiving basic allowances or who would be receiving basic allowances were it not for adjustments which are not result in an incentive allowance payment under the Act. The determination of whether the other activity is full-time shall be based on the number of hours that constitute full-time employment. The methodology for making the determination shall be described in the approved PSA.

(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.

(3) The basic allowance may be reduced by the amount of wages received by classroom training participants who are concurrently enrolled during the same payment period in either full-time work experience, public service employment, or on-the-job training funded under the Act. The determination of whether the other activity is full-time shall be based on the number of hours that constitute full-time employment for regular employees similarly employed at the employing agency or worksite. Incentive allowances for public assistance recipients may, at the option of the prime sponsor, be adjusted downward, provided that the adjustment shall not result in an incentive allowance payment which is lower than the Federal, State, or local minimum wage multiplied by the number of hours of participation, which the trainee attends as required or is absent from for good cause.

§ 95.35 Federal Register date.
(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. When 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.

§ 95.33 Cooperative relationships between prime sponsor and other manpower agencies.

(a) Each prime sponsor shall, to the extent feasible, establish cooperative relationships or linkages with other manpower and manpower-related agencies in the State within its jurisdiction. In particular, with agencies operating programs funded through the Department (Section 106(a)(3)(D)). Prime sponsors are encouraged to utilize the free direct placement services offered by the SESA's.

§ 95.52 Grant application.

(a) (1) Each prime sponsor shall, to the extent feasible, establish cooperative relationships or linkages with other manpower and manpower-related agencies in the State within its jurisdiction. Prime sponsors are encouraged to utilize the free direct placement services offered by the SESA’s.

(2) 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 and to units of general local government within the Balance-Of-State with a population of 25,000 or less.

(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 still receive subsidised employment or training; and

(iii) A summary of any programs to be funded within a prime sponsor’s area with State manpower services funds to the prime sponsor in whose jurisdiction the program is to be funded.

(b) Approval Request Letter.

(1) Application for Federal Assistance. Standard Form 424 as prescribed by PMC 74–7 is being used for the application for the special grant.

(2) Special Grant-Program Planning Summary. The Special Grant-Program Planning Summary is a multiprogram grant form providing for statistical entries on numbers of participants served by vocational education projects and State Manpower Services.

(1) 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.

(ii) Special Grant Program Narrative. The narrative information shall be composed of three separate sections. The Program Narrative form contained in the Form 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 Vocational Education Services.

(3) A summary of all agreements required in § 95.56 between individual prime sponsors and the State Vocational Education Board.

(B) 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. 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.

(2) State Manpower Services Program Narrative. (A) A description of any of the activities allowable under Section 106(c) 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, that the State chooses to provide, detailing those activities to be undertaken and the costs and goals of such activities, including:

(ii) A description of allowable services being delivered under the Act, that the State chooses to provide, detailing those activities to be undertaken and the costs and goals of such activities, including:

(iii) A description of any of the activities allowable under Section 106(c) of the Act, that the State chooses to provide, detailing those activities to be undertaken and the costs and goals of such activities, including:

(2) Coordination of programs financed under Wagner-Peyser Act (see Part V of Attachment A, OMB Circular A–95) to serve geographical regions within the State.

(3) Coordination of program services being delivered under the Act, that the State chooses to provide, detailing those activities to be undertaken and the costs and goals of such activities, including:

(4) Coordination of program services being delivered under the Act, that the State chooses to provide, detailing those activities to be undertaken and the costs and goals of such activities, including:

(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 any arrangements for planning areas (see Part V of Attachment A, OMB Circular A–95) to serve geographical regions within the State.

(7) 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.

(c) * * *

§ 95.53 Application approval and disapproval.

(1) The Governor shall make the final determination to approve or disapprove the application. Where the Governor determines that the application should be approved in whole or in part, the Governor shall describe:

(a) The extent to which the Governor has demonstrated maximum efforts to meet the goals of the prior year’s annual plan.

(b) The extent to which the Governor has demonstrated maximum efforts to meet the goals of the prior year’s annual plan.

(c) The extent to which the Governor has demonstrated maximum efforts to meet the goals of the prior year’s annual plan.

(d) If an application is approved, the Governor shall provide the Governor with a letter indicating approval.

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

(2) Change in the Annual Plan allotment; or

(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.

(b) The program design is altered significantly (see § 95.21(b)(1)(iii)) (D)).

(c) Major grant modifications shall not be initiated solely to adjust planned performance to meet actual performance.

(d) Special Annual Plan modifications are required under any of the following conditions:

(1) 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.

(2) When the cumulative number of individuals to be served or the planned program goals is to be increased or decreased by 15 percent or more.

(3) When a significant change in program design or program goals is required.

§ 96.14 Content and description of grant application.

(a) General. (1) This section describes the contents of a grant application for funds under Title II of the Act. Copies of all forms and instructions are contained in the Forms Preparation Handbook.

(2) An Annual Plan for Title II must be submitted by the Governor to the RA no later than the date of submission to the RA of the Governor's most recent Federal Assistance Application.

(b) 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 programs. A detailed statement on each of those items must be provided as part of the Annual Narrative Description of Program. The Governor shall submit a narrative description that accurately reflects the Title II program.

§ 96.15 Content and description of grant application.

(a) General. (1) This section describes the contents of a grant application for funds under Title II of the Act. Copies of all forms and instructions are contained in the Forms Preparation Handbook.

(2) A denial of a Governor's request for a modification shall be subject to the appeal procedures set out in Part 98.

(3) Substantial change in program description and/or program goals required under paragraph (a) of this section and major grant modifications under paragraph (b) of this section shall be reviewed in accordance with the procedures set out in Part 98.

(4) Narrative description of the changes made and certification that the Governor has fulfilled its obligation under § 95.21 of Subpart A shall be transmitted to the RA with the modification.

(5) The Governor shall provide a copy of the Annual Narrative Description of Program with its revised Annual Plan which is submitted to the RA no later than the date of submission to the RA of the Governor's most recent Federal Assistance Application.
in § 95.14(b)(2) and (c)(4) shall be provided for the Title II area.

3. Program Planning Summary. This form is described in § 95.14(c)(3).

4. Budget Information Summary. This form is described in § 95.15(c)(4).

5. Public Service Employment Operations. This form is described in § 95.15(c)(5).

6. Monthly Schedule. A monthly estimate of total individuals enrolled at
the end of the month and total cumulative expenditures shall be provided. Such
monthly estimate will reflect the activity for each month during the grant period
under Title II.

7. Program Summary. The Program Summary presents a distribution of jobs,
training slots, and funds to be provided to eligible, applicants and subgrantees. It
designates the area to be served, the population and employing agencies of
each area.

§ 96.23 Acceptable public employment positions.

(a) The prime sponsor shall provide equitable service to the unemployed
population in relationship to the population's demographic characteristics—
age, 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 served. 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 percent points from the demographic
breakout identified in paragraph (a) of this section, adequate justification of
the variance must be provided by the RA in its Annual Plan.

(d) The prime sponsor shall take positive steps, such as active recruitment,
to assure that the significant segments in its approved plan of service are
served.

§ 96.27 Eligibility for participation in a Title II program.

(a) 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 con­
nectected 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).

(b) Former manpower trainees.

(c) Program Planning.

(d) Program Planning Summary.

(e) Citizenship may not be used as a
condition to prevent persons from par­
ticipating 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 unem­
ployed population: serving signifi‌
cant segments.

(a) The prime sponsor shall provide equitable service to the unemployed
population in relationship to the popu­
lation's demographic characteristics—
age, 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 served. 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
percent points from the demographic
breakout identified in paragraph (a) of
this section, adequate justification of
the variance must be provided by the RA
in its Annual Plan.

(d) The prime sponsor shall take
positive steps, such as active recruit­
ment, to assure that the significant
segments in its approved plan of service are
served.

§ 96.29 Groups to be provided special consideration within the
significant segment groups served.

Special consideration shall be given to:

(a) Veterans.

(b) Former manpower trainees.

(c) Program Planning.

(d) Program Planning Summary.

(e) Citizenship may not be used as a
condition to prevent persons from par­
ticipating 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 unem­
ployed population: serving signifi‌
cant segments.

(a) The prime sponsor shall provide equitable service to the unemployed
population in relationship to the popu­
lation's demographic characteristics—
age, 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 served. 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
percent points from the demographic
breakout identified in paragraph (a) of
this section, adequate justification of
the variance must be provided by the RA
in its Annual Plan.

(d) The prime sponsor shall take
positive steps, such as active recruit­
ment, to assure that the significant
segments in its approved plan of service are
served.

§ 96.29 Groups to be provided special consideration within the
significant segment groups served.

Special consideration shall be given to:

(a) Veterans.

(b) Former manpower trainees.

(c) Program Planning.

(d) Program Planning Summary.

(e) Citizenship may not be used as a
condition to prevent persons from par­
ticipating 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 unem­
ployed population: serving signifi‌
cant segments.

(a) The prime sponsor shall provide equitable service to the unemployed
population in relationship to the popu­
lation's demographic characteristics—
age, 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 served. 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
percent points from the demographic
breakout identified in paragraph (a) of
this section, adequate justification of
the variance must be provided by the RA
in its Annual Plan.

(d) The prime sponsor shall take
positive steps, such as active recruit­
ment, to assure that the significant
segments in its approved plan of service are
served.

§ 96.29 Groups to be provided special consideration within the
significant segment groups served.

Special consideration shall be given to:

(a) Veterans.

(b) Former manpower trainees.

(c) Program Planning.

(d) Program Planning Summary.

(e) Citizenship may not be used as a
condition to prevent persons from par­
ticipating 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 unem­
ployed population: serving signifi‌
cant segments.

(a) The prime sponsor shall provide equitable service to the unemployed
population in relationship to the popu­
lation's demographic characteristics—
age, 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 served. 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
percent points from the demographic
breakout identified in paragraph (a) of
this section, adequate justification of
the variance must be provided by the RA
in its Annual Plan.

(d) The prime sponsor shall take
positive steps, such as active recruit­
ment, to assure that the significant
segments in its approved plan of service are
served.

§ 96.29 Groups to be provided special consideration within the
significant segment groups served.

Special consideration shall be given to:

(a) Veterans.

(b) Former manpower trainees.

(c) Program Planning.

(d) Program Planning Summary.

(e) Citizenship may not be used as a
condition to prevent persons from par­
ticipating 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 unem­
ployed population: serving signifi‌
cient segments.

(a) The prime sponsor shall provide equitable service to the unemployed
population in relationship to the popu­
lation's demographic characteristics—
age, 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 served. 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
percent points from the demographic
breakout identified in paragraph (a) of
this section, adequate justification of
the variance must be provided by the RA
in its Annual Plan.

(d) The prime sponsor shall take
positive steps, such as active recruit­
ment, to assure that the significant
segments in its approved plan of service are
served.

§ 96.29 Groups to be provided special consideration within the
significant segment groups served.

Special consideration shall be given to:

(a) Veterans.

(b) Former manpower trainees.

(c) Program Planning.

(d) Program Planning Summary.

(e) Citizenship may not be used as a
condition to prevent persons from par­
ticipating 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.
the participant's home comparable to the


distance traveled by others in the juris-
diction similarly employed; and not


vacant due to a strike or based on a re-


requirement that an employee must join


or resign from a union.


§ 96.37 Use of Title II funds for pro-


gram under Title I and III-A.


Funds available to an eligible applicant


may, at its option, be utilized for resi-
dents of the areas of substantial unem-
ployment 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


PSE authorized under other Titles of the


Act, all provisions under this Part, ex-


cept § 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 (see § 21H).


However, when Title II funds are used to


fund public service employment, all


of the provisions of this Part 96 shall


apply.


§ 96.43 Funding of eligible applicants.


(a) In order to be funded, a poten-


tially eligible applicant must agree to


operate a program under Title II by


complying with the provisions of § 97.111


of the regulations for Indian Employ-


ment and Training Programs funded un-


der 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 An-


nual Plan (AP). Detailed instructions


for completing the application are con-


tained in the Forms Preparation Hand-


book.


(1) Prime sponsor agreement. An ap-


plicant applying for the first time shall


not later than 30 days prior to submis-


sion of the Annual Plan, submit to


the Director, Division of Indian and Native


American Programs (DINAP), a signed


copy of the PSA. An applicant 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:


(1) A signatory page (see § 93.14(b)


(1)).


(2) A narrative description of general


information; and


(3) Assurances and certifications.


(2) Annual plan. On a date set by


the Director, DINAP, an Annual Plan must


be submitted to the Director, DINAP.


The submission of the AP is attached to


the instrument and publication procedures


of § 96.45. The Annual Plan consists of:


(1) An Application for Federal As-


sistance. (See § 95.14(c)(1)).


(11) An Annual Narrative Description


of Program;


(111) A Program Planning Summary


(see § 95.14(c)(3));


(1V) A Budget Information Summary


(see § 95.14(c)(5));


(v) A Public Service Employment Oc-


cupational Summary (See § 95.14(c)


(3));


(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 COMPRE-


HENSIVE EMPLOYMENT AND TRAINING


ACT


§ 98.6 Audit.


(e) (1) Each grantee shall establish


and maintain an audit program for its


contractors and subgrantees to the ex-


tent necessary to insure adequate finan-


cial 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 20 U.S.C. 930.


(2) Each grantee shall conduct at least


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 sub-


grantees or contractors providing activ-


ities and services under $100,000 may be


conducted on a sample basis as coor-


dinated 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 dollar amount awarded, during the


two-year period. The auditing of contractors


and subgrantees on a sample basis in no way


lessens the prime sponsor's responsibil-


ity to insure that program activities and


related costs incurred by contractors and


subgrantees are in compliance with Fed-


eral requirements as stated in paragraph


94.5(a). Fixed price contracts for non-


program activities such as typewriter main-


tenance, administrative type procure-


ments such as typewriter maintenance,


administrative supplies, etc., do not re-


quire independent audits. The two-year


audit period shall begin with Fiscal Year


1976.


§ 98.12 Allowable Federal costs.


(b) Restriction on use of funds.—(1)


Public service employment programs.


(1) Not less than 65 percent of the funds


appropriated pursuant to the Act which


are used by an eligible applicant for pub-


lic service employment programs shall


be expended for wages and fringe ben-


efits to persons employed in public serv-


ice jobs (sec. 210).


(2) The remaining 15 percent may be


used for administration, training, sup-


portive services to public service employ-


ment participants; for the acquisition of,


rental, or leasing of necessary sup-


plies, equipment, and materials, except


as limited by paragraph (c) of this sec-


tion; and for the rental or leasing of real


property. An eligible applicant which does


not itself administer the entire pro-


gram may not retain the entire 15 per-


cent for its own use unless this is agreed


to by its subgrantees. Unless otherwise


agreed, all costs incurred in connection


with the administration of the grant shall


be available to subgrantees for administra-


tive costs.


(2) No funds granted under the Act


shall be used, directly or indirectly, as a


contribution for the purpose of obtain-


ing Federal funds under any other law


of the United States which requires a


contribution from the grantee in order to


receive grants in aid under that law. How-


ever, the use of funds granted under the Act as a


matching contribution in order to obtain


additional funds under the Act is not


prohibited.


(3) Unless otherwise provided in para-


94-99, funds provided under one grant


under the Act may not be used to support


costs such as instructors' salaries, train-


ing, and maintenance, and capital im-


provements and for construction, home


repair, weatherization, homesteading, or


construction activities where work performed


will be performed by an outside contractor.


(3) 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 re-


pair and weatherization activities where work performed will


not be performed by an outside contractor.


(b) Restriction on use of funds.—(1)


Public service employment programs. (1) Not less than 65 percent of the funds appropriated pursuant to the Act which are used by an eligible applicant for public service employment programs shall be expended for wages and fringe benefits to persons employed in public service jobs (see 210). The remaining 15 percent may be used for administration, training, supportive 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 does not itself administer the entire program may not retain the entire 15 percent for its own use unless this is agreed to by its subgrantees. Unless otherwise agreed, all costs incurred in connection with the administration of the program shall be available to subgrantees for administrative costs. (2) No funds granted under the Act shall be used, directly or indirectly, as a contribution for the purpose of obtaining Federal funds under any other law of the United States which requires a contribution from the grantee in order to receive grants in aid 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 not prohibited. (3) Unless otherwise provided in parts 94-99, funds provided under one grant under the Act may not be used to support costs such as instructors' salaries, training, and maintenance, and capital improvements and for construction, home repair, weatherization, homesteading, or construction activities where work performed will be performed by an outside contractor. (4) 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/ weatherization activities where work performed will not be performed primarily to the benefit of a profit- making organization. Home repair and weatherization/ weatherization activities shall be limited to dwellings of individuals who are at or below 125 percent of the poverty level (as defined in § 94.4) which are privately owned and occupied, privately owned by a nonprofit organization, units of public housing, or privately owned rental property which are privately owned and approved by the Federal Energy Administration or the Community Services Administration. (704(f)). (5) Costs associated with building repairs, maintenance, and capital improvements of existing facilities used pri-
Part 70), including any amendments 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 that it has already taken for its 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 regulations 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, subgrantees, title II program agents and employing agencies and titles I, II, and VI program participants; and

(iv) Employees of the prime sponsor's jurisdiction not engaged in the administration of the Act, such as members of the IPA.

(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.

(3) Units whose staff are exempt under paragraph (a) 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, in accordance with applicable administrative actions and all required work of the Annual Plan have been completed by the grantee and the grantor. The following procedures will be completed with due regard to the process of development:

(b) By a date specified by the RA, each grantee shall submit a TWX containing the following information on each expiring annual plan:

(1) Total fund availability;

(2) Estimated accrued expenditures;

(3) Total amount of carryover.

(c) The RA shall issue a notice of fund availability to transfer carryover from the previous Annual Plan. A second notice of transfer of carryover, shall be issued by the RA to transfer the carryover from the previous Annual Plan into a new Annual Plan.

(d) In the following months (generally not to exceed six months), the grants 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.

§ 98.22 Nepotism.

(a) Restriction. No grantee, subgrantee, contractor, 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 shall follow the State or local statute in lieu of this policy.

(b) Civil Service. 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, as well 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
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. 97.292), 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.

[F.R. Doc. 77-19558 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, Labor.

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 303 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. Mayrand, Chief, Division of Farmworker Programs, DOL/ETA, 601 D Street NW., Washington, D.C. 20213.

Phone: (202—376—7288).

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, $63,920,000, is 85 percent of the total amount planned for all section 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 not less than 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, 1975.)

Eligible applicants should use the following State planning estimates in developing Fiscal Year 1978 funding requests:

<table>
<thead>
<tr>
<th>State</th>
<th>Fiscal Year 1978 Planning Estimates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
<td>$497,300</td>
</tr>
<tr>
<td>Arizona</td>
<td>$931,500</td>
</tr>
<tr>
<td>Arkansas</td>
<td>$916,100</td>
</tr>
<tr>
<td>California</td>
<td>$1,114,600</td>
</tr>
<tr>
<td>Colorado</td>
<td>$900,900</td>
</tr>
<tr>
<td>Connecticut</td>
<td>$235,700</td>
</tr>
<tr>
<td>Delaware</td>
<td>$340,900</td>
</tr>
<tr>
<td>Florida</td>
<td>$3,113,600</td>
</tr>
<tr>
<td>Georgia</td>
<td>$1,471,600</td>
</tr>
<tr>
<td>Hawaii</td>
<td>$204,300</td>
</tr>
<tr>
<td>Idaho</td>
<td>$791,100</td>
</tr>
<tr>
<td>Illinois</td>
<td>$1,552,200</td>
</tr>
<tr>
<td>Indiana</td>
<td>$1,206,100</td>
</tr>
<tr>
<td>Iowa</td>
<td>$1,104,600</td>
</tr>
<tr>
<td>Kansas</td>
<td>$855,200</td>
</tr>
<tr>
<td>Kentucky</td>
<td>$1,116,300</td>
</tr>
<tr>
<td>Louisiana</td>
<td>$665,000</td>
</tr>
<tr>
<td>Maine</td>
<td>$362,000</td>
</tr>
<tr>
<td>Maryland</td>
<td>$517,100</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>$320,500</td>
</tr>
<tr>
<td>Michigan</td>
<td>$1,239,800</td>
</tr>
<tr>
<td>Minnesota</td>
<td>$1,768,900</td>
</tr>
<tr>
<td>Mississippi</td>
<td>$916,100</td>
</tr>
<tr>
<td>Missouri</td>
<td>$1,173,600</td>
</tr>
<tr>
<td>Montana</td>
<td>$462,400</td>
</tr>
<tr>
<td>Nebraska</td>
<td>$828,400</td>
</tr>
<tr>
<td>Nevada</td>
<td>$163,400</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>$77,500</td>
</tr>
<tr>
<td>New Jersey</td>
<td>$453,600</td>
</tr>
<tr>
<td>New Mexico</td>
<td>$656,100</td>
</tr>
<tr>
<td>New York</td>
<td>$1,526,300</td>
</tr>
<tr>
<td>North Carolina</td>
<td>$3,880,700</td>
</tr>
<tr>
<td>North Dakota</td>
<td>$284,900</td>
</tr>
<tr>
<td>Ohio</td>
<td>$1,269,200</td>
</tr>
<tr>
<td>Oklahoma</td>
<td>$766,800</td>
</tr>
<tr>
<td>Oregon</td>
<td>$1,086,800</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>$1,547,100</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>$80,300</td>
</tr>
<tr>
<td>South Carolina</td>
<td>$1,029,200</td>
</tr>
<tr>
<td>South Dakota</td>
<td>$555,100</td>
</tr>
<tr>
<td>Tennessee</td>
<td>$810,600</td>
</tr>
<tr>
<td>Texas</td>
<td>$4,982,900</td>
</tr>
<tr>
<td>Utah</td>
<td>$335,300</td>
</tr>
<tr>
<td>Vermont</td>
<td>$290,300</td>
</tr>
<tr>
<td>Virginia</td>
<td>$1,297,400</td>
</tr>
<tr>
<td>Washington</td>
<td>$1,980,900</td>
</tr>
<tr>
<td>West Virginia</td>
<td>$499,200</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>$2,166,200</td>
</tr>
<tr>
<td>Wyoming</td>
<td>$245,900</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>$1,867,900</td>
</tr>
<tr>
<td>Total</td>
<td>$63,920,000</td>
</tr>
</tbody>
</table>

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 1976 performance was determined to be satisfactory as recorded in the quarterly Program Status Summary (PSS) reports which are used to assess the grantee's 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 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 resulting at least 85 percent of the planned goal. (For factor 1, level of nonpositive terminations, the grantee was given a positive mark when they demonstrated satisfactory performance for each factor; for factor 11, level of nonpositive terminations, the grantee was given a positive mark when they demonstrated satisfactory performance for each factor. Each grantee was given a positive mark when they demonstrated satisfactory performance for each factor.)

For each factor, each grantee was given a positive mark when they demonstrated satisfactory performance for each factor. Each grantee was given a positive mark when they demonstrated satisfactory performance for each factor. Each grantee was given a positive mark when they demonstrated satisfactory performance for each factor.

The Secretary of Labor will exercise the option contained in 29 CFR 97.219(a) to negotiate Fiscal Year 1978 grants without recompetition. Consequently, all States or areas that did not recompete last year were also excluded from the competitive list.

The following are the organizations which demonstrated satisfactory performance and were selected as grantee for Fiscal Year 1978 sponsor status:

<table>
<thead>
<tr>
<th>States</th>
<th>Fiscal Year 1978 Sponsors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
<td>Alabama Migrant and Seasonal Farmworker Statewide Council.</td>
</tr>
<tr>
<td>California</td>
<td>Colorado of Los Angeles.</td>
</tr>
<tr>
<td>Iowa</td>
<td>Community Action Council of South Texas.</td>
</tr>
<tr>
<td>Louisiana</td>
<td>Economic Opportunities Development Corporation of San Antonio.</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>Farmworkers Corp. of New Jersey.</td>
</tr>
<tr>
<td>Michigan</td>
<td>Farmworkers Corp. of New Jersey.</td>
</tr>
<tr>
<td>Minnesota</td>
<td>Farmworkers Corp. of New Jersey.</td>
</tr>
<tr>
<td>Missouri</td>
<td>Farmworkers Corp. of New Jersey.</td>
</tr>
<tr>
<td>Nevada</td>
<td>Farmworkers Corp. of New Jersey.</td>
</tr>
<tr>
<td>New Mexico</td>
<td>Farmworkers Corp. of New Jersey.</td>
</tr>
<tr>
<td>New York</td>
<td>Farmworkers Corp. of New Jersey.</td>
</tr>
<tr>
<td>Ohio</td>
<td>Farmworkers Corp. of New Jersey.</td>
</tr>
<tr>
<td>Oklahoma</td>
<td>Farmworkers Corp. of New Jersey.</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>Farmworkers Corp. of New Jersey.</td>
</tr>
<tr>
<td>Texas</td>
<td>Farmworkers Corp. of New Jersey.</td>
</tr>
<tr>
<td>Utah</td>
<td>Farmworkers Corp. of New Jersey.</td>
</tr>
<tr>
<td>Virginia</td>
<td>Farmworkers Corp. of New Jersey.</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>Farmworkers Corp. of New Jersey.</td>
</tr>
</tbody>
</table>

Intra-State planning estimates for Texas and California will be published on a per county basis to enable applicants for funding in areas not closed to competition to prepare including requiring grants 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 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.

Ernest G. Green,
Assistant Secretary for Employment and Training.
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 5555 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.
SUPPLEMENTARY INFORMATION: The principal author of this proposed rulemaking is Allan W. Strobel of the Bureau of Land Management, Washington Office, Division of Range Management, assisted by staff of the Division of Legislation and Regulatory Management and Gall L. Achterman of the Solicitor's Office, Department of the Interior.

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 cumbersome and time consuming. 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 objectives of the existing regulations, allocating grazing preferences among ranch operations, was essentially accomplished by 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 cannot only be accommodated through land use planning for multiple use to minimize adverse impact on the land and its resources. Therefore, the proposed regulations based grazing allocations on land location and 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 Lands 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 revenues, 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 land use plans. The statutory provision thus affirms previously adopted administrative policy. 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 regulation in the new Act, some comments are no longer appropriate. The proposed rulemaking was amended and clarifying language added in several places as a result of the greenhouse received. Interested and affected persons and organizations should critically examine this current proposed rulemaking and comment again.

DISCUSSION OF COMMENTS RECEIVED ON THE PROPOSED RULEMAKING OF JULY 28, 1976

SHOULD ALLOCATION OF GRAZING USE BE BASED ON HISTORICAL USE OF THE 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 was clarified by limiting its use to comments that grazing would no longer be allocated on the basis of historic use by dependent private property owners. The concept of commensurability, basing grazing preference 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 grazing. The new proposed regulations do not require the crops or forage to actually be produced. Base land 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 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 decision. The comments also criticized the provision allowing the Bureau to specify the breed of livestock in a permit or lease. This provision was included because of the importance of livestock breed when setting grazing capacity. Comments also criticized prohibiting placing feed or mineral supplements on public lands without authorization. Many noted that salt placement is a necessary and proper part of livestock management which should not require prior authorization. We agree and the new proposed regulations have been changed accordingly.
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 and the sale, vegetative or other public land resources usually in such cases 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 proposed grazing rules with the Bureau and they are billed for scheduled use unless a change in use is allowed in advance. Many comments suggested that changes be allowed up until the first day of the grazing season or year. The suggestion was not adopted because 30 days is needed to evaluate the compatibility of the proposed change with existing operations and management objectives for the allotment and to complete necessary administrative requirements.

SHOULD WILFUL AND NONWILLFUL TRESPASS BE DISTINGUISHED?

Many comments criticized the proposed rules for failing to treat wilful and non-wilful trespass differently. Ranchers believed the penalties were too severe in cases of non-wilful trespass. Environmental groups and others believed they were too lenient in cases of wilful trespass. The existing rules allow collection of twice the value of the forage consumed in the case of wilful trespass. It was suggested the proposed rules did not. The new proposed rules distinguish between wilful and non-wilful trespass and reinstate the double damage provision in cases of wilful 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 these 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 lands with livestock grazing are grouped together and these 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 containing that no one knows who this person is. While we agree that the term causes some confusion, it would be even more confusing to state explicitly who the authorized officer is 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. The徭 authorized delegate has been delegated the authority, through specific Secretarial Bureau delegations, to carry out the management responsibilities of the Secretary of Interior in 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, system of management, and environmental needs. Any Area Manager or District Manager 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 re-establishment of grazing district advisory boards. This was done in a limited way by the Federal Land Policy and Management Act. Regulations governing the 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 concerning the conservation or protection of natural or 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 contended 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 have been violated. These comments have been thoroughly reviewed. The rule proposed in July has not been changed. First, it should be noted that the Bald Eagle Protection Act and the Endangered Species Act do not allow reduction or cancellation of grazing permits or leases only following criminal conviction. This standard was adopted in the proposed rules in order to provide due process and because the Bureau cannot not 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 DOMESTIC 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 permittees and lessees on available forage to provide forage 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 livestock grazing needs. No priority is given to one forage 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 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 define 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 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 purpose of these regulations is to provide for the uniform administration and management of livestock grazing on the public lands, exclusive of Alaska.

§ 4100.0—Objectives

The purpose of these regulatory is to provide for the uniform administration and management of livestock grazing on the public lands, exclusive of Alaska.

Subpart 4170—Penalties

Sec. 4170.3 Final decisions.
4170.4 Appeals.

Subpart 4140—Administrative Remedies

Sec. 4140.3 Final decisions.
4140.4 Appeals.

Subpart 4120—Grazing Permit—Exclusive of Alaska

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 improvement.
4120.6-5 Removal and compensation for loss of range improvements.
4120.6-6 Contributions.

Subpart 4130—Grazing Lease

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.
4130.2-8 Cross permits.
4130.2-9 Fees.
4130.2-10 Payment of fees.
4130.2-11 Permit fees.
4130.2-12 Service charges.
4130.2-13 Changes in grazing use.
4130.2-14 Payment of interest as security for loan.

Subpart 4140—Penalty for Violations

Sec. 4140.1 Penalty for violations.
4140.2 Demand for payment.
4140.3 Impoundment and disposal.
4140.4 Notice of intent to impound.
4140.5-2 Notice of public sale.
4140.5-3 Redemption.
4140.5-4 Sale.

Subpart 4150—State Livestock Requirements

Sec. 4150.1 State livestock requirements.
4150.2 Allotments.
4150.3 Terms and conditions.
4150.4 Allotment management plans.
4150.5 Closure to livestock.

Subpart 4160—Disposal

Sec. 4160.1 Penalties.
4160.2 Protests.
4160.3 Final decisions.
4160.4 Appeals.

Sec. 4170.2 Federal and State law or regulations.
4170.3 Federal or State law or regulations.
4170.4 Feral provisions.

Authority: Sec. 43 U.S.C. 315, 315a-315r, 1781 et seq.
ple-use, environmental, economic, and other objectives as stated in Subpart 1725 of this chapter and in Section 1.02 of the Federal Land Policy and Management Act of 1976, Pub. L. 94–579, 90 Stat. 2745 (43 U.S.C. 1701 et seq.).

§ 4100.0—3 Authority.

(a) The Taylor Grazing Act of June 28, 1934, as amended (43 U.S.C. 315 et seq.), 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 improvement of the public lands and directs the Secretary to manage these lands under principles of multiple use and sustained yield in accordance with land use plans.

(c) The Federal Land Policy and Management Act of 1976 authorizes the Secretary to administer livestock grazing on specified lands in accordance with land use plans.

(d) The Taylor Grazing Act or other authority as specified.

§ 4100.0—4 Definitions.

Whenever used in this part, unless the context otherwise requires, the following definitions apply:


(b) “Allotment” means an area of land designated and managed for grazing of livestock.

(c) “Allotment management plan (AMP)” means a documented program which applies to livestock operations on the public lands, which is prepared in consultation with the permittee(s) or lessee(s) involved, and which (1) specifies the manner in which and extent to which livestock operations will be conducted in order to meet the multiple use and sustained-yield, economic, and other needs and objectives; and (2) describes the type, location, ownership, and general specifications for the improvements to be installed and maintained on the public lands to meet the livestock grazing and other objectives of land management; and (3) 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 one month. 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 grazing lease and grazing preference in whole or in part.

(h) “Class of livestock” means age and/or sex groups of a kind of livestock.

(i) “Contiguous land” means lands 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 to determine fee rates.

(m) “Grazing lease” means a document authorizing use of the 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, goats, and horses.

(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 expired 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 State or 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” means the rehabilitation, protection, and improvement of the public lands to arrest range deterioration and to improve forage conditions, fish and wildlife habitat, watershed protection, and livestock production consistent with land use plans.

(v) “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 centum of all moneys received by the United States as fees for grazing livestock on public lands.

(w) “Range improvement” means a structure, development, or treatment used to rehabilitate, protect, or improve the public lands to advance range betterment.

(x) “Secretary” means the Secretary of the Interior or his authorized officer.

(y) “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 §§ 4103.3 and 4139.4–3, to qualify for grazing use on the public lands an applicant must be engaged 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 § 4110.0—3(f)) if:  

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
(1) It is used in conjunction with a livestock operation which utilizes public lands within a grazing district; or
(2) It is contiguous land, and in certain cases non-contiguous land, used in conjunction with a livestock operation which utilizes wildlife lands outside a grazing district.

(b) The authorized officer shall specify the length of time for which land base property shall be capable of supporting the livestock operation, during the year, taking into consideration the availability and customary use of base properties and the management requirements for the public lands.

(c) An applicant shall provide a legal description of his base property and shall certify to the authorized officer that this base property meets the requirements under paragraph (a) and (b) of this section and § 4110.0-5(d).

§ 4110.2-2 Grazing preference allocation.

(a) Grazing preference shall be allocated to qualified applicants following the allocation of the forage resources between livestock grazing, wild free-ranging 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 lands include 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 the whole tract.

(c) If a grazing preference is attached to base property, the transferee shall file with the authorized officer a properly executed transfer document or a transfer application under paragraph (b) or (c) of this section.

(d) If base property is sold or leased, the transferee shall file with the authorized officer a properly executed transfer document or transfer application 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, and shall approve the assignment of interest and obligation in range improvements on the public lands, and shall issue a grazing permit or lease.

(e) If a grazing preference is being transferred to another base property, the transferee shall file with the authorized officer a properly executed transfer document or transfer application and the amount of grazing preference being transferred, in animal unit months, (1) include a legal description of the old and new base property, (2) contain the concurrence of any lien holder, and (3) 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 whose livestock operation is the grazing preference would not have been established, in which case the consent of the owner(s) of the base property is not required. If the transfer application is 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. The transferee shall file with the authorized officer a properly executed transfer document or transfer application and the amount of grazing preference or any outstanding grazing permit or lease based on such property (s) of the permittee(s) or lessee(s) authorized to graze in the allotment in which the forage is available.

(f) Failure of the transferee to comply with the regulations of this section may 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. No such relinquishment shall be accepted without the written concurrence of any lien holder and the written consent of the owner(s) of the base property to which the preference is attached, unless the applicant is a lessee of the base property without whose livestock operation a grazing preference would not have been established.

§ 4110.3 Changes in available forage.

§ 4110.3-1 Additional forage.

Additional forage may be allocated to qualified applicants for livestock grazing use at the discretion of the authorized officer if this use is consistent with the land use plans.

(a) Additional forage temporarily available, including forage which is temporarily available within an allotment because of a change in grazing use under § 4120.6, may be allocated on a nonrenewable basis.

(b) Additional forage permanently available for livestock grazing use shall be allocated to qualified applicants for livestock grazing use having preference to the acres of the base property involved are located.

(c) If a grazing preference is being transferred, the authorized officer may approve the assignment of interest and obligation in range improvements on the public lands, and shall 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 testamentary disposition, such transfer will not affect the grazing preference or any outstanding grazing permit or lease based on such property for a period of 2 years after the transfer. However, such a transferee shall qualify under paragraph (a) of this section within the 2-year period or the grazing preference shall be subject to cancellation. The authorized officer may grant extensions of the 2-year period where there are delays solely attributable to the administration by the Bureau of Land Management, or the economic impacts on the affected permittees or lessees.

§ 4110.5 Changes in public land acreage.

§ 4110.5-1 Additional land acreage.

When land outside designated allotments becomes available for grazing administration by the Bureau of Land Management, the forage available for livestock grazing may be allocated to qualified applicants at the discretion of the authorized officer if this use is consistent with the land use plans. If there are applicants who were previously authorized to make grazing use of these lands, they shall have the priority of the preference to grazing use of the additional lands.
Otherwise, grazing use will be allocated under § 4110.5.

§ 4110.4-2 Decrease in land acreage.

(a) Where there is a decrease in public land acreage available for livestock grazing within a allotment, grazing permits of grazing leases and grazing preferences shall be cancelled in whole or in part. The cancellations will be equally apportioned by the authorized officer and shall not be made or entered into, or accepted by or on behalf of the United States, unless it has been determined that allotment management plans are necessary, the authorized officer shall incorporate terms and conditions of the condition under this section in grazing permits or leases, or have them changed. The condition under § 4110.3-2 and 4110.4-2. These modifications and cancellations may be made at anytime 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 permittee(s) or lessee(s), approved by the authorized officer and implemented (see § 4100.9-0(c)). The allotment management plan shall include appropriate terms and conditions under § 4120.2-1 and shall prescribe a system of grazing designed to meet specific management objectives. The plan shall include the flexibility within which the permittee or lessee 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 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 permittee(s) or lessee(s).

(d) If allotment management plans have not been prepared, the authorized officer shall incorporate terms and conditions under grazing permits or leases when they is issued. If grazing permits or leases have been issued prior to the preparation of allotment management plans, the authorized officer shall incorporate these plans in the grazing permits or leases when these plans are completed.

(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, vegetation, or other resources of the public lands, the authorized officer may close allotments to grazing by any kind of livestock and for any period of time. The action taken by the authorized officer shall be specified in a notice of closure. The notice of closure 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 § 4160.3(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 livestock 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. The document shall be prepared in consultation with the affected permittee(s) or lessee(s), approved by the authorized officer and implemented (see § 4100.9-0(c)). The allotment management plan shall include appropriate terms and conditions under § 4120.2-1 and shall prescribe a system of grazing designed to meet specific management objectives. The plan shall include the flexibility within which the permittee or lessee 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) All cattle, horses, and burros over 6 months of age shall carry a brand which has been filed with the authorized officer. All sheep and goats over 6 months of age shall be identified with an ear-mark, paint brand, or other marking that has been filed with the authorized officer.

(c) The authorized officer may exempt certain livestock from the mini-
mum requirements under paragraph (b) of this section. An alternative method of identifying the livestock satisfactorily to the authorized officer shall be used in such instances.

3. The authorized officer may require additional or special marking or tagging of the authorized livestock in order to control trespass or in order to otherwise promote the orderly administration of the public lands.

§ 4120.5 State livestock requirements.

Authorized users shall comply with the requirements of the States, which apply to the authorized livestock, as the authorized officer determines.

§ 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 Department. For the purpose of range betterment funds collected for the purpose of on-the-ground range rehabilitation, protection, and improvement of public lands, the States are authorized to install and/or maintain range improvements on public lands as of the date of transfer. If the authorized officer determines that the improvements are no longer serving the purpose for which they were installed or if they fail to meet the standards and design criteria under § 4120.8-3, they shall be removed at the expense of the authorized officer.

(b) Range improvements shall be installed, used, maintained, and/or modified on the public lands in a manner consistent with the land use plans. Prior to installing, using, maintaining and/or modifying range improvements on the public lands, permits 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 range improvements in the land use plans. Where an existing range improvement is significantly inconsistent with these objectives, the authorized officer may modify the improvement to reflect needed changes. Upon failure of the permittee or lessee to comply with the standards and design specified by the authorized officer or failure to correct improvements in the authorized officer's order to modify an existing range improvement, authorization for the improvement may be canceled.

§ 4120.6-4 Assignment of range improvements.

The authorized officer shall not approve the transfer of a grazing preference under § 4112.3-1 nor approve use by the transferee of an existing range improvement, unless the transferee has agreed to compensate the transferor for fair market value of his interest in the authorized improvements within the authorized officer's order to modify an existing range improvement. 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 serving the purpose for which they were installed or if they fail to meet the standards and design criteria under § 4120.8-3.

(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 voted to a public purpose which precludes livestock grazing, the permittees or lessees shall receive fair market value from the United States for their interest in range improvements located on the public lands (les value) which will no 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 material 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 to share proportionately with other authorized users, 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 of the public lands, he may recommend such a rule to the Director. These recommendations shall be subject to public review and comment, as appropriate, before they 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 served upon any parties who are interested in grazing 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 active grazing use, non-use, or combination of active grazing use and nonuse that is authorized and shall include appropriate terms and conditions under § 4120.2.

(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 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 necessary to achieve the objectives in the land use plans or if the land use plans have not been completed. The abovementioned grazing permits or leases shall not be the basis for establishing a term shorter than ten years.

(d) Permittees or lessees holding expiring grazing permits or leases shall be...
given first priority for receipt of new permits or leases if:

1. The lands remain available for livestock grazing in accordance with land use plans (see Subpart 4120).

2. The permittee or lessee is in compliance with the regulations contained in this part and the terms and conditions of his grazing permit or lease.

3. The permittee or lessee accepts the terms and conditions to be included in the new permit or lease by the authorized officer.

§ 4139.2-1 Regular permits or leases.

Regular permits or leases shall be issued for terms of from 1 up to and including 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.

§ 4139.2-2 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 permit or leases.

§ 4139.2-3 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.

§ 4139.3 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 domestic livestock operations. Free-use grazing permits are paid for in full or in part, or fee payment may be deferred until the current market value as determined by the authorized officer, the Bureau of Land Management, or the Secretary in equal annual increments, as otherwise specified in the permit or lease.

§ 4139.4-2 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. These permits shall be charged 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 § 4130.3-1.

§ 4139.4-3 Cross-permits.

Any applicant showing the necessity for grazing the public land with livestock for proper and lawful purposes may be issued a cross-permit upon payment of a fee as otherwise specified in the permit or lease issued on the allotment in which the land offered in exchange is located.

§ 4139.4-4 Cross-Use of public lands.

Any applicant showing the necessity for grazing the public land with livestock for proper and lawful purposes may be issued a grazing permit or lease on 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 charged for livestock grazing on 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 in or on public lands not under Bureau of Land Management control, which are the natural increase of livestock which fees are paid for those born during the season for which the permit or lease authorizes use, and until they are 12 months of age.

§ 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 in or on public lands not under Bureau of Land Management control, which are the natural increase of livestock which fees are paid for those born during the season for which the permit or lease authorizes use, and until they are 12 months of age.

§ 4130.5-2 Refunds.

(a) Grazing fees may be refunded at the discretion of the authorized officer where applications for change in grazing use and related refund are filed prior to the period of use for which the refund is requested.

(b) No refunds shall be made for failure to make grazing use, except during periods or range depletion due to severe drought, fire, or other natural or general epidemic of disease that occurs during the term of a permit or lease.

§ 4130.5-3 Service charge.

Except for actions initiated by the authorized officer, a service charge of $25 shall be made for each transfer of a permit or lease 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 and class and number of livestock, the season(s) of use, the amount of use, and the expiration date of the expiration of the grazing permit or lease.

(b) Requests for grazing use different from the basic grazing schedule should be issued for a term of not more than 10 years. The expiration date of the change-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 the provisions of this part 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. These permits shall be charged 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 § 4130.3-1.

§ 4130.4-3 Cross-permits.

Any applicant showing the necessity for grazing the public land with livestock for proper and lawful purposes may be issued a cross-permit upon payment of a fee as otherwise specified in the permit or lease issued on the allotment in which the land offered in exchange is located. This part and the terms and conditions of any existing management plan for the specific purpose of allowing the grazing of livestock shall be published annually in the Federal Register.
be filed with the authorized officer no later than 30 days before the grazing season or year. Requests for change in use shall be filed no 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 § 4130.5.

(e) 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.

§ 4130.7 Pledge of permit or lease as security for loan.

The authorized officer shall renew a grazing permit or lease that has been pledged as security for a loan from a lending agency for a period of not to exceed 10 years if the loan is for the purpose of furthering the permittee's or lessee's livestock operation, Provided, That the permittee or lessee has complied with the rules and regulations of this part and that such renewal will be in accordance with other applicable laws and regulation.

Subpart 4140—Prohibited Acts

§ 4140.1 Acts prohibited on public lands.

The following acts by permittees and lessees are prohibited on public lands and other lands under Bureau of Land Management control:

(a) Allowing livestock on or driving livestock across these lands in violation of the terms and conditions of a permit or lease, either by exceeding the number of livestock authorized, or by allowing livestock to be on these lands in an area or at a time different from that designated;

(b) Failing to make substantial grazing use as authorized for 2 consecutive years;

(c) Placing feed or mineral supplements, other than salt, for livestock on these lands without authorization;

(d) Failing to comply with the terms of a range improvement cooperative agreement or range improvement permit;

(e) Refusing to finance individually, or to share proportionately with other permittees or lessees, the cost of installation, maintenance and/or modification of range improvements when so directed by the authorized officer if the permittee or lessee will benefit in substantial measure or should reasonably be responsible for such costs;

(f) Installing, using, maintaining, and/or modifying range improvements on these public lands without authorization;

(g) Cutting, burning, spraying, destroying, or removing vegetation without authorization;

(h) Damaging or removing United States property without authorization;

(i) Moisting livestock unlawfully grazing on these lands;

(j) Littering;

(k) Violating any provision of Part 4700 of this subchapter concerning the protection and management of wild free-roaming horses and burros;

(l) Violating any Federal or State law or regulation concerning conservation or protection of natural and cultural resources or the environment including, but not limited to, those relating to air and water quality preservation, and the use of chemical and wildlife, plants, and the use of chemical toxicants;

(m) Interfering with lawfully uses of users;

(n) Knowingly or willfully making a false statement or representation in association applications, range improvement permit applications, and/or amendments therein.

Subpart 4150—Unauthorized Grazing

§ 4150.1 Unauthorized grazing.

Allowing livestock on or driving livestock across public lands and other lands under Bureau of Land Management control without proper authorization is prohibited and constitutes unauthorized grazing use. See § 4140.1(a). Violators shall be liable in damages to the United States for the forage consumed by the unauthorized livestock, for injury to Federal property caused by their unauthorized grazing use, and for expenses incurred in impoundment and disposal, and may be subject to civil penalties or criminal sanction for such unlawful acts.

§ 4150.2 Notice and order to remove.

(a) Whenever it appears that a violation exists and the owner of the unauthorized livestock is known, written notice shall be served upon the alleged violator or his agent by certified mail, or personal delivery and a copy of the notice shall be sent to any known lien holder. The notice shall set forth the act or omission constituting the violation and refer to the specific terms, conditions, or rules of the permit or lease alleged to have been violated. It shall also order the alleged violator to remove the livestock within a specified time. The notice shall allow a special permit to be issued and notice to the alleged violator to show that there has been no violation or to make settlement under § 4150.3. If the alleged violator fails to comply with the notice, the authorized officer may proceed to impound the livestock under § 4150.5.

(b) Where neither the owner of the unauthorized livestock nor his representative is known, the authorized officer may proceed to impound the livestock under § 4150.5.

(c) A notice alleging unauthorized horse or burro use in areas with wild free-roaming horses and burros shall specify that the unauthorized horses or burros can be claimed and gathered only in accordance with the procedures of Part 4700 of this subchapter.

§ 4150.3 Settlement.

The authorized officer shall weigh the facts and circumstances of the case and shall determine if the violation is nonwillful or willful and whether it is a repeated violation. When violations are determined to be nonwillful, 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 which will substantially reduce the amount due the United States in settlement for unauthorized grazing use shall be determined by the authorized officer as follows:

(1) "Nonwillful violations." The value of forage consumed as determined by the average monthly rate for pasture 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.

§ 4150.4 Demand for payment.

Where the livestock have been removed, but satisfactory settlement has not been made within the time allowed under § 4150.2, 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 allow not more than 15 days from date of receipt to settle the obligation.

§ 4150.5 Impoundment and disposal.

Unauthorized livestock remaining on public lands after the date set forth in the notice and order to remove under § 4150.2 may be impounded and disposed of by the authorized officer as provided herein.

§ 4150.5-1 Notice of intent to impound.

(a) A written notice of intent to impound shall be sent by certified mail or personally delivered to the owner, or his agent, and a copy of the notice shall be sent to any known lien holder. Any time after the 5 days of delivery of the notice the unauthorized livestock may be impounded.

(b) Where the owner or agent is unknown, or a known owner or agent refuses to receive or to acknowledge receipt of the notice, notice to impound shall be published in a local newspaper and posted at the county courthouse and a post office near the public land involved. Any time after 5 days of the posting of the notice, the unauthorized livestock may be impounded.

(c) Unauthorized livestock may be impounded without further notice any time within the 12-month period following the effective date of a notice given under this provision.
§ 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. The proposed decision shall provide for a period of 15 days before the date and time fixed for the sale. The sale date shall be at least 3 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 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. If the livestock is sold for less than the highest bid or for less than the amount due under § 4150.3 and the action to be taken under § 4170.1. The proposed decision shall provide for a period of 15 days after receipt for the filing of a protest.

§ 4160.2. Protests.

Any applicant, permittee, lessee, or any other person adversely affected by 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 the 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 known interested individual, 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 decision on appeal therefrom. Final decision shall be in full force and effect only if required for the orderly administration of the range or for the protection of other resource values. See § 4.477 of this title.

§ 4160.4. Appeals.

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 § 4.479 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. Penalties 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 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.

Failing to make substantial grazing use as authorized for 2 consecutive fee years may result in the cancellation of the grazing preference only to the extent of failure to use see § 4140.1(b).

§ 4170.1-2. Conservation and protection of resources.

Violation of § 4140.1 may result in suspension, reduction, or revocation of a permit, lease, or grazing preference where:

(a) Public land administered by the Bureau of Land Management is involved;

(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. Penal provisions.

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, 4730.3, 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-
tection, domestic livestock, maintenance of environment quality, wildlife, and other factors will be considered along with wild free-roaming horse and burro requirements. After determining the optimum number of such horses and burros to be maintained on an area, the authorized officer shall reserve adequate forage and satisfy other biological requirements of such horses and burros and, when necessary, adjust or exclude domestic livestock use accordingly. See §§ 4110.2-2 and 4110.3-2 of this subchapter.

§ 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.

PART 9230—TRESPASS

3. Part 9230 is amended by deleting §§ 9239.3, 9239.3-1, and 9239.3-2 and redesignating "§ 9239.3-3 Alaska." as "9239.3 Grazing, Alaska." as follows:

§§ 9239.3—9239.3-2 [Deleted]

§ 9239.3 Grazing, Alaska. [Redesignated from § 9239.3-3]

GUY R. MARTIN,
Assistant Secretary of the Interior.

JULY 6, 1977.
[FR Doc.77-19908 Filed 7-7-77;8:45 am]
Public Papers of the Presidents of the United States

Annual volumes containing the public messages and statements, news conferences, and other selected papers released by the White House.

Volumes for the following years are now available:

**HERBERT HOOVER**

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1929</td>
<td>$13.30</td>
</tr>
<tr>
<td>1930</td>
<td>$16.00</td>
</tr>
</tbody>
</table>

**HARRY S. TRUMAN**

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1945</td>
<td>$11.75</td>
</tr>
<tr>
<td>1946</td>
<td>$10.80</td>
</tr>
<tr>
<td>1947</td>
<td>$11.15</td>
</tr>
<tr>
<td>1948</td>
<td>$15.95</td>
</tr>
<tr>
<td>1949</td>
<td>$11.80</td>
</tr>
<tr>
<td>1950</td>
<td>$13.85</td>
</tr>
<tr>
<td>1951</td>
<td>$12.65</td>
</tr>
<tr>
<td>1952-53</td>
<td>$18.45</td>
</tr>
<tr>
<td>1953</td>
<td>$14.50</td>
</tr>
<tr>
<td>1954</td>
<td>$10.80</td>
</tr>
<tr>
<td>1955</td>
<td>$13.85</td>
</tr>
<tr>
<td>1956</td>
<td>$14.50</td>
</tr>
<tr>
<td>1957</td>
<td>$14.50</td>
</tr>
<tr>
<td>1958</td>
<td>$14.70</td>
</tr>
<tr>
<td>1959</td>
<td>$14.95</td>
</tr>
<tr>
<td>1960-61</td>
<td>$16.95</td>
</tr>
</tbody>
</table>

**Dwight D. Eisenhower**

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1953</td>
<td>$14.60</td>
</tr>
<tr>
<td>1954</td>
<td>$17.20</td>
</tr>
<tr>
<td>1955</td>
<td>$14.50</td>
</tr>
<tr>
<td>1956</td>
<td>$17.30</td>
</tr>
<tr>
<td>1957</td>
<td>$14.50</td>
</tr>
<tr>
<td>1958</td>
<td>$12.65</td>
</tr>
<tr>
<td>1959</td>
<td>$14.95</td>
</tr>
<tr>
<td>1960-61</td>
<td>$17.30</td>
</tr>
<tr>
<td>1962</td>
<td>$18.45</td>
</tr>
<tr>
<td>1963</td>
<td>$14.35</td>
</tr>
<tr>
<td>1964</td>
<td>$13.30</td>
</tr>
<tr>
<td>1965</td>
<td>$12.35</td>
</tr>
</tbody>
</table>

**JOHN F. Kennedy**

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1961</td>
<td>$14.35</td>
</tr>
<tr>
<td>1962</td>
<td>$15.55</td>
</tr>
<tr>
<td>1963</td>
<td>$15.35</td>
</tr>
</tbody>
</table>

**Lyndon B. Johnson**

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1963-64 (Book I)</td>
<td>$15.00</td>
</tr>
<tr>
<td>1963-64 (Book II)</td>
<td>$15.25</td>
</tr>
<tr>
<td>1965 (Book I)</td>
<td>$12.25</td>
</tr>
<tr>
<td>1965 (Book II)</td>
<td>$12.35</td>
</tr>
<tr>
<td>1966 (Book I)</td>
<td>$13.30</td>
</tr>
<tr>
<td>1966 (Book II)</td>
<td>$12.25</td>
</tr>
<tr>
<td>1967 (Book I)</td>
<td>$12.85</td>
</tr>
<tr>
<td>1967 (Book II)</td>
<td>$13.50</td>
</tr>
<tr>
<td>1968-69 (Book I)</td>
<td>$14.05</td>
</tr>
<tr>
<td>1968-69 (Book II)</td>
<td>$12.80</td>
</tr>
</tbody>
</table>

**Richard Nixon**

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1969</td>
<td>$17.15</td>
</tr>
<tr>
<td>1970</td>
<td>$18.30</td>
</tr>
<tr>
<td>1971</td>
<td>$18.85</td>
</tr>
<tr>
<td>1972</td>
<td>$18.55</td>
</tr>
<tr>
<td>1973</td>
<td>$16.50</td>
</tr>
<tr>
<td>1974</td>
<td>$12.30</td>
</tr>
</tbody>
</table>

**Gerald R. Ford**

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1974</td>
<td>$16.00</td>
</tr>
</tbody>
</table>

Published by Office of the Federal Register, National Archives and Records Service, General Services Administration

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-0094]

Over-the-Counter Drugs

Establishment of a Monograph for OTC Internal Analgesic, Antipyretic and Anti­rheumatic 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.

Address: Written comments to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

For Further Information Contact:
William E. Gilbertson, Division of OTC Drug Evaluation (HFD-510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857.

Supplementary 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)(6) (21 CFR 330.10(a)(6)), the Commissioner is issuing this proposed rule containing the monograph recommended by the Panel establishing conditions under which OTC internal analgesic, antipyretic and antirheumatic products are generally recognized as safe and effective and not misbranded; a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that they would result in the drug not being generally recognized as safe and effective or would result in misbranding; a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that the available data are insufficient (Category II) 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; a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that the available data are insufficient (Category II) 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; a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that the available data are insufficient (Category II) 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; a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that the available data are insufficient (Category II) 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.

The Commissioner recognizes that new additional data or information not previously available to the Panel regarding the safety, effectiveness and appropriate labeling of the additional antacid ingredients 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. 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 conclusions 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 scientific 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 approved. The Panel's recommendations may include revisions in labeling, particularly limitations of indications for use, and additional warnings against unsafe use. In addition, revised dosage schedules may become necessary.

In the final order for antacid products published in the Federal Register of June 4, 1974 (39 FR 19662), the antacid monograph provides that any safe and effective analgesic, as determined by the internal analgesic monograph, may be used in combination with an antacid for the treatment of occasional minor aches, pains, and for acid indigestion and for acid indigestion and for acid indigestion and for acid indigestion and for acid indigestion and for acid indigestion. The Commissioner recognizes that the revised dosage schedules recommended by the Panel may be required by the final order for antacid products.
and pH and the product is identified as highly buffered aspirin for solution with labeling only as analgesic and/or antipyretic.

At some 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 anti-rheumatic 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 due to establishment of 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 of the Advisory Review Panel on OTC Internal Analgesic 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 environmental impact assessment is on file with the Office of the Hearing Clerk, Food and Drug Administration, Rm. 4-63, 5500 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 follows:

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 § 330.10 (formerly § 130.361). (See the Federal Register of May 11, 1972 (37 FR 9044), which were made effective immediately. Pursuant to these regulations, the Commissioner issued in the Federal Register of July 21, 1972 (37 FR 14633) 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. Winston Bellville, M.D., Chairman from August, 1976
William H. Barr, Ph.D.
Julius M. Coon, M.D., Ph.D.
Ina F. Redmond, Ph. D., resigned January, 1977
Naomi F. Rothfield, M.D.
George Sharpes, M.D.

The Panel was first convened on October 24, 1972 in an organizational meeting. Working meetings were held on November 21 and 22, 23, February 28 and 27, April 12 and 13, November 10 and 12, July 30 and 31 and September 25 and 26, October 22 and 23, November 19 and 20, and December 17 and 18, 1972; March 11 and 12, April 10 and 11, May 8 and 9, July 8, 9 and 10, September 25 and 26, October 11 and 12, and December 9 and 10, 1973; February 25, 26 and 27, August 14 and 15, October 8 and 9, November 10 and 19, 1975; April 8 and 9, May 20 and 21, 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 Elmers Van Els, nominated by the Consumer Federation of America, served as the consumer liaison and Joseph M. Pisani, M.D., nominated by the Proprietary Association, served as the industry liaison.

The following FDA employees served: Brigitta Dussler, M.D., served as Executive Secretary and continued until August 1976 following by Lee Geismar who also served as Panel Administrator. Lee Quon, R.Ph., served as Drug Information Analyst until August 1973, followed by Thomas H. McMahon, M.D., until May 1976, 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 present their views at the meeting:

Cleland Baker
Dorothy L. Carter-Staples, M.D.
Robert B. Chase, M.D.
John M. Clayton, M.D.
A. R. Cook, M.D.
Harold H. Cooper, Ph.D.
Constantine J. Pallides, M.D.
Edward W. Fishel, M.D.
George S. Goldstein, M.D.
Arthur Grollman, M.D.
Robert John, M.D.
George S. Goldstein, M.D.
Julius M. Coon, M.D., Ph.D.
John Baum, M.D.
David Katz, M.D.
Harold Mielke, M.D.
John M. Clayton, Ph.D.
Gordon Benson, M.D.
Ronald F. Miller, M.D.
William T. Beaver, M.D.
John M. Clayton, M.D., Ph.D.
Sidney Wolfe, M.D.
J. W. Hoyer, M.D.
Dietrich Lorke, M.D. (Germany)
George S. Goldstein, M.D.
W. K. Poole, M.D.
Ninfa I. Redmond, Ph. D., resigned January, 1977
Mervyn A. Sahud, M.D.
Arthur M. Kass, M.D.
Stunner J. Yaffe, M.D.
George S. Goldstein, M.D.
Sidney Wolfe, M.D.
Mervyn A. Sahud, M.D.
Ninfa I. Redmond, Ph. D., resigned January, 1977
Ronald G. Murray, M.D.
J. Edward Smiley, M.D.
Arthur Grollman, M.D.
John M. Clayton, M.D., Ph.D.
S. I. Rapaport, M.D.
H. M. Gault, M.D.
Dietrich Lorke, M.D. (Germany)
Dietrich Lorke, M.D. (Germany)
Dietrich Lorke, M.D. (Germany)
Dietrich Lorke, M.D. (Germany)

The following individuals were given an opportunity to appear before the Panel: John M. Clayton, Ph.D.
William T. Beaver, M.D.
Gordon Benson, M.D.
Ronald F. Miller, M.D.
Arthur Grollman, M.D.
Henry M. Gault, M.D.
Thomas Haley, M.D.
Raymond Houndé, M.D.
W. Hoover, M.D.
Harold Mielke, M.D.
Ronald F. Miller, M.D.
S. I. Rapaport, M.D.
Jane Schaller, 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 submissions, 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—ANTIRHEUMATIC 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 not generally recognized as safe and effective or are misbranded.

William Madison, Ph.D.
Arnold D. Marcus, M.D.
S. I. Rapaport, M.D.
J. Gilbert McMahon, M.D.
Bernard L. Mirkin, M.D.
Fred Mueller
William R. T. Barlow, M.D. (Australia)
William M. O'Brien, M.D.
Peter D. Orlovakas, M.D.
W. E. Poole, M.D.
Laurje Prellott, M.D. (Scotland)
Adien R. L. Ringette, Esq.
Mervyn A. Sahud, M.D.
George Schleiner, M.D.
Ceci Sione, M.D., C.H.B., D.P.H.
J. Edward Smiley, M.D.
Ralee Sweeney, Ph.D.
Garrett W. Swenson, Esq., R.Ph.
Monte E. Trout, M.D.
Walter Tucker, Jr., Ph.D.
Ralph Vinegar, Ph.D.
Ralph G. Waltergren, M.D.
T. E. Watson
Richard M. Weich, Ph.D.
Harvey Weiss, M.D.
Sidney Wolfe, M.D.
Summer J. Yaffe, M.D.

The following individuals were given an opportunity to present their views at the meeting: John M. Clayton, M.D.
William T. Beaver, M.D.
Gordon Benson, M.D.
Ronald F. Miller, M.D.
S. I. Rapaport, M.D.
Jane Schaller, 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 submissions, 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—ANTIRHEUMATIC 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 not generally recognized as safe and effective or are misbranded.
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 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.

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 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 Federal Register.

I. SUBMISSION OF DATA AND INFORMATION

Pursuant to the notice published in the 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:

A. SUBMISSIONS BY FIRMS

<table>
<thead>
<tr>
<th>Firm</th>
<th>Marketed products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott Laboratories, Inc., North Chicago, Ill. 60694</td>
<td>Children’s Chewable Aluminum Aspirin, Buffered Aspirin, Aspirin Compound No. 2, Buffered Aspirin, Sodium Salicylate</td>
</tr>
<tr>
<td>Berry &amp; Withington Co., Cambridge, Mass. 02149</td>
<td>Aspirin, Aspirin Compound No. 2, Buffered Aspirin, Sodium Salicylate</td>
</tr>
<tr>
<td>Block Drug Co., Inc., Jersey City, N.J. 07302</td>
<td>BC Powder, BC Tablets, B &amp; R Tablet No. 171-A, Boericke &amp; Runyon Tablets No. 200</td>
</tr>
<tr>
<td>Boericke &amp; Tafel, Philadelphia, Pa. 19107</td>
<td>Arthritis Strength Bufferin, Bufferin, Dissolve, Excedrin, Excedrin P.M., Neolin</td>
</tr>
<tr>
<td>Bristol-Myers Co., New York, N.Y. 10022</td>
<td>Persilin</td>
</tr>
<tr>
<td>Cooper Laboratories, Inc., Wayne, N.J. 07470</td>
<td>Curtis A-R Pain Relief, Calgarin, Camo Inlay Tablets, Cefizin, Fabrin, Triaminicin, Tussageic Tablets/Suspension, Ursinus Inlay Tablets</td>
</tr>
<tr>
<td>Curtis Drug Co., Decatur, Ill. 62531</td>
<td>Phenola, Teniap</td>
</tr>
<tr>
<td>Dorsey Laboratories, Lincoln, Nebr. 68501</td>
<td>Aspirin Suppositories, Pergocec, Dilone</td>
</tr>
<tr>
<td>Edgar Larsen, Lafayette, Calif. 94549</td>
<td>Pediaclin</td>
</tr>
<tr>
<td>Estes Laboratories, Inc., Portland, Ind. 46333</td>
<td>Estes Nu-Ral, Pano</td>
</tr>
<tr>
<td>The Dow Chemical Co., Research Center, Zionsville, Ind. 46077</td>
<td>EZ-IT APC, Goody’s Headache Powders</td>
</tr>
<tr>
<td>Eli Lilly and Co., Indianapolis, Ind. 46206</td>
<td>Hoover Powders, Dr. Lewis’ Preparation for Rheumatism</td>
</tr>
<tr>
<td>Endo Laboratories, Inc., Garden City, N.Y. 11530</td>
<td>Tylenol Chewable Tablets, Tylenol Drops, Tylenol Elixir, Tylenol Tablets</td>
</tr>
<tr>
<td>Eneglotaria Medicine Co. of Puerto Rico, Santurce, P.R. 00907</td>
<td>Tempra Drops, Tempra Syrup, Tempra Tablets</td>
</tr>
<tr>
<td>L. W. Estes Co., Inc., Washington, D.C. 20010</td>
<td>Alka-Seltzer, Norwich Aspirin, Nels Elixir, Nels Tablets</td>
</tr>
<tr>
<td>R. L. Gaddy, Pharmacist, Tallahassee, Fla. 32302</td>
<td>A.P.C. with Codeine, A.P.C., Aspirin, Buffered Aspirin, Tapanol, Super-in</td>
</tr>
<tr>
<td>Good’s Manufacturing Corp., Winston-Salem, N.C. 27102</td>
<td>Better’s Medicine, Arthralgen, Fabalate</td>
</tr>
<tr>
<td>Goody’s Manufacturing Corp., Winston-Salem, N.C. 27102</td>
<td>Apcrin</td>
</tr>
<tr>
<td>Hoover Laboratories, Inc., Fort Washington, Pa. 19034</td>
<td>Aspirin Compound No. 2, Buffered Aspirin, Sodium Salicylate</td>
</tr>
<tr>
<td>Mead Johnson Labs., Evansville, Ind. 47721</td>
<td>Aspirin, Aspirin Compound No. 2, Buffered Aspirin, Sodium Salicylate</td>
</tr>
<tr>
<td>Miles Laboratories, Inc., Elkhart, Ind. 46514</td>
<td>Aspirin, Aspirin Compound No. 2, Buffered Aspirin, Sodium Salicylate</td>
</tr>
<tr>
<td>Norwich Pharmacal Co., Norwich, N.Y. 13815</td>
<td>Aspirin, Aspirin Compound No. 2, Buffered Aspirin, Sodium Salicylate</td>
</tr>
<tr>
<td>Pfohls, Inc., Memphis, Tenn. 38101</td>
<td>Aspirin, Aspirin Compound No. 2, Buffered Aspirin, Sodium Salicylate</td>
</tr>
<tr>
<td>Purdue Frederick Co., Yonkers, N.Y. 10701</td>
<td>Aspirin, Aspirin Compound No. 2, Buffered Aspirin, Sodium Salicylate</td>
</tr>
<tr>
<td>Republic Drug Co., Inc., Buffalo, N.Y. 14207</td>
<td>Aspirin, Aspirin Compound No. 2, Buffered Aspirin, Sodium Salicylate</td>
</tr>
</tbody>
</table>

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

Sandoz Pharmaceuticals, East Hanover, N.J. Piogesic. 07936.
Templetons, Inc., Buffalo, N.Y. 14223.
USV Pharmaceutical Corp., Tuckahoe, N.Y. 10707.
Warren-Teed Pharmaceutical, Inc., Columbus, Ohio 43211.
T. E. Watson Co., Sarasota, Fla. 33578.

Acetaminophen (N-acetyl p-aminophenol; paracetamol)
Acetanilid
Aluminum aspirin
Aminoacetic acid (glycine, glycocoll)
Aminobenzoic acid (para-aminobenzoic acid (PABA))
Antipyrine
Ascorbic acid (vitamin C)
Aspirin (acetylsalicylic acid)
Bryonin
Caffeine
Calcium carbaspirin
Calcium carbonate
Calcium phosphate dibasic (monocalcium phosphate)
Cassia
Cascarilla sagrada
Choline salicylate
Cincodeine hydrochloride
Citrate caffeine
Citric acid
Codeine phosphate
Dextronmethanphol hydrobromide
Dihydroxyaluminum aminoacetate (aluminum glycinate)

In addition, the following firms made related submissions:
Firm: Submission
Monsanto Industrial Chemicals Co., St. Louis, Mo. Aspirin, Phenacetin, Salicylamide.
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>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>Calcium carbonate</td>
<td>III (S)</td>
<td>III (S)</td>
<td>III (S)</td>
</tr>
<tr>
<td>Phenyltoloxamine</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
</tr>
<tr>
<td>Pyrilamine maleate</td>
<td>III (S)</td>
<td>III (S)</td>
<td>III (S)</td>
</tr>
<tr>
<td>Salicylameide</td>
<td>III (E)</td>
<td>III (E)</td>
<td>III (E)</td>
</tr>
</tbody>
</table>

2. Adjuvant agents. The Panel has discussed adjuvants and their classification elsewhere in this document. (See part VI. below—ADJUVANTS AND CORRECTIVE AGENTS.) The agents identified below are included as active ingredients because they were submitted as such pursuant to the notice published in the Federal Register of July 21, 1972 (37 FR 14333) 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 (glycine, glycocollic) Calcium carbonate Calcium phosphate dibasic (monocalcium phosphate)
Citric acid Dihydroxyaluminum aminocetate (aluminum glycinate)
Dihydroxyaluminum sodium carbonate Dried aluminum hydroxide gel Magnesium carbonate Magnesium hydroxide Sodium bicarbonate Soda carbonates
(b) Direct acting adjuvant agents:
(1) Caffeine containing ingredients:
Caffeine Citrated caffeine
(2) Antihistamine containing ingredients:
Metacyclophenylbutazone Phenylamine 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.1. above—Active ingredients.)

The following agents were deferred for review to the Advisory Review Panel on OTC cold, cough, allergy, bronchodilator and antiasthmatic drug products:
- Ascorbic acid
- Nux vomica

- Phentolamine maleate (for uses other than as an analgesic adjuvant)

- Phenylamine maleate (for uses other than as an analgesic adjuvant)

- Phenylamine maleate (for uses other than as an analgesic adjuvant)

- Potassium bromide

- Phentolamine maleate (for uses other than as an analgesic adjuvant)

- Nux vomica

- Nux vomica

- Phenylamine maleate (for uses other than as an analgesic adjuvant)

- Nux vomica

- Potassium bromide

- Phentolamine maleate (for uses other than as an analgesic adjuvant)

- Nux vomica
2. Mechanism of action of an analgesic agent. The Panel has defined an OTC analgesic drug as an agent useful to alleviate the symptoms of mild to moderate pain.

The analgesics alleviate pain principally by a peripheral effect (blockade of pain impulse generation) rather than by a central effect. The best evidence for this is based on the studies of Linch, who in 1967, induced experimental pain in animals and human volunteers and showed that the actions of aspirin and acetaminophen were predominantly on the peripheral nervous system rather than on the brain (Ref. 2).

In addition, there is evidence that a portion of the pain relief provided by analgesics that also have anti-inflammatory activity is due to a peripheral effect of decreasing the inflammation which removes one source of stimulation of pain receptors (Ref. 3). The basic mechanisms of action of the analgesics are further discussed in the analgesic section below. (See part III, below—ANALGESIC AGENTS.)

3. Fever. The ordinary individual has a normal body temperature of 98.6° F (37°C). The temperature is normal if a 0.5° C variation during a 24-hour period or over several days, is still considered by the Panel within the normal range. Fever is defined as a body temperature above 98.6° F (37°C). (Ref. 4) and is a common sign that may or may not be accompanied by pain.

Many of the analgesics are also effective antipyretics (fever reducers) and may be safely used for self-medication when fever is due to the common cold or flu. However, fever also may indicate a serious illness and good medical practice dictates its cause, when not known, be determined immediately especially if it is marked, over 103° F (39.5° C) persists for more than 3 days, or recurs. The Panel recommends that labeling of antipyretic products include the warning: If fever persists for more than 3 days (72 hours), or recurs, consult your physician.

The Panel notes one author who states that the use of antipyretics has been abandoned because only a symptom which sometimes is beneficial (Ref. 5). Another author indicates that currently antipyretics are seldom used for the purpose implied by their name because effects related to reducing fever are now turned more profitably to removing its cause (Ref. 6).

The Panel concurs with the authors' views that in general, use of antipyretics is limited to relief of fever, which is symptomatic of an underlying illness. The fact that fever is in most often a symptom 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, it was often the only way in which the physician could distinguish among the myriad of variables influencing him. With the introduction of antibiotics, antipyretics are not as important as they once were (Ref. 6). Today, in some instances, fever or its absence can be used as a sign of 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 recommends that appropriate 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 when it is normal. The hypothalamic nuclei in the brain stem play a primary role in the regulation of body temperature. In fever, the balance between heat production and heat loss is disrupted and the body temperature will increase if the body temperature at a higher than normal level. The antipyretics are said to set the "thermostat" (hypothalamus) and will decrease toward normal 98.6° F (37° C). Heat production is not changed but heat loss is increased by increased peripheral blood flow and sweating. The peripherad effects of antipyretics on peripheral blood flow or the sweating mechanism but rather to a central action on the hypothalamus.

Elevation in body temperature can occur after injury, infection and inflammation. The causative agents of fever are referred to as pyrogens. Pyrogens may be differentiated into two basic categories: Those pyrogenic substances which are external to the body such as those produced by infectious agents and referred to as exogenous pyrogens and those pyrogenic substances which are produced by the body referred to as endogenous pyrogens. The article by Milton (Ref. 7), a modern view on the pathogenesis of fever and the mode of action of antipyretic drugs is discussed. He notes that it is now generally accepted that the cells capable of producing endogenous pyrogens are activated either by exogenous pyrogens or by endogenous factors. These endogenous factors include”

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
rectly into the central nervous system, produced fever in a majority of the animal species studied, and that the fevers produced are similar to those resulting from peripheral administration of these pyrogens. However, he points out that there is a lack of evidence to demonstrate that pyrogens can enter the central nervous system from the periphery.

The role of pyrogens and their effect on the administration of drugs have produced a rise in deep body temperature and the mechanism by which antipyretic drugs reduce fever may be related to the role of the prostaglandins. Prostaglandins are naturally occurring substances found in the body and consist basically of the fatty acid, prostanoid. These agents are known to be released from various tissue following nervous or chemical stimulation of blood forming cells. They have many macabolic effects. Milton notes that the first evidence that prostaglandins might be involved in the pathogenesis of fever was in 1971 when a specific prostaglandin-like substance was injected directly into the third ventricle of a cat's brain, resulting in a rapid rise in deep body temperature. In 1972 other workers (Ref. 8) confirmed these findings by injecting a prostaglandin only in the cat but also in the rabbit and rat. More importantly, these studies showed that the hyperthermia produced was sustained only as long as the infu­

sion lasted and the site of action was found to be in the preoptic area of the anterior hypothalamus.

Furthermore, Milton (Ref. 7) describes seizures in which cerebral spinal fluid from the third ventricle of the brain of the cat was assayed for contractile activity which in turn could be related to prostaga­
gland activity. It was found that in the absence of fever, produced by injecting pyrogen directly into the third ventricle. Follow­

ing the administration of the antipyretic drug acetaominophen, the fever abated and the contractile activity of the cerebrospinal fluid was again low. In subsequent studies in the cat, in which a microinfusion of this antipyretic was injected directly into the aorta during fever, it was found that the prostaglandin-like activity of the cerebrospinal fluid increased in all cases during the febrile response and that following the administration of these antipyretic drugs, i.e., aspirin, acetaominophen and indometacin, fever was abolished in all cases and at the same time the prostaglandin content of the cerebrospinal fluid decreased.

Milton found that acetaominophen, but not salicylates, generally, may produce a fall in deep body temperature when adminis­
tered to the conscious cat. When prostaga­
gland was infused, deep body tempera­ture rose. When the temperature had returned to normal level, then the drugs produced vasodilatation and panting but had no effect on the shivering and deep body temperature which fell slight­ly, reaching a new plateau level that was sustained until the infusion was stopped. From these studies, the author concluded that the effects of the antipyretic drugs were not mediated through inhibition of prostaglandin synthesis but were due to an action of the two drugs (indo­

methacin and acetaominophen) on the heat loss mechanisms concerned. Aspirin did not affect deep body temperature in either the afebrile state or during prosta­
glandin infusion. He concluded that the results could be regarded as further evidence that the prostaglandins are not involved in normal thermal regulation.

5. Inflammation. Inflammation and many other conditions that are accom­panied by pain and sometimes fever. In many rheumatic conditions the object of the therapy is to stop the disease proc­

ess. This usually requires doses of drug larger than those recommended for OTC use. Furthermore, symptomatic self-medication with relief of accompanying pain may still allow permanent degener­

ate processes to continue. In certain in­flammation, anti-inflammatory therapy is indicated, e.g., inflammation of the joint or skin due to a bacterial in­fection, and if it is not provided early in the course of the disease, infection of the blood stream or spread of infection may occur. Therefore, the Panel concludes that these OTC drugs for the treatment of inflammatory conditions and rhe­

matic disease should be used only under the advice and supervision of a physician. For these reasons, which are explained more fully below in the antirheumatic ingredient section, the Panel further concludes that OTC analgesics do not control OTC labeling for treating inflam­

matory or rheumatic conditions (See part V. below—ANTIRHEUMATIC AGENTS). 6. Mechanism of action of an antirheumatic agent. The Panel has defined an OTC antirheumatic drug as an agent which reduces joint or muscle tenderness or swelling.

Despite their long history of use, the precise mechanism(s) whereby salicylates exert anti-inflammatory actions re­

mains unclear; numerous mechanisms of action have been proposed. They may interfere with edema formation (Refs. 9, 10, and 11), inhibit the release of some inflammatory material from plasma pro­
tein (Ref. 12), interfere with the move­

ment of ions such as sodium and potas­

sium across cell membranes (Ref. 13), interferes with the move­

ment of cells in connective tissue (Ref. 14), or inhibit or compete with the actions of other active substances (Refs. 15 through 22). However, all these possible mechanisms are controversial and the use of these OTC drugs for the treatment of headache. A brief survey of the OTC analgesic market will readily indicate the extensive use of claims for "headache", "simple head­ache", "common headache", "occasional headache", and in many combination drug products containing additional non­

aspirin active ingredients terms such as "sinus headache" or "nasal tension headache". Regardless of the descriptive terminology used, the OTC analgesic may be considered a simple analgesic which can originate in any part of the body. Most headaches are transient usually lasting less than 1 day. However, some types are chronic and may recur over months or years. Most chronic and recurrent head­

aches may be caused by more serious underlying diseases such as vascular dis­

turbances, brain tumor or abscess, intracranial lesions, or lesions of the eye, nose, ear, or throat.

7. Headache (cephalalgia). OTC an­

gleic products are commonly used for the treatment of headache. A brief survey of the OTC analgesic market will readily indicate the extensive use of claims for "headache", "simple head­ache", "common headache", "occasional headache", and in many combination drug products containing additional non­

The Panel has defined an OTC antirheumatic drug as an agent which reduces joint or muscle tenderness or swelling. Vascular headache includes the classical "common migraine headache", where­as psychogenic headaches are usually attributed to anxiety or depression. Traction and inflammatory headache includes those attributed to organic dis­

turbances, brain tumor or abscess, intra­
cranial lesions, or lesions of the eye, nose, ear, or throat. Wolff (Ref. 40) has differentiated headaches into two major categories based upon their origin, i.e., those that arise mainly as a result of stimulation of intracranial structures and those that arise mainly as a result of stimulation of tissues outside the head or adjacent to the skull. He describes 11 major types of headaches. In most cases each type could be further classified into one or more subtypes.
One type of vascular headache, the hypertensive headache, is related to elevation in the systemic arterial blood pressure. A sudden rise in arterial blood pressure, whether due to hypertension or to ingestion of a large quantity of sodium, causes headache by virtue of a sudden dilation of the pain-sensitive intracranial blood vessels. Another type of vascular headache is the common migraine, which has as an aggravating factor 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 its throbbing, unilateral, unilateral head pain. OTC analgesics are usually not appropriate for the treatment of hypertensive or migraine headaches which require diagnosis of their cause by a physician and usually treatment with drugs available only by prescription.

Next to migraine, the most common vascular headache is the toxic vascular headache, which is usually accompanied by OTC analgesics indicated. Diamond and Dallesio (Ref. 40), note that generalized vasodilation may occur as a consequence of any significant fever, the vasodilation usually becoming more intense as the fever rises. It has even been suggested that alcohol can produce a toxic vascular headache which is commonly termed the "hangover" headache. Another common form of toxic vascular headache occurs after withdrawal of caffeine. This caffeine withdrawal headache is common in heavy coffee drinkers and is discussed in the caffeine withdrawal statement later in this document (See part VI, paragraph B.3, below—Caffeine (citrate caffeine)).

The second major type of headache is the psychogenic headache, which is considered one of the most common forms of headache. Apprehension, anxiety, post-traumatic experiences, and depression can precipitate the symptoms. This form of headache is usually associated with 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 analgesics, whereas agents such as opiates or barbiturates that alter respiration to pain may grant significant, though transient, relief (Ref. 39). Panel concurs and finds the use of OTC analgesics for the persistent psychogenic headaches undesirable.

The terms "spastic contraction" and "tension" headache have been used synonymously for almost 40 years. These headaches are not vascular in nature or associated with traction or inflammation. Psychogenic headaches, which 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 diffuse in nature and usually difficult to describe. Various factors which may precipitate such headaches include the individual's marital relations, occupation, social relationships, life stresses, and habits.

The third major group of headache includes the "true" vascular and the headache evoked by organic disease. The term traction headache has been defined "to describe the often nonspecific headache seen with mass lesions of the brain, meningiomas, aneurysms, or brain edema from whatever cause" (Ref. 37). Traction and inflammatory headaches are associated with inflammatory disease of the meninges, and in particular, meningitis. Wolff notes that "the intensity of the headache is related to sinus disease. The symptoms include localized pain within the frontal sinus of a deep, dull aching, or throbbing character. The diagnosis of a precise paranasal disease by a physician the underlying cause of such a sinusitis or allergic rhinitis can be properly treated.

The frequency, duration, location, and severity of the headache may be useful in determining its cause. The diagnosis of the occasional headache can usually be related to the physician the underlying cause of such a sinusitis or allergic rhinitis can be properly treated.

The frequency, duration, location, and severity of the headache may be useful in determining its cause. The diagnosis of the occasional headache can usually be related to the physician the underlying cause of such a sinusitis or allergic rhinitis can be properly treated.

The frequency, duration, location, and severity of the headache may be useful in determining its cause. The diagnosis of the occasional headache can usually be related to the physician the underlying cause of such a sinusitis or allergic rhinitis can be properly treated.
PROPOSED RULES

The Panel reviewed the labeling requirements previously adopted by the Food and Drug Administration for OTC (analgesic, antipyretic, and antirheumatic) products (21 CFR Part 201). These requirements provide for labeling information on the size of the container display for the principal display of ingredient(s), the identity of ingredients, directions for use and general and specific warnings. The Panel concurs that these general requirements should be adopted for each OTC preparation. The labeling of individual active ingredients will be discussed later in this document.

After reviewing all submitted labels of OTC analgesic, antipyretic, and antirheumatic preparations, the Panel recommends the following additional requirements:

1. Ingredients. The Panel concludes that analgesic, antipyretic, and antirheumatic products should contain only active ingredients for each active ingredient (pharmaceutical necessities) as may be necessary for product formulation. All such drug products should identify the active and inactive ingredients. The list of all such drug products should be listed by the established name. Since the United States is converting to the metric system, the label should state that the quantity of active ingredients should be stated in standard metric units. The recommended dosage in metric units, e.g., 325 mg per teaspoonful, 325 mg per tablet, etc., should be stated in apothecary units, e.g., 325 mg (5 gr) per teaspoonful, 325 mg (5 gr) per tablet, etc., until the metric system becomes official. The Panel reviewed the labeling requirements adopted by the Food and Drug Administration for OTC analgesic, antipyretic, and antirheumatic products containing sodium and magnesium salts (21 CFR Part 331). The Panel concludes that they be adopted for OTC analgesic, antipyretic, and antirheumatic products containing sodium and magnesium salts. The Panel recommends that the labeling of products containing more than 5 mEq (125 mg) sodium in the maximum recommended daily dose be stated in the warning statement. The Panel concludes that sodium should be reported in the principal display of ingredient(s), the identity of ingredients, directions for use and general and specific warnings. The Panel recommends that the labeling of products containing more than 5 mEq (125 mg) sodium in the maximum recommended daily dose be stated in the warning statement. The Panel concludes that sodium should be reported in the principal display.
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 analgesic-antipyretic products. In years past it was believed that the greater the number of claims, the better the product. Often the claims were 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 to the consumer.

The Panel recognizes that well-controlled clinical studies have been conducted with various analgesic-antipyretic agents in patients with specific types of pain such as postpartum pain, pain due to cancer, pain following tooth extraction, etc. It is the Panel's opinion, however, that "pain" is sufficiently broad to encompass all the studies in populations with pain of specific etiology and therefore it is in the public's best interest to emphasize the use for pain generally rather than list on the labeling all the specific types of pain that have been shown 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 toothache", "teething", "dental procedures pain", "menstrual discomfort", "aches", "body aches"; "simple headache"; "nervous headache"; "tension headache", "pain due to head colds"; "aches"; "pain of inoculations and immunizations"; and several other claims. 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 obscurity 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 manufacturing company states that "pain due to headache, and for the reduction of fever" as an indication of these drugs to be used for the self-treatment of diseases.

An important area of the Panel's recommendations is with the labeling of OTC analgesic-antipyretic products. The Panel believes that the term "minor pain" is sufficiently broad to encompass the many slightly different claims found on the labeling of presently marketed OTC analgesic-antipyretic products. In years past it was believed that the greater the number of claims, the better the product. Often the claims were 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 to the consumer.

The Panel recognizes that well-controlled clinical studies have been conducted with various analgesic-antipyretic agents in patients with specific types of pain such as postpartum pain, pain due to cancer, pain following tooth extraction, etc. It is the Panel's opinion, however, that "pain" is sufficiently broad to encompass all the studies in populations with pain of specific etiology and therefore it is in the public's best interest to emphasize the use for pain generally rather than list on the labeling all the specific types of pain that have been shown 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 toothache", "teething", "dental procedures pain", "menstrual discomfort", "aches", "body aches"; "simple headache"; "nervous headache"; "tension headache", "pain due to head colds"; "aches"; "pain of inoculations and immunizations"; and several other claims. 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 obscurity 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 manufacturing company states that "pain due to headache, and for the reduction of fever" as an indication of these drugs to be used for the self-treatment of diseases. Therefore, the Panel recommends the restriction of the claims that may be made for analgesic-antipyretic products and has concluded that the general indications statement "For the temporary relief of occasional minor aches, pains, and headache, 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 imply that the preparation is for the treatment of disease entities, such as arthritis. This is especially important for preparations containing antirheumatic agents (salicylates). 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 joint damage if taken 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. Therefore, the labeling for preparations containing salicylates should include the statement: "Take this product for the treatment of arthritis only 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 analgesic-antipyretic products are unavailing to self-diagnosis or treatment. Consumers with these conditions, such as several types of arthritis, gout, and acute rheumatic fever, should be under 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 or self-treat. 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", "arthritis strength", "arthritis formula", "arthritis treatment", etc., in product names or labeling is unacceptable to the Panel. As will be noted later in this document, the Panel concurs with the Arthritis Foundation's opposition to the term "arthritis brand name" and also concurs with their recommendation that sufferers of the disease would be best served if the term "arthritis" were banned from the labeling and advertising of these products, leaving the choice of drug treatment to the physician. (See part V. below—ANTIRHEUMATIC AGENTS.)

The only terms acceptable to this Panel are those included in the general OTC indication statement for all analgesic-antipyretics, i.e., "For the temporary relief of occasional minor aches, pains and headache, and for the reduction of fever.

3. General and specific warnings. The Panel decided additional statements need to be included on the labeling of analgesic-antipyretic products for proper self-medication and awareness of the consequences of overdose. These statements should come under the general headings of warnings and cautionary statements.

The Panel agrees with the current regulation of OTC dosage (1 g) containing the general warning statement "Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately; and considers it reasonable and proper for all OTC medications. In regard to specific warnings or cautions the Panel recommends that potential users be alerted to the possibility of 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 policy should not regard these products as medicines 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 are medicines that should not be allowed. Any reference to "arthritis", "arthritis strength", "arthritis formula", "arthritis treatment", etc., in product names or labeling is unacceptable to the Panel. As will be noted later in this document, the Panel concurs with the Arthritis Foundation's opposition to the term "arthritis brand name" and also concurs with their recommendation that sufferers of the disease would be best served if the term "arthritis" were banned from the labeling and advertising of these products, leaving the choice of drug treatment to the physician. (See part V. below—ANTIRHEUMATIC AGENTS.)

The consumer should be informed of any possible signs of known toxicity and any indication requiring discontinuation of 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 III. paragraph 1.D.1.) It is important for the consumer to recognize this symptom. With continued dosing, serious intoxication may occur due to the mode of salicylate metabolism.
For example, a small increase in the salicylate dose ingested may cause a disproportionate increase in the salicylate blood level and could result in serious consequences.

Unfortunately, acetylsalicylic acid has no similar sign of toxicity or "safety valve" to alert the consumer to possible danger; since the toxicosis caused by aspirin is characterized by severe liver damage which is not as amenable to therapy as salicylate intoxication. This is discussed later in this document. (See part III, paragraph B.3.b. below—Acetylsalicylic acid.)

Therefore, the Panel decided to include the warning, "Stop taking this product if ringing in the ears or other symptoms occur", on all products containing salicylates, and the warning, "Do not exceed recommended dosage because severe liver damage may occur" on all products containing acetylsalicylic acid. (Ref. 2)

Likewise, consumers should be alerted to possible serious side effects from therapeutic doses of these products. Some evidence suggests that aspirin may be involved in the causation of Reye's syndrome. (See part III, paragraph B.1.a.(2)(i) below—Adverse effects during pregnancy.) Therefore, the Panel concludes that it is necessary to include the labeling warning statement, on all aspirin-containing products, "Do not take this product during the last 3 months of pregnancy except under the advice and supervision of a physician.

The labeling of several currently marketed aspirin products contains the advice that the product should be taken with a full glass of water. Baum (Ref. 1) also states that aspirin should be taken with a large glass of fluid. (Ref. 2) The Medical Letter also advises that "to minimize gastrointestinal irritation, any aspirin tablet should be taken with a full glass of water." The Panel could not find any controlled studies to support the contention that the quantity of water used to administer the drug has any effect relative to safety or efficacy. However, it is the opinion of the Panel that this advice is sound, since the water would be expected to facilitate dissolution of the drug and reduce the irritation of the mucosa of the stomach from aspirin particles as discussed elsewhere in this document. (See part III, paragraph B.1.a. (2)(i) below—Adverse effects on the gastrointestinal tract.) The Panel believes that the labeling for aspirin products should apply to all salicylates. Therefore, the Panel concludes that the labeling for products containing salicylates intended for oral administration as a solid dosage form, e.g., tablets, state for adults, "Adults: Drink a full glass of water with each dose" and for children under 12 years, "Children under 12 years: Drink water with this medication." The Panel concludes that the purpose of OTC preparations is to provide for the temporary relief of self-limited symptoms and not for the self-treatment of disease entities. If OTC products are used for a long period of time to treat symptoms which indicate a potentially serious problem, a disease requiring medical supervision could be overlooked.

The Panel also states that aspirin should be taken with a full glass of water. (Ref. 2) (ii) below—Adults: Drink a full glass of water with each dose.

The Panel recognizes that currently there are many marketed products containing a large variety of analgesic, antipyretic and antirheumatic drugs. These products are marketed containing either single ingredient preparations 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 may be many marketed products containing nonaspirin ingredients, e.g., acetaminophen, or derivatives of salicylic acid other than aspirin, e.g., sodium salicylate, which in most cases contain labeling 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 information, the advertising expenditures for internal analgesic drugs are greater than for other OTC drug categories (Ref. 2). It was noted that analgesic promotion in this country has reached a new level of sophistication with advertising references to whole new ailments such as "file cabinet backache" or "camper noise fatigue." While the National Association of Broadcasters and the Proprietary Association representing many OTC drug manufacturers have been active in developing codes for the advertising of prescription or OTC medicines, the Panel believes that government requirements for the inclusion of warnings and cautionary language are inadequate, particularly as it relates to the advertising upon children (Ref. 2).

The Panel notes that the Food and Drug Administration does not regulate the advertising of OTC drug products. Therefore, there is no proper authority, i.e., the Federal Trade Commission, with the full support and active cooperation of the Food and Drug Administration, more effectively regulate commercial advertising of analgesic, antipyretic and antirheumatic preparations on the basis of the labeling recommendations contained in this document. Further, the Panel strongly urges the Federal Trade Commission to require 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 regulation of OTC drug advertising on those television programs watched most often by children or whose viewing audience includes large numbers of children.

The Panel has noted, with concern, certain aspects of commercial advertising of OTC medicines that urge the consumption of these drugs without directing attention to adequate warnings regarding the possible immediate hazards of use or the potential hazards from their long-term use.

This concern was shared by representatives of consumer and children's advocacy groups, by representatives of the OTC drug industry and manufacturers, the broadcast media, and researchers from the academic world at a 2-day conference on televised OTC drug advertising that was sponsored by the Federal Trade Commission and the Federal Trade Commission on May 20 and 21, 1976. At the three Panels
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 better 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), and that all marketed products containing aspirin, 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 are labeled 325 mg or 5 gr aspirin. A significant number of marketed aspirin dosage units are marketed with less than 325 mg and some with 300 mg aspirin labeled as 5 gr.

Most individuals these dosages are assumed to be equivalent but on a weight basis they are actually not equivalent. Confusion arises because there are two systems of weight measurement commonly used. One system, which has been historically used in pharmacy is the apothecary system of weights based on the "grain" (gr) and the other being the more universal metric system based on the "gram" (g). The apothecary weight of 1 g is equivalent to the metric system weight of 1 gr. The apothecary weight of 1 gr is approximated as equal to 60 mg. Therefore, a 5 gr aspirin dosage unit should actually contain 324 mg aspirin but is sometimes labeled to 300 mg of active ingredient, this making for a difference of 24 mg of aspirin.

A further factor contributing to a wide range in the amount of available aspirin is the provision of the United States Pharmacopeia 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 content of 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 product to another brand. This could represent a possible difference of 45% or almost 1 gr aspirin between two different aspirin products. It is to avoid the confusion that presently exists in the conversion between the two systems of weight measurement, i.e., between the apothecary system (gr) and the metric system (mg), the Panel recommends that the amount of aspirin in a 325 mg (5 gr) standard dosage unit be established on the basis of the apothecary weight of 1 gr being equivalent to the metric system measurement of 65 mg.

The Panel also recommends that this equivalence between the apothecary and metric systems be used for all ingredients. The following table illustrates equivalent values for the two systems as used throughout this document:

<table>
<thead>
<tr>
<th>Equivalent Values for Apothecary and Metric Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apothecary (gr)</td>
</tr>
<tr>
<td>1.0</td>
</tr>
<tr>
<td>1.25</td>
</tr>
<tr>
<td>5.0</td>
</tr>
<tr>
<td>10.0</td>
</tr>
<tr>
<td>65.0</td>
</tr>
</tbody>
</table>

The Panel has evaluated the amounts of aspirin contained in the submissions for marketed products submitted to the review (See part I, paragraph A above—Submissions by Firms). For example, of the submissions reviewed by the Panel, 22 pertained to dosage forms containing aspirin as a "single" ingredient. In 16 of these single ingredient products (50 percent), the amount of aspirin differed from the standard 325 mg (5 gr). The range was from a low of 227 mg for a chewable gum to a high of 650 mg in a single tablet. This represents a variation of 70 to 200 percent of the standard 325 mg (5 gr) aspirin dosage unit available as a single ingredient in such marketed products.

The Panel has provided the following table to illustrate the variations in the amount of aspirin contained in submitted products:

<table>
<thead>
<tr>
<th>Amount of Aspirin Contained in Submitted Products Where Aspirin Was the Single Analgesic Ingredient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredient</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>Grains of aspirin</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

The Panel is aware of the widespread and common belief that the usual amount of aspirin an adult should ingest is "two tablets." The Panel believes that this can cause a problem if a person accustomed to buying and properly interpreting "two tablets" every 4 hours, he may receive as little as 590 mg or as much as 1,300 mg aspirin. The Panel is concerned that the 1,300 mg dosage will achieve the desired effect but with the potential hazard of toxic overdose. Since aspirin is the most common drug used in the United States, the latter situation is critically important. If a person takes 1,300 mg aspirin every 4 hours for several dosing intervals, serious aspirin intoxication may result. This is due to both the absolute quantity of aspirin taken and to the rapidity of the absorption of aspirin, which is discussed later in this document. (See part III, paragraph B.1.a.(2) below—Safety.)

As an example, a 20 percent increase in dosages causes 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 in 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 for the 300 mg tablet to a high of 345 mg for the 325 mg tablet), represent a 20 percent variation in dosage.

This could be a problem in the area of pediatric overdosing. If a pediatrician instructs a parent to give a child half of an aspirin tablet, the child could, depending upon the strength of the tablet, be exposed to a potentially serious aspirin overdose. In the case of aspirin (Feversafe), for an infant or small child this is especially hazardous because the young child cannot tolerate symptoms of tinnitus (ringing of the ears), one of the early symptoms of aspirin overdose. Further, the symptoms could persist not to exceed 4,000 mg in 24 hours. The Panel has provided the following table to illustrate the variations 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 be labeled to indicate either 325 mg aspirin per dosage unit for adults or 80 mg (1.22 gr) per dosage unit for children under 12 years of age.

The Panel recommends an adult oral dose of 325 mg (5 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 is particularly 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 specifically, the adult oral dosage of 800 mg (10 gr) is the amount consumers believe they are ingesting, i.e., two 325 mg (5 gr) tablets.

However, the Panel recognizes that the consumer may be ingesting 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 contain only 325 mg (5 gr) 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 is 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 not less than 325 mg (5 gr) (a maximum dosage of not greater than 650 mg (10 gr)) aspirin, acetaminophen or sodium salicylate. In addition, the Panel concludes that only nonstandard dosage units containing not less than 325 mg (5 gr) aspirin, acetaminophen or sodium salicylate should be used in marketed adult strength products containing acetaminophen as the single active ingredient.

The Panel recommends that any product containing an amount different from 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 shall be labeled appropriately "Contains nonstandard strength of X milligram (grain) aspirin, acetaminophen or sodium salicylate per dosage unit compared to the established standard of 325 mg (5 gr) aspirin per dosage unit", "Contains nonstandard strength of 500 mg (7.69) gr acetaminophen per dosage unit", or "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 dosages. The Panel has defined 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 range. The Panel has examined the data submitted and finds for purposes of clarity that it is necessary to define the components of the dosage schedules which include a minimum effective dosage, a usual single dosage, a usual effective dosage range, a maximum single dosage, and a maximum daily (24 hours) dosage. 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 necessary 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 range between the minimum effective dosage and the usual single dosage.

(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 body size (usual height) or overweight (obesity) require a higher dosage. To meet this contingency, the Panel defines the maximum single dosage as the maximum amount of drug that is safe and effective for use in a 24-hour period.

The Panel has established 1,000 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 routinely even when it may not be 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 daily dosage for the standard drugs (aspirin, acetaminophen and sodium salicylate). The Panel concludes that only nonstandard dosage units of 500 mg (7.69) are recognized for acetaminophen in addition to the standard unit of 325 mg (5 gr) since the Panel is unaware of any other nonstandard units currently available in marketed adult strength products containing acetaminophen as the single active ingredient. The recommended dosage schedules are described in section d. below.

c. Recommended dosage for products containing nonstandard dosage units. The Panel concludes that nonstandard dosage units as dosage units containing not less than 325 mg (5 gr) aspirin, acetaminophen or sodium salicylate may be marketed if the Panel finds for in OTC labeling, and the maximum daily dosage for the standard drugs (aspirin, acetaminophen and sodium salicylate). The Panel concludes that only nonstandard dosage units of 500 mg (7.69) are recognized for acetaminophen in addition to the standard unit of 325 mg (5 gr) since the Panel is unaware of any other nonstandard units currently available in marketed adult strength products containing acetaminophen as the single active ingredient. The recommended dosage schedules are described in section d. below.

d. Recommended adult dosage schemes. Besides the establishment of standard and nonstandard dosage units, the Panel has also established standard and nonstandard dosage schedules for their use.

The Panel concludes that the standard dosage schedule be utilized but recognizes the current availability of nonstandard dosage schedules. Therefore, the Panel recommends the following dosage schedules:

Recommended adult dosage schedules for standard and nonstandard aspirin, acetaminophen or sodium salicylate dosage units

<table>
<thead>
<tr>
<th>Dosage unit</th>
<th>Initial dosage units</th>
<th>Frequency</th>
<th>Dosage unit (milligrams)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(milligram (grain))</td>
<td>(tablets/hours) units/day</td>
<td></td>
<td>(milligram (grain))</td>
</tr>
<tr>
<td>Standard dosage schedule under: 325 (5)</td>
<td>2</td>
<td>9 after 4</td>
<td>12 (3,900)</td>
</tr>
<tr>
<td>Nonstandard dosage schedule under:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>325 (5)</td>
<td>3 to 5 (800 to 1,200)</td>
<td></td>
<td>12 (3,900)</td>
</tr>
<tr>
<td>650 (10)</td>
<td>1 to 2 (600 to 1,200)</td>
<td>1 after 3 or 4 after 6</td>
<td>6 (1,800)</td>
</tr>
<tr>
<td>975 (15)</td>
<td>1 to 2 (850 to 1,200)</td>
<td>1 after 3 or 4 after 6</td>
<td>6 (1,800)</td>
</tr>
<tr>
<td>1,350 (20)</td>
<td>1 to 2 (1,000 to 1,200)</td>
<td>1 after 3 or 4 after 6</td>
<td>6 (1,800)</td>
</tr>
<tr>
<td>1,500 (25)</td>
<td>1 (1,500)</td>
<td>1 after 3 or 4 after 6</td>
<td>6 (1,800)</td>
</tr>
</tbody>
</table>

1. The amount of drug contained is a single dosage unit.
2. The maximum number of dosage units that cannot be exceeded when dosing is initiated.
3. The number of dosage units per time interval.
4. Dosage units that cannot be exceeded in 24 hours regardless of the initial number of dosage units taken or the frequency of repeated dosing.
5. This recommended dosage schedule does not apply to acetaminophen since only the 500 mg (7.69) nonstandard dosage unit is recognized by the panel.

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

**OTC ANALGESIC EQUIVALENCE DRUGS**

<table>
<thead>
<tr>
<th>Standard 325 mg</th>
<th>Comparison drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aspirin</strong></td>
<td>Aluminum aspirin.</td>
</tr>
<tr>
<td><strong>Acetaminophen</strong></td>
<td>Aspirin.</td>
</tr>
<tr>
<td><strong>Sodium salicylate</strong></td>
<td>Choline 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 nonaspirate active ingredients with labeling claims similar to products containing aspirin is confusing and recommends that an analgesic label be used. The term “analgesic” 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 and 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 the 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 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.”

b. **Products containing a standard drug in an amount different from the standard dosage unit.** (1) **Acetaminophen.** If the Food and Drug Administration is unable to implement the Panel’s advice that products contain only 325 mg (5 gr) aspirin per dosage unit, 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 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 the Food and Drug Administration cannot implement this recommendation, the labeling shall state “Contains nonstandard strength acetaminophen.”

(2) **Sodium salicylate.** If the Food and Drug Administration is unable to implement the Panel’s advice that products contain only 325 mg (5 gr) sodium salicylate per dosage unit, 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 nonstandard strength of X mg (X gr) sodium salicylate per dosage unit.” The actual amount 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. In the event the Food and Drug Administration cannot implement this recommendation, the labeling shall state “Contains nonstandard strength sodium salicylate.”
PROPOSED RULES

F. STATEMENT ON RECOMMENDED DOSAGE SCHEDULES

1. Statement on standard and non-standard salicylate dosage schedules. The Panel has defined the components of a dosage schedule elsewhere in this document. (See part II. paragraph E.3. above: Analgesic-antipyretics recommended dosage.) The basis of the Panel's conclusions regarding recommended dosage schedules was discussed below.

a. Factors in selection of optimal dosage schedules. The Panel recognizes that one of the most important and critical factors in maximizing the safe and effective use of salicylates is 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 deaths 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 clearly less serious than the early signs of dosage regimens. (Refs. 3 and 4) and said to occur at lower plasma salicylate levels compared to toxicities resulting from large single doses (Ref. 1). Secondly, the propensity for serious toxicities following multiple dosing can now be explained by the recent discovery that the salicylates have 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 significant increases in salicylate plasma levels during multiple dosing.

A third problem in defining the dosage regimens is that aspirin is used extensively both orally and rectally, and there have been different dosage schedules, e.g., antipyretic effect or antirheumatic 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 multiplicity of products currently marketed presents a critical problem. In the case of salicylates 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 done in a systematic manner to risk considerations. The Panel finds, however, that there are no generally accepted protocols or procedures for the objective evaluation of the often cited but seldom quantified "benefit to risk 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 measurements.

The absence of a reasonable procedure that can be used to objectively compare the relative effectiveness and safety of different dosage forms, tablet strengths, therapeutic regimens or therapeutic indications, e.g., headache or rheumatoid arthritis, is particularly disadvantageous in the case of OTC salicylates. This is due partly because of the toxicologic 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 dosage intervals.

Therefore the 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 toxicologic monitoring or for a dose level that is required for safe use and whether this monitoring must be carried out by an individual with training beyond that which can be conveyed to the public or 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 on the above assumptions discussed below semi-quantitative methods were used for risk to benefit considerations in salicylate dosing.

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 regimens for pediatric dosing and dosage regimens in which data to support the conclusions of the Panel are not included in 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 safe 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 very clearly salicylate blood concentration correlates quite well with early signs of dosage related salicylate toxicity. Tinnitus (ringing in the ears) and deafness which are considered to be early signs of salicylate toxicity, occur above a salicylate concentration of 20 mg/100 ml of plasma.

The correlation of salicylate blood levels with early signs of salicylism provides a means for the determination of salicylate plasma levels as a quantifiable means to compare the toxic potential of different dosage regimens. Single dosage and multiple dosage regimens should result in plasma salicylate levels below 30 mg/100 ml for 95 percent of the population. The mean steady state 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 975 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 for salicylate 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 daily maximum salicylate 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 the total daily dosage or mean hourly rate provide a significantly greater risk without a compensating therapeutic benefit. A single dosage of 975 mg provides greater benefits to many regimens 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 in dosage unit should provide adequate warnings limiting the number and dosage instructions limiting the number and dosage frequency the number such that the total daily dosage and mean hourly dosage 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 thus deviation from the standard dosage regimen. However, there have been no studies designed to evaluate this contention. The Panel concluded that the additional risk is probably minimal provided that the labeling provides adequate notice that such products contain nonstandard amounts per dosage unit and has some dosage regimens that are suitably modified so as not to exceed maximum daily and hourly dosage rates specified by the Panel. Since the modified dosage schedules for nonstandard products would be expected to provide blood levels and total body salicylate levels comparable to those obtained with the standard strength products, any claims of greater strength, e.g., adult aspirin, would be misleading and incorrect.

d. Criteria for determining optimal dosage regimens. Wagner (Ref. 5) has summarized some useful criteria that have been used to evaluate comparative risk to benefit ratios for drugs. Listed below are those formulae that are applicable to multiple dosages in animals but can be applied to multiple dosages in humans with the following definitions:

\[
\text{(1)} \quad C_{D} = \frac{EF}{Q_{D}}
\]

\[
\text{(2)} \quad C_{E} = \frac{E_{C}}{D_{E}}
\]

\[
\text{(3)} \quad D_{E} = \frac{Q_{E} \times E_{D} + D}{Q_{D} \times E_{D} + D} = D
\]

\[
\text{(4)} \quad D_{E} = \frac{Q_{E} \times E_{D} + D}{Q_{D} \times E_{D} + D} = D
\]

(1)  
Minimal therapeutic dose

(2)  
Maximum tolerated dose

(3)  
Jandetzký's therapeutic characteristic (TE):

(4)  
Ehrlich's therapeutic index (EHI), is generally used for a single dosage in animals but can be applied to multiple dosages

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 cases the differences are given in different units such as daily dosage, m² or mg/kg/4 hours without sufficient additional data on the patient characteristics to allow exact conversion to comparable procedures. In the number of days the dosage regimen was administered and the types of patients (rheumatoid arthritics) compared to normal subjects also made some published data difficult to assess.

Nevertheless, there are data from pharmacokinetic and clinical studies which provide a firm basis for establishing a safe and effective dosage regimen consistent with the usual pharmacokinetic characteristics of the salicylates.

On the basis of these studies reviewed below, the Panel established standard and nonstandard dosage schedules. The schedules shown below reflect the Panel's recommendations of a minimum initial and maintenance dosage of 325 mg (5 gr), a maximum initial single dosage of 750 mg (11.5 gr) to be used only once, and minimum maintenance dosage of 600 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 1,000 mg every 6 hours or a maximum daily dosage of 4,000 mg. These dosage schedules are stated in terms of the initial starting number of dosage units, the number of dosage units per time interval and the total number of dosage units per day (24 hours).

(1) Hourly dosage rate. Because of the unusual non-linear kinetics of salicylates, some changes in dosage schedules which were considered to have potentially little or no effect on steady state blood levels can result in clinically significant changes in the case of salicylates. For example, if salicylates behaved like most other drugs which have linear kinetics, the mean steady state blood level would essentially be the same for a total daily dosage regardless of whether it is given as four dosages taken every 4 hours or in two dosages taken every 8 hours. In the case of salicylates, a change of the hourly dosage rate can lead to potentially toxic levels and it is necessary to put limits on the hourly dosage rate as well as on the total daily dosage. On the basis of clinical data and pharmacokinetic calculations, the maximum critical hourly rate is 187 mg/hour for an adult.

This consideration is particularly important in the case of some currently marketed salicylate products containing 7/8 gr aspirin per dosage unit with a recommended dosage schedule of 15 gr (757 mg) every 4 hours for four dosages during the day. Although the total daily dosage is within recommended limits, the hourly dosage rate is 244 mg/hour which is 50 percent greater than the recommended limit of 187 mg/hour.
strictly true, the apparent rate of elimination is quite constant at the dosages corresponding to their plasma concentrations where toxicity begins to occur, i.e., above 20 mg/100 ml. The following simple model correlates quite well with the published data:

\[ A = \frac{D}{V_m} - M \]

where \( A \) is the rate of accumulation of drug in the body per unit time (hour or day); \( D/V_m \) 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 (Ref. 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 amount 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 greatly increases with dosage levels in the OTC range. Their simulations show that a dose of 0.5 g (7.5 mg/hr) when given every 8 hours will reach a constant maximum level of salicylate in the body (plateau level) of less than 0.3 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:

<table>
<thead>
<tr>
<th>Relationship between dosage unit, frequency and hourly dosage rate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dosage unit</strong></td>
</tr>
<tr>
<td>(mg)</td>
</tr>
<tr>
<td>------</td>
</tr>
<tr>
<td>250 (3)</td>
</tr>
<tr>
<td>400 (6.1)</td>
</tr>
<tr>
<td>421 (6.2)</td>
</tr>
<tr>
<td>478 (7.46)</td>
</tr>
<tr>
<td>500 (7.46)</td>
</tr>
<tr>
<td>600 (10)</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 dosing is initiated.
3. The amount of aspirin (milligram) taken at each time interval divided by the number of hours in a time interval.
4. 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.
5. The amount of aspirin (milligram) taken at each time interval divided by the number of hours in a time interval gives the hourly dosage rate.

(1) 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 both safe and normal 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. However, for children, 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 instances, the upper limit may be greatly magnified at the urine pH 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 6.2 by administration of sodium bicarbonate. When urine pH was allowed to fall to the usual range below 6 (5.6 to 5.9), the average salicylate plasma concentration level (increased to 27.9 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 was also taking antacids which increase the urine pH. For this reason, Levy and Leonards (Ref. 11) recommend that in the treatment of rheumatoid arthritis the urine pH should be routinely monitored particularly if antacids are being taken.

The data of Brewer (Ref. 12) illustrates 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 800 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 200 mg/hour/m², and -10 mg/L/hour during zero input. Therefore, during dosing the values of the equation (DC/dt) Vd D/√'Vmdm, where (D/m²) Vd D/√'Vm is 10 (mg/L/hour) Vm=200 mg/hour/m², and during the second 12 hour period of zero input (-10 mg/L/hour) Vd = Vm. The apparent volume of distribution (Vd) can be calculated from the equation 2(16 mg/L/hour) Vm=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 rate determined in this study for an average adult of 1.73 m² body surface area is 173 mg/hour which 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 rate exceeds the maximum elimination 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 during the second 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 36 mg/100 ml, the upper desired therapeutic level for rheumatoid arthritis, to 45 mg/100 ml to 67 mg/100 ml to 77 mg/100 ml to 27 mg/100 ml to 77 mg/100 ml to 27 mg/100 ml to 77 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 should be noted that the maximum individual elimination rates will be just above and below this standard dosage input rate and therefore the range multiple dosage selection will be very large. This is in fact the case. The plasma levels range from 14 mg/100 ml to 82 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 33.8 mg/kg (standard deviation is 5.3), and therefore, the ratio of body weight to surface area was 22.7 mg/kg (standard deviation is 5.4). Therefore, the mean maximum dosage per kg of body weight for this group would be...
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).

### Table: Relationship between dosage and dosage interval (with constant daily and hourly dosage rates) to steady state concentration

<table>
<thead>
<tr>
<th>Dosage interval (hours)</th>
<th>Average dosage rate (milligram/hour)</th>
<th>Number of doses per day</th>
<th>Total daily dosage (milligram)</th>
<th>Maximum amount in body (milligram)</th>
<th>Minimum amount in body (milligram)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>167</td>
<td>100</td>
<td>1,670</td>
<td>4,000/24</td>
<td>4,000/24</td>
</tr>
<tr>
<td>3</td>
<td>167</td>
<td>100</td>
<td>1,670</td>
<td>4,000/50</td>
<td>4,000/50</td>
</tr>
<tr>
<td>6</td>
<td>167</td>
<td>50</td>
<td>1,670</td>
<td>4,000/50</td>
<td>4,000/50</td>
</tr>
<tr>
<td>12</td>
<td>167</td>
<td>25</td>
<td>1,670</td>
<td>4,000/50</td>
<td>4,000/50</td>
</tr>
<tr>
<td>24</td>
<td>167</td>
<td>10</td>
<td>1,670</td>
<td>4,000/50</td>
<td>4,000/50</td>
</tr>
</tbody>
</table>

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 adjusted to maintain the same average dosage rate every hour.

(iv) **Maximum safe single dosage.** The Panel concludes that a large adult dosage of 975 to 1,000 mg may provide increased therapeutic benefit in some cases without significantly increasing the probability of toxicity provided that the dosage is administered only once as a single dosage or as the initial dosage in a multiple dosage regimen. The use of an initial (loading) dosage is a common practice in designing multiple dosage regimens for many drugs. The multiple dosage regimen results in an accumulated amount of drug in the body at steady state which is greater than the amount produced by a single maintenance dosage.

For most drugs which follow linear kinetics, the use of a higher initial (loading) dosage permits the desired steady state drug level in the body to be reached more quickly without changing the ultimate steady state drug level that is reached for a given maintenance dosage. For drugs such as the salicylates, which follow nonlinear kinetics, the amount of the loading dosage is more critical. If the dosage is too large or given repetitively, it may actually increase the final amount of drug in the body at steady state that is reached with a given multiple dosage level. The maximum initial dosage recommended by the Panel is only for use as a single nonrepeated dosage or as the initial dosage used only to initiate a multiple dosage schedule. The recommended maximum initial dosage is recommended, therefore, on the assumption that it will be used only once as a margin of safety for inadvertent overdosage. The maximum number of doses of the 975 to 1,000 mg maximum single dosage at the usual dosage intervals would significantly increase the dosage level and therefore significantly increase the risk relative to any possible increase in analgesic or antipyretic effect.

The maximum single dosage was selected as the single dosage which produced plasma salicylate levels of 2,000 mg/ml to 10 mg/100 ml (Ref. 15) and which would be achieved by the minimum 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.

Leonard (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 every 4 hours.

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 doses 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 dosages 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 plasma 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 plasma concentrations are similar, the increased area under the curve for the higher dosage may indicate potential differences in the two regimens, however. 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-antipyretic use. It 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 salicylism which occurs at 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 (Ref. 16). A target concentration of 20 mg/100 ml for the treatment of rheumatoid arthritis is usually sought; in this range most of the beneficial effects with aspirin can often tolerate higher doses (30 mg/100 ml) in the treatment of rheumatoid arthritis, but monitoring for toxicity is essential (Refs. 17 and 18). Children often develop other symptoms (nausea, hyperventilation) before experiencing tinnitus (Refs. 13 and 17).

Done found a very poor correlation between serum salicylate concentrations at the time of observation and the severity of salicylate intoxication (Ref. 19). The serum salicylate concentrations were extrapolated back to the time of ingestion (S), assuming a half-life value of 20 hours (Kt=0.85485 hr), 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 to be first symptoms and 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 great majority of effects are rapidly reversible and correlate quite well with individual plasma levels except for patients who are already deaf, the incidence of tinnitus and consequent hearing loss are the most reliable and earliest indicators of potentially toxic doses.

Salicylates can produce two effects on hearing function, tinnitus which is a ringing 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 hearing test was demonstrated in volunteers receiving doses of three tablets (975 mg) every 4 hours (244 mg/hour) for 4 days (Ref. 21).

Similar effects of increasing aspirin dosage on actual hearing loss were studied by Myers et al. (Ref. 22). Audiometric measurements were made before and after administration of aspirin to 25 patients.

Myers et al. found that a dosage of 5,000 to 8,000 mg of drug 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 40 decibels for all frequencies which were reversible in all patients within 3 to 10 days.

Hearing loss does not occur below salicylate plasma concentrations of 20 mg/100 ml. Seventeen of 21 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 occurred 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 Morgan et al. (Ref. 24). Neither tinnitus nor deafness occurred below a salicylate dosage below 20 mg/100 ml which is greater than required for analgesia and antipyresis for 95 percent of patients.

(3) Relationship between analgesic effects, dosage, and plasma salicylate concentrations. Although it has not been possible to relate analgesic effect with plasma salicylate concentrations, a relationship between oral dose and analgesic effect has been well-established for several different types of clinical pain.

In almost all well-controlled studies, analgesic effect cannot be distinguished from placebo at dosages below 325 mg. However, higher dosages of 650, 975 and 1,300 mg have been shown to be significantly different from placebo. (See Part III. paragraph B.1.a.(1) below—effectiveness.) Dosages above 650 mg do not produce a significant increment in degree or degree of pain relief in most studies. In some studies, however, dosages of 975 mg (three 325 mg tablets) to 1,300 mg (four 325 mg tablets) appeared to provide a reliable basis for calculation of dose-response curves which appear to be increasing above 650 mg. The difference between the larger dosages compared with 650 mg generally could not be shown to be statistically significant but the apparent increase in the dose-response curve above 650 mg dosages suggests that greater pain relief may be obtained in some individuals with some types of pain with single doses of 975 to 1,300 mg.

Although the dose-response curves in a few studies suggest that larger dosages may produce a slightly greater incidence of analgesia than a 650 mg dosage, there are important limitations in this assumption.

First, the relationship of increased analgesia to increased dosage is not linear but, like many drugs, the effect is proportional to the logarithm of the dosage. Second, the increase in response is generally relatively small because the dose-response curve is relatively flat requiring large increases in the dosage to obtain a relatively small increase in analgesic response.

A related consideration is that most studies of analgesic effects have involved only single dosages. There is relatively little information on the dose-response curves after multiple dosages.

Although limited, current data appear to justify the hypothesis that an initial dosage of 975 mg may prove more beneficial than 650 mg for alleviating pain in a few individuals. For reasons discussed below, an increase in dosage above 650 mg would probably not greatly increase the potential of systemic toxicity if taken only once or twice. If the larger dosage is taken according to the usual multiple dosage schedule, significantly increased potential for toxic effects may be expected. Furthermore, there are no data available to show that multiple dosages greater than 650 mg will provide any greater clinical benefit for analgesic and antipyretic effects.

Although it has not been possible at this time to correlate analgesic effect with the plasma salicylate concentrations, it is possible to determine the plasma salicylate concentrations that are attained with the dosage of aspirin and correlate this with the analgesia. Since toxicity correlates with plasma salicylate concentrations much better than with the dosage of salicylates, it is appropriate to determine plasma salicylate concentrations and compare the toxicity potential of dosages and dosage regimens required for a certain therapeutic effect, e.g., analgesic or anti­arthritis effects, by comparing the corresponding plasma salicylate concentrations.

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, 23, 26, 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. However, it is not possible at this time to employ as large a dosage as possible to ensure a therapeutic effect, e.g., analgesic or anti­rheumatic effects, by comparing the corresponding plasma salicylate concentrations.

Second, the increase in response is generally relatively small because the dose-response curve is relatively flat requiring large increases in the dosage to obtain a relatively small increase in analgesic response.
to the patient and, depending on the dosage and condition, special monitoring for adverse effects may be required and the appropriate dosage must be determined for each patient.

Fremont-Smith and Bayles (Ref. 29) gave increasing dosages of salicylate to 11 hospitalized patients with rheumatoid arthritis, and low dosage of salicylate (16.6 g daily) was stopped because of auditory effects, until the largest tolerated dose was reached. In most cases, the dosage 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 produced an important anti-inflammatory effect in rheumatoid arthritis which was in addition to the analgesic effect. This effect, which could be quantitated 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 active rheumatoid arthritis, whether mild or severe, should receive salicylates regularly in the largest tolerated dosage. The average maximum tolerated dosage was 5.2 g daily.

Boardman and Hart (Ref. 30) compared placebo with prednisone, paracetamol, high dosages of salicylate (5.3 g daily), and low dosages of salicylate (13.6 g daily) administered in multiples of 10 g (660 mg) tablets given in four equal doses daily for 7 days followed by 7 days rest. Therapeutic response was objectively determined by a predesigned significant change 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 salicylate but not by low doses of salicylate, paracetamol or placebo. Changes in joint size, compared sequentially with placebo, proved the most objective means of assessing the anti-inflammatory effect. The authors concluded that the drug known to have anti-inflammatory effects but no significant direct analgesic effects. It is significant that the drug therapies with analgesic, but not anti-inflammatory effect such as paracetamol and low aspirin doses, produced slight improvements in grip strength and patient preference compared to placebo, presumably due to the analgesic effects, but had no effect on joint swelling.

With the high dosage of aspirin (5.3 g/day) improvement of joint size occurred in 3 of 7 patients (43 percent) in the first trial and 7 of 11 in the second trial in which the drug was given in the first or second week of a crossover study with a placebo. The mean decrease in joint size was 5 mm and 4 mm for the two studies. In a study in which a low dosage of salicylate (2.6 g) was compared with a high dosage of salicylate, improvement was noted in 1 of 11 patients in the first trial when the low dosage was given first and in patients where the high dosage was given first indicating a possible residual effect of the high dosage of salicylate. Tinnitus occurred in 4 of 18 patients at the higher dosage and in none of 33 patients receiving the low dosage.

The authors conclude that their study confirms earlier reports that according to their criteria of objective clinical response, anti-inflammatory effects are essentially nonexistent with the lower dosage of aspirin. The Panel concludes there is an abundance of published literature which clearly shows that self-medication of even minor symptoms constitutes an unacceptable risk. The Panel recognizes that because of the high price of aspirin and the short 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. The Panel 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 high price of aspirin and the short 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. No drug known to have anti-inflammatory effects, but had no effect on joint swelling.

In summary, on the basis of pharmacokinetic considerations, the Panel concludes there is an abundance of published literature which clearly establishes that self-medication of even minor symptoms of rheumatoid arthritis constitutes an unacceptable risk. The Panel recognizes that because of the high price of aspirin and the short 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.

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 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 high price of aspirin and the short 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. The Panel concludes there is an abundance of published literature which clearly shows that self-medication of even minor symptoms constitutes an unacceptable risk. The Panel recognizes that because of the high price of aspirin and the short 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.

In summary, on the basis of pharmacokinetic considerations, the Panel concludes there is an abundance of published literature which clearly establishes that self-medication of even minor symptoms of rheumatoid arthritis constitutes an unacceptable risk. The Panel recognizes that because of the high price of aspirin and the short 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. The Panel concludes there is an abundance of published literature which clearly shows that self-medication of even minor symptoms constitutes an unacceptable risk. The Panel recognizes that because of the high price of aspirin and the short 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.

In summary, on the basis of pharmacokinetic considerations, the Panel concludes there is an abundance of published literature which clearly establishes that self-medication of even minor symptoms of rheumatoid arthritis constitutes an unacceptable risk. The Panel recognizes that because of the high price of aspirin and the short 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.


2. Statement on standard and nonstandard nonsalicylate dosage schedules. The components of a salicylate dosage schedule also apply to a nonsalicylate dosage schedule. (See part II. paragraph E.3. above—Analgisic-antipyretic recom mendation below—Dosage schedules 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 acetylaminophen in animals and man than of aspirin. However, there is good evidence that the pharmacokinetics of this drug are simpler than those for aspirin, and that acetylaminophen probably shows linear kinetics. However, the Panel finds it reasonable to recommend the use of acetylaminophen in the same dosages as those recommended for the use of standard aspirin dosage units, i.e., 600 and 650 mg. (See part II. paragraph E.3. above—Recommended dosage for products containing standard dosage units.)

Of particular concern to the Panel in considering the possibility of increasing the dosages of acetylaminophen was the paucity of data regarding the toxic effect of acetylaminophen from single dosages that exceed the dosages recommended for chronic use of the drug for longer than the 5-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 acetylaminophen and its relationship to dosage level. (See part III. paragraph B.1.b.(2) below—Safety.)

Until data based on clinical efficacy studies were available, the Panel considered toxicological studies to be available to justify an increase in the dosage of acetylaminophen. The Panel believes it unwarranted to introduce dosages that exceed the dosages recommended for aspirin. Also, the Panel concludes that only nonstandard dosage units of 500 mg may be recognized for acetylaminophen in addition to the standard dosage unit of 325 mg since the Panel is aware that dosages of acetylaminophen are currently marketed as pediatric dosage units. The Panel further modified this proposal (Pediatric Schedule C) which is discussed more fully below. It should further be noted, that based upon a review of the use of aspirin in children, the Panel also considered the pediatric dosage schedules for acetylaminophen. While not included in the example for aspirin in Pediatric Schedule C, the Panel has included appropriate pediatric dosage recommendations for the other salicylates.

b. Discussion. The following dosage schedule based upon current recommendations 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 gr) aspirin tablets

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Number of tablets taken</th>
<th>Total dosage (single dosage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>3 through 5</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>6 through 11</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>12 to 14</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

#: As directed by physician

As was pointed out by one drug manufacturer, this dosage schedule was estimated based upon 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 are also included in the Panel's report. (Refs. 10 and 11) In one study, dosages were made in children between the ages of 6 months and 72 months (6 years). For the same age groups, the acetaminophen dosages 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 240 mg aspirin and acetaminophen, respectively (Ref. 11). In the second study, the dosage for children 30 to 48 months of age was 180 mg for both aspirin and acetaminophen (Ref. 11). These pediatric dosages are higher than the currently 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 recommended by industry. (Ref. 12) Under this regimen for marketed products (Pediatric Schedule A), the dosage required (not to exceed 5 doses per 24 hours) unless directed otherwise by a physician. This schedule may be more appropriate for patients weighing more than 40 kg if dosage input exceeds maximum of five dosages daily. It is considered that the body surface area per age curve may result in over- or underdosage particularly in older children (body weight of 40 kg or more). This is more clearly shown in the data of Makela et al. (Ref. 12) In this study, 100 mg/kg daily was administered every 8 hours. This dosage regimen generally resulted in plasma levels of 24 to 27 mg percent which is adequate for patients with rheumatoid arthritis but excessive for analgesic-antipyretic effects. Additionally, in 7 of the 19 subjects (37 percent), toxicity occurred which was associated with plasma levels of more than 35 mg percent (35.7 mg percent to 48.3 mg percent). In 50 percent of the cases, the patients were 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 the most accurate predictor of dosage. There are other reasons why the Panel believes that body surface area should be the standard means of calculating clinical dosage. The Panel believes that the prediction of toxicity 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 are toxic 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 linearly 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 the input calculated on a weight basis (D=100 mg/kg daily) was greater than 3.0 g/m² daily when calculated on the basis of surface area: greater than the maximum output of 3.0 g/m² daily. This was not considered in the Panel's report. A second reason for calculating dosing regimens on the basis of surface area is that the body surface area is essentially (linearly) proportional to age for

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
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 7 years and deviation between the Panel's recommended schedule (Pediatric Schedule C) and the industry proposal occurs 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 and antipyretic effects and provide a safety margin in the event of an inadvertent 50 percent increase in dosage. This conversion of age to total dosage is approximated from ages 2 to under 12 years by the relationship:

\[ \text{mg/day} = 600 \times (\text{age} - 2) \]

It is important to note that the use of the full maximum daily adult dosage of 32 ± 0.5 g/m² may exceed the critical dose rate toxicity level. The total daily dosage of salicylate divided by the usual body weight will be about 2.8 mg/kg/day which is equal to the lower level of the toxic level found by Makela (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 2.4 ± 0.2 g/m² daily dosage to about 38 mg/100 ml.

The dosages established are based upon the 1.5 g/m² daily dosage for that age as described by Done (Ref. 15). 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 addition, pediatric dosage schedules for other aspirin salts and all other salicylates were considered by the Panel. While not included in the example for aspirin and 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.

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 single dosage schedule every 4 hours for 66 mg (1.25 gr) aspirin or acetaminophen**

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Dosage (mg)</th>
<th>Total dosage (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 2</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>2 to 4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>4 to 6</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>6 to 8</td>
<td>5</td>
<td>20</td>
</tr>
<tr>
<td>8 to 10</td>
<td>6</td>
<td>24</td>
</tr>
<tr>
<td>10 to 12</td>
<td>7</td>
<td>28</td>
</tr>
</tbody>
</table>

*Not to exceed 2 single dosages in 24 h or to be used for more than 5 d except under the advice and supervision of a physician.

**Conclusion.** In view of these findings, the Panel concludes that it is appropriate to revise the currently marketed OTC pediatric dosage recommendations. In its evaluation of the data, the Panel adopted the definition 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 38441): "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 poison control centers that there is a higher 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 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 (1.25 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. While the Panel realizes 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 and acceptable since it correlates closely with dosages calculated on the basis of surface area.

**Recommendation.** The Panel recommends that the proposed (new) pediatric single dosage schedule described above (Pediatric Schedule C) be used in labeling of future marketed products. The Panel recognizes that, if their recommendation is implemented by the Food and Drug Administration, there will be difficulty in an interim上市 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 (1700.15(a), (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. The Panel endorses the (Pediatric Schedule C) 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 in the containers in which acetaminophen oral products are packaged as well as to 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 80 mg (1.25 gr) tablets intended...
for oral use in children should contain no more than 36 tablets to reduce the hazard of accidental poisoning, as set forth in 21 CFR 201.314(c)(2) for products containing 30 mg (1.23 gr) tablets of aspirin for pediatric use. The Panel recommends that the OTC packaging 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**

1. OTC Volume 090142.

**G. DRUG COMBINATION STANDARDS**

1. **General comment.** The Panel has combined the active ingredients submitted for review into three pharmacological categories, i.e., analgesic, antipyretic and antihistaminic. For purposes of establishing standards for safe and effective drug combination products, the Panel develops a policy not to include the antihistaminic pharmacological activity in the standard. This policy is based upon the Panel's conclusion, described later in this document, that there are no acceptable Category I claims for OTC labeling as an antihistaminic. (See part V, paragraph B.1. below—Category I labeling).

2. **Two major types of combination products were** considered by the Panel. One group of products consists of only combination of analgesic and/or antipyretic active ingredient reviewed for safety and effectiveness by this Panel. The other group of products consists of combinations of analgesic and/or antipyretic active ingredients reviewed for safety and effectiveness by the Panel. The two major types of combination products, the Panel has found, to the claimed effects and that the combination of ingredients is least as safe and effective as the 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 Panel recommends include combinations of analgesics, combinations of antipyretics or an analgesic-antipyretic combination. However, the Panel has found that the active ingredients of combinations which are classified as analgesics are also antipyretics. Therefore, even though three variations are possible, in reality, the ingredients currently available all possess analgesic and antipyretic properties. The Panel is not opposed to the concept of combinations of nonanalgesic-nonantipyretic active ingredients reviewed for safety and effectiveness by the Panel. The nonanalgesic-nonantipyretic ingredients were deferred to other OTC Advisory Panels for 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 concludes that in order to be included in the proposed drug monograph.

A possible rationale for the use of analgesic-antipyretic combination products is that each individual active ingredient is additively or synergistic. This additive or synergistic effect could be due to the drugs acting by different mechanisms or perhaps exerting their effect at different pharmacologic sites.

In reviewing combination ingredients in the marketplace, the Panel applied the OTC Drug Review regulation (21 CFR 330.10(a)(4)(IV)) which states:

An OTC drug may combine two or more safe and effective ingredients and may be recommended as safe and effective when each active ingredient makes a contribution that is recognized in the approved labeling as an antihistaminic ingredient, the active ingredients do not increase the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe 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 effects and that the combination provides rational concurrent therapy. Therefore, even though there may be some rationale for the use of analgesic-antipyretic combination products 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 therapeutic doses of the individual active ingredients when used alone.

The Panel recommends that 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. **Combination of ingredients in combination products.** The Panel recommends 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 in an ingredient and the potential increased risk to the user without a concurrent increase in benefit.

Therefore, with fewer ingredients there is a better chance of reduced risks due to toxic effects, undesirable additive or synergistic effects, allergic or idiosyncratic reactions.

The Panel recommends that not more than two active analgesic-antipyretic ingredients 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 corrective agents which are discussed later in this document. (See part VI. below—Adjuvants and Corrective Agents.) 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 may serve to improve the safety of the product, or to provide relief for symptoms designated by this or other panels or beneficially influence the actions of the active ingredients.

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 Antiasthmatic Products, as published in the Federal Register of September 9, 1976 (41 FR 38334), regarding the labeling of inactive ingredients:

For various reasons, individuals may wish to avoid using certain inactive ingredients found in drug products. These reasons may be allergic reactions, idiosyncratic responses, fear of safety (whether valid or not), or personal dislike. It is impossible to make a free choice in this regard unless the complete list of drug products are listed on the label. Therefore, this Panel strongly recommends that the Food and Drug Administration require that the labeling of inactive as well as active ingredients in descending order of quantities present in all drug products.

In support of this position the Panel notes that food products are already required to have such labeling, and since the purpose of labeling food products is to prevent contamination of disease, it would seem much more compelling to have this information on all drugs. By labeling with the intent to expose the consumer to the smallest number of ingredients possible, the Panel has previously recommended that marketed products contain only those ingredients essential to the product.

3. Labeling of active ingredients. The Panel agrees that each claimed active ingredient in a combination product must make a contribution to the claimed effect(s).

Labeled indications should only be for the combinations of symptoms appropriate to the activity of the combined ingredients. The consumer should be adequately informed through the labeling of the therapeutic capabilities of the product by emphasizing the use of the product only when all such symptoms are present. Labeling should, therefore, fully describe the specific active ingredients so that a consumer may select an appropriate product for relief of symptoms.

b. Standards for Category I combination products. a. Each active ingredient and its labeling in a combination product must be generally recognized as safe and effective (Category I).

b. One Category I analgesic-antipyretic active ingredient or a combination of two such 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 may serve to improve the safety of the product, or to provide relief for symptoms designated by this or other panels or beneficially influence the actions of the active ingredients.

Nonanalgesic-nonantipyrctic active ingredients may be included in products only if they are in safe and effective dosage forms to 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 Antiasthmatic Products, as published in the Federal Register of September 9, 1976 (41 FR 38334), regarding the labeling of inactive ingredients:

For various reasons, individuals may wish to avoid using certain inactive ingredients found in drug products. These reasons may be allergic reactions, idiosyncratic responses, fear of safety (whether valid or not), or personal dislike. It is impossible to make a free choice in this regard unless the full complete list of drug products are listed on the label. Therefore, this Panel strongly recommends that the Food and Drug Administration require that the labeling of inactive as well as active ingredients in descending order of quantities present in all drug products.

In support of this position the Panel notes that food products are already required to have such labeling, and since the purpose of labeling food products is to prevent contamination of disease, it would seem much more compelling to have this information on all drugs. By labeling with the intent to expose the consumer to the smallest number of ingredients possible, the Panel has previously recommended that marketed products contain only those ingredients essential to the product.

3. Labeling of active ingredients. The Panel agrees that each claimed active ingredient in a combination product must make a contribution to the claimed effect(s).

Labeled indications should only be for the combinations of symptoms appropriate to the activity of the combined ingredients. The consumer should be adequately informed through the labeling of the therapeutic capabilities of the product by emphasizing the use of the product only when all such symptoms are present. Labeling should, therefore, fully describe the specific active ingredients so that a consumer may select an appropriate product for relief of symptoms.

b. Standards for Category I combination products. a. Each active ingredient and its labeling in a combination product must be generally recognized as safe and effective (Category I).

b. One Category I analgesic-antipyretic active ingredient or a combination of two such 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 may serve to improve the safety of the product, or to provide relief for symptoms designated by this or other panels or beneficially influence the actions of the active ingredients.

Nonanalgesic-nonantipyrctic active ingredients may be included in products only if they are in safe and effective dosage forms to 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 Antiasthmatic Products, as published in the Federal Register of September 9, 1976 (41 FR 38334), regarding the labeling of inactive ingredients:

For various reasons, individuals may wish to avoid using certain inactive ingredients found in drug products. These reasons may be allergic reactions, idiosyncratic responses, fear of safety (whether valid or not), or personal dislike. It is impossible to make a free choice in this regard unless the full complete list of drug products are listed on the label. Therefore, this Panel strongly recommends that the Food and Drug Administration require that the labeling of inactive as well as active ingredients in descending order of quantities present in all drug products.

In support of this position the Panel notes that food products are already required to have such labeling, and since the purpose of labeling food products is to prevent contamination of disease, it would seem much more compelling to have this information on all drugs. By labeling with the intent to expose the consumer to the smallest number of ingredients possible, the Panel has previously recommended that marketed products contain only those ingredients essential to the product.

3. Labeling of active ingredients. The Panel agrees that each claimed active ingredient in a combination product must make a contribution to the claimed effect(s).

Labeled indications should only be for the combinations of symptoms appropriate to the activity of the combined ingredients. The consumer should be adequately informed through the labeling of the therapeutic capabilities of the product by emphasizing the use of the product only when all such symptoms are present. Labeling should, therefore, fully describe the specific active ingredients so that a consumer may select an appropriate product for relief of symptoms.

b. Standards for Category I combination products. a. Each active ingredient and its labeling in a combination product must be generally recognized as safe and effective (Category I).

b. One Category I analgesic-antipyretic active ingredient or a combination of two such 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 may serve to improve the safety of the product, or to provide relief for symptoms designated by this or other panels or beneficially influence the actions of the active ingredients.

Nonanalgesic-nonantipyrctic active ingredients may be included in products only if they are in safe and effective dosage forms to 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 Antiasthmatic Products, as published in the Federal Register of September 9, 1976 (41 FR 38334), regarding the labeling of inactive ingredients:

For various reasons, individuals may wish to avoid using certain inactive ingredients found in drug products. These reasons may be allergic reactions, idiosyncratic responses, fear of safety (whether valid or not), or personal dislike. It is impossible to make a free choice in this regard unless the full complete list of drug products are listed on the label. Therefore, this Panel strongly recommends that the Food and Drug Administration require that the labeling of inactive as well as active ingredients in descending order of quantities present in all drug products.

In support of this position the Panel notes that food products are already required to have such labeling, and since the purpose of labeling food products is to prevent contamination of disease, it would seem much more compelling to have this information on all drugs. By labeling with the intent to expose the consumer to the smallest number of ingredients possible, the Panel has previously recommended that marketed products contain only those ingredients essential to the product.
causes an increase in occult bleeding and in some individuals massive gastrointestinal bleeding. The adverse effects of aspirin on the gastrointestinal tract are discussed elsewhere in this document. (See part VI, paragraph B.1.a. 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 1.9 mg 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 intended therapeutic component measured by the method established in §331.25 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 must be included on the principal display panel:

1. 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!
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 II, paragraph B.2.e.—Caffeine irritation.)
   b. Combination products containing Category I analgesic-antipyretic(s) combined with any active ingredient(s) not included in 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 hypersensitive individuals.)

d. Combinations of analgesics with sedative, tranquilizer and sleep aid ingredients are considered irrational since in some instances use of such drugs should not be treated by fixed-ratio combination products. Conditions requiring treatment with such drugs should be treated with single ingredients. Vitamins combined with analgesics may encourage unnecessary prolonged use of analgesics and are therefore classified as Category II.

6. Standards for Category III combination products. a. Combination products containing a Category III analgesic-antipyretic analgesic or a combination of two Category II analgesic-antipyretic active ingredients are classified as Category III.
   b. Combination products containing any Category I analgesic-antipyretic active ingredient at less than 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. Combination products containing one Category I analgesic-antipyretic active ingredient or a combination of two such ingredients as provided above in standard No. 4.b. combined with caffeine used as an adjuvant are classified as Category III.

The Panel concludes that there are insufficient data available to evaluate the safety of aspirin. 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 B.2 below—Combination products containing an analgesic, antipyretic and/or antirheumatic adjuvant.)

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 caused by occasional sleeplessness". The Panel concurs with the recommendations of the Advisory Review Panel on OTC Sedative, Tranquilizer and Sleep-Aid Drug Products published in the Federal Register of December 8, 1975 (40 FR 57315) that there is little evidence to show that this ingredient contributes to analgesic, antipyretic and/or antirheumatic effects. The Panel finds that there is inadequate data 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 B.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 caffeine used as an adjuvant are classified as Category III.

The Panel concludes that there are insufficient data available to evaluate the safety of aspirin. 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 B.2 below—Combination products containing an analgesic, antipyretic and/or antirheumatic adjuvant.)

7. Standards for testing Category III combination products. The Panel concludes that there are insufficient data available to evaluate the safety of aspirin. 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 B.4 below—Antihistamine-containing ingredients.)
cution at this time, and part V. paragraph 

The Panel is aware that instances exist 
where individuals suffering from serious 
ilness 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 suffering from chronic 
illnesses will use OTC analgesics, antipy­ 
retics and antirheumatic drugs.

The Panel concludes that the warn­ 
ing on products containing salicylates should read “Caution: Do not take this product if you are presently taking a prescription drug for anticoagulation or other medical conditions that may interact with salicylates, aspirin in particular, and prescri­ 
ption drugs otherwise.”

Therefore, the Panel recommends that 
the labeling caution against the concurrent 
use of salicylates and some prescription 
drugs not be changed in the manner suggested elsewhere in this document. (See part III. 

B.1.a. (2) viii) below—Adverse ef­ 
efects of concomitant use with other 

drugs occur, but due to the varying clini­

cal significance, these interactions do not 
merit inclusion in the warning.

Individuals who are currently taking 
anti-inflammatories or aspirin, may experi­
ence increased risk of bleeding.

The Panel is cognizant of the severity of this 
interaction. Yet, because of the toxicity 
of methotrexate physicians always care­

tul patients of the need for a 

warning.

Another interaction occurs between 
salicylates and drugs used to scudify the 
skin since acidic urine decreases the 

excretion rate of salicylates and thus in­

creases their half-life (Refs. 4 and 5).

Sulfonamides are antibacterials 

employed primarily in the treatment of uri­

nary tract infections. Sulfonamides have 

been reported to increase serum salicy­

late levels by displacement from plasma 

protein binding sites (Ref. 5). Even 

though this interaction can potentially 
be serious, sulfonamides are usually used 
for treatment of acute infections not for 

chronic conditions and thereby do not 
merit inclusion in the warning.

When salicylates are taken with 
sulfonamides, salicylates accumulate in the 

blood due to decreased salicylate excretion and 

acidic excretion is increased (Ref. 5). This 

interaction is probably not important 

since it is unlikely that the salicylate-sulfon­

amide interaction will result in toxic 

salicylate levels in the blood.

REFERENCES

(1) Woodbury, D. M. and E. Fingl, 
“Analgesic-Antipyretics, Anti-Inflammatory 
Agents, and Drugs Employed in the Therapy of 
Gout,” in “The Pharmacological Basis of 
Therapeutics,” 4th Ed., Edited by Goodman, 
L. S. and A. Gilman, The Macmillan Pub­

(2) Levine, W. G., “Anticoagulant, Anti­
thrombotic, and Thrombolytic Drugs,” in 
“The Pharmacological Basis of Therapy,” 4th Ed., 
Edited by Goodman, L. S. and A. 

(3) Laurence, D. R., “Clinical Pharma­
cology,” Churchill Livingstone, Edinburgh 

(4) Cluff, L. S. and J. O. Petrie, “Clinical 
Effects of Interaction Between Drugs,” 
American Elsevier Publishing Co., Inc., 

(5) “Evaluations of Drug 
Interactions,” 20 Ed., American Pharmaceutical 

I. DEFINITIONS

The Panel has adopted and uses the following definitions throughout this 
document:

1. Acetaminophen analgesic equiva­

lence. The analgesic effectiveness 
for a product containing acetaminophen 
when compared to the standard acet­
aminophen 325 mg (5 gr) dosage unit.

2. Acetaminophen (pediatric dose 

age unit). A single dosage unit containing 40 
mg (1.25 gr) acetaminophen for children 
under 12 years.
3. Acetaminophen (standard dosage unit). A single dosage unit containing 325 mg (5 gr) acetaminophen.

4. Direct acting. An adjuvant 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.

5. Therapeutic effect of the active agent modifies the disposition (absorption, metabolism, excretion or distribution) of the active agent.


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. Adjuvant. 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 carbashpin when compared to the standard dosage unit 325 mg (5 gr) dosage unit.

11. Aspirin (buffered). A solid dosage form containing 325 mg (5 gr) aspirin with sufficient buffering capacity and an acid neutralizing capacity per 325 mg of aspirin is equal to or greater than the level of the initial 10-minute period as measured by the method established in §331.25 of the OTC antacid monograph 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 the OTC antacid monograph and provided the product is identified as buffered aspirin with labeling 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 29 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 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 level of their 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 for the treatment of the condition for which the test drug is available to the site(s) of action.


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 salicylic acid when compared to the sodium salicylate 325 mg dosage unit.

18. Sodium salicylate (standard dosage unit). A single dosage unit containing 325 mg sodium salicylate.

1. EFFECTS OF PRODUCT FORMULATIONS ON DRUG ABSORPTION AND PHARMACOLOGIC EFFECTIVENESS.

1. General Comment. Analgesic, antipyretic and antiinflammatory drugs are the most frequently used of all 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 relief", "special pain relieving formula", "so strong and so gentle", "acts 5 times faster than aspirin", "reaches peak action 12 times faster than aspirin", "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 to the consumer and the intent of the labeling claims is not always clear.

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 for over-the-counter products containing analgesics combined with antacid or buffering ingredients.)

The Panel was charged to evaluate the safety and effectiveness of these OTC drugs 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 their therapeutic effectiveness. For example, buffered aspirin preparations may be considered because some buffered preparations may have significant effects on the rate of dissolution and subsequent absorption of aspirin (Ref. 1). The pharmaceutical 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.)

For many years drug manufacturers were primarily concerned with the appearance and acceptability. Later, product stability became increasingly important. In the past decade it has become evident that the materials and methods used in the formulation or preparation of the dosage forms (coatings, etc.) can greatly affect the onset, duration and intensity of the pharmacologic effects of some drugs. The relationships between dosage formulations and the onset and extent of absorption and resultant plasma concentrations are the basis of the new area of study termed bioequivalencies. Bioequivalence is a closely related term and is used to describe the situation when the rate and extent to which the active ingredient is absorbed into the bloodstream from the finished dosage form being tested relative to some standard product which has been shown to be clinically effective. It is assumed that the test drug is available to the site(s) of the drug's action to the same extent as the standard drug product when the concentrations obtained are identical with respect to the same active substances. It is important to note that the use of bioequivalence as established by essentially identical plasma concentrations between dosage forms or products containing two different drug delivery systems delivers the same active principal(s) to the general bloodstream. Furthermore, unless additional correlations between the active substances and pharmacologic effects have been established, it is not possible to use differences in the plasma time curves of the active substances to infer that differences in biological response will necessarily occur. For example, one could compare the blood levels of aspirin and the active metabolite salicylic acid obtained from a capsule formulation which used a calcium salt of aspirin as opposed to a direct salicylic acid formulation only to produce clinical effects. If the blood level time curves were superimposable, it would be reasonable, based on all known studies, to assume that the for­ mulation has no significant effect on the absorption and intensity of pharmacological effects. However, if one product were substantially more rapidly absorbed than the other, one cannot conclude that there is necessarily a corresponding difference in onset of effect. The mathematical relationship between changes in blood levels and corresponding changes in onset, or intensity of analgesic response is not presently known for aspirin.

The Panel finds that there are several processes and factors that govern the ultimate effectiveness of an active ingredient and can influence the time demonstration until its pharmacologic effects, e.g., relief of minor aches and pains, become evident. These factors include the disintegration or breakup of the dosage form (solids) into granules or aggregates in the aqueous fluid, of the stomach or intestine. Another critical factor is the rate and extent of dissolution which involves the further transfer of drug in the fine solid particles into a dispersion of molecules or ions in an aqueous solution. The disintegration and dissolution...
of the dosage form are actually two different processes. Until recently, however, rapid disintegration was thought to be the most critical factor involved with rapid availability of the drug for absorption into the systemic circulation. Official standards only required disintegration data from most tablets.

It is now understood that it is the dissolution rate of the drug that most often determines the overall rate of absorption from most tablets.

The most critical factor involved with the different processes is the solution rate of the drug that most often determines the overall rate of absorption. Various studies have clearly demonstrated that each finished dosage form, e.g., tablet, solution, etc., directly affects the dissolution rate and bioavailability of the active ingredient. There are also data that demonstrate differences even in the dissolution rates for the same dosage form, for example, between two unbuffered aspirin tablets, or between an unbuffered and buffered aspirin tablet.

Whereas the Panel can find correlations between changes in product formulation and the drug levels achieved in the blood, the relationship of these blood levels to the degree and onset of pharmacologic effect is not yet understood (Ref. 2). It is obvious that a given level of drug in the blood produces comparable blood levels to the degree and onset of pharmacologic effect. Therefore, differences in formulation between them can affect the bioavailability, i.e., bioavailability as manifested in blood levels of the active ingredient(s) contained in them. The Panel recognizes the variety of claims made for these different formulations, and has attempted to evaluate the safety and effectiveness of active ingredients in formulations relating to possible differences between dosage forms were developed by the drug manufacturers to meet other needs of the consumer, such as the difference between a tablet and a solution can affect the absorption characteristics of a drug product and consequently its therapeutic performance. However, the Panel recognizes that despite any apparent correlation between the drug levels achieved in the blood and the pharmacologic effectiveness of the active ingredient, differences in formulation such as the difference between a tablet and a solution can affect the absorption characteristics of a drug product and consequently its therapeutic performance. However, the Panel emphasizes that there is no evidence that blood drug levels (a measure of bioavailability) correlate directly with pharmacologic effectiveness.

The submissions to the Panel for 14 different dosage forms (formulations) of OTC internal analgesics, antipyretic and antirheumatic active ingredients are listed in the following chart:

<table>
<thead>
<tr>
<th>Dosage Forms in Submissions of Marketed Drug Products</th>
<th>Number of submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets:</td>
<td></td>
</tr>
<tr>
<td>Unbuffered</td>
<td>62</td>
</tr>
<tr>
<td>Buffered</td>
<td>13</td>
</tr>
<tr>
<td>Chewables</td>
<td>6</td>
</tr>
<tr>
<td>Enteric-coated</td>
<td>2</td>
</tr>
<tr>
<td>Timed-release</td>
<td>1</td>
</tr>
<tr>
<td>Capsules</td>
<td>1</td>
</tr>
<tr>
<td>Powders</td>
<td>1</td>
</tr>
<tr>
<td>Gums</td>
<td>1</td>
</tr>
<tr>
<td>Liquid dosage forms:</td>
<td></td>
</tr>
<tr>
<td>Drops</td>
<td>1</td>
</tr>
<tr>
<td>Elixir</td>
<td>1</td>
</tr>
<tr>
<td>Highly buffered (effervescent) aspirin for solution</td>
<td>1</td>
</tr>
<tr>
<td>Susensions</td>
<td>3</td>
</tr>
<tr>
<td>Syrups</td>
<td>3</td>
</tr>
<tr>
<td>Suppository dosage forms:</td>
<td></td>
</tr>
<tr>
<td>Suppository</td>
<td>1</td>
</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 are marketed in a solid dosage form. Of these, the tablet in several variations, i.e., unbuffered, buffered, 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 recognizes the variety of claims made for these different formulations, and has attempted to evaluate the safety and effectiveness of active ingredients in formulations relating to possible differences between dosage forms 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 possible 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 can 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—Assessment of Data: Tablet dissolution testing procedure. The other major tablet solid dosage form is buffered aspirin products. Buffering agents have been used for aspirin tablets to increase the dissolution rate in an attempt to hasten 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 and 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 commonly used which the Panel has designated 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 analgesic 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.b. below—Buffered aspirin acid neutralizing testing procedure.)

The quantity of alkaline buffers is sufficiently high 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 absorption 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 after the dissolving particle, resulting in a 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 for aspirin standard testing procedures are discussed elsewhere in this document. (See part VI, paragraph B.I.d. below—Labeling claims for marketed products containing analgesics combined with antacid or buffering ingredients.)

The quantity of alkaline buffers in these highly buffered preparations is greater than that in buffered tablet preparations. In this case, the pH of the gastric fluid is increased. Some highly buffered aspirins have been shown to significantly decrease gastric ulcer bleeding that results from direct effects of aspirin on the gastric mucosa and are discussed later in this document. (See part III, paragraph C.I.a. below—Buffered aspirin neutralizing testing procedures.)

PROPOSED RULES

The quantity of alkaline buffers in these highly buffered preparations is greater than that in buffered tablet preparations. In this case, the pH of the gastric fluid is increased. Some highly buffered aspirins have been shown to significantly decrease gastric ulcer bleeding that results from direct effects of aspirin on the gastric mucosa and are discussed later in this document. (See part VI, paragraph B.I.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 in solution dosage forms. In one study (Ref. 4) the 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 todissolve was varied between 1 and 20 minutes depending on the buffering agent used. In general, it was determined that carbon dioxide producing buffering agents (sodium bicarbonate, magnesium carbonate, sodium citrate, and sodium carbonate) gave more rapid dissolution than the readily water-soluble buffering agents (sodium ascorbate and sodium citrate), and both of these classes of buffering agents gave much faster dissolution than water-insoluble buffering agents such as aluminum compounds and magnesium compounds other than magnesium carbonate.

From the available data, 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 between studies comparing unbuffered aspirin with buffered aspirin. The absence of data showing that any buffering agent actually does affect the dissolution rate of the aspirin products and to what extent.

Also, the Panel notes that an adequately buffered aspirin product may not exhibit a faster dissolution rate than an unbuffered product. In some studies, unbuffered aspirin performs as well as buffered aspirin products.

The totality 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 glycinate and magnesium carbonate (Ref. 5). In this study, three unbuffered products were tested. He found that 68 percent of the unbuffered 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 unbuffered product and the buffered product, the same difference as between two 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 variation in dissolution rates among unbuffered aspirin products can be as great as the difference between unbuffered and buffered aspirin products. In this study another buffered salt of aspirin, namely calcium acetalsaliclycate, 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 carbonate (Ref. 6). The dissolution half-times (the time required for half (150 mg) of a 300 mg tablet to go into solution) were determined. The dissolution half-time of the unbuffered aspirin product was less than 5 minutes as compared to dissolution half-times of the six unbuffered aspirin products, which were all greater and ranged from 8 1/2 to 13 1/2 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 acetalsaliclycate complex carbonate 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 to 72 percent of the buffered aspirin dissolved in 10 minutes, 81 percent of the calcium acetalsaliclycate carbonate complex dissolves in 8 minutes.

This study showed again that marketed unbuffered aspirin products have a wide range of dissolution rates. The six products exhibited dissolution half-times of 8 1/2, 8 1/4, 10 1/4, 11 1/2, 13 and 13 1/2 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 tablets. Some investigators have reported that the buffered form is more rapidly absorbed and causes less gastric irritation than the unbuffered drug. Other workers have found no significant difference between unbuffered aspirin and buffered aspirin. It is now clear that because of the differences in dissolution rates of different brands of both unbuffered and buffered aspirin products, different results would be expected 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.I. below—Aspirin standard testing procedures.)

Cheewable tablets offer a convenient method of administering the drug to individuals who have difficulty in swallowing whole tablets. This dosage form is especially popular for use in children. There are many marketed children's chewable aspirin tablets, which are usually flavored, containing 60 mg (1.23 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 fact that the use of tablets to undergo changes on aging which can markedly alter their release characteristics (Ref. 10). In addition, the absorption of aspirin from physically unstable 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 many drugs. The Panel finds these chewable, flavored tablets acceptable and recommends that all such tablets containing salicylates for children under 12 years be labeled, "Drink water with each dose". In addition, as noted elsewhere in this document, because aspirin can increase bleeding, the Panel recommends that chewable tablets be labeled, "Do not take this product for at least 7 days after tonsillectomy or oral surgery except under the advice and supervision of a physician". (See point (b) (i) below—Mucosal erosion of the mouth.)

The Panel is aware that in the case of aspirin most of these products are packaged or more. The substitution of undental opening by small children. However, regardless of the method of packaging, the Panel recommends that the container be labeled with the warning, "Keep out of reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately."

Enteric-coated tablets were developed in an attempt to eliminate the local irritation in the stomach caused by some analgesics. Accordingly such tablets were designed to dissolve in the small intestine rather than in the acid gastric fluids. Therefore, when taking an enteric-coated tablet, the individual must take into consideration the delayed action of these products. 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 tablett dosage form. The preparation from finely divided powders is directly related to the large surface area of these products. Powders have the advantage of being easier to administer 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 their unpalatable taste. 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 ready to be used routinely. The Panel recommends that powders containing salicylates be mixed with a full glass of water and stirred prior to use.

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 since no convincing data are available that micronizing confers any favorable properties to aspirin beyond those found with regular aspirin.

Capsules are solid dosage forms in which the active ingredients(s) is enclosed either in a hard or soft, soluble container or shell of a suitable form of gelatin. Its principal advantage is that the product 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 preparation from finely divided powders is directly related to the large surface area of these products. Powders have the advantage of being easier to administer 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 their unpalatable taste. 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 ready 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 single tablet to treat mild pain. Product labeling for postpartum patients. Stubbe et al. (Ref. 12) suggest that a cellulose acetate phthalate coating on tablets slows salicylate release and increases the duration of action. There was little gastric blood loss with this coating and the salicylate blood levels were higher the following morning than with uncoated aspirin. One longer-release aspirin preparations is currently marketed. The labeling on these products suggests that they provide long lasting relief, are useful at bedtime for relief of pain during the last few hours of the dosage interval, and should therefore be deferred to the professional advice of a physician for local effect properly belongs to the Ear, Nose, and Throat, in general and should therefore be referred to the Otological and Rhinological 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 desired and legitimate, which may claim recommended by the Panel. (See part III, paragraph B.1. below—Catezory I Labeling.) However, such product formulations containing aspirin should include the warning, "Do not take this product for at least 7 days after tonsillectomy or oral surgery except under the advice and supervision of a physician."

Aspirin is a component of tablets discussed above, oral mucosal damage may occur as a result of the use of chewing gum aspirin products and the effect of aspirin on blood clotting may be a factor in such situations.

b. Liquid dosage forms. Although liquid dosage forms are used for OTC internal analgesic, antipyretic and anti-inflamatory drug products, they are not as commonly available as the solid dosage forms. Proper or read food is not readily available in liquid form. It is reasonably stable in dry air, but in the presence of moisture is slowly hydrolyzed to acetic acid and salicylic acid. Current methods of administering choline salicylate and salicylamide are available in liquid preparations. Theoretically, liquid dosage forms, i.e., drops, elixirs, solutions, syrups, should have one chief advantage over solid dosage forms in that they are more rapidly absorbed and consequently should have a more rapid onset of action. However, because of the difference in the onset of clinical analgesia can be shown, this theoretical speculation is moot.

These preparations, which are usually flavored for children, are often promoted for use as drops for children to relieve the pain and discomfort of teething, tonsillectomy, etc. Drops may be administered orally directly from a calibrated dropper or mixed with food or liquid prior to use. The elderly and individuals who have difficulty swallowing solid dosage forms may find the liquid dosage forms easier to take.

As pointed out earlier, a more rapid absorption of liquid dosage forms, one would expect peak blood levels and therapeutic effectiveness to be attained sooner than with solid dosage forms. No significant advantages in this respect, however, has been demonstrated.

c. Rectal suppository dosage forms. Practical reasons underlie the necessity for the use of the suppository dosage form. Its use is indicated, for example, in individuals who are vomiting, are unconscious, are suffering from extreme gastric irritation, or are otherwise delayed in taking an oral dosage form. In such individuals, administration may be practical. Suppositories are dosage forms that melt and undergo dissolution, after rectal insertion, releasing the active ingredient(s) which are then absorbed and produce their pharmacologic effect. There are limiting factors which can influence each step: melting, dissolution, or absorption. The composition of the suppository base can be a very important limiting factor. If it fails to melt at body temperature or melts too slowly, the individuality may pass the intact suppository without receiving any pharmacologic effect. On the other hand, if the base melts too rapidly and the active ingredient(s) is in contact with mucous membranes, adverse effects may result. (Ref. 13) This is a problem, especially for drugs such as aspirin which may cause local irritation.

Variability in the melting time of suppository bases may result in variations in the blood levels of the active ingredient (bioavailability) so that the pharmacologic and therapeutic effectiveness of the drug may be reduced. An example of variations in the bioavailability of suppositories is demonstrated in a study in which the salicylate absorption from five brands of commercially available suppositories was studied in four adult male subjects (Ref. 13). All subjects received each of the five brands at intervals of at least 1 week. The urinary excretion rates of total salicylate served as an index of the extent of absorption from the five brands of suppositories. The rate of absorption from the suppositories was slow compared to absorption of the drug given orally. Generally in the 3-hour retention period, only about 40 percent of the dose was absorbed from one of the five brands, and an average of only about 25 percent of the dose was available from the other four brands. It was found that longer retention times tended to diminish the differences in absorption between brands. Only after a 10-hour retention period was absorption of the drug nearly complete in most cases. Generally, the slow absorption from the suppositories, and the inability to control the retention time due to defecation needs, make the use of suppositories a questionable dosage form for aspirin or salicylate therapy.

Because suppositories may have different melting or dissolution rates and therefore unpredictable bioavailability of the drug contained in them, the blood levels achieved may be too low to be therapeutically effective or very high and produce toxic effects. Therefore, the Panel recommends that suppository formulations demonstrate blood levels (rate and extent of absorption) or pharmacologic effectiveness comparable to and the incidence of side effects (including irritation) not greater than, those seen with preparations given in conventional dosage. Furthermore, suppositories can produce irritation to the anal mucosa. The extent of the irritation depends on the active ingredient and the chemical composition of the base. For these reasons, each suppository formulation must be subjected to studies in human subjects. (See part III, paragraph B.1.a(2) (ii)-(b) (2) below—Rectal irritation.)

3. Factors affecting drug absorption. A decrease in the rate and extent of gastrointestinal absorption (bioavailability) of a drug may produce a decreased pharmacologic effect of the drug. Not only can the formulation influence drug absorption but physiological vari-ables of gastrointestinal function can profoundly determine the bioavailability of the drug. Factors affecting gastrointestinal function such as gastric emptying, intestinal transit time, and intestinal motility may affect the availability of the drug for absorption into the systemic circulation. Poorly absorbed drugs have a longer residence time in the gastrointestinal tract which 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, 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 unavailable. For the evaluation of the effectiveness of an OTC analgesics, or analgesiometry, must be in the form of measurements 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. 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 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 readily 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 the effectiveness of a claimed OTC antipyretic drug is discussed later in this document. (See part IV, paragraph C. below—Data Required for Evaluation.)

c. Antirheumatic effectiveness. The critical measurements in evaluating the effectiveness of an OTC antirheumatic agent is its ability to restore joint function and prevent progression of the disease. These drugs reduce joint or muscle tenderness or swelling. Rheumatoid arthritis is still not curable and therefore treatment must include the use of an analgesic. Canine studies in assessing a claimed antirheumatic drug is the fact that the disease itself may change spontaneously. Adequate study design is critical in the assessment of antirheumatic effectiveness. Aspirin is one of the most commonly prescribed drugs for the treatment of rheumatic diseases and is used not only as an analgesic but as an anti-inflammatory agent. Because the effect, large doses administered over a prolonged period of time are usually necessary. The Panel's recommendations pertaining to the evaluation of the effectiveness of a claimed OTC antirheumatic drug are discussed later in this document. (See part V, paragraph C. below—Data Required for Evaluation.)

d. Drug blood level determinations. May be utilized either in the literature or in data submissions to the Panel. have utilized drug blood levels as a measure of analgesic effectiveness. Aspirin is commonly used as a standard analgesic for 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 complex and not presently 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 at a given period of time, e.g., 10 to 20 minutes after administration, the higher absorption rate 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 comparison of the clinical effect with the establishment of a correlation between blood level and clinical analgesia.

e. Onset, duration and intensity of pharmacologic effects. The Panel recognizes that labeling related to the onset, intensity and duration of pharmacologic effects can influence the consumer's selection of a product but can find no convincing evidence to support labeling which suggests a faster onset of effectiveness, e.g., "fast pain relief". Other than possibly for timed-release preparations no evidence was found to support claims such as "nighttime 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, the Panel recommends that any addition of small amounts of some buffering agents to aspirin enhances the rate of absorption of the drug, thus causing less gastrointestinal irritation. Consequently, some more 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, there are buffered aspirin preparations that are not absorbed any faster than unbuffered aspirin products, as noted above. However, the Panel is concerned that demonstration 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 salicylate and salicylates in man

1. Absorption. Aspirin and salicylate absorption varies from person to person by passive diffusion across the mucosal surfaces of the nondissociated lipid-soluble molecules (salicylic acid and acetylsalicylic acid) across gastrointestinal membranes and is influenced by gastric pH. If the pH is increased, salicylate will remain 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. Orally ingested salicylates are absorbed rapidly, primarily from the stomach but also from the upper and middle small intestine. Appreducible plasma 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 lasts for about 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 the usual therapeutic dose. (Ref. 21). Salicylate undergoes biotransformation which occurs in many tissues but particularly in the liver by the enzymes...
The three chief metabolic products are salicylic acid (the glycine conjugate), the ether or phenolic glucuronide, and the ester or acylglucuronide. In the cells of the liver, salicylic acid is oxidized to gentisic acid (2,5-dihydroxybenzoic acid) and to 2,3-dihydroxybenzoic and 2,3,5-trihydroxybenzoic acids. These metabolites are found in the urine; the conjugates and salicylic acid have also been identified in plasma, liver, and some other tissues. The concentration of the metabolites in plasma is generally only about 1 percent of the total plasma salicylate.

The biotransformation route of aspirin in man have been reviewed by Levy and Leonards (Ref. 3). Aspirin is hydrolyzed rapidly in the body to salicylic acid which is conjugated in part with glycine to form salicylic acid and with glucuronide to form acyl and phenolic glucuronides. A small fraction of 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 entirely in urine. The study of aspirin metabolism has been reviewed by Gellhorn (Ref. 1) in his short review of salicylate metabolism states:

"All processes of biotransformation and excretion are first order with the exception of the formation of salicyluric acid with glycine. The formation of salicylic acid and with glucuronide acid to form the ether glucuronide is further hydroxylated to gentisic acid. If the urinary excretion is decreased, the percent of the dose recovered in urine has been reported to be between 3.5 and 6.5 mg per dose (Refs. 1 and 2). Levine (Ref. 1) found an appreciable variation of salicylate elimination by half-life probably reflect differences in salicylic acid formation capacity (glycine conjugation) and is probably genetically determined. Levy has pointed out (Ref. 3) that: "Any search for genetic differences in salicylate elimination by half-life of salicylic acid with glycine reached a maximum rate constant for this process (which requires more caution is necessary when large, toxic effects (due to drug accumulation) are involved."" He has also expressed concern (Ref. 4) about how little is known concerning the formation of salicyluric acid in children and the literature to suggest that salicylates may be a factor in the development of salicyluric acid formation capacity (glycine conjugation) and is probably genetically determined.

"The half-life of salicylic acid in doses between 300 and 650 mg has been reported to be between 3.1 to 3.2 hours (Ref. 1). However, when the dose is increased to 1 g, the half-life is increased to 5 hours (Refs. 4 and 5). If the dose is increased to 2 g the half-life is increased to about 9 hours (Ref. 4). Not only is the half-life markedly increased, but the urinary excretion also decreases as the dose is increased from 0.32 g to 0.67 g (Refs. 4 and 6). If the urinary excretion is decreased, more salicylate will be retained in the body with a great toxic potential since it will probably occupy most of the available albumin binding sites and displace other drugs or endogenous products, e.g., bilirubin.

The percent of the dose recovered in 7.5 hours of urine collection is 71.5 percent after a 1.32 g dose, 55 percent after a 0.64 g dose and 52.1 percent after a 0.32 g dose (Ref. 2). These values, if extrapolated, may call for a change in dosing intervals rather than in change in dosing intervals. However, it is not known whether a toxic effect (due to drug accumulation) is involved". The authors (Ref. 5) also recommended adjusting individual dosage intervals as follows: "The appearance of side-effects (such as tinnitus), indicative of overdosage due to drug accumulation, may call for a change in dosing intervals rather than in change in dosing intervals. However, it is not known whether a toxic effect (due to drug accumulation) is involved in this study have potentially important therapeutic and pharmacogenetic implications. 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 model was developed, and values for appropriate kinetic 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 were found to be unusual both qualitatively and quantitatively, and the results of the present study have potentially important therapeutic, toxicologic, and pharmacogenetic 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, when the dose is increased to 1 g, the half-life is increased to 5 hours (Refs. 4 and 5). If the dose is increased to 2 g the half-life is increased to about 9 hours (Ref. 4). Not only is the half-life markedly increased, but the urinary excretion also decreases as the dose is increased from 0.32 g to 0.67 g (Refs. 4 and 6). If the urinary excretion is decreased, more salicylate will be retained in the body with a great toxic potential since it will probably occupy most of the available albumin binding sites and displace other drugs or endogenous products, e.g., bilirubin. The percent of the dose recovered in 7.5 hours of urine collection is 71.5 percent after a 1.32 g dose, 55 percent after a 0.64 g dose and 52.1 percent after a 0.32 g dose (Ref. 2). These values, if extrapolated, may call for a change in dosing intervals rather than in change in dosing intervals. However, it is not known whether a toxic effect (due to drug accumulation) is involved in this study have potentially important therapeutic and pharmacogenetic implications. 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 model was developed, and values for appropriate kinetic 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 were found to be unusual both qualitatively and quantitatively, and the results of the present study have potentially important therapeutic, toxicologic, and pharmacogenetic implications."
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 85 mg/100 ml of plasma at 2 hr to 100 to 120 min. After ingestion by a fasting human subject, the drug may reach its peak plasma level in 40 minutes and then take 3 hr. In the treatment of rheumatic fever, the desired plasma level is in the range of 15 to 25 mg/100 ml of plasma. On several occasions daily. Sustained-action tablets are also available, which may plateau over many hours and require less frequent dosing than conventional tablets; however, after larger doses salicylates tend to be excreted less rapidly, thereby reducing the need for sustained tablets.

A large part of the salicylate in the blood is bound to plasma proteins. Of this fraction, at least 85 percent is bound but are more with the remainder adhering to alpha and beta globulins. The percentage which is protein-bound ranges from 65 percent at 50 mg/100 ml in plasma to 90 percent at 50 mg/100 ml. Binding involves primarily the free carboxyl group, but the phenolic group may also contribute to binding. Aspirin itself, however, undergoes little or no binding. Binding may be strikingly altered in disease states. Although sodium salicylate may bind to albumin to the same degree per molecule, the total albumin concentration may be markedly lowered, thus reducing binding by about 50 percent.

The salicylate concentration is usually greater in the serum than in whole blood. It appears that albumin is exquisitely 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 act actually to double the blood level. However, the analgesic response to bradykinin has worn off. It seems obvious that assays of the site of action are more meaningful than those in plasma and more difficult to obtain. In a few cases salicylate concentrations in joint fluids have been measured. Although unbound concentrations in joint fluid are similar to plasma, they are not necessarily related to plasma.

The salicylates are distributed throughout a volume of body water much greater than that of the extracellular fluid. Studies on rats showed that the concentrations in the liver, kidney, and lung 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 that in the maternal serum. Salicylates have also been found in milk.

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 equivalent to the volume of distribution of water. Since salicylate is present within cells in various tissues, this suggests a markedly uneven distribution of salicylate in the body. The concentration of salicylate in intracellular fluid is lower than in plasma, in part because of the lower pH of the former. The movement of salicylate across some cell membranes is pH dependent and appears also to be insulin dependent. Salicylate does not accumulate in insulin-resistant tissues in acute rheumatic fever; hence, a selective distribution is not the basis for its therapeutic effects.

Furthermore, Woodbury adds that "only traces (of aspirin) are present in sweat, bile and feces."

Excretion. It has already been mentioned how salicylates are excreted in the urine (vide supra) (Ref. 2).

Practically all of a given dose can be recovered in the urine as free, salicylic acid, salicylurate, and conjugates of salicylic acid. Renal excretion of salicylates is directly related to the plasma concentration. The renal elimination of aspirin is the same as that of other salicylates (Ref. 11). Salicylates are eliminated at a constant rate without regard to the plasma concentration, provided the dose is not exceeded.

The salicylic acid in the urine is completely hydrolyzed to salicylate and excreted as such, in contrast to probenecid, which is not hydrolyzed, but serves to slow its excretion and the renal elimination of other drugs, such as morphine.

Acetaminophen is rapidly and almost completely absorbed from the gastro-intestinal tract (Ref. 1). It has been suggested that some dietary components could alter the absorption of acetaminophen administered orally. In particular, the effect of the 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 16 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 minutes (Ref. 1). In an unpublished 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 2 hours (Ref. 4). In an unpublished study (Ref. 5), the mean plasma half-life using several pharmaceutical forms was 148±42 minutes.

Acetaminophen is relatively uniformly distributed throughout most body tissues (Ref. 1). Binding of the drug to plasma proteins is variable and depends on the dose. During acute intoxication, as much as 30 to 50 percent may be bound to plasma proteins (Ref. 1). Dearden and Tomlinson (Ref. 6) studied the protein binding affinities of some p-substituted 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 acetaminophen is eliminated mainly by these two pathways. By chromatography and infrared spectroscopy the glucuronide was the major metabolite and sulfate was a minor metabolite.

They found that 36 percent of acetaminophen administered was excreted as the sulfate and 49 percent as the glucuronide. These results are consistent with the observation that acetaminophen sulfate in man may be capacity-limited in the 1 to 2 g dose range (Ref. 8). This has been shown by Levy and Yamada by the fact that acetaminophen glucuronides or sulfate conjugates are responsible for the major metabolites found in the urine. The metabolites of acetaminophen have been separated and determined quantitatively in urine by gel filtration using Sephadex G 10 (Ref. 9). These authors have found that the most important metabolites to be the glucuronic acid and sulfate. Other metabolites found were S-(1-acetamido-4-hydroxyphenyl)-acetic acid, S-(1-acetamido-4-hydroxyphenyl) mercaptopropionic acid. Using the technic minor quantities of free acetaminophen were also found in the urine. Using this technique the total recovery was 100 percent and the administered dose was accounted for as follows:

- 30 to 35 percent as glucuronide.
- 15 to 20 percent as sulfate.
- 10 to 15 percent as mercapturate.
- 5 to 10 percent as a mercapturate.
- 2 to 5 percent as a mercapturate.
- 1 to 2 percent as cystine conjugate.
- 1 to 2 percent as free acetaminophen.

It has been suggested that the hydroxylated metabolites are responsible for methemoglobin formation and hepatoxicity (Ref. 1). The administration of acetaminophen to patients with impaired renal function results in increased accumulation of acetaminophen conjugates in plasma because of poor excretory capacity (Ref. 1). Changes 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 formation of acetaminophen glucuronide and sulfate. This effect was counteracted or prevented by the administration of L-cysteine (a source of sulfate). This interaction may have significance in patients with impaired hepatic function, and certain pharmacological considerations since the inclusion of salicylamide in an analgesic mixture will inhibit the two major processes for the elimination of acetaminophen. This interaction should be more important if one considers the capacity-limited formation of sulfate described above (Ref. 8). On the other hand, concurrent administration of salicylamide and other potential inactivating agents such as aspirin, with antipyretic and analgesic activity, e.g., salicylates, salicylamide, aniline derivatives, phenylhydrazines, etc. It is the latter group of mild analgesics that have generally been associated with OTC use.

The Panel concludes that no OTC analgesic product should be taken by adults for more than 5 days except under 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 narcotics (opioids) and other strong analgesics. The mild analgesics can be chemically divided into two main subgroups: Those agents chemically related to the strong analgesics, e.g., codeine, ethanamines, and ptychophen, and those analgesics like aspirin, with antipyretic and anti-inflammatory or antirheumatic activity, e.g., salicylates, salicylamide, aniline derivatives, phenylhydrazines, etc. It is the latter group of analgesics that have generally been associated with OTC use.
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 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 persist, or new or unusual ones occur, consult your physician. Therefore, the Panel recommends that all OTC analgesics contain the warning for adults, “Do not take this product for more than 5 days. If symptoms persist, or new or unusual ones occur, consult your physician” and for children under 12 years of age, “Do not take this product for more than 5 days. If symptoms persist, or new or unusual ones occur, consult your physician.”

C. CATEGORY OF DATA

1. CATEGORY I conditions under which analgesic agents are generally recognized as safe and effective and not misused:

- **Aspirin**
  - Magnesium salicylate
  - Acetylsalicylic acid
  - Calcium carbaspian
  - Sodium salicylate

  a. **Aspirin**. The Panel concludes that aspirin is a safe and effective OTC analgesic when taken in the recommended dosage range 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, almost 19 billion dosage units 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. Thousands of articles have been written on aspirin since the first pharmacological data were reported in the literature by Dreser in 1899 (Ref. 1). Virtually all of the experiments discussed in this articles should be considered 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 a variety of pain states” (Ref. 2). Beaver, in his extensive discussion of mild analgesics in 1965, summarized the findings of over 40 controlled human studies demonstrating the superiority of aspirin to placebo prior to 1965.

Beaver 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, Laeng (1962), 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, Houde 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 (milligrams)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beecher et al.</td>
<td>Postoperative</td>
<td>600</td>
</tr>
<tr>
<td>Boyle et al.</td>
<td>Malignant, outpatients</td>
<td>650</td>
</tr>
<tr>
<td>Bubba and Fleib</td>
<td>Postpartum</td>
<td>600</td>
</tr>
<tr>
<td>Carlinson and Magnusson</td>
<td>Headache, outpatients</td>
<td>1,000</td>
</tr>
<tr>
<td>Cass et al.</td>
<td>Mixed chronic</td>
<td>300 to 600</td>
</tr>
<tr>
<td>Cass et al.</td>
<td>Mixed chronic</td>
<td>325 to 600</td>
</tr>
<tr>
<td>Dorsman and Lasagna</td>
<td>Headache, outpatients</td>
<td>625</td>
</tr>
<tr>
<td>Do et al.</td>
<td>Headache, outpatients</td>
<td>600</td>
</tr>
<tr>
<td>Ehrlich et al.</td>
<td>Mixed headache</td>
<td>600</td>
</tr>
<tr>
<td>Finkberg et al.</td>
<td>Mixed headache</td>
<td>600</td>
</tr>
<tr>
<td>Frost et al.</td>
<td>Mixed headache</td>
<td>325</td>
</tr>
<tr>
<td>Hey et al.</td>
<td>Headache, inpatients and outpatients</td>
<td>600</td>
</tr>
<tr>
<td>Hume et al.</td>
<td>Headache, outpatients</td>
<td>650</td>
</tr>
<tr>
<td>Kantor et al.</td>
<td>Headache, outpatients</td>
<td>600</td>
</tr>
<tr>
<td>Laeng et al.</td>
<td>Headache, outpatients</td>
<td>600 and 1,200</td>
</tr>
<tr>
<td>Magee &amp; Dejong</td>
<td>Headache, outpatients</td>
<td>600 and 1,200</td>
</tr>
<tr>
<td>Marca et al.</td>
<td>Headache, outpatients</td>
<td>600 and 1,200</td>
</tr>
<tr>
<td>Murray et al.</td>
<td>Headache, outpatients</td>
<td>600 and 1,200</td>
</tr>
<tr>
<td>Orkin et al.</td>
<td>Headache, outpatients</td>
<td>600</td>
</tr>
<tr>
<td>Petcoff et al.</td>
<td>Headache, outpatients</td>
<td>600 and 1,200</td>
</tr>
<tr>
<td>Rolf et al.</td>
<td>Headache, outpatients</td>
<td>600 and 1,200</td>
</tr>
<tr>
<td>Sunshine et al.</td>
<td>Headache, inpatients and outpatients</td>
<td>600</td>
</tr>
<tr>
<td>Toreto et al.</td>
<td>Headache, inpatients and outpatients</td>
<td>600</td>
</tr>
<tr>
<td>Valentine &amp; Martin</td>
<td>Headache, inpatients and outpatients</td>
<td>600</td>
</tr>
<tr>
<td>Zeller et al.</td>
<td>Headache, inpatients and outpatients</td>
<td>600</td>
</tr>
</tbody>
</table>

In 1967, Murray compared placebo, 648 mg aspirin, 325 mg acetaminophen plus 325 mg salicylamide, and 487 mg acetaminophen plus 487 mg salicylamide 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-salicylamide mixtures in 69 percent and 76 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 from common head-aches, the most frequent reason for aspirin ingestion.

The blood level below which aspirin is ineffective as an analgesic has not been adequately demonstrated because analysis has not been shown to correlate directly with levels of salicylates in the blood. However, Beaver 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 headaches (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 of aspirin. An intermediate dose of about 500 mg was not used. Bloomfield et al. (1972) studied 650 mg aspirin, 250 mg mefenamic acid, 50 mg pentazocine, 650 mg acetaminophen, 650 mg phenacetin, 65 mg codeine, 65 mg propoxyphene, 25 mg promazine, 75 mg diazepam, and placebo all given orally to patients with pain due to unreactable cancer (Ref. 16). They concluded that aspirin was “superior to all agents tested.”

However, in 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 600 mg aspirin in patients with postoperative pain (Ref. 3). In this study even the low dose of 300 mg aspirin was significantly better than the placebo.

In another study, Modell and Houde showed a dose related increase in pain relief even when 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. Those receiving 300 mg and 600 mg of aspirin had the same 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 aspirin. 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 1968, Bloomfield et al. confirmed Kantor’s results regarding the differing levels of effectiveness of aspirin in relieving the pain of methegmine.

Murray and Hill (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 levels of pain while meperidine was preferable at the severe pain level (Ref. 11). However, these same researchers in another double-blind study in patients with pain following gynecological surgery could not differentiate meperidine, aspirin or placebo in their pain in the near 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 illustrated one of the inherent difficulties in analgesicometry.

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 with aspirin exceeded that of codeine (Ref. 14).


labeling can be established to provide for safe OTC use of the drug. The safety of aspirin is discussed below. The Panel has reviewed the metabolism of aspirin elsewhere in this document. (See part II, paragraph K, above—Absorption, Distribution, Biotransformation, Metabolism, and Excretion of Aspirin and Salicylates in Man.)

Because of the extensive use and research on this drug, the Panel has been able to identify many of the safety considerations and has summarized them in the following table:

**SUMMARY OF SAFETY CONSIDERATIONS WITH USE OF ASPIRIN**

**ADVERSE EFFECTS ON THE BLOOD**

Aspirin interferes with blood clotting. Persons with a history of blood coagulation defects, or receiving anticoagulant drugs or with severe anemia should avoid the drug.

**ADVERSE EFFECTS ON THE GASTROINTESTINAL TRACT**

The drug may potentiate peptic ulcer, cause stomach pain or heartburn. Aspirin causes an increase in occult bleeding and in some persons massive gastrointestinal bleeding.

**ADVERSE EFFECTS ON HYPERSENSITIVE INDIVIDUALS**

Aspirin produces allergic and anaphylactic reactions in hypersensitive individuals, especially certain types of asthma, ranging from rash, hives and swelling to asthmatic attacks which may be life-threatening.

**ADVERSE EFFECTS DURING PREGNANCY**

Aspirin interferes with maternal and infant blood clotting and lengthens the duration of pregnancy and parturition time. Aspirin produces teratogenic effects in animals and increases the incidence of stillbirths and neonatal deaths in humans.

**ADVERSE EFFECTS ON THE CENTRAL NERVOUS SYSTEM**

Aspirin when taken in overdose produces stimulation (often manifested as tinnitus) followed by depression of the central nervous system.

**ADVERSE EFFECTS ON THE KIDNEY**

Aspirin may rarely cause an increase of existing severe kidney disease.

**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 anticoagulant and antidiabetic drugs, some drugs used for the treatment of gout and may have an additive ulcer-producing effect with some drugs used in arthritis.

**ADVERSE EFFECTS RESULTING IN IRON DEFICIENT ANEMIA**

Aspirin used chronically may cause a persistent iron deficient anemia.

1. **Adverse effects on the blood.** In addition to the well-known association between aspirin ingestion and gastrointestinal bleeding discussed below, aspirin and salicylic acid have been implicated but not always proven as factors in heparin-induced thrombosis (postsectionectomy), nose, rectum, vagina, postsurgical wounds and dental extraction sites (Ref. 1 through 6). The major hemostatic mechanisms involved are the effects of aspirin and salicylates. Large doses on prothrombin production and the effects of aspirin in small doses (but not salicylates) on platelet function, which results in an increased bleeding time and possibly other effects such as fibrinolysis (Ref. 7).

   (a) Decrease in prothrombin production. High doses of aspirin and salicylic acid (6,000 to 10,000 mg daily) taken for several days may cause a decrease in prothrombinemia, i.e., a decrease in the amount of prothrombin (blood clotting factor II) in the circulating blood (Refs. 1 and 4) which may be reversible (Ref. 5). It is important to emphasize that this effect of salicylates does not usually result in clinically significant alteration of the coagulation mechanism except in patients who may be partially deficient in vitamin K. Susceptible patients include those receiving anticoagulant therapy; patients consuming high doses of aspirin or salicylates chronically, e.g., patients with rheumatoid arthritis; patients with liver disease; patients with deficiencies of vitamin K, which is a substance required for prothrombin synthesis (Ref. 8).

   As noted above, hypoprothrombinemia is produced by both aspirin and other salicylates when taken in high doses. In one study a daily total dose of 3,200 mg sodium salicylate produced no change in prothrombin time, 8,600 mg produced a slight change and 10,000 mg produced marked changes in prothrombin time (Ref. 6). Aspirin or salicylate-induced hypoprothrombinemia has been implicated in postsectionectomy bleeding, epistaxis (nose bleed), and postsurgical extractions on bleeding sites (Refs. 9 and 10), although other mechanisms such as a platelet effect (discussed below) may be involved.

   (b) Increased bleeding time and inhibition of platelet aggregation. Aspirin increases bleeding time and inhibits the in vivo and in vitro aggregation of platelets.

   Bleeding time is defined as the duration of time that bleeding continues after a superficial puncture of about 1 mm is made in the skin. This occurs with doses of aspirin far below those required for a hypoprothrombinemic effect. The effect of aspirin on bleeding time in a patient with bleeding tendencies was noticed many years ago by Frick who attributed it to an effect of aspirin on capillary fragility (Ref. 11). Later, Quick showed that 2 hours after ingestion of 1,300 mg aspirin, but not sodium salicylate, a small but significant increase in the bleeding time occurred in normal subjects. A much greater increase was observed in patients with mild coagulation defects such as von Willebrand's disease and hereditary hemorrhagic telangiectasia. It has been calculated that aspirin, due to the presence of the acetyl group, may interfere with or compete with some vascular factor, such as cholinesterase, involved in the vascular tone of small vessels (Ref. 12). However, the results of a recent study submitted to the Panel, demonstrated, by an in vitro method, that aspirin did not have any effect on cholinesterase inhibition (Ref. 14). In the study, aspirin, salicylic acid and physostigmine (a known inhibitor) were compared. The dosages of aspirin and salicylic acid were correlated to the average amount of nonprotein bound aspirin and salicylic acid found in human plasma up to 2 hours after ingestion of two aspirin (650 mg) tablets. The findings indicated inhibition with physostigmine and none with aspirin. While it is clear that inhibitors may prove to be a factor, it is presently well established that the primary effect of aspirin on bleeding time and hemorrhage is due to a potent irreversible effect on platelet function which inhibits the in vivo and in vitro aggregation of platelets.

   The effects of aspirin on platelet function were shown almost simultaneously by several independent groups (Refs. 13 through 20). The effect of a single dose of 1,600 mg aspirin on platelets will persist 2 to 3 days and not completely disappear until 7 or 8 days (Ref. 15). Since this is roughly the life span of a platelet, it indicates irreversible damage to platelet function.

   Weiss and Aledort reported that bleeding time was prolonged by a mean value of 3.3 minutes in 10 normal male subjects receiving 330 mg aspirin (Ref. 16). They first reported that aspirin interfered with platelet connective tissue reaction by inhibiting the release of adenosine diphosphate (ADP) which results in prolongation of bleeding time.

   Mielke et al. showed the standard Ivy Test to be very reproducible, if the wound is standardized ("template bleeding time") (Ref. 21). Aspirin 975 mg (15 gr) increased the mean bleeding time from 5.5 minutes to 9.5 minutes on repeated tests by different investigators (Ref. 22). The population distribution of this trait appeared to be heterogeneous.

   Mielke and Britton found that a 300 mg dose of aspirin each day maintained the prolongation of bleeding time and that no greater effect was obtained with higher doses (900 or 1,800 mg) (Ref. 22).
Other analgesic drugs which show marked inhibition of platelet aggregation include indomethacin, ibuprofen, mefenamic acid, and amidopyrine. Less marked inhibition of platelet aggregation was noted with oxyphenbutazone. No effect was noted with sodium salicylate 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 and 25). Platelets adhere to exposed collagen fibers within seconds after damage occurs to small vessels. This interaction is mediated by fibrinogen and platelet factor 4, which facilitates platelet aggregation into a loosely (first phase) and then tightly (second phase) packed plug. The plug formation precedes the formation of a fibrin mesh which eventually forms a clot. It is now known that aspirin inhibits ADP release in phase one and/or phase two aggregations and also in the final interaction with collagen fibers. Plug formation may be relatively unimportant when major arteriolar damage occurs because other available mechanisms are more effective; but it is thought to be important for the hemostatic mechanism in capillary (oozing) bleeding (Refs. 24 and 26).

This type of bleeding is now believed to be involved in the types of gastrointestinal bleeding that is potentiated by aspirin (Refs. 25, 27, 28, and 29) as well as other sites of bleeding such as the posttonsillectomy tonsillar bed, or surgical wounds, or tooth sockets following extraction. The demonstrated effect of aspirin on platelet function and the importance of this process in the hemostasis of ooze type of small vessel bleeding provide a rationalization for the wide variety of sites of bleeding that have been associated with aspirin. Some of these types of bleeding are briefly reviewed below.

Nonthrombocytopenic purpura (bleeding in the tissues in a patient with a normal platelet count) associated with aspirin ingestion has been described as a hypersensitivity reaction (Ref. 33). However, idiocynergis was ruled out in three cases of purpura in children with normal platelet counts who received usual doses of aspirin (Ref. 37). The authors attributed the bleeding to a demonstrated platelet dysfunction due to inhibition of ADP release following aspirin therapy, rather than vascular or hypersensitivity reactions. It is of interest that in two cases with no family history of bleeding disorders, the patients were sisters (9-year-old and 14-month-old). However, the father on two occasions within a 3-year period had experienced severe gastric bleeding after a single intake of 2,000 and 1,000 mg doses of aspirin, respectively.

Buchtinghaus and Tenhaeff (1975) stated that 11.16 of 24 patients taking aspirin developed hematomas (a swelling filled with extravasated blood) in the wound regions following abdominal surgery or hysterectomies (Ref. 33).

De Vries and Ten Cate have suggested that thrombocyte damage may be responsible for many cases of menorrhagia (excessive menstrual discharge), post-extraction bleeding in dentistry, and chronic purpura (hemorrhage into the skin resulting in discoloration) (Ref. 34). The occurrence of bleeding from the tonsillar bed following topical application of aspirin through gargles or aspirin-containing chewing gums have been reported (Ref. 35). Hemo­dynamic function in infants immediately following post­tonsillectomy patients medicated with aspirin (Ref. 36). The bleeding occurred on the 6th or 7th postoperative day and could be controlled only with packing and suturing. No hemorrhage occurred in the 100 patients medicated with acetaminophen in an identical manner. Similar results were also reported by Hersh who carried out a controlled study in patients having dental extractions (Ref. 30). Hersh (Ref. 30) conducted a randomized controlled study in patients undergoing dental extraction. Not taking an aspirin-containing analgesic in the 7 days prior to extraction and who were continued on aspirin, the incidence of post-extraction bleeding was the largest of the three groups studied.

A high incidence of posttonsillectomy hemorrhage was also reported by Fox and West (Ref. 37) in children given an aspirin-containing chewing gum. The incidence of bleed within 2 weeks of delivery was given either aspirin or acetaminophen for post-tooth extraction pain. Significantly more bleeding was noted among those who received aspirin. Of those persons who received aspirin and who had taken aspirin in the 7 days prior to extraction and who were continued on aspirin, the incidence of post-extraction bleeding was the largest of the three groups studied.

The effects of aspirin on hemostasis in the newborn may be particularly hazardous since infants metabolize drugs slowly and are particularly susceptible to central nervous system hemorrhage (Ref. 38). Bleeding episodes in newborns may be higher in those whose mothers had aspirin-induced decrease in clotting ability (Ref. 39). The effects of aspirin on maternal and newborn hemostatic mechanisms are discussed in more detail later in this document. (See part III. paragraph B.l.a. (2) (fr) (c) below—Effects on maternal and newborn hemostatic mechanisms.)

(c) Relationship between systemic platelet effects and gastrointestinal bleeding

Platelet aggregation which is discussed below, is the most frequent serious bleeding problem associated with aspirin. Several authors have recently pointed to the probable overimbalance in mass gastrointestinal hemorrhage in gastrointestinal bleeding (Refs. 5, 15, 24, 26, 29, and 40). There is growing evidence that the systemic effect of aspirin on platelets is a significant factor in a causal relationship between aspirin ingestion and subsequent gastrointestinal hemorrhage. Several lines of reasoning and recent experimental evidence support this conclusion.

Aspirin-induced platelet dysfunction will significantly promote bleeding when the platelet plug is the primary factor in hemostasis. This is usually true for the oozing type of bleeding which occurs within 3 days of starting aspirin ingestion (Ref. 41). It is important to note that the role of platelet dysfunction in gastrointestinal bleeding has been well-documented in a causal relationship between aspirin ingestion and subsequent gastrointestinal hemorrhage (Refs. 28 and 41). It is also precisely the vascular condition which many hematologists state is most dependent upon platelet plugs to stop bleeding (Refs. 25, 26, and 29).

Cast (Ref. 42) has pointed out that alteration of platelet function alone is usually not sufficient to initiate bleeding. This is evident in the bleeding episodes found in the patient described which usually involve tissues subjected to prior injury, i.e., tonsillectomies. Thus, gastrointestinal bleeding involving platelet dysfunction would not be initiated by aspirin ingestion alone. Other factors to be present to initiate epithelial and capillary damage and perhaps to promote local blood flow (Ref. 43). This is consistent with the longitudinal and retrospective studies which have hypothesized that the incidence of massive gastrointestinal hemorrhage relative to the high incidence of aspirin use and current theories on the multiple factor etiologies of massive gastrointestinal bleeding (Ref. 44) which is also consistent with the difficulty of de-
developing a suitable animal experimental model or designing adequate epidemiologic studies for causal relationships. Some experimental evidence to support the role of platelet function in gastrointestinal hemostasis was presented by Schmid et al. (Ref. 31). These authors showed that decreased platelet function produced by aspirin, but not sodium salicylate, correlated with the extent of blood loss following aspirin ingestion. It is perhaps significant that vitamin K was found to be effective in several of these experiments, thus indicating a role for vitamin K in the maintenance of normal platelet function. This systemic effect is independent of the dose of aspirin used.

For the various reasons discussed above, the Panel has concluded that because aspirin can promote or increase bleeding after it has been absorbed into the bloodstream, all preparations containing aspirin should be labeled with the appropriate labeling warning, "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 concludes that this recommended warning should also apply to all salicylates. (See part III. paragraph B.1. below—Category I Labeling.)

REFERENCES
(30) Rapaport, S. L., letter solicited by the Panel April 8, 1974 is included in OCT Volume 030132.
(38) Rapaport, S. L., letter solicited by the Panel April 8, 1974 is included in OCT Volume 030132.
Safety and labeling include the increased disease variables of interest relative to particular types of gastrointestinal incidence, and severity of adverse effects dose required to produce these effects, mechanisms involved and whether as-given to claims that adverse effects may use of aspirin. Particular attention was such as massive bleeding. highly buffered effervescent solutions. be reduced by a particular type of dos­-age form such as buffered tablets. or bleeding in such individuals following intestinal bleeding because of the in­-crease in contact with mucous membranes of the mouth: a local anesthetic effect have resulted in oral lesions on the roof of the mouth. Rectal irritation. They placed a quarter of several commercial plain, buffered and combination aspirin tablets between the lower lip or cheek and gums of 26 normal subjects for 30 to 60 minutes. In every episode. Gastric distress occurs in 60 to 70 percent of patients with hemorrhagic gastritis. (Refs. 14 and 15). In ulcer pa­tients, the incidence of recurrent gastric distress, e.g., dyspepsia, it may be possible to warn as many as 80 percent of the high risk population. The Panel concludes that by merely identifying those patients with a history of gastrointestinal ulcer or recurrent gastrointestinal disease. the gastrointestinal tract (Refs. 1, 6, 10, 18, 23, and 24). The effect is acute and occurs in most normal individuals (Ref. 10) and has also been demonstrated in several animal species (Refs. 6, 25, and 29). Prolonged contact with aspirin preparations (tablet, suppository) indicated that the oral route pro­duced a severe lesion of the inner wall of the cheek which promptly healed upon discontinu­ation (Refs. 27 and 30). Kawashima et al. (Ref. 30) in 1975 reported that aspirin tablets applied directly to the mucous membranes of the mouth in contact with mucous membranes of the mouth: 30 minutes produce a white opaque buccal mucosa capable of being peeled off with the slightest ma­nual pressure. The local anesthetic effect may be reduced by a particular type of dose of buffered aspirin tablets or combination aspirin tablets. (Ref. 6). Mucosal erosion of the mouth. Aspirin-containing gum has produced a severe lesion of the inner wall of the cheek which promptly healed upon discontinu­ation (Refs. 27 and 30). Rectal irritation. The Panel concludes that aspirin taken rectally in a suppository dosage form may have a direct local irritant effect on surface mucosal cells. The irritation effect of rectally administered aspirin can be alleviated by changes in the composition of the matrix of the suppository vehicle. The adverse effects of aspirin appear to be related to the chemical composition of the suppository base (Refs. 31 and 32) and not to the amount of active ingredient from the suppository base (Ref. 33). Aspirin suppositories (1,300 mg aspirin per suppository) made of a cocoa-butter or a carbowax base were administered to dogs every 4 hours for a total of 3,900 mg daily for 3 days (Ref. 31). The experimental dogs in the study all showed signs of mucosal irritation. The irritation ranged from a distinct hyperemia to hemorrhagic ulcerative lesions. Perfora­tions and death also occurred. The four dogs receiving the control suppository bases showed no rectal mucosal changes. The authors concluded that "prolonged rectal administration of aspirin supposi­tories may be potentially hazardous" and recommended that "additional studies to evaluate the extent of irritation and ulcerative hemorrhagic lesions in the hu­man rectum be undertaken. The irritation ef­fects of aspirin suppositories seem to be indicated." Serum salicylate determinations in 40 human subjects adminis­tered 650 mg aspirin orally (tablets) and rectally (cocoa-butter base supposi­tories) indicated that the oral route pro­duced 10 times the amount of salicylate in serum as the rectal route after single oral doses of aspirin.
voked significantly higher blood salicylate levels (p is less than 0.001) than the rectal route (Ref. 31).

In a study reported by Cacchillo and Haas (Ref. 22), 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 (tableted) was given 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 the glycerinated gelatin bases. Glvcerinated gelatin based suppositories showed a high incidence of prolonged burning and pain, and the subjects desired to expel the suppository. There was no statistically significant difference between the absorption of aspirin orally and the other two bases. It was found that a rapid absorption through this vehicle is assured when employed rectally, 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 Boré, Ekenved, Elfrick and Sygren (Ref. 32). Male volunteers were administered 750 mg and 1,000 mg aspirin in the formulated suppositories with two neutral triglyceride mixtures as the bases, i.e. Witepsol H15 with a melting range of 33.5° to 35.5° C and Witepsol E75 with a melting range of 39° to 40° 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 the first study, 25 volunteers administered the two aspirin suppository formulations on the first 2 days of the week for 3 consecutive weeks. A dose of 1,000 mg of aspirin was given to some subjects on the third day. It was found that a rapid absorption 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 damaging effect on mucosal tissue which is not dependent on the presence of hydrogen ion, bile or other contents of the stomach. This effect is illustrated by the appearance of a gastric ulcer (Ref. 6). Prolonged contact with 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 rats initially produced coagulation of mucus and opacification of the adjacent mucosa. Sloughing of the buccal (mouth) tissue exposed to aspirin (Ref. 6). These changes were attributed to coagulation of the mucous layer and desquamation of the mucosa. They showed focal necrosis with underlying secondary capillary damage. The direct mucosal desquamation and focal necrosis produced by aspirin is not a local inflammatory reaction (Ref. 35), as 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. 6). Accumulation of DNA in gastric fluid occurred in about 10 minutes in 9 of 12 subjects receiving aspirin (Ref. 6) which is similar to the percent of subjects showing direct irritation to aspirin in the gastroscopic observations of Douthwaite and Lintott (Ref. 23).

The direct observations by gastroscopy of the effects of aspirin on the gastric mucosa by Douthwaite and Lintott in 16 subjects receiving 3,000 mg aspirin were dominated by 1 of the 16 patients. Salicylic acid also caused direct gastric irritation but was less severe. Contact with 20 percent alcohol for 10 minutes did not have a direct effect on the gastric mucosa. The Panel concludes that the 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 other ions of the gastric acid (Refs. 35, 36, and 35 through 43). Absorption of aspirin or salicylic acid into the mucosal cell causes increased permeability via breakdown of the cell membrane. This protects the stomach lining from its own acid secretions. Excessive backflux of hydrogen ion into the cell further damages the cell, causing erosion of the entire gastric cell. Excessive 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 (Ref. 35 through 41, 44, and 45). This mechanism, referred to as the "pump mechanism," or 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 involved in the formation of minor bleeding into the stomach (occult bleeding). This mechanism may contribute in some cases to gastritis and major gastrointestinal bleeding (Refs. 44 and 45). Some investigators believe that all gastrointestinal effects of aspirin do not occur from occult bleeding to hemorrhagic erosive gastritis to major gastrointestinal hemorrhage are all related to a single factor, aspirin. It may contribute at least in the beginning stages of aspirin-induced gastric ulcer by chronic doses of aspirin (Ref. 46). It is also probably a factor in hemorrhagic erosive gastritis directly initiated by multiple doses of aspirin. It may contribute to major bleeding. In this case it may initiate major bleeding. However, as will be noted in subsequent sections, there are other factors which can initiate hemorrhagic erosive gastritis. In this case, aspirin has other effects independent of gastric acid which may be of equal or greater significance in contributing to massive gastrointestinal bleeding.

(b) Other mechanisms of aspirin damage. The Panel agrees that there is very good evidence in both animals and man that the Davenport mechanism is an important effect of aspirin. However, other mechanisms are the only effect of aspirin on the gastrointestinal tract and thus the only basis...
for aspirin's role in initiating, exacerbating, potentiating or facilitating gastric ulceration. However, new findings with current experimental data and clinical studies.

(1) Additional factors in the Davenport mechanism. According to the Davenport mechanism, the gastric content, salicylic acid or sodium salicylate, increases hydrogen ion across the barrier into the interstitial spaces, where the pH is higher, where aspirin or salicylic acid is 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 (sodium salt) is more rapidly absorbed than aspirin in man, but it produces significantly less occult bleeding and occult blood loss in 13 subjects was 6.3 ml, 1.9 ml, 1.2 ml and 0.7 ml for aspirin, salicylic acid, salicylic acid with buffer, and control respectively. An explanation for the differences between these compounds and the direct cellular effects of aspirin and 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 (sodium salt) is more rapidly absorbed than aspirin in man, but it produces significantly less occult bleeding and occult blood loss in 13 subjects was 6.3 ml, 1.9 ml, 1.2 ml and 0.7 ml for aspirin, salicylic acid, salicylic acid with buffer, and control respectively. An explanation for the differences between these compounds and the direct cellular effects of aspirin and 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 (sodium salt) is more rapidly absorbed than aspirin in man, but it produces significantly less occult bleeding and occult blood loss in 13 subjects was 6.3 ml, 1.9 ml, 1.2 ml and 0.7 ml for aspirin, salicylic acid, salicylic acid with buffer, and control respectively. An explanation for the differences between these compounds and the direct cellular effects of aspirin and 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 (sodium salt) is more rapidly absorbed than aspirin in man, but it produces significantly less occult bleeding and occult blood loss in 13 subjects was 6.3 ml, 1.9 ml, 1.2 ml and 0.7 ml for aspirin, salicylic acid, salicylic acid with buffer, and control respectively. An explanation for the differences between these compounds and the direct cellular effects of aspirin and 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 (sodium salt) is more rapidly absorbed than aspirin in man, but it produces significantly less occult bleeding and occult blood loss in 13 subjects was 6.3 ml, 1.9 ml, 1.2 ml and 0.7 ml for aspirin, salicylic acid, salicylic acid with buffer, and control respectively. An explanation for the differences between these compounds and the direct cellular effects of aspirin and 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 (sodium salt) is more rapidly absorbed than aspirin in man, but it produces significantly less occult bleeding and occult blood loss in 13 subjects was 6.3 ml, 1.9 ml, 1.2 ml and 0.7 ml for aspirin, salicylic acid, salicylic acid with buffer, and control respectively. An explanation for the differences between these compounds and the direct cellular effects of aspirin and 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 (sodium salt) is more rapidly absorbed than aspirin in man, but it produces significantly less occult bleeding and occult blood loss in 13 subjects was 6.3 ml, 1.9 ml, 1.2 ml and 0.7 ml for aspirin, salicylic acid, salicylic acid with buffer, and control respectively. An explanation for the differences between these compounds and the direct cellular effects of aspirin and salicylic acid are ionized and the hydrogen ion is dissociated.

(2) Vascular effects. In contrast to the Davenport mechanism which assumes that aspirin is ionized and the mucosal cell is mediated through hydrogen ion possibly by causing release of histamine with secondary vascular involvement, there is evidence that in some types of hemorrhagic erosive gastritis the reverse occurs where the initial effect is on the mucosal vasculature. Weiss et al. (Ref. 10) state that the primary local effect is direct vascular injury of the lamina propria followed by capillary hemorrhage and hypoxia (deprivation of oxygen) which produces necrobiosis of the neck of cells and exfoliation of the gland. It is now believed that some types of hemorrhagic 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 atrophic gastritis. Thus regardless of the initial mechanism, whether hydrogen ion barrier is disrupted or not, the initiation of histamine release from the mast cells in the mucosal capillary region and initial vascular damage or resuming 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 vagotony decreases gastric bleeding may not be a result of decreased gastric acid as commonly stated but resuming of mucosal blood from the capillaries. Nylander and Ojerud (Ref. 58) reported that blood was resuspended from the mucosal capillaries by the direct arterovenous shunts in the submucosa after vagotony. Occult bleeding can be readily measured by well-known techniques used for the detection of blood in the feces, such as the use of radioactively-tagged red blood cells (Ref. 57). Therefore, there are many studies and reliable data on the relationships between occult bleeding and various types and formulations of analgesics (Ref. 58).

There is good evidence that the addition of sufficient buffering to decrease gastric acid 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 preparations will markedly increase occult bleeding (Ref. 62). While these individuals with unusual susceptibilities may provide some insight into the factors related to clinically important massive upper gastrointestinal bleeding, the average occult bleeding following aspirin ingestion in normal individuals or in individuals with peptic ulcers apparently has no relationship to massive upper gastrointestinal bleeding (Refs. 6 and 9).

There appears to be no difference between the average increase in occult bleeding in normal individuals and major bleeders. Correlations between occult bleeding and massive bleeding have been

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

PROPOSED RULES

35389
never been shown. Occult bleeding and massive gastrointestinal hemorrhage should not be considered as 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 relatively rare and unpredictable in most normal people. Massive bleeding is relatively rare and unpredictable.

Persons with active peptic ulcer (Refs. 7 and 8) or persons who have recently experienced a massive gastrointestinal hemorrhage (Refs. 7 and 10) do not show greater occult 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 Pierson (Ref. 64) in 1961 showed that occult bleeding was not greater in persons taking anticoagulants even though prothrombin activity is greatly reduced. Massive bleeding, however, has been associated with hypoprothrombinemia resulting from high doses of aspirin. (See part III paragraph 1.1a. (1) (a) above.) Occult bleeding is relatively common 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 occurring from aspirin ingestion appears to have very little correlative or predictive value in the diagnosis or study of the major clinically important gastro-intestinal effects produced by aspirin such as inflammation and massive bleeding.

(1) Gastric ulcers. The Panel notes that chronic use of aspirin may directly cause gastric ulcers (Refs. 16 through 19 and 66 through 86). Several types of studies show that chronic aspirin use significantly increases the risk of peptic ulcers but not duodenal ulcers (Refs. 80, 81, and 82). Chronic use of aspirin is associated with an increased incidence of uncomplicated nonbleeding ulcers bleeding from ulcers and perforated gastric ulcers (Refs. 18, 86, and 87). Epigastric pain is common in all of these cases. Continued use of aspirin can delay ulcer healing even though ulcer therapy has started (Ref. 18). Discontinuation of aspirin leads to rapid recovery (Refs. 3 and 18). Readmission of aspirin can re-activate gastric ulcer (Ref. 17).

Acute ulcer - aspirin can 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 several authors over the past twenty years (Refs. 18 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 strongly supported by evidence. These include the demonstration that aspirin causes ulcers in animal models; direct observation of isolated cases in man; several recent well-controlled prospective studies where analgesic ingestion biases were eliminated; demonstration of increased gastric ulcers in a population in which increased chronic use occurred due to abuse; evidence that characteristics of the lesion are different in aspirin users than nonaspirin users; and evidence that the site of the ulcer lesion can be affected by the dosage form used.

Therefore, it appears that the Panel conservatively estimated that 10 out of every 100,000 aspirin users would develop a non-bleeding gastric ulcer requiring hospital admission. This study estimated that 1.2 per cent 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).

Watson and Gyntelberg (Ref. 88) determined the life incidence of peptic ulcer to be 9.2 per cent in a sample of 5,249 men aged 40 to 59 in Copenhagen which is similar to the incidence reported in the American population. The study concluded that in 4,753 males the year incidence of peptic ulcer was 1.2 per cent. Only 15 per cent of these were new (previously diagnosed) ulcer cases and only 24 per cent of new ulcer cases were attributable to aspirin use. Ulcer cases during the year accounted for only about 3.6 per cent (15 per cent x 0.24) of total cases for the year.

Thirty per cent of subjects ingested aspirin regularly compared to 16 per cent of controls (p is less than 0.02). In only one of these subjects was aspirin taken for ulcer symptoms.

It can be conservatively estimated that 16 per cent of the ulcer cases were associated with aspirin which is equivalent to a 19 per cent annual incidence rate (19 per 1,000) for men between 50 and 59. However, only 3.6 per cent of these (15 per cent x 0.24) can be attributed to aspirin use. Thus if only hospitalized new cases were used to calculate possible annual cases of aspirin-induced ulcer in 50 to 59-year-old men, one would conclude that the annual incidence associated 0.68 cases per 1,000 or 0.068 per 100,000 total population 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. Thus the total incidence of aspirin-related gastric ulcer may be higher than generally as-sumed.

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, “Evidence which has been 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. 80), Schneider (Ref. 24), Muir and Cossar (Refs. 2 and 3) and Weiss (Ref. 10).

Acute use of aspirin can precipitate massive hemorrhage in gastric and duodenal ulcers. The mortality of massive bleeding in peptic ulcer patients is about 8 to 10 per cent (Refs. 61 through 70).

The Panel believes that initiation or exacerbation of peptic ulcer, stomach irritation and intestinal distress should not take aspirin without first consulting a physician.

Pepptic ulcer has been estimated to occur in 5 to 10 per cent of the general population at one time or another (Ref. 67). In 1967 it was estimated that 3.5 million individuals suffered from gastric ulcer (Ref. 70). Less than 0.5 per cent of ulcer patients are hospitalized annually, involving hemorrhage in about 25 to 30 per cent of these admissions (Refs. 67 and 86). An estimated 400,000 new cases occur eight to ten times more frequent than gastric ulcer but the annual incidence of new cases per 1,000 adult male population at risk is 3.1 for duodenal ulcers and 1.4 for gastric ulcers. Gastric ulcers occur twice as frequently in men as in women (Ref. 69).

The direct ulcerigenic effect of long term aspirin use and massive bleeding from aspirin ulceration necessitated a study of aspirin use related to aspirin ulceration. Cameron (Ref. 19) presented evidence that patients with duodenal ulcers but there is no evidence that aspirin produces duodenal ulcers (Ref. 69). Kiser (Ref. 18) commented that the role of aspirin in the production of gastric ulcers has been underestimated because most studies have not dealt with the long term effects of prolonged aspirin ingestion with the exception of the studies by Douglas and Johnson (Ref. 74) and Muir and Cossar (Refs. 2 and 3). Cameron (Ref. 19) points out that the protocol for a large Veterans Administration cooperative study on gastric ulcer published in 1971 excluded patients taking ulcerogenic compounds such as corticosteroids and phenothiazine but did not mention aspirin. Patients and physicians in Cameron’s study seldom associated aspirin with their ulcers.

(1) Evidence for a causal role in gastric ulcer. The role of aspirin in the production of peptic ulcer has been underestimated because most studies have not dealt with the long term effects of prolonged aspirin ingestion with the exception of the studies by Douglas and Johnson (Ref. 74) and Muir and Cossar (Refs. 2 and 3). Cameron (Ref. 19) presents evidence that patients with peptic ulcer, particularly those with gastric ulcers. Cameron (Ref. 89) states, “Evidence which has been 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. 80), Schneider (Ref. 24), Muir and Cossar (Refs. 2 and 3) and Weiss (Ref. 10).

Increased incidence of ulcer is analgesic abuse. The unusually high incidence of analgesic use in Australia,
particularly in women, provides evidence for a causal relationship between aspirin, usually in combination, and chronic peptic ulcer. This population is significant out not only because of the very high prevalence of chronic, daily aspirin use but also the significantly greater incidence of daily use by women compared to men, first noted by Billington in 1960 (Refs. 71 and 72). The increased use of analgesics by women who take analgesic compounds is clearly for other than gastro-intestinal symptoms. If increased chronic use of aspirin does result in a higher incidence of gastric ulcer, then this effect should be evident in the Australian population. A correlation between increased analgesic use and increased incidence of ulcer was shown by Douglas and Johnson (Ref. 74) and confirmed by several others (Refs. 18, 17, 19, 76, 77, and 78). It is possible that phenacetin, an ingredient in almost all abused analgesic combinations, contributes to ulcer of aspirin. 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 in the absence of aspirin. Although kidney disease continues to develop in these two countries (Ref. 19). Other differences are noted. In the Duggan study the overall mortality of peptic ulcer patients who appeared to have aspirin-related ulcer was 11 percent. There was a statistically significant association between gastric ulcer and the incidence of 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 powder which was the usual compound tablets for analgesic use. Other workers, for example, Pritchard and colleagues, aspirin-induced gastric ulcer healed rapidly with a good prognosis when aspirin was withdrawn (Ref. 15). In the Duggan study the overall mortality of patients with a fatal 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.

(3) 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 with matched controls found that chronic aspirin use (15 tablets per week or more) was associated with gastric ulcer in 53 percent of 61 patients compared to 10 percent of controls. When patients who took aspirin for their symptoms of ulcer were excluded, 45 percent of the ulcer patients took aspirin. The difference between ulcer cases and control subjects was highly significant statistically. When the same correction was applied to duodenal ulcer patients only 16 percent of the remaining 25 duodenal ulcer patients were regular aspirin users which was not statistically different (p is greater than 0.1) from controls.

(4) Proportion of patients taking aspirin-related gastric ulcer lesions. Aspirin-related gastric ulcer patients have lesions which are generally of the same shape, size and appearance as in nonaspirin ulcer patients. However, the location and distribution of aspirin-induced lesions in the stomach and the condition of the surrounding mucosa appear to be different. Interestingly, the distribution of aspirin lesions is independent of the dosage form as well as the drug. McDonald (Ref. 91) found that aspirin-related ulcers occurred most frequently on the greater curvature of the antrum. He claimed that only the aspirin-related ulcers were found in this region and were surrounded by normal pyloric gland mucosa. In the Minnesota series (91), the aspirin-related ulcer was found within 1 inch of the pyloric sphincter in 65 percent of patients with gastric ulcer associated with heavy aspirin use, as compared to 21 percent of gastric ulcer patients taking aspirin (p is less than 0.05). Cameron (Ref. 89) in 1976 noted that 90 percent of the ulcers related to regular aspirin use (15 tablets weekly or more) were in the antral region compared to 56 percent in patients who took less than 15 aspirin tablets per week (occasional and non-users).

In some parts of Australia, however, where powders rather than tablets are almost exclusively used, aspirin-related ulcers are not located in the antral region and, indeed, Gilles and Skyring (Ref. 78) excluded all antral ulcers from their study. However, a greater incidence of smoking compared to matched controls.

(5) Acute exacerbation of ulcers. Kiser (Ref. 18) described the effects of continued aspirin administration on chronic gastric ulcer patients. Two had mild anemia with no overt bleeding. Delayed healing occurred with continued aspirin use. All healed well when aspirin was discontinued. Recurrence was observed when aspirin was used again. Alp et al. (Ref. 17) stated that the ulcer patients who continue to smoke, drink and take aspirin have a much higher incidence, 87 percent compared to 49 percent (a two-fold increase) of reactivation of ulcers. Exacerbation or recurrence of ulcer symptoms following aspirin ingestion was demonstrated by Muir and Cossar (Ref. 3) for 14 of 34 gastric ulcer patients who were called taking aspirin within 24 hours of their symptoms.

Several other authors have shown that activation of ulcers occurs peripherally after aspirin ingestion (Refs. 12 and 13).

(6) Massive gastrointestinal bleeding. By far the most serious adverse effect of the action of aspirin on the gastrointestinal 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-
The incidence of massive bleeding is low, relative to the frequency of aspirin use, the total occurrence is not insignificant. Three different recent studies involving 1,615 hospitalized patients receiving aspirin (7 per 1,000). The incidence of aspirin use was estimated at 25 per 100,000 (0.25 per 1,000).

A third report by Levy (Ref. 84) estimated the frequency of major 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. 93). 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 gastrointestinal bleeding, including those associated with aspirin ingestion (Refs. 15 and 16).

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. Gastroenterological studies conclusively show that acute use of aspirin is causally related to massive bleeding (Refs. 84 and 95). The Panel believes that some of the criticisms of the aspirin to the punched out bleeding erosions but not to 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 not some undefined effect such as hypersensitivity or a capillary or conglutination defect.

Several other authors have observed mucosal erosions and hemorrhage associated with aspirin particles by gastroscopy and histological examination (Ref. 23) and during surgery (Ref. 3).

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. 94), Kelly (3 cases) (Ref. 85), Waterson (Ref. 103) and Brown and Mitchell (Ref. 86).

(iii) Case-control clinical studies. In the opinion of the Panel, there is sufficient evidence from experimental and clinical studies and the experimental designs to warrant the conclusion that aspirin ingestion is a contributory factor in increased incidence of major gastrointestinal hemorrhage. Much clinical evidence involves retrospective case-control studies comparing the incidence of aspirin use in cases compared to a variety of control populations (Refs. 4, 19, 22, 84 through 87, 90, 92, and 94 through 101).

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 indicates that the drug used was not for symptoms related to the disease condition and the control group matched for all important variables except bleeding (Refs. 2, 22, 84, and 94 through 101).

Because gastric distress is such a common component of gastrointestinal disease, in some studies all cases of acute upper gastrointestinal hemorrhage in individuals both with and without aspirin ingestion were excluded as possible cases involving aspirin as a causal gastric pain associated with peptic ulcer or contributory factor (Refs. 2 and 84). These studies do not consider the importance of aspirin taken either for unrelated reasons or for the chronic gastric pain associated with peptic ulcer or gastritis will initiate bleeding from existing lesions.

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 aspirin use in the general population 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 control in all 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, 19, 22, 84 through 87, 90, 92, and 94 through 101).

The choice of Alvarez and Summendrill (Ref. 22) in using dyspeptic patients as controls was criticized by Langman (Ref. 104) because these patients may have been warned about 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 warned by 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. 96) was designed to meet the criteria described by Langman. They found a statistically significant relationship between short-term use of aspirin (within 72 hours of hospital admission) and major upper gastrointestinal bleeding. A second study also 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 the incidence of "heavy" aspirin use (used for 4 or more times a week for 12 weeks) with non­bleeding 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 major upper gastrointestinal bleeding were twice as high, being about 28 per 100,000 per year. The incidence rate in heavy aspirin users was two times as high as that in non-aspirin users, being about 56 per 100,000 per year. The yearly incidence rate of new cases of nonbleeding stomach ulcers in individuals not taking aspirin is 3 per 100,000 per year. In heavy aspirin users the incidence rate rose to 10 per 100,000 per year. Both of these differences were statistically significant. Thus, the increase in admissions for new major 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 this study rules out the "explanation" that the causal relationship between regular "heavy" use of aspirin and major upper gastrointestinal bleeding and 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 of the total 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 the incidence of the individual total hospital admitted to the hospitals used aspirin at least once a week for 3 months and 6.3 percent of the total took aspirin four or more times a week for 3 months.

It is worth emphasizing that this study provides no information on the "effect" of aspirin intake to upper gastrointestinal bleeding in patients who have predisposing conditions such as established chronic peptic ulcer disease. Evaluation of such cases in a case-control study would 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 association between chronic or heavy aspirin use and the study primed subjects. It only studied subjects with chonic use of aspirin. It therefore ignored the largest group. While this may be true in the cited study, others and caffeine products have proved 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 predisposed sites.

Of the total number of cases of peptic (stomach) ulcer (517) and upper gastrointestinal bleeding (467) only 242 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 the patients had been given aspirin after admission. Furthermore, this study did not examine the possible effect of one 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 that this study does not prove that asymptomatic patients will produce stomach ulcers or gastric bleeding. The study was designed such that only chronic aspirin use was studied. Any individual who had taken aspirin less than 3 months was not included in the study. Even though these bleeding gastro­intestinal hemorrhage have examined only acute use of aspirin, usually only 24 to 72 hours prior to bleeding. The association between bleeding and "heavy" use of aspirin was statistically significant in the study of 43 patients with newly diagnosed cases of uncomplicated nonbleeding intestinal ulcer. In the study, 7.9 percent of 63 patients were heavy users of aspirin compared to 6.9 percent of controls. In the 43 patients with newly diagnosed duodenal ulcer who had major bleeding 11.6 percent were heavy aspirin users compared to 8.3 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 93 patients and 112 controls reported in Ref. 79. In 1969 also found a relationship between chronic aspirin use and the ingestion of a combination product that contained aspirin, phenobarbital, and caffeine (APC). They found the incidence of peptic ulcer but found no association between duodenal ulcer (intestinal ulcer) and analgesic consumption. Preglycolic ulcers are near the exit valve of the stomach, which 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 not simply a cause of the excess of peptic ulcers in middle-aged women in eastern Australia (Ref. 89).

(2) Difference between case and control in the frequency of gastrointestinal bleeding. Unfortunately the details of aspirin consumption in patients with major gastrointestinal bleeding has not been given in most studies. The careful done prospective study of Alvarez 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. This study reported that aspirin ingestion was associated with gastric bleeding declines exponentially with time. The majority of patients who bled took aspirin within 1 day prior to 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 hemorrhage in patients with peptic ulcer (Ref. 2). It is important to realize that while the increased bleeding asso­ciated with gastric bleeding declines exponentially with time. The majority of patients who bled aspirin in producing hemorrhage is acute. If one plots these data as the cumulative occurrence of aspirin ingestion, relative to total use, for bleders and nonbleeders, it is clear that the probability of aspirin ingestion is not statistically significant.

Second, the effect of aspirin in producing hemorrhage is acute. If one plots these data as the cumulative frequency of aspirin occurrence, relative to total use, for bleders and nonbleeders, it is clear that the probability of aspirin ingestion is not statistically significant.
but can potentiate bleeding from both gastric and duodenal ulcers suggests that different mechanisms are involved.

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 Cammack had hematemesis or melena in the previous 6 months (Ref. 19). The occurrence of acute lesions associated with patients in the trauma-sepsis group is not necessarily dependent upon aspirin ingestion since they are also seen in patients who were not taking aspirin. Furthermore, the nature of the acute lesions remains the same as the 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 the incidence of gastric mucosal 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 superficial epithelium (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 direct observation with a gastroscope during surgery. In studies in which gastroscopic examinations were not performed this lesion is probably included in the "erosive gastritis" category. In more, 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) and cancer. All of the clinical evidence of hemorrhagic erosive gastritis has been associated with a variety of disease states, alcohol and aspirin alone or together are most frequently identified as the precipitating agents (Ref. 61).

Sugawa, Lucas and Walt (Ref. 105) followed 132 patients with acute erosive gastritis (64 after sepsis or trauma, 40 after alcohol intake and 8 after aspirin ingestion). They were studied by serial gastroscopy 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 out of 40 patients had striking antral involvement. Red based erosions were the main lesion in this group. Aspirin erosions were more frequent in the body, but were seen throughout the stomach. An unusual number of patients developed superficial white based ulcerations after aspirin.

Katz and Siegel (Ref. 14) reported that bleeding from acute erosions outnumber acute ulcers as a source of bleeding by 7 to 1, in the aspirin-related group. A rare person 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 ulcer is unrelated to the presence or absence of ulcers.

Katz and Siegel (Ref. 14) reported that bleeding from acute erosions outnumber acute ulcers as a source of bleeding by 7 to 1, in the aspirin-related group. A rare person 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 ulcer is unrelated to the presence or absence of ulcers.

Katz and Siegel (Ref. 14) reported that bleeding from acute erosions outnumber acute ulcers as a source of bleeding by 7 to 1, in the aspirin-related group. A rare person 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 ulcer is unrelated to the presence or absence of ulcers.

Katz and Siegel (Ref. 14) reported that bleeding from acute erosions outnumber acute ulcers as a source of bleeding by 7 to 1, in the aspirin-related group. A rare person 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 ulcer is unrelated to the presence or absence of ulcers.

Katz and Siegel (Ref. 14) reported that bleeding from acute erosions outnumber acute ulcers as a source of bleeding by 7 to 1, in the aspirin-related group. A rare person 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 ulcer is unrelated to the presence or absence of ulcers.

Katz and Siegel (Ref. 14) reported that bleeding from acute erosions outnumber acute ulcers as a source of bleeding by 7 to 1, in the aspirin-related group. A rare person 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 ulcer is unrelated to the presence or absence of ulcers.

Katz and Siegel (Ref. 14) reported that bleeding from acute erosions outnumber acute ulcers as a source of bleeding by 7 to 1, in the aspirin-related group. A rare person 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 ulcer is unrelated to the presence or absence of ulcers.

Katz and Siegel (Ref. 14) reported that bleeding from acute erosions outnumber acute ulcers as a source of bleeding by 7 to 1, in the aspirin-related group. A rare person 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 ulcer is unrelated to the presence or absence of ulcers.

Katz and Siegel (Ref. 14) reported that bleeding from acute erosions outnumber acute ulcers as a source of bleeding by 7 to 1, in the aspirin-related group. A rare person 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 ulcer is unrelated to the presence or absence of ulcers.
they are not under arteriolar control (Ref. 14); massive bleeding is more frequently observed in individuals who have inborn clotting deficiencies. While hemophilia has long been recognized to be a contraindication to aspirin use, other clotting deficiencies which are less severe have been detected because of their reaction to aspirin (See part III paragraph B.1.a (2) above. Adverse effects on the blood.; and large increases of gastrointestinal occult blood loss are frequently associated with individuals who are more likely to have existing mild bleeding sites. The effects of aspirin on platelet function require only small doses. The effect may persist for several days. This dose-time response is consistent with some reports of massive bleeding following one or two aspirin tablets 1 or 2 days before massive bleeding occurs (Ref. 86).

(4) 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. 35) found a definite association between the route of aspirin (within 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 of the separate diagnostic groups, i.e., duodenal and gastric ulcer, gastritis etc., only the duodenal group showed a high significance of the association with gastric bleeding. It is of significance that of the separate diagnostic groups, i.e., duodenal and gastric ulcer, gastritis etc., only the duodenal group showed a high significance of the association with gastric bleeding.

Even though highly buffered aspirin decreases the average occult bleeding loss in most studies (Ref. 79), it appears that frequently high buffered aspirin, one or two subjects who have taken highly buffered aspirin solution have sporadic, large increases in gastric bleeding. Increased occult “spouters” or “outliers” have occult bleeding losses which are often significantly greater—statistically than the average for all subjects in the study (Ref. 77). Seemingly occult bleeding is not found to the unusual excessive bleeder or eliminating these “outliers” from the study begs the issue that buffering decreases blood loss and probably ignores the variable of exaggerated responder which is so characteristic of massive gastrointestinal bleeding.

Locally applied aspirin produces massive bleeding from capillary beds of tissue such as the tonsillar areas of the throat (See part III paragraph B.1.a (2) (ii) (b) (i) 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 significant 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). However, many physicians prefer to be implicated in massive bleeding associated with duodenal ulcer patients to the same or greater extent as in 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 same factors as those 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 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 bloodstream can produce major bleeding, all preparations containing aspirin regardless of formulation should bear a warning: "Caution: Do not take this product if you have stomach distress, ulcers or bleeding problems except under the advice and supervision of a physician".

REFERENCES

(7) Grant, "Gastric Ulcer in South Australia."
(12) O'TC Volume 090160
(13) OTC Volume 090160
(18) Kiser, J. R., "Chronic Gastric Ulcer Associated with Aspirin Ingestion. A Report"
(24) Holt, P. R., "Measurement of Gastric Acid Through the Gastric Mucosa and Its Effect on the Gastric Mucosal Barrier," Journal of Laboratory and Clinical Medicine, 56:206-213, 1960.
(44) Barbour, G. H. and V. C. Dickerson, "Gastric Ulceration Produced in Rats by Oral and Subcutaneous Aspirin," Archives of Internal Medicine, 95:355-359, 1955.
(49) Billington, B. P., "Gastric Ulcer: Age, Sex, and a Chronological Approach," Australian Annals of Medicine, 9:111-121, 1960.
The Phenestin Test in the Detection of Analgesic Abuse.

The Influence of Some of the Salicyl Compounds

The Role of Salicylates in Massive Gastrointestinal Hemorrhage II—Manifest Bleeding.


The Phenistix Test

Hypersensitivity reactions are varied, including the following types:

(a) Immediate (urticaria or angioedema (Refs. 14, 15,16, 54), laryngeal edema, nasal congestion, rhinorrhea with sneezing, and eye irritation)

(b) Delayed (dermal and pulmonary) has been estimated to be about 0.3 percent of the general population (Refs. 1 and 5).

(c) Moderate (hives, asthma, and eczema (Ref. 17)).

(d) Severe (anasarca, asthmatic crisis, and even life-threatening in some individuals that have a significantly higher reaction (Ref. 18)).

The second group are those who usually exhibit dermatological reactions, such as urticaria or angioedema (Refs. 14, 15, 16, and 19), but may also have asthma following aspirin ingestion (Ref. 19).

The Panel concludes that aspirin can precipitate hypersensitivity reactions by different mechanisms in different groups of patients who may have entirely different characteristics. The acceptable types of substitute analgesics would also appear to be entirely different for the different groups.

The Panel also considered the suggestion that the warning to asymptomatic persons that aspirin plays in the pathogenesis of different types of hypersensitivity reactions; characterization of subgroups that can be used to identify individuals that have a significantly higher risk of reaction with aspirin; and identification of other substitute analgesics such as ibuprofen and phenylbutazone (Refs. 20 and 21). Analgesics agents which do not affect prostaglandin synthesis inhibitors including indomethacin, flufenamic acid, mefenamic acid, ibuprofen and phenylbutazone (Refs. 20 and 21).
Asthma may range from mild, brief attacks to severe and prolonged attacks and, rarely, death. Secondary symptoms may involve urticaria, allergic asthma and, rarely, anaphylactic shock. Allergy of this type belongs to a subgroup of the so-called "immune" class of disease termed Type II or intrinsic, nonallergic aspirin sensitivity (Type II) aspirin responders. Intrinsic, nonallergic type and are quite different from asthmatics not sensitive to the drug (usually Type I atopic asthma). Type II aspirin responders make 1/2 to 1/3 the usual number of asthma attacks during a time when the patient's asthma was stable. A dose of 600 mg aspirin was given as two tablets which also contained 150 mg magnesium hydroxide and 150 mg aluminum hydroxide per two tablets. Other tablets, containing 200 mg magnesium hydroxide and 200 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 monitored and the patient's respiratory rate, in and out, was kept constant. Pulmonor. Eight of 42 (19 percent) challenges were positive. These results, combined with 14 patients with a history of intolerance to aspirin, yield a prevalence of aspirin intolerance of 8 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 particularly high incidence of aspirin sensitivity 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 (reagin), such as pollen or a food, 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 a subgroup of the so-called "immune" class of disease termed Type II or intrinsic, nonallergic aspirin sensitivity (Type II) aspirin responders. Intrinsic, nonallergic type and are quite different from asthmatics not sensitive to the drug (usually Type I atopic asthma).

Aspirin-induced asthmatics are usually the Type II, intrinsic, nonallergic type and are quite different from asthmatics not sensitive to the drug (usually Type I atopic asthma). The majority of the atopic (reagin-mediated or Type I) aspirin responders are said to carry no greater risk of aspirin sensitivity than the general population. The distinctly different characteristics of the low risk patient are: An early onset of atopic (reagin-mediated) asthma; a family history of 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.

The mechanism involved in the intrinsic nonallergic aspirin-sensitive asthma 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 inhibited prostaglandin synthesis (Refs. 20 and 21). Indomethacin produced a bronchoconstrictor effect in 11 patients tested after a dose of 5 mg. Therapeutic doses of mafenamic acid and flufenamic acid, and 200 to 500 mg phenylbutazone produced a bronchoconstrictor effect in most patients. These five drugs all inhibited microsomal prostaglandin synthetase. Salsalicylamide, acetaminophen, benzoylamine and chloroquine did not inhibit prostaglandin synthetase and did not produce bronchoconstriction.

(c) Urticular (dermal) hypersensitivity reactions. Speer states that the most common manifestations of aspirin sensitivity are urticaria (hives) and angioedema (giant hives) rather than asthma. (Ref. 15). Urticular reactions (hives) are generally considered as part of the general aspirin sensitivity syndrome. However, urticarial reactions frequently occur independently. Different mechanisms may be involved. These patients frequently have other allergies (food, drugs) and do not always react to all aspirin preparations. Urticaria and nasal polyps found in aspirin-induced asthmatics. In 112 patients found sensitive to aspirin (15 percent of all patients seen in a 10-year period) there were 14 cases of urticaria and/or angioedema and 38 cases of asthma. Of interest is the fact that four of these patients also reacted to acetaminophen. Of these, three developed urticaria and one asthma.

In contrast to aspirin-induced asthma which is usually precipitated only by aspirin and not salicylic acid, both aspirin and sodium salicylate will exacerbate chronic urticaria in 20 to 25 percent of cases (Refs. 14 through 16).

Polish workers et al., using the rat mast cell technique, which is thought to detect IgE immunoglobulin reactions, were able to distinguish between two groups of patients hypersensitive to aspirin (Ref. 19). Dermal reactions are not uniformly life-threatening. There are indications that life-threatening anaphylactic shock is often associated with patients with dermal rather than asthma reactions to aspirin. Thus while typical (intrinsic, nonallergic) aspirin hypersensitive patients (Type II) can frequently use salicylic acid or acetaminophen or other analgesics which do not inhibit prostaglandin synthesis without cross-sensitivity, this does not appear to be true with urticarial and possibly anaphylactoid type reactions in the atopic type (Type I) aspirin responders.

The American Academy of Allergy in 1973 (Ref. 25) approved the following recommendation: While recognizing that acetylsalicylic acid (aspirin) is a valuable drug, the American Academy of Allergy recommends that a form similar to the following form of a proposed warning for aspirin should state, "This medicine 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 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


(iv) Adverse effects during pregnancy. 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, either alone or in combination with other drugs, to 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 injection on the length and duration of pregnancy and parturition time (length of labor and delivery); and the impairment of hemostatic mechanisms by aspirin (but not other salicylates) 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 described followed by the Panel's conclusions and recommendations.

11 of pregnancy. However, the doses used were, on a weight basis, much greater than the therapeutic doses used in man. The authors suggested that in drug tests for teratogenic potential the drug should also be given after injection of sodium salicylate 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, as anomalies of the ribs and vertebrae showed the highest incidence after injection on the 9th day. Again, the A/Jax strain, and the progeny from A/Jax females crossed with CBA males were shown to be the most susceptible. The Panel has elected to separate and review the available data according to the above effects. Teratogenic potential and fetal lethality will be described followed by the Panel's conclusions and recommendations.

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

PROPOSED RULES • 35399

11 of pregnancy. However, the doses used were, on a weight basis, much greater than the therapeutic doses used in man. The authors suggested that in drug tests for teratogenic potential the drug should also be given after injection of sodium salicylate 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, as anomalies of the ribs and vertebrae showed the highest incidence after injection on the 9th day. Again, the A/Jax strain, and the progeny from A/Jax females crossed with CBA males were shown to be the most susceptible. The authors suggested that in drug tests for teratogenic potential the drug should also be given after injection of sodium salicylate 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, as anomalies of the ribs and vertebrae showed the highest incidence after injection on the 9th day. Again, the A/Jax strain, and the progeny from A/Jax females crossed with CBA males were shown to be the most susceptible. The Panel has elected to separate and review the available data according to the above effects. Teratogenic potential and fetal lethality will be described followed by the Panel's conclusions and recommendations.

The Panel's study of salicylate in pregnancy has been limited to the use of sodium salicylate in doses of 60 to 180 mg (maximum 500 mg/kg) and to their reciprocal crossings. It was found that the fetal resorption rate increased steadily the later in pregnancy sodium salicylate was given to the A/Jax females. The highest fetal resorption rate was observed when the injection was given on the 12th and 13th day of gestation. Larson 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 different 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, 11, 13, 15 or 17) to pregnant primiparous females and to their reciprocal crossings. It was found that the fetal resorption rate increased steadily the later in pregnancy sodium salicylate was given to the A/Jax females. The highest fetal resorption rate was observed when the injection was given on the 12th and 13th day of gestation.
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 intriguing, it must be noted that again extremely high doses were used since the LD₅₀ for females of the strain used (A/Jax) was determined to be 760 mg/kg of body weight.

Serum levels of salicylate in rodent models also must be considered. Although these observations are interesting, it must be noted that here teratogenic doses used in rodents probably increased. Although these observations are interesting, it must be noted that here teratogenic doses used in rats were considerably in excess of that likely to be used therapeutically in pregnant women. However, Wilson (Ref. 5) have shown that doses of aspirin five to six times higher than the teratogenic doses used in rodents produced embryotoxicity and fetal malformations in this species. It should be emphasized that the daily dose of 350 mg/kg was 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, Wilson and Schumacher (Ref. 7) that the teratogenic potential of a given dose of aspirin in man 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 inhibiting salicyluric acid formation, but whether such interaction could raise the salicylate concentration in maternal blood sufficiently to cause embryotoxicity still remains an open question. Wilson has further discussed the role of benzoic acid-containing ingredients later in this document. (See part VI. paragraph B.2. benzoic acid-containing ingredients.)

Since these and other reports have appeared, questions are sometimes raised about the possible embryotoxicity of salicylates, particularly aspirin, in view of its widespread use as an analgesic and the high doses used in arthritis. For purposes of comparison, it should be noted that the use in the average adult female of aspirin in such manners would be equivalent to 70 mg/kg for an average 55 kg (122 lb) woman.

Recently, Beall and Klein (Ref. 9) have reported a study in which a dose of 250 mg/kg (administered on days 8 through 10 of pregnancy) with and without food restrictions. They found that the controls (group I) (food ad libitum, no drug administration) had 2.9 percent of abnormal progeny. Group II (250 mg/kg aspirin, no food ad libitum) had 23.8 percent of abnormal fetuses. Group III animals on a restricted diet (6 g of aspirin and 6 g of food) had 48.8 percent of abnormal fetuses of 5.3 percent. However, Group IV receiving 250 mg/kg aspirin plus food restriction had an incidence of 95.8 percent malformed fetuses.

The types of anomalies observed included rib anomalies, cranial/mandibular, umbilical hernia, scoliosis, anophthalmia, cleft lip and palate, etc.

The data also show a significantly increased number of resorptions in group IV when compared to other groups; although the authors do not give a significant difference in this paper. 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 has already been emphasized, on a weight basis the doses used in the animal studies (50 mg/kg) and applied or 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 480 to 600 mg/kg, the animal doses were also at levels that would be lethal to humans (equivalent to 84 to 96 aspirin 325 mg (5 gr) tablets). When one considers that the human aspirin dose, such as a dose of 150 mg/kg, there was little or no adverse reaction. As noted above, the total maximum daily dose of aspirin recommended by the Panel for adults is 100 mg/kg, or about one-half the dose in mice of 150 mg/kg. However, extrapolation from animal data to humans is not always a matter of simple arithmetic and conversion. There is a basis for the belief that 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. Interspecies differences in metabolism are extremely common.

(2) Human studies. Studies related to the use of salicylates by pregnant women were aimed at trying to make an assessment of the risks involved. Obviously, ethical and moral reasons preclude specially designed randomized studies that would examine the effects of salicylates on pregnancy. The Panel has therefore had to rely mainly on 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 1965 was performed in Wales by Richards (Ref. 10). The mothers of the malformed infants were matched with an equal number of controls, who had given birth to normal infants. The final results of the interviews in the homes of each mother, showed 2.5 percent 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 were not given.

Richards reported that a very high percentage of the reported malformations were possibly of maternal origin such as cleft lip and palate, etc. However, the Panel finds that the results do not exclude that some salicylates could have acted as a causative factor. The type and severity of the anomalies observed in human studies vary considerably. The作者 concluded that the results of the investigation "suggest that either the type or dosage of salicylate (Ref. 2) was too low or that the conditions for which they are being used have given such an action." It should be noted that in addition to salicylates, other drugs had been taken by some of the mothers during pregnancy, such as antibiotics, sulfonylmethanes, steroids, sedatives, iron, oral contraceptives, antimetics, 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 administration of salicylates and the malformation found in the infants. The author acknowledged that there are several limitations to a retrospective study such as the fact that a "large number of tests of significance were performed and many of these apparently significant differences could have arisen merely by chance." Statistical tests of significance and indicated that of the 101 tests that showed statistical significance, he considered that 51 of these statistically significant results could have occurred by chance.

In reviewing the study, the Panel finds several limitations which prevent a valid interpretation of the findings. Even the author acknowledges limitations to a retrospective study and admitted the fact that the results may be affected by bias on the part of the interviewer or the mother; events, drugs and dosages may have been forgotten; emphasis was placed on the whole of the first trimester, whereas the critical periods of development are short and occur at different times for different organs; and lastly that a large number of 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 or other drugs but to evaluate congenital malformations and environmental influences in pregnancy. Many factors besides drugs were evaluated such as illnesses during first trimester, smoking and diet habits, employment, accommodations, water supply, etc.
proposed rules

Nevertheless, the Panel concludes that regardless of the circumstances, the Panel views the summary conclusions of the authors as very important. Namely, the fact that Richards found many statistically significant associations between drug intake and birth defects, those of greatest interest (and possible importance) being: (i) Use of salicylates, (ii) other certain drugs (antiepileptics) and (iii) the effects of diet. In the first trimester considered to be unbalanced or doubtful. Of importance to this Panel, the author found the taking of salicylates in the first trimester resulted in the following significant findings:

- Statistically significant differences between the alimentary tract (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).

- The authors' summary comments emphasize the need for caution in presuming teratogenic effects on the basis of the associations found in the study. They do recommend that any drug which carries a suspicion of teratogenicity should be studied more extensively when prescribed. More interestingly, they recommend that OTC drugs such as salicylates should be avoided.

A retrospective study in Finland reported by Richards (Ref. 10) also observed talipes. Since the average dose of aspirin per mother in the study group was reported to be a little over half that in the control group, this indicates a woman does not necessarily have to be an abuser or take large quantities of the drug to have the effect at risk.

The authors' summary comments emphasize the need for caution in presuming teratogenic effects on the basis of the associations found in the study. They do recommend that any drug which carries a suspicion of teratogenicity should be studied more extensively when prescribed. More interestingly, they recommend that OTC drugs such as aspirin should be avoided.

A retrospective study in Finland reported by Saxen (Ref. 12) in 1975 investigated the association between oral clefts in infants and drugs taken by their mothers during pregnancy. Five hundred ninety-nine cases of oral clefts (cleft lip, cleft palate) were selected. The external blood level was high so was the maternal factor. When the present and past pregnancies of the women were explored, a cumulative secondary effect from some past pregnancies of the women were found. In considering the results, it should be kept in mind that this study was partially prospective and partially retrospective. The information concerning intake of drugs was obtained from welfare center records (prospective) whereas questionnaires were completed by the mothers during their first visit (retrospective). The information concerning intake of drugs was obtained from welfare center records (prospective) whereas questionnaires were completed by the mothers during their first visit (retrospective). Although it was reported that in the first trimester of pregnancy, 14.9 percent of the mothers of the malformed infants took salicylates as compared to 5.6 percent of the controls (p is less than 0.001), approximately the same percentage of mothers of malformed infants and of the controls took salicylates. This is likely due to the fact that the women might remember exactly when during pregnancy they took salicylates. Since a correlation with the intake of other drugs during pregnancy was also studied, the authors concluded that the number of significant tests performed, the possibility of chance correlations must be taken into account; but the fact that the significant differences in the first trimester, lessens the probability that these differences arose by chance. Saxen also points out that other drugs administered simultaneously may alter the response to a drug.
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 (Ref. 11) 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 elevated cord-blood 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 effect it may be more related to their level of salicylate than a constantly elevated level. Turner and Collins concluded, "Our findings do not support the suggestion that salicylates are teratogenic, but they do suggest that chronic salicylate ingestion is associated with an increase in perinatal mortality and with decreased intraterine growth."

In a recent study reported by Slone et al. (Ref. 15), the results of a prospective study suggest that aspirin is not teratogenic. In the study, which was conducted in 12 hospitals throughout the U.S., 50,282 mother-child pairs were selected for evaluation. Prior to delivery, data were collected on drugs taken, maternal illnesses, complications, etc. However, full details of dosages were not recorded but the heaviest use of aspirin, which was recorded, was for 8 or more days in any lunar month. Aspirin had been the most commonly used drug which was taken by 32,164 women during pregnancy. With regard to evaluating complications, the first 4 lunar months of pregnancy were studied in which aspirin had been taken by 14,864 women. In fact, during this period, 5,128 women (heavy users) had taken aspirin during the 4th lunar month alone at least 1 of the first 4 lunar months. To fully evaluate the data, the authors developed risk factors for each of the outcomes identified. These included comparisons of children with and without each of the outcomes in terms of such factors as antenatal visits, personal characteristics of mother and offspring, age, illness, genetic factors (prior malformed siblings), etc.

The findings of the study in terms of malformations according to aspirin exposure during the first 4 months of pregnancy are as follows:

**Congenital Malformations Following Aspirin Exposure: Early Pregnancy**

**Group I:** Containing 5,128 "heavily" aspirin-exposed mother-child pairs. (See description of heavy users above.)

**Group II:** Containing 2,798 aspirin-exposed mother-child pairs.

**Group III:** Containing 35,418 non-aspirin-exposed mother-child pairs.

**Findings of study**

<table>
<thead>
<tr>
<th>Parameter measured</th>
<th>Group I</th>
<th>Group II</th>
<th>Group III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number malformed</td>
<td>43</td>
<td>63</td>
<td>2,423</td>
</tr>
<tr>
<td>Percent of group</td>
<td>0.7</td>
<td>0.6</td>
<td>0.3</td>
</tr>
<tr>
<td>Relative risk</td>
<td>1.60</td>
<td>1.06</td>
<td>1.00</td>
</tr>
</tbody>
</table>

When the children were further divided according to outcome, i.e., uniform malformations (CNS, cardiovascular, etc.) and nonuniform malformations (intrauterine heart and clubfoot), the data show that both aspirin exposure groups were similar to the unexposed group. The standardized relative risk of child 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 any exposure to aspirin during the first 4 lunar months, the standardized relative risk of uniform and major malformations did not differ from each other. However, 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 teratogenic 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."

The data presented here are not in accord with previous studies (Refs. 14 and 16). The striking differences between the study of Slone et al. and those of Collins and Turner (Ref. 16) and Turner and Collins (Ref. 14) are not as dramatic as it may appear at first sight. The studies in the American and Australian papers were widely differing and probably the main difference lies in the definition of "heavy user" 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. 15) concluded that the study gave no evidence that aspirin ingestion during pregnancy was associated with congenital malformations. They pointed out that from the statistical view point the relative risk estimates for uniform malformations and for major malformations 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 teratogenic 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."
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 laboring periods 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 56 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-medicated 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>285.5±13.5</td>
<td>275.2±16.0</td>
<td>278.6±20.0</td>
</tr>
<tr>
<td>Length of labor (hours)</td>
<td>32.1±10.6</td>
<td>7.3±6.1</td>
<td>6.9±4.3</td>
</tr>
<tr>
<td>Birth weight (g)</td>
<td>3,072±970</td>
<td>2,972±538</td>
<td>2,870±490</td>
</tr>
<tr>
<td>Estimated blood loss (ml)</td>
<td>241±214</td>
<td>241±214</td>
<td>241±214</td>
</tr>
</tbody>
</table>

The findings of the study in terms of incidence of main clinical features from regular salicylate ingestion during pregnancy are as follows:

**Results of study groups**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Group I</th>
<th>Group II</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stillbirths</td>
<td>1.41</td>
<td>1.32</td>
<td>2.20</td>
</tr>
<tr>
<td>Neonatal deaths</td>
<td>1.4</td>
<td>1.7</td>
<td>3.4</td>
</tr>
<tr>
<td>Cesarean section</td>
<td>1.4</td>
<td>2.0</td>
<td>4.3</td>
</tr>
<tr>
<td>Neonatal weights</td>
<td>4.3</td>
<td>5.0</td>
<td>6.9</td>
</tr>
<tr>
<td>Complicated deliveries</td>
<td>4.3</td>
<td>5.0</td>
<td>6.9</td>
</tr>
</tbody>
</table>

Because the numbers in the survey were small, the findings in present and past pregnancies of the women in the study were combined when assessing the antepartum hemorrhage, postpartum hemorrhage and transfusion at delivery, and all of these were found to be significantly increased in the constant takers group (p is less than 0.001). The stillbirths and perinatal death rates of the combined pregnancies of this group were also much greater than in the controls (p is less than 0.01 and less than 0.005, respectively).

In another recent study reported by Shapiro et al. (Ref. 19), the results showed no evidence that aspirin taken during pregnancy is a cause of stillbirth, neonatal death, or reduced birth weight. In this study, the collaborative perinatal project previously described by Sione et al. (Ref. 15) was used. The 50,282 mother-child pairs previously described were reduced to 41,337 mother-child pairs by the following modification:

When a mother was enrolled in the study more than once, a random pregnancy was selected. This was done because perinatal deaths in prior siblings may increase the risk of subsequent perinatal death. Pregnancies lasting less than 7 lunar months were excluded. Since as explained below, the definition of heavy aspirin exposure used here was party dependent upon the duration of pregnancy.

As in the previous study, women were divided into those who were not exposed to aspirin (14,956), those with intermediate exposure but poorly defined (24,866) and those who were heavily exposed (1,515). Heavy exposure was defined for pregnancies lastig at least 8 lunar months, as aspirin taken for at least 8 days per lunar month in at least 6 lunar months. For pregnancies of 7 lunar months duration, the drug had to be taken for at least 8 days in each of at least 5 lunar months.

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>1,515 heavily aspirin-exposed mother-child pairs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>40.5% of babies were delivered by caesarean section</td>
</tr>
</tbody>
</table>

**Group II:** Containing 24,866 intermediate aspirin-exposed mother-child pairs

**Group III:** Containing 14,956 non-aspirin-exposed mother-child pairs.
The findings demonstrate that in this study there is no evidence that aspirin taken during 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.

Criticisms of the study by Slone 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 as used by pregnant women in the United States is related to perinatal mortality or low birth weight."

**Findings of study**

<table>
<thead>
<tr>
<th>Parameter measured</th>
<th>Group I</th>
<th>Group II</th>
<th>Group III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number stillbirths</td>
<td>21</td>
<td>298</td>
<td>205</td>
</tr>
<tr>
<td>Percent of group</td>
<td>1.4</td>
<td>1.2</td>
<td>1.1</td>
</tr>
<tr>
<td>Number of neonatal deaths</td>
<td>17</td>
<td>232</td>
<td>166</td>
</tr>
<tr>
<td>Percent of group</td>
<td>1.7</td>
<td>1.0</td>
<td>1.3</td>
</tr>
<tr>
<td>Mean birth weight (g) [Standardized (and S.E.M.)]</td>
<td>3,226±(±0.4)</td>
<td>3,306±(±0.6)</td>
<td>3,206±(±0.1)</td>
</tr>
</tbody>
</table>

**Effects on maternal and newborn hemostatic mechanisms.**

1. **Interference with maternal hemostatic mechanisms.** — In the study of Lewis and Schulman previously mentioned (Ref. 18), three of six oral bleeding patients in Group I patients taking large doses of aspirin for at least 6 months of gestation, was 346±158 mg compared to 244±114 mg and 235±97 mg in the two controls 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 more than 150 ml of blood in patients requiring transfusions at delivery" was markedly increased when group I (constant takers) was compared to controls. In the same study, the authors noted that the mean blood levels of aspirin in patients requiring transfusions at delivery was significantly increased when groups I and II (constant and intermittent takers) were compared to the controls group (12 percent vs. 0 percent, respectively).

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 whose mothers had not taken aspirin. Two potentially adverse drug reactions detected were platelet dysfunction and diminished factor XII (Hageman Factor) in neonates born of mothers who had taken ordinary doses of aspirin during the last week of pregnancy. Aspirin-induced platelet dysfunction may have clinical relevance particularly during difficult traumatic deliveries or in the presence of other hemorrhagic defects. The authors conclude that "until the clinical significance of these findings is more fully evaluated, it would seem prudent to restrict aspirin during the last month of pregnancy."

Preliminary studies of premature infants whose mothers have ingested aspirin during the week preceding delivery suggest that this drug might be a risk factor to these infants and produce clinical bleeding (Ref. 21). Studies are now in progress to confirm this preliminary finding.

Haslam, Ekert and Gillman (Ref. 22) have reported one case of a "life-threatening gastrointestinal hemorrhage" requiring two transfusions in a newborn whose mother had taken calcium aspirin (3 tablets of 300 mg on each of the last 3 days of pregnancy, making a total of 2,700 mg). The baby required a transfusion to a children's hospital because of vomiting blood 1 hour after age as well as rectal hemorrhage (30 ml of blood). Platelet function studies showed that platelet aggregation was impaired. Three weeks after the transfusions, the platelet function had returned to normal.

On the other hand, Turner and Collins (Ref. 14) examined the infants born to mothers who took salicylates regularly 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.** In the presence of salicylic acid in neonatal urine specimens, they have shown intraperinatal fetal exposure to aspirin or other salicylates. Umbilical cord sera from 272 consecutively exposed 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 was significantly depressed (p is less than 0.03). The authors reported that unrecognised fetal exposure to salicylate was surprisingly common during late pregnancy. In view of comparable serum protein concentrations, the depression in the mean reserve albumin binding capacity is unlikely to be related to different albumin concentrations between the positive sera and control sera samples. Since salicylate does not bind to albumin, its albumin binding sites (Refs. 24 and 25) 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 assessment and management of neonatal hyperbilirubinemia (Ref. 23).

Turner and Collins (Ref. 14) had shown that the babies of 144 mothers who took salicylates regularly 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 salicylates 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 infants is higher than that of the mother (Ref. 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 aspirin.

Furthermore, another factor to consider is that the apparent volume of distribution for salicylates is higher in the neonate (.300 to 350 ml/kg) than 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 Garrettson, Procknal and Levy (Ref. 29) have described the placental transfer and kinetics of elimination of salicylates in an infant whose arthritic mother took 6 g/day aspirin during her entire pregnancy. The baby was born with a salicylic acid concentration of 25 g/100 ml plasma. While salicylate elimination was slower than in normal adults, it was more rapid than in the newborn whose mother had taken only one small dose of aspirin shortly before delivery. The slower rate of elimination in this infant when compared to an adult is due to immaturity of the glucuronidation pathway and immaturity of the renal excretory mechanism.

**Conclusions and recommendations.** Any relationship regarding the possibility of any iatrogenic 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 these 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 salicylates and fetal teratogenicity 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. However, no 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 review state that because so many tests of significance were necessary some of the results of the tests may be due to chance. Most of the studies relating to pregnancy did show that in women taking salicylates, adverse effects to the mother and the fetus were significantly increased. However, salicylates in cord-blood were correlated with high levels of salicylates in maternal blood. In cases where such correlations were found, adverse effects were significantly increased in the mother and in the infant at delivery. The adverse effects consisted of an increase in the length of pregnancy and labor, and bleeding before and after delivery (Ref. 16). The fetus was adversely affected as evidenced by a decreased birth weight, and an increase in the stillbirth rate, perinatal mortality rate and decreased albumin binding capacity (Ref. 14).

The Panel is particularly concerned with the effects of chronic aspirin ingestion on the fetus, i.e., decreased birth weight, increased stillbirth rate, perinatal mortality and prolonged parturition. The Panel is particularly concerned with the effects of increasing duration of use. Changing hemostatic mechanisms in the newborn and increasing maternal blood loss may be a hazard particularly in premature labor and thus at any time during the last 3 months of pregnancy.

For the reasons detailed in the above paragraphs, the Panel concludes that there is a potential hazard to the use of aspirin during pregnancy and recommends the following warning on all aspirin-containing products: "Do not take this product during the last 3 months of pregnancy except under the advice and supervision of a physician."

References


(9) Bial, J. R. and M. F. Klein, "Enhancement of the Regular "Safe" Aspirin by Food Restriction In Rats," draft of paper submitted for publication is included in OTC Volume 03015-0.


(21) Personal communication to the Panel (from W. A. Bleyer contained in OTC Volume 03015-0).


(30) "Adverse effects on the central nervous system. The lethal dose of aspirin or other salicylates probably is between 20 to 30 g for adults (Ref. 1) but doses of 200 to 300 mg/kg in children usually cause only minor effects. The major toxic signs and symptoms arise from stimulation followed by depression of the central nervous system. Stimulation reveals itself in many ways (e.g., tinnitus, rapid breathing, confusion, unusual or bizarre behavior, vomiting, mania and even generalized convulsions. In severe poisoning, the stimulation is followed by depression as shown by respiratory failure, collapse of the cardiovascular system and coma. Tinnitus has been studied recently in man (with rheumatoid arthritis) by Mongan et al. (Ref. 3). In 59 subjects they noted tinnitus to be present in two individuals taking 12 aspirin tablets (3,900 mg) daily. The highest incidence of tinnitus was reported by those patients (14) taking 16 tablets per day. They found the serum salicylate level was invariably greater than 15.6 mg/100 ml when tinnitus was reported. They also observed a lack of correlation between the total daily aspirin ingestion and serum salicylate concentration. Furthermore, although the fact that patients with preexisting hearing loss will not report tinnitus as plasma salicylate concentrations increase.

It has been known for some time that salicylates produce a reversible ototoxicity manifested by deafness (Ref. 4). This was discussed recently by Jick et al. (Ref. 5) who studied drug-induced deafness in 11,526 hospitalized patients. Following aspirin, deafness was noted in 11 per 1,000 patients exposed. It is important for physicians to monitor patients receiving aspirin regularly at higher dosages for hearing loss as well as the presen-
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 100 deaths per year result from accidental or intentional salicylate and congener poisoning. 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 salicylates and congeners for the years 1968 to 1974 (Ref. 3):

<table>
<thead>
<tr>
<th>Year</th>
<th>Children under 5 yr</th>
<th>All ages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1968</td>
<td>61</td>
<td>190</td>
</tr>
<tr>
<td>1969</td>
<td>58</td>
<td>190</td>
</tr>
<tr>
<td>1970</td>
<td>64</td>
<td>190</td>
</tr>
<tr>
<td>1971</td>
<td>46</td>
<td>190</td>
</tr>
<tr>
<td>1972</td>
<td>26</td>
<td>190</td>
</tr>
<tr>
<td>1973</td>
<td>25</td>
<td>190</td>
</tr>
<tr>
<td>1974</td>
<td>22</td>
<td>190</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 resulting in a higher than necessary incidence of toxic reactions most of which, fortunately, are mild and innocuous.

However, with the consumption of aspirin exceeding 19 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

(8) Adverse effects on the kidney. Aspirin has been suggested as a contribut-...
PROPOSED RULES

The rat kidney is different than that of man. Being unilobar and having a long slender papilla, it has been suggested that the rat kidney may be much more susceptible to papillary damage (Ref. 10). 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. Melcer and Hufnagel (Ref. 11) observed the nephrons in 10 pigs over 18 months at a dose higher than that usually used by humans without any evidence of renal injury to any of the animals.

(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 less than 10 cases of renal aspirin necrosis reported in the world literature that are associated with the use of aspirin only (Refs. 1, 6, 9, 10, 18 and 19). The possibility of a causative role of aspirin when used alone in large long term doses has been the subject of several epidemiologic studies.

A recent study of the Boston Collaborative Drug Surveillance Program reported results of 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 likely because the study design (error due to drug, dose, time) is such that real associations are unlikely to be detected. (See part III, paragraph B.2.d.(ii) (b) below—Epidemiologic studies.) This study also could not show any association between renal dysfunction and ingestion of phenacetin compounds.

The better controlled long-term prophylaxis of Dubay clearly showed an association between analgesic abuse of phenacetin combination and decreased renal function (Ref. 4). No such correlation could be demonstrated in those using aspirin preparations containing only aspirin.

In a recent study by Emkey and Mills (Ref. 5), it was shown that prolonged high doses of aspirin given to patients with rheumatoid arthritis and phenacetin-induced significant kidney damage. They studied all patients with rheumatoid arthritis followed at the Massachusetts General Hospital Arthritis Clinic who had been taking aspirin for 10 or more years. There were 36 patients whose average age was 60.5 years, mean duration of therapy was 23 years, and mean daily intake was 5 g aspirin. The average total amount of aspirin ingested was 42 kg.

Studies of renal function and urinary abnormalities revealed that although minor histological or functional renal abnormalities were present, no permanent kidney damage could be demonstrated in these patients.

Macklon and coworkers (Ref. 6) initially studied renal function in 17 patients with rheumatoid arthritis who had ingested 5 to 20 kg aspirin. Renal function was assessed by measuring serum creatinine, creatinine clearance and proteinuria. Fourteen of these patients were followed up after 2 years. No evidence of permanent renal damage was found.

The New Zealand Rheumatism Association Survey in 1974 (Ref. 6) of 763 British and 145 patients with osteoarthritis showed no association between aspirin (alone) intake and a renal score designed to identify analgesic nephropathy. Analgesic nephropathy was detected in three patients taking APC (aspirin, phenacetin and caffeine) compounds, one taking aspirin and phenylbutazone and one taking aspirin acetophenetidin. The New Zealand Rheumatism Association concluded that there is risk from APC compounds but not aspirin alone. However, aspirin may have an additive or potentiating effect with other analgesics.

Bulger (Ref. 7) found a correlation between the total dose of aspirin ingested and the depression of creatinine clearance in rheumatoid arthritis. This finding is confirmed for age of the patients, and none had a creatinine clearance less than 50 even though one patient took a total dose of 40 kg aspirin.

The Panel concludes, that in view of the results of these studies and the use of aspirin-phenacetin and the very few reports implicating products containing aspirin alone with renal papillary necrosis, it is unlikely that aspirin is an initiator of renal papillary kidney disease. However, it has been suggested that products containing aspirin, alone, can exacerbate and/or perpetuate the progression of 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. 18) or other possible mechanisms. Burry (Ref. 21) speculates that the initial damage occurs in the ascending limb of the loops of Henle. Ischemia may be caused by inhibition of prostaglandin E synthesis by aspirin. Phenacetin and its metabolites inhibit histidine 1-carboxylase activity on cells with salicylate-induced suppression of the hexose monophosphate shunt. Burry and others have suggested that aspirin may contribute to renal papillary necrosis. Even though aspirin alone is rarely associated with renal papillary necrosis (Refs. 8 and 21).

REFERENCES

(17) Adverse effects on the liver. Several recent studies have confirmed that aspirin causes a reversible hepatotoxicity (Refs. 1 through 9). Increased hepatic dysfunction after aspirin ingestion has been identified by increased serum activity of transaminase (Refs. 1 through 4), serum glutamic oxaloacetic transaminase (SGOT) (Ref. 2), serum glutamic pyruvic transaminase (SGPT) (Ref. 2) and decreased activity of aspartate esterase (Ref. 9).

The increased incidence of hepatotoxicity has generally been observed in children but both sexes treated for systemic lupus erythematosus or rheumatoid arthritis requiring moderate doses over a period of 14 days (Ref. 2). Bullinger and Dubois (Ref. 2) found a function of dose (Refs. 2 and 19), 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 experience elevated transaminase activity (Ref. 2).

Smeenk and Plotz gave aspirin four times daily at a dose sufficient to obtain a serum salicylate level of 25 to 30 mg/100 ml (Ref. 6). They observed increased transaminase activity in 3 of 18 rheumatoid arthritis or polymyalgia rheumatica patients. Peculiarly, in a variable serum 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.

In 1972, Johns and Johnson reported dose-related hepatotoxicity of salicylates in six children with severe rheumatoid arthritis (Ref. 2). Elevated SGOT and SGPT activities were observed in all patients and were noted only when serum salicylate levels were above 25 mg/100 ml. The effects occurred with sodium and choline salicylate at levels were above 25 mg/100 ml. A reduction of the dose reversed the effect. The Johnstone effect is dependent on salicylate acid level, rather than aspirin per se and is a reversible process. Clinical symptoms were also manifest in four patients. Liver biopsies were obtained 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 3 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-induced enzyme activities decreased after aspirin administration in 8 of 14 patients with liver damage but slightly increased in those patients without liver disease. The decreased liver function of the patients with elevated transaminase in six of the eight patients with liver disease was reported.

In view of the recent findings which have confirmed that aspirin causes a reversible hepatotoxicity in children and adults with systemic lupus erythematosus or rheumatoid arthritis and for other reasons elaborated elsewhere in this document, the Panel concludes that aspirin 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 not necessary.

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 for which aspirin is indicated, and is a function of any preexisting liver disease. The opinion of the Panel, a warning that aspirin may cause liver disease is not warranted.

### References


11. "Adverse effects of concomitant use with other drugs or by persons with certain diseases" (Ref. 10).

12. "Caution: As the Panel has
The concurrent use of salicylates with uricosuric drugs results in the inhibition of the excretion of uric acid in the urine (uricosuria) and thereby results, in effect, in the antagonism of the activity of these drugs (Ref. 5). Uric acid is normally reabsorbed into the body and not excreted by the kidney. The uricosuric agents used in OTC block the reabsorption of uric acid from the urine to 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 to reduce high uric acid levels in gout, but in OTC doses, aspirin causes retention of uric acid. Hence in the latter instance the uricosuric effect of the uricosuric agents may be counteracted. This interaction in low OTC doses may cause a suppression of uricosuria which results in uric acid reten­tion, a phenomenon 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 in the kidneys. Concurrent administration decreases 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 gives general warning advice against the use of salicylates concurrently with prescription drugs used in the treatment of gout.

Uricosuric inhibition in gout.

Individuals with gout have high serum uric acid levels. Several prescription drugs are prescribed for gout to decrease uric acid blood levels by increasing the renal excretion of uric acid in the urine. These drugs include probenecid, the sulfipyrazone and phenylbutazone. Aspirin has been reported to specifically interfere with the uricosuric action of sulfipyrazone. High serum uric acid levels and mutual supression of uricosuria may occur in humans when both drugs are used concurrently (Ref. 6).

The concurrent use of salicylates with uricosuric drugs results in the inhibition of the excretion of uric acid in the urine (uricosuria) and thereby results, in effect, in the antagonism of the activity of these drugs (Ref. 5). Uric acid is normally reabsorbed into the body and not excreted by the kidney. The uricosuric agents used in OTC block the reabsorption of uric acid from the urine to 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 to reduce high uric acid levels in gout, but in OTC doses, aspirin causes retention of uric acid. Hence in the latter instance the uricosuric effect of the uricosuric agents may be counteracted. This interaction in low OTC doses may cause a suppression of uricosuria which results in uric acid reten­tion, a phenomenon 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 in the kidneys. Concurrent administration decreases 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 gives general warning advice against the use of salicylates concurrently with prescription drugs used in the treatment of gout.

Uricosuric inhibition in gout.

Individuals with gout have high serum uric acid levels. Several prescription drugs are prescribed for gout to decrease uric acid blood levels by increasing the renal excretion of uric acid in the urine. These drugs include probenecid, the sulfipyrazone and phenylbutazone. Aspirin has been reported to specifically interfere with the uricosuric action of sulfipyrazone. High serum uric acid levels and mutual supression of uricosuria may occur in humans when both drugs are used concurrently (Ref. 6).

The concurrent use of salicylates with uricosuric drugs results in the inhibition of the excretion of uric acid in the urine (uricosuria) and thereby results, in effect, in the antagonism of the activity of these drugs (Ref. 5). Uric acid is normally reabsorbed into the body and not excreted by the kidney. The uricosuric agents used in OTC block the reabsorption of uric acid from the urine to 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 to reduce high uric acid levels in gout, but in OTC doses, aspirin causes retention of uric acid. Hence in the latter instance the uricosuric effect of the uricosuric agents may be counteracted. This interaction in low OTC doses may cause a suppression of uricosuria which results in uric acid reten­tion, a phenomenon 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 in the kidneys. Concurrent administration decreases 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 gives general warning advice against the use of salicylates concurrently with prescription drugs used in the treatment of gout.

Uricosuric inhibition in gout.

Individuals with gout have high serum uric acid levels. Several prescription drugs are prescribed for gout to decrease uric acid blood levels by increasing the renal excretion of uric acid in the urine. These drugs include probenecid, the sulfipyrazone and phenylbutazone. Aspirin has been reported to specifically interfere with the uricosuric action of sulfipyrazone. High serum uric acid levels and mutual supression of uricosuria may occur in humans when both drugs are used concurrently (Ref. 6).

The concurrent use of salicylates with uricosuric drugs results in the inhibition of the excretion of uric acid in the urine (uricosuria) and thereby results, in effect, in the antagonism of the activity of these drugs (Ref. 5). Uric acid is normally reabsorbed into the body and not excreted by the kidney. The uricosuric agents used in OTC block the reabsorption of uric acid from the urine to 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 to reduce high uric acid levels in gout, but in OTC doses, aspirin causes retention of uric acid. Hence in the latter instance the uricosuric effect of the uricosuric agents may be counteracted. This interaction in low OTC doses may cause a suppression of uricosuria which results in uric acid reten­tion, a phenomenon 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 in the kidneys. Concurrent administration decreases 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 gives general warning advice against the use of salicylates concurrently with prescription drugs used in the treatment of gout.

Uricosuric inhibition in gout.

Individuals with gout have high serum uric acid levels. Several prescription drugs are prescribed for gout to decrease uric acid blood levels by increasing the renal excretion of uric acid in the urine. These drugs include probenecid, the sulfipyrazone and phenylbutazone. Aspirin has been reported to specifically interfere with the uricosuric action of sulfipyrazone. High serum uric acid levels and mutual supression of uricosuria may occur in humans when both drugs are used concurrently (Ref. 6).

The concurrent use of salicylates with uricosuric drugs results in the inhibition of the excretion of uric acid in the urine (uricosuria) and thereby results, in effect, in the antagonism of the activity of these drugs (Ref. 5). Uric acid is normally reabsorbed into the body and not excreted by the kidney. The uricosuric agents used in OTC block the reabsorption of uric acid from the urine to 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 to reduce high uric acid levels in gout, but in OTC doses, aspirin causes retention of uric acid. Hence in the latter instance the uricosuric effect of the uricosuric agents may be counteracted. This interaction in low OTC doses may cause a suppression of uricosuria which results in uric acid reten­tion, a phenomenon 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 in the kidneys. Concurrent administration decreases 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 gives general warning advice against the use of salicylates concurrently with prescription drugs used in the treatment of gout.
An interaction which the Panel does not consider enough of a hazard to justify inclusion in this warning concerns the concurrent use of salicylates with drugs that result in changing the pH of the urine. Some substances, such as ascorbic acid (vitamin C), increase the acidity of the urine, thereby increasing 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. 2).

For some conditions that require prescription drugs but which do not require the constant or daily supervision of a physician, the Panel recommends that a warning on the labeling of any salicylate 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 therapeutic indications of the salicylate type, i.e., anticoagulants and drugs used in the treatment of gout, diabetes, and arthritis, is adequate for the labeling of OTC salicylates.

REFERENCES

(1) Woodbury, D. M. and E. Fingl, "Ana­
egesic-Antipyretics, Anti-Inflammatory Agents, and Drugs Employed in the Therapy of Gout," in "The Pharmacological Basis of Therapeu­

(2) Levine, W. G., "Anticoagulant, Anti­
thrombotic Drugs," in "The Pharmacological Basis of Therapeu­


(8) Adverse effects resulting in iron de­
cicient 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 and cause 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). It is known that anemia associated with some rheu­
matoid diseases will improve when the disease is brought under control with therapeutic doses of aspirin. Aspirin has not been determined to be an im­
portant consideration in the diagnosis of anemia in children (Ref. 6).

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 (produced by aspirin) may not always be ignored; this applies especially to the extent to which the patient is already ana­
emic and in a bad state generally. The taking of aspirin over a long period is most common in the case of persons suffering from rheu­
matic arthritis. Many such patients are anaemic, a state of which has always been regarded as a consequence of the rheumatic process rather than of aspirin ingestion. If aspirin is the cause of bleeding, it may be asked whether this has not likewise often played a more or less important part in bringing about anemia.

Holt (Ref. 2), in a study in which gastro­
testinal blood loss was measured af­
ter aspirin ingestion, found that 63 per­
cent of 36 subjects who were ingesting 40 gr of aspirin (8 tablets daily) were losing blood and that 17 percent lost more than 6 ml (an average of 20-fold over control values). Ten of the 35 were "healthy" volunteers tested at the same doses, all 10 bled with an average blood loss of 5.7 ml daily. Fourteen out of the remaining 25 subjects who bled had an average blood loss of 3.3 ml daily. These latter subjects were patients with negative his­
tories of gastrointestinal bleeding. This difference was found not to be statisti­
cally significant. Holt concluded that this degree of blood loss is exceptionally large and 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 1936 (Ref. 3). The authors des­
cribed two cases of patients with severe anemia due to the ingestion of salicy­
lates. The first, a 29-year-old man, com­
plained of fatigue and exertional dysp­
nea. For 7 years he had suffered from migraines 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 fea­
tures of iron deficiency. A history failed to show that iron had ever been taken, and after responding to intravenous iron therapy he was discharged to the outpa­
tient department where he was followed with oral iron treatment. Six months later he was admitted to the hospital with severe anemia (hemoglobin 4.2 g/100 ml). He again responded favorably to intravenous iron therapy and then continued iron injections as an outpa­
tien. The clinical and hematological find­
ings were compatible with iron deficiency anemia due to chronic hemorrhage. Oc­
cult blood tests in the stools were nega­
tive while the patient was hospitalized. It was difficult to diagnose the reason for the anemia.

Then, on two occasions aspirin (18 gr) was administered three times daily and the occult blood less showed strongly positive results. Confirmation of the relationship between salicylate consump­
tion and the anemia was obtained when the patient was advised to discontinue the intake of aspirin. Iron therapy could soon be discontinued and at the time of publication there was no recurrences of the anemia.

The other case described in this re­
port was that of a 29-year-old woman who was admitted to the hospital for the treatment of anemia. She also com­
pained of fatigue and exertional dysp­
nea, as well as epigastric pain and "acid-reflux gastritis." She had been treated for 2 years for "rheumatoid arthritis" she took up to "30 salicylate tablets" weekly. Her history also included a complication of hemorrhage during her "fourth con­
finement" (fourth child delivery) for which she had received transfusions of OTC salicylates and iron tablets. Examination re­
vealed severe anemia (hemoglobin of 5.5 g/100 ml) apparently due to iron de­
ciciency. She responded well to oral iron therapy after leaving the hospital she regularly attended the outpatient clinic. The anemia-recurred and required con­
tinuous iron therapy which had to be supplemented on two occasions with intra­
venous iron. She had a dilatation and curetage 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 and the patient 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 taking aspirin four times daily which was fol­
lowed 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 she had been decreased from 4.6 to 11.2 g/100 ml. Eventually, after repeated exhortations the patient stopped taking salicylates and recovered. This latter case has been described in what may be a fortuitous manner and the pur­
pose 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 curation but dilatation and curetage and eventually even hysterectomy at the age of 29 years.

Stubble has described 16 cases of severe iron deficiency anemia due to blood loss associated with aspirin ingestion (Ref. 4). Stubble comments:
In every patient the use of aspirin, even if not the sole cause, played an important role in the pathogenesis of the anemia. There were no indications of peptic ulcer, pustular meninges or hemorraghic diathesis in any of the patients. It appears that the use of aspirin certainly does not need to be extraneous to play a predominant role. The main feature of these 15 patients, all of whom developed strongly positive bedside reactions after the administration of aspirin, were:

(ii) Reason for taking aspirin: rheumatic complaints, 4; headache, 19 (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 possibility.

All the patients reported by Stubbe had also a low serum iron and a high iron binding capacity.

One of the review of the clinical, pathological and pathogenetic aspects of gastric mucosal injury induced by aspirin described two other cases of aspirin-induced anemia (Ref. 5). The first case was that of an 15-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 confided 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 "Cr-tagged red blood cells" and after the administration of 2 g aspirin daily for 2 weeks the results of the tests were disclosed to the patient he stopped taking salicylates, and without any transfusion his hematocrit rose from 34 percent upon admission to 25 percent 2 weeks later. A month later it was 34 percent and 3 months later it was normal.

The second case described in this report was that of a 49-year-old woman who was admitted with a severe anemia after an episode of melena. The patient later admitted taking an aspirin-containing preparation on an average of 100 tablets weekly; over the previous 6 months. This one 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, "sedative." His hemoglobin was 8.2 g/100 ml and his blood showed an iron deficiency anemia pattern. After he stopped taking aspirin, the anemia did not recur.

The second case involved another 3-year-old child with a hemoglobin of 4.3 g/100 ml and his blood again showed an iron deficiency anemia pattern. The results of occult blood tests were positive on the first 3 days after admission. From repeated history-taking, it was found that the boy had been taking two to three 300 mg aspirin tablets daily for many months as a "sedative". The third 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 ache, headaches and sleeplessness.

Case 4 involved a 12-year-old girl with a hemoglobin of 7.1 g/100 ml and again the blood film showed iron deficiency anemia. She eventually admitted having taken salicylates (predominantly aspirin) for many months before admission to the hospital.

Case 5 was a 8-month-old infant who had a hemoglobin of 7.4 g/100 ml and the blood film showed iron deficiency anemia. It was found that the baby received 2 "junior" 150 mg aspirin daily for the previous 6 to 8 weeks for febrile episodes. Tests for bacteria and salicylates in the stools of the baby when 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 exerted during aspirin therapy and that when pallor, fatigue and easy exertion are the symptoms the possibility of aspirin-induced anemia should be investigated.

References


(7) PROPOSED RULES

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

(9) PROPOSED RULES

35411

(10) (i). For products containing more than 325 mg (5 gr) per dosage unit. Adult oral dosage is 325 mg (5 gr) per dosage unit. (ii) Nonstandard schedule. Adult oral dosage is 325 mg (5 gr) over 3 hours while symptoms persist not to exceed 1,219 mg (18.75 gr) in 24 hours for not more than 5 days. Children 4 to under 6 years oral dosage is 162.5 mg (2.5 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 of a physician.

(11) (ii) For products containing 80 mg (1.23 gr) per dosage unit. Children 11 to under 12 years oral dosage is 480 mg (7.38 gr) every 4 hours while symptoms persist not to exceed 2,000 mg (33.87 gr) in 24 hours for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice of a physician.

(12) (ii) 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 325 mg (5 gr) but not more than 421 mg (6.48 gr) every 4 hours while symptoms persist not to exceed 1,209 mg (18.54 gr) in 24 hours for not more than 5 days. Children 4 to under 6 years oral dosage is 162.5 mg (2.5 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 of a physician.

(13) (ii) For products containing more than 421 mg (6.48 gr) but not more than 485 mg (7.38 gr) per dosage unit. Adult oral dosage is more than 421 mg (6.48 gr) but not more than 485 mg (7.38 gr) per dosage unit.
children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(a) 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 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 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 aspirin for the dose level is the "dosage unit" and may be replaced by the applicable dosage form such as tablet or capsule.

6. Acetaminophen. The Panel considers acetaminophen is a safe and effective OTC analgesic when taken in accordance with the product's labeling. For products containing the standard aspirin dosage unit.

In the previous discussion on "standard strength" dosage forms, the Panel made clear the need to indicate both the quantity of aspirin per tablet, teaspoon or other dosage unit. While the Panel recognizes that a particular product may contain aspirin per dosage unit from the established standard of 325 mg (5 gr) aspirin per dosage unit. (See part II, Paragraph F, above—Standard Dosage Unit and Analgesic Equivalence Value.)

The Panel recommends that all products containing aspirin be clearly labeled as containing an amount of aspirin per dosage unit. 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 alert those individuals having sensitivity to aspirin.

(a) 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 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 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 aspirin for the dose level is the "dosage unit" and may be replaced by the applicable dosage form such as tablet or capsule.

In addition, the Panel recommends the following specific labeling: (i) "Caution: 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". (ii) "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 exceed 3,880 mg (59.68 gr) in 24 hours for more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician."

(d) Labelling. The Panel recommends the Category I labeling for analgesic active ingredients. (See part III, paragraph B.1. below—Category I Labelling.) In addition, the Panel recommends the following specific labeling: (1) Warnings. (2) Precautions. (3) Contraindications. (4) Use in special populations. (5) Pregnancy and lactation. (6) Laboratory tests. (7) Overdosage. (8) Formulations.

In a double-blind study Wallerstein and Houde compared aspirin, acetaminophen and placebo in a population of hospitalized cancer patients. The time-effect curves were similar for acetaminophen and aspirin and both were significantly different from placebo.

Lasagna, Davis and Pearson (Ref. 9) carried out a double-blind study in 373 patients who had undergone child birth. Acetaminophen, phenacetin and aspirin, 600 mg of each, were compared against placebo. They concluded that acetaminophen may be an alternative to aspirin, and acute pain was not significantly different from each other (Refs. 10 and 11).

In the study of Moertel, Ahmann, Taylor and Schwartau (Ref. 13) acetaminophen rated fourth after aspirin, mefenamic acid and phenacetin in the pain trials and the patient assessment. It ranked second to aspirin in efficacy and ranked third in a mean percentage relief of pain. They concluded that acetaminophen or phenacetin would be a reasonable alternative in case of aspirin intolerance.

In A.M.A Drug Evaluations (Ref. 14), acetaminophen effectiveness is described as follows: "The analgesic and antipyretic efficacy of phenacetin and acetaminophen is equal to that of aspirin; however, unlike aspirin, these two analgesics do not have anti-inflammatory or uricosuric effects and thus are not as useful in the treatment of rheumatic diseases."

The Panel reviewed unpublished well-controlled double-blind studies where acetaminophen was studied in patients with migraines headache. Additionally, in another double-blind crossover study of patients with migraine headache (Ref. 17) patients received the
a combination of 65 mg isometheptene, 325 mg acetaminophen and 100 mg di-
chloralphenazone, (b) 325 mg acet­
aminophen and (c) placebo. Only the combinations, since placebo was superior to placebo in this type of headache.

In another study, not controlled, a combination of acetaminophen and Vi­
tamin C was studied in 45 patients with pain of different etiology (Ref. 18). The
doses used were four to six tablets (con­taining 330 mg acetaminophen) per 24
hours. Nine of these patients had head­
ache, 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 Per­
rin (Ref. 19) acetaminophen in combi­
nation with Vitamin C (doses not given)
was evaluated in 1,000 patients with pain of
different etiology. Of these, 96 patients
were admitted into the study for head­
saches, 400 for other reasons possibly related to pain, but only 18 percent of the
patients included. However, the following statement is made: “patients with headache reacted well and were alleviated rapidly.” Un­
fortunately, patients with other head pain are not specified for these patients.
An additional 68 patients in the study are identified as having “neuralgias and neu­
ritis” but the response of this group of patients is not stated.

In another single-blind study (Ref. 20), 500 mg acetaminophen was com­
pared with a combination of 300 mg acetaminophen, 5 mg hydroxyzine, 30 mg procepxone 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 acetamino­
phen is effective in relieving the pain of
headache, and that it is a general anal­
gesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is
considered to be equivalent to aspirin in
clinical testing. Therefore, acetaminophen is effective in relieving the pain of
surgical headache. The Panel concludes that increased risk may be a
consequence of poisoning in man by large
single doses of acetaminophen, appar­ently usually taken for suicidal purposes.
Prescott, Roscoe, Wright and Brown (Ref. 26) observed liver damage in 17 of 27 patients who had taken at least 15 g; one went into a coma induced by liver
degeneration and died. In this report, no estimate was given of the lowest dose
thought to have caused liver damage. The Panel concludes that increased risk may be a
consequence of poisoning in man by large
single doses of acetaminophen, apparently usually taken for suicidal purposes.

The Panel concludes that increased risk may be a
consequence of poisoning in man by large
single doses of acetaminophen, apparently usually taken for suicidal purposes.

The Panel concludes that increased risk may be a
consequence of poisoning in man by large
single doses of acetaminophen, apparently usually taken for suicidal purposes.

The Panel concludes that increased risk may be a
consequence of poisoning in man by large
single doses of acetaminophen, apparently usually taken for suicidal purposes.
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, blood levels of unchanged drug indicated decreased capacity of the liver to conjugate this drug. In healthy adults, metabolism is by the glucuronide conjugation pathway, whereas in those with liver cirrhosis, the formation of conjugated acetaminophen is decreased. In studies on infants, acetaminophen is excreted by a different mechanism, indicating that the overall elimination by conjugation of the drug could be demonstrated indicating that these two types of observations would not be expected to show diminished levels of drug. As expected, as would be expected from the pharmacokinetic characteristics of this drug, the time to peak levels of acetaminophen in children with liver cirrhosis was 3 to 4 hours. In patients with cirrhosis, acetaminophen is eliminated more slowly from the blood. The effects on excretion and blood levels of the conjugates and free acetaminophen reflected a partial inhibition of the glucuronide and sulfate conjugation pathways. The decision to continue acetaminophen as part of the treatment regimen in patients with liver cirrhosis should be individualized. Patients with chronic liver disease who have had a recent episode of active alcoholic hepatitis (4.5±1.5 hours) and patients with cirrhosis (3.5±1.3 hours) should not be treated with acetaminophen without closer monitoring. The half-life of unconjugated acetaminophen is 3 to 4 hours in some cases. In patients with chronic liver disease, acetaminophen is metabolized through the conjugation pathways and further conjugation with cysteine to a nontoxic conjugate.

An alternative explanation for the increased susceptibility of chronic alcoholics to the hepatotoxicity of acetaminophen is that the increased half-life of acetaminophen is due to the increased half-life of unchanged drug. In studies on infants, acetaminophen was eliminated more slowly from the blood. The effects on excretion and blood levels of the conjugates and free acetaminophen reflected a partial inhibition of the glucuronide and sulfate conjugation pathways. The decision to continue acetaminophen as part of the treatment regimen in patients with liver cirrhosis should be individualized. Patients with chronic liver disease who have had a recent episode of active alcoholic hepatitis (4.5±1.5 hours) and patients with cirrhosis (3.5±1.3 hours) should not be treated with acetaminophen without closer monitoring. The half-life of unconjugated acetaminophen is 3 to 4 hours in some cases. In patients with chronic liver disease, acetaminophen is metabolized through the conjugation pathways and further conjugation with cysteine to a nontoxic conjugate.

One cannot conclude that because an increased acetaminophen half-life occurs in association with acute liver damage caused by acetaminophen, that increased acetaminophen half-life is caused by preexisting liver disease. The nature of the injury to the kidney observed in such acute cases is apparently not related to the type of injury (parenchymal necrosis) which typically results from long-term abuse of analgesic drugs.

Kidney damage has been described in numerous cases in which the liver injury has been induced by acetaminophen overdose. A case of papillary necrosis of the kidney injury has been reported (Ref. 59) following prolonged use of acetaminophen at a dose of 11 to 18 g daily for 6 months in combination with proportionately large doses of chlorpromazine. Two other cases, though questionably attributed to acetaminophen (Ref. 54), involved in one case of death caused by 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".

There have been no clinical studies of the effects of acetaminophen on metabolic pathways other than the glucuronide and sulfate conjugation pathways through which acetaminophen may be metabolized. In this connection Mitchell et al. (Ref. 46) have postulated that a minor but as yet unidentifiable 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 stores may be overwhelmed and the reactive metabolite reacts chemically with protein, which results in necrosis. It is pertinent to know whether liver disease might affect the liver toxicity of acetaminophen by interfering with the production of this toxic metabolite or by altering pathways of 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 resection of half-life of acetaminophen the half-life is usually increased to 4 hours (Ref. 35).

Decreased metabolism of acetaminophen has been observed in alcoholic hepatitis (Ref. 43) and patients with chronic liver disease, which 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 metabolite with glutathione to a less toxic conjugate.

An alternative explanation for the increased susceptibility of chronic alcoholics to the hepatotoxicity of acetaminophen is that the increased half-life of acetaminophen is due to the increased half-life of unchanged drug. In studies on infants, acetaminophen was eliminated more slowly from the blood. The effects on excretion and blood levels of the conjugates and free acetaminophen reflected a partial inhibition of the glucuronide and sulfate conjugation pathways. The decision to continue acetaminophen as part of the treatment regimen in patients with liver cirrhosis should be individualized. Patients with chronic liver disease who have had a recent episode of active alcoholic hepatitis (4.5±1.5 hours) and patients with cirrhosis (3.5±1.3 hours) should not be treated with acetaminophen without closer monitoring. The half-life of unconjugated acetaminophen is 3 to 4 hours in some cases. In patients with chronic liver disease, acetaminophen is metabolized through the conjugation pathways and further conjugation with cysteine to a nontoxic conjugate.
study the increase was significant in one of eight subjects on acetaminophen and two of nine subjects on the same dosage schedule of phenacetin. The 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 urine concentrating ability in 6 of 13 patients after their intake of 2 to 30 kg acetaminophen over a period of 2 years. Battenman and Grossman (Ref. 7) found no evidence of liver or kidney disturbances in human subjects receiving 3.6 g daily for up to 116 weeks.

In an experiment on dehydrated dogs, Blumel and Goldberg (Ref. 62) found a big effect on kidney papillae in the papillae of the kidney after a single dose of phenacetin, and a similar concentration of the drug in the renal papillae was observed after a single dose of aspirin. However, Nakra et al. recently reported that some patients who continued to abuse acetaminophen, single entity or in analgesic mixtures, exhibited no such effects and did not differ from aspirin or placebo. However, the effects of phenacetin are considered to constitute the basis of the potential for abuse of analgesic preparations containing this drug. In comparing the subjective effects of phenacetin and acetaminophen in 20 healthy male volunteers, Battenman and Grossman (Ref. 61) found that phenacetin "depressed mood, energy, and mentation," while acetaminophen in the same dose, 28 mg/kg, had no such effects and did not differ from aspirin or placebo. However, Nakra et al. recently reported that some patients, especially housewives, have used acetaminophen as a "pick-me-up" and raise the possibility that some will abuse it.

No comparison has yet been made with regard to the relative abuse potential of analgesic mixtures of phenacetin and similar mixtures of acetaminophen. A longitudinal study of patients on phenacetin combinations, especially those thought to be addicted to aspirin, will be required before this question can be answered. However, consider the lack of effects of analgesics on the sensorium similar to those of phenacetin it is justifiable to conclude that acetaminophen, as a single entity or in analgesic mixtures, does not have the abuse potential demonstrated for analogous mixtures of phenacetin. Reports on acute oral toxicity of phenacetin from proprietary products, as shown, will not be required before the use of the drug.

The Panel concludes that the OTC packaging requirements for safety closures and the restriction 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 50 mg (1.23 gr) tablets intended for oral use in children should contain no more than 36 tablets to reduce the hazard of accidental ingestions by children. The Panel further concludes 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 50 mg tablets intended for use in children should contain no more than 36 tablets to reduce the hazard of accidental ingestions by children.

REFERENCES


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

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

CHILDREN—8.8.8.8.

42 FR 33110


(47) Wright, N and L. L. Prescott, "Po-
PROPOSED RULES

35417

minophen per dosage unit, if the Food and Drug Administration is unable to implement this recommendation the Panel recommends that only nonstandard dosage units of 500 mg (7.69 gr) be recognized for acetaminophen in addition to the standard dosage unit of 325 mg (5 gr). The Panel recommends that products containing 500 mg (7.69 gr) of acetaminophen per dosage unit be clearly labeled on the principal display panel: "Contains nonstandard 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". The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

Calcium carbaspirin. The Panel concludes that calcium carbaspirin is a safe and effective OTC analgesic when taken in the recommended dosage of 414 to 828 mg every 4 hours while symptoms persist not to exceed 4,968 mg in 24 hours for not more than 10 days.

(1) Effectiveness. Calcium carbaspirin is a complex of calcium acetylsalicylate and urea (Ref. 1). This compound is also frequently referred to as calcium aspirin. This nomenclature has produced some confusion with another preparation which consists of aspirin, calcium carbonate, and citric acid, which occasionally is referred to as "soluble" calcium aspirin. Because calcium carbaspirin is a larger molecule than aspirin, a larger amount (414 mg) will be required to produce the same pharmacological effect as that produced by 325 mg of aspirin. Levy and Hayes have reported that the dissolution rate for this compound is faster than that for aspirin (Ref. 2). However, Beaver noted that the rate of absorption into the bloodstream was similar to that of aspirin (Ref. 3). Bonica and Allen have reported that there is no evidence that it offers a clinically significant advantage (over aspirin) in the treatment of pain which analgesic effects are achieved (Ref. 4).

The previous discussion in this document with regard to effectiveness of aspirin including the limitations on maximum adult oral dosage (Ref. 5) are relevant here with a slight modification based upon potency (414 mg instead of 325 mg). In addition, the previous discussion on aspirin dose-response relationship regarding the lack of correlation between blood levels and threshold levels of analgesia, rapidity of onset of analgesia, and duration of pain relief, are equally applicable to calcium carbaspirin. (See part III, paragraph B.I.a. above—Effectiveness.)

(2) Safety. Evidence indicates that calcium carbaspirin is as safe as aspirin when taken in equivalent doses (Ref. 5). It is a complex of urea and calcium acetylsalicylate which is hydrolyzed (broken down) in the gastrointestinal tract to aspirin, calcium, and urea. While calcium is known to have a relatively low dissolution rate than aspirin, the amounts of calcium and urea formed from the breakdown of therapeutic doses of calcium carbaspirin would not be expected to have any pharmacological effects. It is assumed that calcium and urea are not absorbed in significant quantities. Thus the severity and incidence of adverse reactions probably would be the same as those observed with aspirin. Calcium carbonate, which consists of aspirin, calcium carbonate, and citric acid, is less than 0.01).

One article reported a series of studies using radioactive labeled chromate to determine gastrointestinal blood loss when aspirin and calcium carbaspirin were ingested (Ref. 7). The authors concluded that calcium carbaspirin produced significantly less gastrointestinal bleeding in patients (aspiron 65 percent with bleeding, calcium carbaspirin 5 percent with bleeding) with no previous history of dyspepsia. A comparison between aspirin, placebo and calcium carbaspirin revealed no significant differences for the same subjects (Ref. 7), and this difference was highly significant (p is less than 0.01).

In an unpublished study submitted by the manufacturer (Ref. 5), 20 patients with known intestinal ulcers and 20 patients with arthritis were followed for 9 months. Stool tests for blood using the testing reagent guaiac were used. A comparison between aspirin, placebo and calcium carbaspirin revealed guaiac reactivity in all three situations for the specific subjects (Ref. 7), and this difference was highly significant (p is less than 0.01).

The Panel concludes that while slightly less gastrointestinal bleeding may result from the use of calcium carbaspirin, not enough data are available to definitely substantiate this effect quantitatively from that of aspirin. Consequently, all cautions required for aspirin should be required for calcium carbaspirin.

(3) Dosage. Adult oral dosage is 414 to 828 mg every 4 hours while symptoms persist not to exceed 4,968 mg in 24 hours for not more than 10 days. Children 4 to under 6 years oral dosage is 517.5 mg every 4 hours while symptoms persist not to exceed 3,105 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.

The only studies which show that the side effects of calcium carbaspirin may be different from those of aspirin are those of Meador and Cossar (Ref. 9) in a study with patients undergoing gastrectomy summarized their finding as follows: "Soluble calcium aspirin has shown no significant signs of gastric irritation in 90 gastrectomy specimens. Standard aspirin has shown markedly serious gastric lesions in 8 out of 102." These authors also found that calcium carbaspirin produced significantly less gastrointestinal bleeding in 20 patients (aspiron 65 percent with bleeding, calcium carbaspirin 5 percent with bleeding) with no previous history of dyspepsia.

The Panel recommends that products containing calcium carbaspirin be clearly labeled on the principal display panel: "Contains nonstandard strength of 500 mg (7.69 gr) of calcium carbaspirin per tablet (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 414 mg calcium carbaspirin per tablet (dosage unit) shall be labeled, "Equivalent to 325 mg (5 gr) aspirin per tablet".


(8) Levy, Gumtow and Rutowski (Ref. 4) have also reported that choline salicylate is more effectively absorbed than aspirin. They found that 73 percent of patients who took aspirin reported an average daily loss of blood in the stool of over 10 ml daily for aspirin. Choline salicylate resulted in an average daily loss of 4.8 ml for the patients taking choline salicylate.

(9) Lange (Ref. 9) selected 19 patients who had shown signs of occult (unseen) or manifest (noticeable) bleeding under ordinary salicylate treatment. He concluded that there was less incidence of blood 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.

In the case of choline salicylate, the Panel notes that although choline salicylate may not contain buffering ingredients as highly buffered aspirin does, it is known that choline salicylate may, for this reason, have similar performance action. In addition, the Panel concludes that any claim regarding the claims of rapid absorption and the consequent rapid onset of analgesia made for highly buffered aspirin products also apply to choline salicylate products. (See part VI. paragraph B.1.d. below—Labeling claims for marketed products containing analogues combined with antacid or buffering ingredients.)

In the case of choline salicylate, the Panel notes that although choline salicylate may not contain buffering ingredients as highly buffered aspirin does, it is known that choline salicylate may, for this reason, have similar performance action. In addition, the Panel concludes that any claim regarding the claims of rapid absorption and the consequent rapid onset of analgesia made for highly buffered aspirin products also apply to choline salicylate products. (See part VI. paragraph B.1.d. below—Labeling claims for marketed products containing analogues combined with antacid or buffering ingredients.)

PROPOSED RULES

The labeling as proposed (Ref. 13) includes claims for choline salicylate such as "Taken on an Empty Stomach, Starts Acting 5 Times Faster Than Aspirin," and "Provides Gentle-To-The-Stomach Action."

Other claims made for this product have been discussed by the Panel elsewhere in this document. (See part III. paragraph B.2. below—Category II Labeling.) As for the claims mentioned above, the Panel concludes that its remarks regarding the claims of rapid absorption and the consequent rapid onset of analgesia made for highly buffered aspirin products also apply to choline salicylate products. (See part VI. paragraph B.1.d. below—Labeling claims for marketed products containing analogues combined with antacid or buffering ingredients.)

In the case of choline salicylate, the Panel notes that although choline salicylate may not contain buffering ingredients as highly buffered aspirin does, it is also known that choline salicylate may, for this reason, have similar performance action. In addition, the Panel concludes that any claim regarding the claims of rapid absorption and the consequent rapid onset of analgesia made for highly buffered aspirin products also apply to choline salicylate products. (See part VI. paragraph B.1.d. below—Labeling claims for marketed products containing analogues combined with antacid or buffering ingredients.)

In the case of choline salicylate, the Panel notes that although choline salicylate may not contain buffering ingredients as highly buffered aspirin does, it is also known that choline salicylate may, for this reason, have similar performance action. In addition, the Panel concludes that any claim regarding the claims of rapid absorption and the consequent rapid onset of analgesia made for highly buffered aspirin products also apply to choline salicylate products. (See part VI. paragraph B.1.d. below—Labeling claims for marketed products containing analogues combined with antacid or buffering ingredients.)
not to exceed 3,262.5 mg in 24 hours for not more than 5 days. Children 2 to under 4 years oral dosage is 217.5 mg for every 4 hours while symptoms persist not to exceed 1,632.5 mg in 24 hours for not more than 5 days. Children 4 to under 6 years oral dosage is 262.5 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 part III, paragraph H.1. below—Category I Labeling.) In addition, if the product is formulated as a long acting salicylate, the following specific labeling: (1) Warning. "Do not take this product if you are allergic to aspirin except under the advice and supervision of a physician.

(5) Dosage Information. In the previous discussion on "standard strength" dosage forms the Panel made clear the need to include 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 Analegesic Equivalence Value. 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 Panel concludes that magnesium salicylate 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 1,632.5 mg in 24 hours for not more than 10 days.

(1) Effectiveness. This ingredient has been used since 1888 when it was first cited in an editorial of Pharmazeutische Aehrzte (Ref. 1). The same year Caldwell (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, antirheumatic and antidiarrheal and still listed among its uses "typhoid fever 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 was compared on the basis of salicylate blood levels. This study was double-blind and analgesia was evaluated in 22 patients with several types of arthritis. They concluded that magnesium salicylate was preferable to aspirin, although it has side effects similar to aspirin and the other salicylates. Unlike aspirin and the other acetylated salicylates, magnesium salicylate has not been associated with any thrombocytopenic mechanism. However, magnesium salicylate in large doses does have an effect on another aspect of the clotting mechanism, an hypoprothrombinemic effect. There is no evidence of gastrointestinal bleeding and irritation similar to aspirin.

Unpublished studies on magnesium salicylate, utilizing the gastrocamera, revealed some variation between aspirin and magnesium salicylate when irritation of the stomach walls was assessed. Irritation to the mucous membranes of the stomach did occur in the presence of both drugs (Ref. 9). Other studies have indicated that aspirin causes more sodium chromate Cr6+ in patients treated with magnesium salicylate, while asymptomatic 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 not consistent nor significant (Ref. 11).

The Panel has reviewed the possible systemic toxicity of magnesium ions with...
recommended doses of magnesium salicylate. Unless renal insufficiency is present, toxicity due to the absorption of magnesium is unlikely in the recommended daily dosage of 325 to 650 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 is difficult to achieve 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. 13). 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 is 28.3 mEq magnesium which does not pose a safety problem. However, for any product containing magnesium in which the maximum daily dosage exceeds 50 mEq of magnesium, the labeling should contain a statement. The nonacetylated salicylate is not a product if you have kidney disease except under the advice and supervision of a physician. 

(3) 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 467.5 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 466.3 mg every 4 hours while symptoms persist not to exceed 2,031.5 mg in 24 hours for not more than 5 days. Children 4 to under 6 years oral dosage is 325 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 oral dosage is 162.5 mg every 4 hours while symptoms persist not to exceed 612.5 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.

(4) Labeling. The Panel recommends the Category I labeling for analgesic active ingredients. (See part III, paragraph B.1 below—Category I Labeling.) In addition, the Panel recommends the following specific labeling in the warning: “Do not take this product if you have kidney disease except under the advice and supervision of a physician.”

(3) For products containing more than 50 mEq of magnesium in the recommended dosage forms the Panel recommends labeling to 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 differs from the standard of 325 mg sodium salicylate per dosage unit. (See Part II, paragraph E. above—Standard Dosage Unit and Analgesic Equivalence Value.)

The Panel recommends that products containing magnesium salicylate be clearly labeled on the principal display panel: “Equivalent to X mg per dosage unit.” In the statement “equivalent to” follows an 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 “doseage 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 325 mg sodium salicylate per tablet.”

REFERENCES


(2) Causwell, A. W., "Rational Selection of the Salts of Salicylic Acid for the Therapeutics,” Therapeutic Gazette, 4:783-742, 1888.


(5) McCoy, F. W., "A Comparative Salicylate Study of Magan and Aspirin in Healthy Non-Rheumatic Subjects," draft of unpublished paper is included in OTC Volume 030042.

(6) Sanders, J. F., "Effectiveness of Magnesium Tablets in Osseroarthritis Patients," draft of unpublished paper is included in OTC Volume 030042.

(7) Sanders, J. F., "Effectiveness of Magnesium Salicylate," draft of unpublished paper is included in OTC Volume 030042.

(8) Battersman, R. C., "Double-Blind Assessment of Mangan, Aspirin and Placebo Tablets in Episodic Glomerulonephritis," draft of unpublished paper is included in OTC Volume 030042.

(9) Vickers, F. N., "Controlled Gastrocamera Study of Mangan and Aspirin," is included in OTC Volume 030042.


(11) Brown, E., "Mangan—Serum Magnesium," draft of unpublished paper is included in OTC Volume 030042.


f. Sodium salicylate. The Panel concludes that sodium salicylate is a safe and effective OTC analgesic when used in the recommended dosage of 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.

(1) Effectiveness. Sodium salicylate had already been in use for about 25 years when aspirin was introduced into therapy in 1899. Aspirin was introduced on the basis that it was more palatable and caused less gastrointestinal disturbances than sodium salicylate (Ref. 1). It has been demonstrated that aspirin (acetylsalicylic acid) is superior to sodium salicylate. 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 being superior to an equivalent 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 (Refs. 3 and 4).

Frey has reported that aspirin was more effective than sodium salicylate in the treatment of the common headach (Ref. 5).

The A.M.A. Drug Evaluations (Ref. 6) mentions sodium salicylate as an analgesic and states that it is less effective than equianalgesic dosages 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. However, it is said 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.

(2) 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 death and or a serious allergic reaction. In addition, sodium salicylate, as well as the other nonacetylated salicylates, are not known to affect the platelet aggregation process involved in the clotting mechanism. Some researchers using patients with large doses have shown that the effect of another aspect of the clotting mechanism, an antihypertrombinic 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 bleeding from the gastrointestinal tract dose in large doses have indeed taken place.

Grossman et al. reported that sodium salicylate, aspirin, and calcium aspirin all gave a significant increase of blood in the stools as compared to the controls. This was determined using the radioactively-labeled red blood cell technique (Ref. 8). Stubbie, Pieterman and Van Heulen after studying 130 patients found that there was much less blood found in the stools when using sodium salicylate as compared to aspirin (Ref. 9). Scott et al. in 1981 also reported decreased bleeding with sodium salicylate as compared to aspirin (Ref. 10).

Leardons and Levy (Ref. 11) have shown that 325 mg sodium salicylate
TABLES caused a gastrointestinal blood loss of 1.2 ml daily above control values but the blood loss attributable to aspirin tablets was appreciably greater, 5.6 ml daily above control values.

Furthermore, the effects of prolonged salicylate administration on the carbohydrate metabolism of patients ranging in age from 5 to 18 years have been studied. Glucose or other carbohydrates were given orally at a dose of 1 g/kg after measuring the fasting blood sugar. It was found that although the fasting blood sugar was lower than normal, sugar concentrations determined 30 and 60 minutes after the carbohydrate administration remained abnormally high. With the single ingestion of 0.6 g of sodium salicylate did not produce these changes in glucose metabolism (Ref. 12).

These latter reports are not sufficiently clear to permit any definitive conclusion to warrant a labeling warning. The Panel has reviewed the relationship between sodium intake and hypertension and found that it is generally accepted that sodium intake is one of the factors involved in the pathophysiology of hypertension. In experimental animals, sodium salts may precipitate marked hypertension in the presence of certain endocrine and/or renal diseases. Even in the absence of abnormalities, blood pressure increases with sodium intake. However, in the presence of normal renal function, the rise in pressure is moderate (Ref. 18).

The doubling of salt and water intake raises the mean blood pressure in man by 10 mm Hg (Ref. 19). Apart from hypertension, edema may develop in persons with heart failure or renal disease with high salt intake. The presence of these conditions increases with age (Refs. 14, 15, and 16). The recommended maximum daily dosage of 4,000 mg of sodium salicylate contains 25 mg of sodium which is 1.625 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 325 mg every 4 hours while symptoms persist not to exceed 1,219 mg in 24 hours for not more than 5 days. Children 6 to under 9 years oral dosage is 406.3 mg every 4 hours while symptoms persist not to exceed 1,825 mg in 24 hours for not more than 5 days.

Children 11 to under 12 years oral dosage is 497.5 mg every 4 hours while symptoms persist not to exceed 1,900 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.

(ii) For products containing more than 325 mg but not more than 650 mg per dosage unit. Adult oral dosage is more than 325 mg but not more than 421 mg initially, followed by more than 421 mg every 3 hours while symptoms persist not to exceed 2,437.5 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 650 mg but not more than 850 mg per dosage unit. Adult oral dosage is more than 650 mg but not more than 855 mg initially, followed by more than 855 mg every 4 hours while symptoms persist not to exceed 2,031.5 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 850 mg but not more than 1,000 mg per dosage unit. Adult oral dosage is more than 850 mg but not more than 1,000 mg initially, followed by more than 850 mg every 4 hours while symptoms persist not to exceed 1,005 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 1,000 mg but not more than 1,219 mg per dosage unit. Adult oral dosage is more than 1,000 mg but not more than 1,219 mg initially, followed by more than 1,219 mg every 4 hours while symptoms persist not to exceed 1,437.5 mg in 24 hours for not more than 5 days. Children 9 to under 11 years oral dosage is 406.3 mg every 4 hours while symptoms persist not to exceed 2,437.5 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.

(vi) For products containing more than 1,219 mg but not more than 1,625 mg per dosage unit. Adult oral dosage is more than 1,219 mg but not more than 1,625 mg initially, followed by more than 1,625 mg every 4 hours while symptoms persist not to exceed 1,625 mg in 24 hours for not more than 5 days.

For products containing more than 1,625 mg but not more than 2,031.5 mg in 24 hours for not more than 5 days. Children 11 to under 12 years oral dosage is 497.5 mg every 4 hours while symptoms persist not to exceed 1,900 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.
PROPOSED RULES

1. The Panel has classified acetanilid not safe for use as an OTC analgesic when taken in the recommended dosage of 200 to 300 mg but is not safe for OTC use.

2. The literature up to 1946 dealing with acetanilid in both acute and chronic poisoning in man include methemoglobinemia, sulfhemoglobinemia and hemolytic anemia. The toxic reactions to acetanilid in man include methemoglobinemia, various psychic and neurologic disorders, insomnia and headache. The latter symptom tends to lead to further use of the drug, which becomes habit-forming. Evidence of the habit-forming properties of acetanilid is reviewed by Gross (Ref. 1).

In man it has been shown that about 65 percent of an administered dose of acetanilid is converted to acetaminophen, and about 0.04 percent is metabolized to aniline (Ref. 4). The analgesic and antipyretic properties of acetanilid are attributed to its major metabolite, acetaminophen, while the toxic effects are attributed to other as yet unidentified metabolic derivatives of the minor metabolite, aniline. Phenylhydrazine, which is a potential metabolite of acetanilid, has been postulated as a metabolite of aniline which could account for the methemoglobinemia caused by acetanilid.

In the final analysis, the metabolism of acetanilid through aniline is held responsible for the toxic effects of the drug. Furthermore, it may be assumed that many individuals who are highly sensitive to the toxic action of acetanilid have a genetically determined capacity to metabolize greater amounts of the drug through the aniline pathway.

3. Evaluation. The Panel concludes because of the high incidence of toxic side effects and the relatively unfavorable margin of safety, the Panel makes no recommendations for further study of acetanilid for its analgesic effectiveness.

4. Safety. The Panel concludes that acetanilid is not safe for use as an OTC analgesic.

The literature up to 1946 dealing with the toxic reactions to acetanilid in man has been reviewed in detail by Gross (Ref. 1). Though acetanilid has long been generally recognized as an effective analgesic and antipyretic, no well-controlled studies of its effectiveness in the clinical situation have been reported, and it has not been quantitatively compared with aspirin in this respect in controlled tests in humans.

Because of its relative toxicity compared to other drugs used for the same therapeutic purposes there is little or no commercial interest in the drug at the present time. Two industry submissions (Refs. 2 and 3) contained only the labels of two products containing 120 mg and 150 mg of acetanilid, respectively, with caffeine and other miscellaneous ingredients. No effectiveness or safety data were submitted. One of these products has been withdrawn from the market.

Current pharmacology texts consistently either ignore acetanilid completely, or mention it only as of historical interest and condemn its use as an analgesic and antipyretic.

Because of the high incidence of toxic side effects and the relatively unfavorable margin of safety, the Panel makes no recommendations for further study of acetanilid for its analgesic effectiveness.

Due to the warning label on the prescription drug for anticoagulation (thinning the blood), diabetes, gout or arthritis except under the advice and supervision of a physician.

REFERENCES

(2) OTC Volume 030093.
(3) OTC Volume 090097.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
b. Codeine preparations (codeine, codeine phosphate, codeine sulfate). The Panel concludes that codeine is an effective analgesic when taken in the recommended oral dosage of 30 to 60 mg and is safe for prescription use but be cause of its analgesic liability and any other adverse effects is not safe 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 in effective analgesic doses be considered for OTC use.

(1) Effectiveness. In a collaborative study, cited by Eddy et al. (Ref. 1), the oral effectiveness of codeine, theophylline, 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 90 mg codeine were compared with 300 and 1200 mg aspirin. The study showed the estimated potency of codeine to be approximately 10 times that of aspirin. These results indicate that the effectiveness of 30 to 60 mg codeine as an analgesic is 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.

On the other hand, Lasagna (Ref. 2) concluded that codeine, generally a moderately effective analgesic, but not superior, on the average to aspirin when 10 mg to 20 mg codeine/dose and it was no longer needed. Oral doses of 30 mg codeine combined with 100 to 400 mg aspirin were administered when postoperative pain began to subside so that parenteral medication was no longer needed. Oral doses of 30 mg codeine were compared with 300 mg aspirin. The study showed the estimated potency of codeine to be approximately 10 times that of aspirin. These results indicate that the effectiveness of 30 mg codeine as an analgesic is comparable to the recommended analgesic OTC dosage range of 325 to 650 mg aspirin.

(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 major pharmaceutical text and details need not be reiterated here.

The AMA Drug Evaluations (Ref. 4) state, "adverse reactions to antitussive doses of narcotics occur infrequently and usually are not severe; the degree of reaction is usually given for analgesia" and "Dependence liability of codeine is less than with morphine or meperidine, and physical dependence occurs only rarely from codeine. However, the abuse of the drug, particularly in the form of cough syrup, is not uncommon."

Codeine as a single ingredient regardless of the dosage form has been recommended for use as an oral analgesic; however, the potential for dependence of this ingredient leading to severe restrictions under the Federal Controlled Substances Act as a Schedule II prescription (high potential for abuse) drug. When combined with other active medicinal ingredients in quantities of not more than 1,000 to 8,000 mg codeine/100 ml container or 90 mg codeine/dosage unit, codeine is classified as a Schedule III prescription drug. Only in quantities of 200 mg codeine/ 1200 mg caffeine and approximately 10 mg to 20 mg codeine/dose and 50 mg caffeine combined with other non-narcotic active medicinal agents is codeine classified as a Schedule V OTC (low potential for abuse) 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 dosage restricted to prescription use and at the doses permitted to be sold in OTC 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 only be used under proper medical supervision. For these reasons, the Panel recommends that the analgesic use of codeine continue to be restricted to prescription use only.

The Panel agrees with this limitation on OTC sale. The Panel notes that the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator and Antisthastic Drug Products, in their report published in the Federal Register of September 3, 1976 (41 FR 38268) found that codeine is suitable for OTC use as an antitussive in the dosage range of 10 to 20 mg. If the studies reported by Eddy et al. (Ref. 1) which showed that the potency of codeine is approximately 10 times that of aspirin are considered, this dosage range for codeine is approximately comparable to a range of 100 to 200 mg aspirin, which is about ⅓ of the effective analgesic dosage range of 325 to 650 mg aspirin. At the doses permitted to be sold OTC, codeine is ineffective as an analgesic.

Codeine is often combined with analgesic-antipyretic drugs for prescription use. Eddy et al. (Ref. 1) cite 25 studies in which these drugs are given in the usual doses. For short term use, he considered that the evidence suggested codeine is a more reliable and effective agent.

Codeine is combined with other drugs to form cough syrups. The Panel notes that the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator and Antisthastic Drug Products, in their report published in the Federal Register of September 3, 1976 (41 FR 38268) found that codeine is suitable for OTC use as an antitussive in the dosage range of 10 to 20 mg. If the studies reported by Eddy et al. (Ref. 1) which showed that the potency of codeine is approximately 10 times that of aspirin are considered, this dosage range for codeine is approximately comparable to a range of 100 to 200 mg aspirin, which is about ⅓ of the effective analgesic dosage range of 325 to 650 mg aspirin. At the doses permitted to be sold OTC, codeine is ineffective 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 in effective analgesic doses be considered for OTC use.
tion as an analgesic, and even the manufacturer who previously marketed the inadvisably promoted the use of iodopyrine as a goitrogenic agent. The Panel concludes that although it may be possible to determine by appropriate testing whether the ingredient has analgesic activity or not, it is essential to further evaluate its safety.

(2) Safety. The Panel concludes that iodopyrine is not safe for use as an OTC analgesic. Iodopyrine is the product of a reaction between antipyrene and iodine. Free iodide is liberated after oral ingestion by humans. The Panel can find no rationale for administering a claimed analgesic as an iodide salt because of the danger of iodism (iodine poisoning). The Panel finds that the toxic effects of the ingredient are due to the iodide. It should be noted that approximately 40 percent of iodopyrine is converted to its iodide form when fed to young rats, and that the data suggest that the effects of iodopyrine and an ingredient are due to the iodide. It should be noted that approximately 40 percent of iodopyrine is converted to its iodide form when fed to young rats, and that the data suggest that the effects of iodopyrine and an ingredient are due to the iodide.

Iodopyrine when fed to young rats has been shown to retard growth (Ref. 4). However, the study did not demonstrate any goitrogenic effect. Toxic effects include increased peripheral blood cell death and poor health and deaths. The drug had no effect on the size or morphology of the thyroid. Single doses of iodopyrine inhibited the incorporation of radioactive iodine into the thyroid tissue of adult and young rats. The iodopyrine was iodinated at about the same rate as that of comparable doses of iodide. It was concluded by the investigators that in order to produce a thyroidal effect, iodopyrine had to be present in the thyroid gland. They further noted that the effects of iodopyrine and an equivalent amount of iodide are similar, suggesting that the only effect of iodopyrine on the thyroid is due to iodide.

Wilkinson et al. (Ref. 5) have reported a case of iodide-induced hypothyroidism, which is characterized by the presence of iodide (identified as 18 mg phenacetin with 12 mg iodide). A 24-year-old male was hospitalized with signs of hypothyroidism, including weight gain, depression, and general weakness. Iodine deficiency is known to cause hypothyroidism. In this case, the patient had a goiter and had been using iodopyrine-containing combination product for 17 years, 3 times a day since the age of 7 years until admission into the hospital. Earlier, at the age of 11 years, he was found to have a goiter. Following the clinical diagnosis in the hospital of iodide-induced hypothyroidism, the drug was discontinued and 3 months later all features of hypothyroidism had remitted.

The Medical Letter has reported that congenital goiter and hypothyroidism can result in the fetus when a pregnant woman consumes high-concentration drugs (Ref. 6). Iodides, themselves, are not known to cause malformation of the fetus. However, iodides do cross the placental barrier and after about the 12th week of gestation are taken up by the thyroid. The Medical Letter concluded that, because of these potential hazards, prolonged use of iodide preparations should be avoided by pregnant women. It was further concluded that normal children and adults also carry some risk of goiter.

Morgans and Trotter (Ref. 7) have reported the development of goiter in pregnant women who had been taking an iodopyrine-containing combination drug product. In all cases, the goiters became smaller when the patients were given the same product without iodopyrine. However, the Panel notes that the Panel concludes that although it may be possible to determine by appropriate testing whether the ingredient has analgesic activity or not, it is essential to further evaluate its safety.

(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 00096.
(3) OTC Volume 000145.

Phenacetin. The Panel concludes that phenacetin is an effective OTC analgesic but not safe for OTC use because of the high potential for harm to the kidney and the possibility of hemolytic anemia and methemoglobinemia resulting from abuse and the lack of compensating benefits. At the same time, the drug's pain threshold-raising effects are of the same order as those of aspirin, but they are careful to mention the "unreliability" of pain threshold measurements.

(1) Effectiveness. The nonaspartyl phenacetin was first synthesized in 1887 (Ref. 1). It was introduced as a therapeutic agent before controlled clinical trials were established. It was first used as an analgesic and then as an analgesic. It is used in the treatment of pain for over 80 years. In contrast to the salicylates, this drug has no anti-inflammatory or antirheumatic properties and therefore is mostly used for the relief of "ordinary aches and pains." However, Mandel and Davison (Ref. 1) stated that phenacetin is an effective OTC analgesic but not safe for OTC use because of the high potential for harm to the kidney and the possibility of hemolytic anemia and methemoglobinemia resulting from abuse and the lack of compensating benefits. At the same time, the drug's pain threshold-raising effects are of the same order as those of aspirin, but they are careful to mention the "unreliability" of pain threshold measurements.

(2) Safety. (i) 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, serious blood disorders such as methemoglobinemia and hemolytic anemia can result 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 6 months of life (Ref. 8). 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 20 tablets daily of an analgesic compound containing 250 mg phenacetin, entered the hospital with sulfhemoglobinemia. Her infants, bodies, and hemolytic anemia had developed 4 hours later and the infant had methemoglobinemia, Heinz bodies, and marked ery-
Several different types of studies consistently suggest temporal and dose relationships between phenacetin ingestion and the development of severe renal papillary necrosis. The Panel, and consulting reviewers, studies following changes in renal function in the same individual or groups of individuals when phenacetin is removed, replaced, or readministered. There is strong evidence for a direct causal effect. Follow-up studies in countries after complete removal of phenacetin from non-prescription use have shown a decrease in the incidence of kidney damage associated with analgesic abuse as will be discussed later in this document. (See part III. paragraph B.2.d. (2) (i) below—Evidence for a relationship between containing this drug and kidney disease.)

This not only supports the assumption of causality but also the conclusion that removal from 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 described. 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 realization that it can be prevented is one of the problems that 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.

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 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 nonanalytic purposes. This is probably due to its euphoric and stimulant effects. For example, analgesic-induced kidney disease has occurred most often in middle-aged women with an anxiety syndrome (Refs. 5, 6, 11, 15, and 17 through 20) or 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 Lassenga (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 less empathogenic than acetaminophen and aspirin did not differ from a placebo. It is of interest that this is the only study found in which a depressant effect was noted rather than euphoria or stimulant effects which have been noted by Ziegler (Ref. 19), Moeschlin (Ref. 5), and Gaell, Kielholz and Heg (Ref. 23).

The acute central nervous system (CNS) effects appear to be due to a direct effect 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 minimal blood levels of acetaminophen were usually achieved at a stage when the CNS effects were diminishing.

There appears to be a dual liability involved in the central nervous system effects. Initially there is a mild depressant effect. The initial 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 sleep disturbance begin to appear (Refs. 5, 18, 20, 25). Individuals with these symptoms experience temporary relief shortly after taking phenacetin but these symptoms then appear. Abnormal (epileptiform activity) brain EEG patterns (Ref. 25) 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 a psychiatric patient population. Sixteen of 181 patients (9 percent) took an average of 5.2 kg aspirin (1.3 to 16 kg range) and 3.3 kg phenacetin (1.5 to 11 kg range). An additional 26 patients (14.40 percent) had taken analgesic products daily for 6 months. In virtually all cases the products were taken for psychological rather than analgesic effects.

The evidence for a relationship between phenacetin abuse and kidney disease. (1) Epidemiological studies. Evidence that ingestion of phenacetin-containing analgesics can result in renal disease can be drawn from either epidemiological studies or direct experimental studies. For ethical reasons direct experimentation is generally possible only in animals which without collaborative studies in humans are usually inconclusive. Therefore the primary evidence regarding the role of phenacetin in kidney disease must be derived from a variety of epidemiological studies. These are generally retrospective case-control studies in which patients with renal disease (cases) are compared with patients who do not have renal disease (controls) relative to the frequency or degree of drug intake. Several types of epidemiological studies (Refs. 12, 16, 22, and 28 through 30) of possible relationships between phenacetin-containing compounds and kidney disease were initially selected by the Panel for detailed study for one or more of the following reasons: The studies were carried out over a period of 10 years, 1962 to 1972, in different settings. Many of these studies were instrumental in the decision of various countries to remove phenacetin from nonprescription use; in most of the studies, large numbers of patients and controls were studied and statistical evaluation of the data was possible; and several types of experimental design models were used to assess drug intake and renal disease variables. Therefore the source of possible bias, and deficiencies in experimental design would be expected to be different in the various studies.

The association between renal disease variables and phenacetin intake have been established by showing that the incidence of kidney disease is higher in people who abuse analgesics (abuse is usually defined as a total intake of 1 kg or greater). This has been shown by many investigators including Nordengfelt and Ringertz (Ref. 47), Larson and Mullen (Ref. 48), Gault, Rudwal and Redmond (Ref. 49), Burry (Ref. 18), and Murray, Lawson and Linton (Ref. 50). In addition, the incidence of analgesic abuse is higher in people who have renal disease. This relationship has been shown by Olafsson, Gudmundsson and Brekkan (Ref. 50), Wilson (Ref. 41), and Murray and Goldberg (Ref. 15).

Even though a statistically valid association between two variables may be shown, this does not necessarily prove that a causal relationship exists. It must be shown that one variable is the direct consequence of the other. To prove that a cause and effect relationship exists between two variables in an epidemiological case-control study, it is necessary to show that all other interacting variables are constant and are the same in the patient and control populations. This is usually not possible in the clinical setting.

There are other types of analysis which take into consideration well-established pharmacological principles relating to dose-response relationships as a function of time, that can be used to examine causal relationships between drug intake and drug effect. If a true causal relationship exists between some function of drug intake (independent variable) and some measure of renal disease (dependent variable), then the following relationships between the drug intake and renal disease variables would be expected: If the variables are continuous functions, i.e., not all-or-none phenomena, then a correlation should exist between the degree of drug use (rate or total amount of drug intake) and the degree or incidence of renal dysfunction. Evidence for a continuous dose response curve has been given by Grimlund (Ref. 12), Burry and coworkers (Ref. 16), and Olafsson, Gudmundsson and Brekkan (Ref. 50). If drug intake is expressed as a change in the independent variable (drug intake) should be followed by a corresponding change in the dependent variable (degree incidence of renal disease). This has been shown in individuals (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 show a corresponding change in the degree of renal disease (the 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. Several examples of this type of data were found (Refs. 12, 39, and 43).

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 detailed, continuing studies of employees of a large company and other workers who manufacture phenacetin provide some of the most significant epidemiological information regarding phenacetin abuse and its consequences (Ref. 12). This community provides data to demonstrate a possible relationship between the degree of analgesic intake, incidence of renal dysfunction, and the disease prognosis, the time involved in development of nephropathy (kidney disease), and the effect of removal of phenacetin from the OTC drug market on the degree of analgesic abuse and the incidence of kidney disease. These data present very strong evidence for the association between phenacetin-containing analgesic products and kidney disease.

The town of Huskvarna had a population of 13,000 in 1863. Three thousand of these workers at the Huskvarna Factory were exposed to phenacetin throughout the year. In 1943, Dr. Horton, a leading town physician, introduced a product containing 500 mg of phenacetin and 150 mg caffeine which immediately gained widespread acceptance and began to be widely misused.

The use of the product apparently was primarily to increase working ability at the Huskvarna Factory where its virtues were extolled by senior workers to new apprentices. Fifty years later, a serious attempt was made through advertising to get the workers away from guns, small machinery, etc. Following an influenza epidemic in 1918 to 1919, Dr. Hegg (Ref. 23). The consumption continued unabated. When phenacetin was removed from this product in 1961, most habitual users kept taking the product and estimates of sales figures at pharmacies indicated the high consumption of the product had not been significantly changed even though users knew it had been altered and stated it did not have an "effect" as the previous preparation.

Phenacetin was removed from this product as a result of the action of the
Swedish government in 1961, which removed phenacetin from all OTC products. Consequently, the consumption of phenacetin-containing tablets and powders fell from 31.4 million units in 1959 to 1.8 million in 1962. Nordenfelt (Ref. 29) evaluated the effect of removal of phenacetin from the OTC drug market by following all deaths from uremia (blood poisoning due to kidney failure) from 1960 to 1970 in Jenkapings County Hospital (the hospital which normally received Huskvarna residents). Definitive diagnosis of uremia was made on autopsy of 180 patients. 86 (47 percent) of whom were abusers of analgesic drugs. The ratio of men to women was consistent with earlier years (54 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 others. In 1970 only 3 deaths due to uremia were noted.

This study showed that while removal of phenacetin 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 analgesic kidney injury in other countries is due most likely to a difference in the incidence of abuse rather than susceptibility since in this town it was the male workers who used phenacetin compounds in large quantities.

The study of Grimlund, the Huskvarna factory physician, provides a clear correlation between the degree of drug intake and the incidence of kidney impairment measured by two renal function variables, the inability to concentrate urine and increased serum creatinine (greater than 1.5 percent is a measure of uremic blood poisoning). Grimlund (Ref. 12) also carried out a prospective follow-up study on 64 patients with serum creatinine levels above 1.5 percent (uremic blood poisoning) over a period of time from 16 months to 4 years. There was a correlation between the degree of elevated serum creatinine and prognosis in patients. Three types of relationships were established by the Grimlund study and are summarized as follows:

1. In 956 representative Huskvarna employees in apparent good health, it was found that renal function was reduced in 34 percent of phenacetin takers but only in 2.4 percent of nonphenacetin takers.
2. The incidence of renal dysfunction, as measured by serum creatinine and decreased concentrating ability, increased proportionately to the amount of phenacetin ingested, and is indicative of a dose-response relationship (Ref. 12).

The following table summarizes these findings:

<table>
<thead>
<tr>
<th>Phenacetin—amount ingested—</th>
<th>0</th>
<th>1 to 6 kg</th>
<th>5 to 9 kg</th>
<th>10 to 29 kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence in total population</td>
<td>7.0</td>
<td>12.7</td>
<td>4.8</td>
<td>2.7</td>
</tr>
<tr>
<td>Incidence in group</td>
<td>2.4</td>
<td>19.0</td>
<td>70.0</td>
<td>76.0</td>
</tr>
<tr>
<td>Incidence of reduced concentrating ability in group</td>
<td>2.4</td>
<td>15.0</td>
<td>10.0</td>
<td>72.0</td>
</tr>
</tbody>
</table>

The degree of elevated serum creatinine correlated with the prognosis of recovery or death in the patients is summarized in the following table:

<table>
<thead>
<tr>
<th>Correlation of serum creatinine to patient prognosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum creatinine (milligram percent)</td>
</tr>
<tr>
<td>--------------------------------------</td>
</tr>
<tr>
<td>1.5 to 2.5</td>
</tr>
<tr>
<td>2.6 to 3.5</td>
</tr>
<tr>
<td>3.6 to 5.5</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

In addition to an evaluation of the renal, several of these studies were also submitted to two consultant review groups (Refs. 51 through 53) for an independent evaluation of the validity of statistical procedures and factors in the experimental design which would support or invalidate the conclusions of the study. 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 phenacetin-containing analgesic compounds and kidney disease and that statistically there is an increased incidence of uremic blood poisoning (obstruction, diabetes, papillary necrosis) over a period of time from 18 months to 4 years.

Several other researchers have found a correlation between the degree of phenacetin intake and probability of serious kidney damage (Refs. 18, 34 and 38). The prospective post-mortem study of Barry, de Jersey and Weeden (Ref. 16) provides significant evidence for phenacetin involvement in renal papillary necrosis. Pathological diagnosis and degree of analgesic consumption, as determined by questionnaires, was determined independently. In 407 autopsies when other possible reasons for renal papillary necrosis (obstruction, diabetes, and papillary amyloidosis) were excluded, severe papillary necrosis (42
Papillary necrosis was 37 percent. This result in a 73 percent probability of reis similar to the findings of Bell, Kerr, and Lenton (Ref. 38). The study took 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. Clausen (Ref. 46) observed that analgesic nephropathy. The Panel finds the incidence of renal papillary necrosis in patients taking nonphenacetin containing products was from 4 to 8 years. Renal function of those who continued to use analgesics containing aspirin only or aspirin with phenacetin was measured by creatinine clearance and in two rats who received an aspirin-caffeine-containing product. The study showed that aspirin function continued to deteriorate when aspirin-containing products were abused but the rate of progression was significantly less rapid (4.9 ml/min/year compared to 12.9 ml/min/year) for phenacetin compounds.

Furthermore, the incidence of deaths due to uraemia 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 g acetaminophen daily) and aspirin for phenacetin in 2 patients (0.1 to 1.8 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 removing analgesic compounds from the OTC drug market can be seen in countries 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 result of the study of Nordenfelt, in Australia and Switzerland, countries which have 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 (kidney failure) in 52 cases of analgesic nephropathy has decreased when phenacetin compounds were removed from nonprescription use (Ref. 43).

In Switzerland, where nonprescription phenacetin compounds are still available, the deaths due to uraemia have not changed during the period from 1966 to 1971. The total number of uraemic deaths each year during this period were 73, 71, 69, 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 payments for these products from National Health 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.

As briefly mentioned above, the lag time between ingestion of drug and the appearance of kidney effects is relatively long (5 to 10 years) and the causal relationship between chronic phenacetin intake and analgesic-induced kidney disease. Burry and others 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 of 5 or more years in 64 percent of patients and more than 10 years in 62 percent of patients. Thus after 10 years of use, one would see only 38 percent of the total number of individuals who ultimately will develop symptoms. This provides an explanation for the continued spread of renal papillary necrosis for several years after drug intake is stopped.

In 35 patients from Huskvarna who died of uraemia the time between initial dosage and onset of symptoms was 5 to 10 years. The time between onset of symptoms 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. 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 evidence of any reasonable explanation in most reported cases. Other authors have provided other valid reasons or data to clearly refute any serious considerations of analgesic nephropathy being a result of analgesic abuse.

Burry and others (Ref. 16) refuted the idea that patients take analgesics to alleviate the pain of kidney infection (pyelonephritis). In his study of 100 patients he was unable to find any evidence that the act of excluding phenacetin compounds from 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.

(2) Mechanism of action producing nephropathy. The difficulty of showing the mechanism by which phenacetin and aspirin cause kidney disease even when large amounts of phenacetin are administered over long periods of time has been a primary factor in the belief of some authorities that it is not the agent but the dosage of 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 different species, type of diet, water intake, and others. Clausen (Ref. 46) found rabbits given either 325 mg aspirin or phenacetin orally developed interstitial nephritis (kidney inflammation) with both drugs and an increased susceptibility to kidney infection. Abrams et al. (Ref. 84) found papillary necrosis (kidney disease) in two rats who received an aspirin-phenacetin-caffeine combination. Renal papillary hemorrhage (kidney bleeding) was noted in rats orally given both phenacetin alone and in the aspirin-phenacetin-caffeine combination. Prasad et al. (Ref. 55) administered phenacetin to Sprague-Dawley rats (300 mg for 10 days, or 450 mg for 10 days, or 600 mg for 20 days) resulting in physiologic and histologic evidence of renal damage.

FEDERAL REGISTER, VOL. 42, NO. 121—FRIDAY, JULY 8, 1977
dysfunction including papillary necrosis in 3 of 39 rats. Boyd et al. (Refs. 56 and 57) found that hepatorenal necrosis (diverticulum type) occurred in acute toxicity to phenacetin when influenced by diet and mode of administration (dietary against intragastric). Eissa and Talanti (Ref. 58) showed 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 acetaminophen in water. 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 Rose showed that dose-related methoxyflurane nephrotoxicity 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 site of kidney injury are the renal papillae with constriction or obstruction of blood vessels in the kidneys. Kincaid-Smith has shown early lesions in the efferent vasa recta of rats treated with phenacetin and aspirin/phenacetin/caffeine (Ref. 60).

Abrahams and Levin have observed platelet deposition in the vasa recta in treated animals (Ref. 61).

Secondary chronic atrophic lesions in the overlying renal cortex result in changes which have been referred to as "chronic interstitial nephritis" (Ref. 62).

The medullary blood flow is particularly susceptible to a number of drugs and poisons that medulla is quite sensitive to ischemia.

It is possible that the anemia which accompanies or perhaps precedes renal effects may contribute to the ischemia.

The histologic and electron microscopic studies of Gault et al. (Ref. 37) provide a clearer picture of the relationship between disease development and functional changes in analgesic-induced kidney disease. The first events are morphologic changes in interstitial collagen and medullary sclerosis accompanied by slight changes in concentrating ability. A reduction in creatinine clearance, one of the usual diagnostic methods to detect renal disease, is not apparent until significant medullary sclerosis and papillary necrosis occur.

Differential diagnosis of analgesic-induced kidney disease is difficult to assess and is undoubtedly underestimated for several reasons. First, it is clear that unless physicians are alerted to the possibility of analgesic-induced kidney injury and specifically consider it during diagnosis, it is likely to be missed (Refs. 54, 63, and 65). Secondly, accurate drug histories are frequently not obtained because of the reluctance of the patient or oversight by the interviewer, and thirdly, the distinguishing characteristic of analgesic-induced kidney disease may be biased due to underestimates of the values given for incidence of and amount of drug used.

The experiences reported by many investigators indicate that correlations between drug intake and disease variables may be biased due to underestimates of the values given for incidence of and amount of drug used.

Several authors have stated that there is a definite tendency of patients to withhold information on the frequency and degree of analgesic intake, particularly if a stigma of abuse has been associated with intake of these drugs. In the case of patients with analgesic-induced kidney disease that he reported on the 13 patients with analgesic abuse (Ref. 63). Koch states that renal papillary necrosis associated with analgesic abuse can be distinguished morphologically from renal papillary necrosis associated with diabetes and other non-drug-related causes.

Rubenstein et al. (Ref. 64) commented that the difficulty of establishing drug intake may often be the failure of the physicians to include direct questioning of analgesic intake in routine interviews rather than a reliable story of the patient, noting that each of the 13 patients with analgesic-induced kidney disease that he reported on the 13 patients with analgesic abuse (Ref. 63). Since these patients were known to the authors who did not suspect an excessive analgesic intake. A history of excessive drug ingestion was readily obtained when the patients were specifically asked regarding the frequency of drug use.

Although early workers did not believe the renal lesion to be specifically related to analgesic abuse, and, in fact, originally described the pathology as chronic pyelonephritis or interstitial nephritis. There is general agreement among authorities that a specific type of kidney injury, renal papillary necrosis, is the primary lesion observed most often with analgesic abuse (Ref. 65). Koch states that the association between analgesic abuse and renal papillary necrosis is likely to be missed unless a conscious effort is made, and the true incidence is likely to be much higher than reported.

An additional factor for poor detection of analgesic-induced kidney injury has been related to the erroneous conclusion frequently reached in the literature that because analgesic-induced kidney injury has not been reported in a given area or country it does not exist.

Such statements often attempt to relate differences between countries in the number of cases reported to possible ethnic or environmental differences between these countries rather than a difference in accurate diagnosis and thus may compound the basic problem of lack of awareness in the medical community.

The slow rate at which the medical and scientific community throughout the world has become aware of and reported new cases of analgesic-induced kidney disease clearly shows the difficulties of using reported cases at a given point in time as an estimate of the true incidence in a given country.

In 1967 Shelley (Ref. 67) reviewed over 10,000 cases of analgesic-induced kidney disease throughout the world. Thirty years later this total has been reported by Spühler and Zollinger in 1953. These reports were largely from Scandinavia and other countries. Prior to 1966, there were only 11 cases reported in Great Britain. That year Pregnancy Statistics reported 36 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, Kamalians and de Wardener (Ref. 69) detected 16 cases at a small 200 bed hospital in London. Seven of these patients had first been seen in other departments of the hospital before the diagnosis of analgesic-induced kidney disease. 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, is probably rather than a number.

The same lag time in reporting of the problem has occurred in Canada. In 1967, 12 patients underwent intravenous pyelography. Nevertheless, in eight cases, the initial diagnosis was chronic pyelonephritis even though the cardinal signs of renal papillary necrosis were present including small kidney (seven cases), clubbed calices (five cases) and lobulated outline (three cases). Bell concluded that the detection of renal papillary necrosis is likely to be missed unless a conscious effort is made, and the true incidence is likely to be much higher than reported.

PROPOSED RULES
14 years after the first Swiss report, there were only seven cases reported in Canada. In 1963, Koch reported 26 cases of kidney injury in 195,004 cases (0.013 percent) of analgesic abuse in a civilian community between 1961 to 1966. Fifteen of these cases (58 percent) were analgesic abusers who had taken more than 1 kg phenacetin-containing products (Ref. 83). For many years, Linton (Ref. 40) reported 22 patients with analgesic-induced kidney disease seen in two hospitals in Montreal over a 4-year period. In 1972, 100 cases in two Ontario cities, London and Glasgow, were reported by Linton and colleagues (Ref. 49) reported 22 patients with analgesic-induced kidney disease seen in two hospitals in Montreal over a 4-year period. In 1972, 100 cases in two Ontario cities, London and Glasgow, were reported by Linton (Ref. 40). In Canada analgesic kidney disease now accounts for 5.5 percent of all renal dialysis in Ontario.

A similar time lag is now occurring in recognition of the association of kidney tumors with phenacetin abuse which was first noted in 1965 in Sweden, 12 years after the association between analgesic compounds and kidney disease was noted. For many years, Linton (Ref. 40) pointed out that reports had not come from any other country suggesting that perhaps factors other than phenacetin may be involved (Ref. 70). Finally, in 1974, six cases from various areas of the U.S. were reported by the Minneapolis Regional Kidney Disease Program (Ref. 78). These cases have now been reported in several other countries, showing again that a low incidence of reported disease in a particular region does not necessarily assume that the incidence is low. (4) Incidence of analgesic-induced kidney disease in U.S. It has been stated that analgesic kidney disease is less frequent in the U.S. than in other countries with similar per capita ingestion of phenacetin-containing analgesics. Recent evidence suggests that the lower incidence of reported cases may simply represent differences in detection rather than real differences as has been seen in other countries. In the past 10 years about 100 cases of analgesic kidney disease have been reported in the literature in the U.S. (Refs. 71 and 72). Murray and Garnick (Ref. 73) have now reported a review of 200 patients with newly diagnosed chronic interstitial nephritis at the University of Pennsylvania Hospital during the period 1965 to 1972, had abused analgesic compounds, which was considered a likely cause of renal disease (Ref. 15). This is similar to the incidence of 3 to 17 percent of analgesic abusers in patients with otherwise unexplained end-stage renal disease in Canada (Ref. 41) 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 in incidence 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 nor did the primary intern in 15 of 20 patients who had been seen previously. Other studies, 7 of the patients denied analgesic intake, and accurate drug histories could be obtained only from relatives. 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>Countries surveyed</th>
<th>Minimum incidence of renal papillary necrosis</th>
<th>Per capita consumption of phenacetin (grams per year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>0.15 to 0.5</td>
<td>6 to 7</td>
</tr>
<tr>
<td>Canada</td>
<td>0.15 to 0.5</td>
<td>6 to 7</td>
</tr>
<tr>
<td>Copenhagen</td>
<td>1.05</td>
<td>25</td>
</tr>
<tr>
<td>Edinburgh</td>
<td>0.54 to 0.59</td>
<td>12</td>
</tr>
<tr>
<td>Scotland</td>
<td>0.5</td>
<td>12</td>
</tr>
<tr>
<td>United States</td>
<td>0.16 to 0.26</td>
<td>10</td>
</tr>
</tbody>
</table>


This Panel has requested information on the cases of analgesic kidney disease that had been detected in several renal dialysis centers. A total of 105 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. 13) of analgesic abuse was identified as the primary cause of renal disease in 30 (1.5 percent) of 2,335 chronic hemodialysis patients treated in 91 dialysis centers in the U.S. during the years 1971, 1972. Of 323 deaths in 1974, seven (2.1 percent) were 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. 13). 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 has previously occurred in the United Kingdom and Canada.

(c) Cancer of the urinary tract. During the past few years, several reports have been made of cases of phenacetin-containing products with cancer of the renal pelvis (kidney) and urinary bladder. The first report, in 1965, was a retrospective study by Hullemgren et al. of 150 patients with cancer of the renal pelvis in the Huvskarns Hospital (Ref. 76). All but two had renal papillary necrosis associated with long term analgesic use.

Björk and colleagues (Ref. 77) reported a study of 192 patients with documented nephropathy in which patients were followed for a period of 1 to 11 years (average 5.3 years). During this time, three patients developed renal pelvic carcinoma (cancer of the kidney) and another two patients developed cancer of the urinary bladder. No tumors were found in 56 individuals with chronic pyelonephritis (cystitis, 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. 78) it was shown that renal pelvic carcinoma (cancer of the kidney) is an infrequent disease in Sweden, the average yearly incidence being only 11 cases per 156,000 inhabitants which is about 1,000 times lower than the incidence reported for analgesic abusers. A more recent study by Johansson and coworkers (Ref. 79) was based upon known abusers of phenacetin compounds (29 men and 33 women) who had been admitted to the hospitals of the renal pelvis (cancer) treated at the hospitals throughout Sweden. All tumors were diagnosed during the years 1968 through 1972. All patients had been abusers of drug products containing phenacetin. The preparation used by 80 percent of the patients contained 0.5 g phenacetin, 0.5 g antipyrine and 0.1 g caffeine. The other patients (20 percent) took compounds of the same composition but containing varying amounts of the same ingredients. In 38 patients, detailed data of drug intake were available. The average total ingestion of phenacetin was estimated to be 9.1 kg. Chronic kidney disease had been established in 33 patients for a period of 3 to 15 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 (permanent kidney injury) was made in all but five of the patients. In two patients, examination was not possible. Of the cases, 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 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 has previously occurred in the United Kingdom and Canada.

(c) Cancer of the urinary tract. During the past few years, several reports have been made of cases of phenacetin-containing products with cancer of the renal pelvis (kidney) and urinary bladder. The first report, in 1965, was a retrospective study by Hullemgren et al. of 150 patients with cancer of the renal pelvis in the Huvskarns Hospital (Ref. 76). All but two had renal papillary necrosis associated with long term analgesic use.

Björk and colleagues (Ref. 77) reported a study of 192 patients with documented nephropathy in which patients were followed for a period of 1 to 11 years (average 5.3 years). During this time, three patients developed renal pelvic carcinoma (cancer of the kidney) and another two patients developed cancer of the urinary bladder. No tumors were found in 56 individuals with chronic pyelonephritis (cystitis, 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. 78) it was shown that renal pelvic carcinoma (cancer of the kidney) is an infrequent disease in Sweden, the average yearly incidence being only 11 cases per 156,000 inhabitants which is about 1,000 times lower than the incidence reported for analgesic abusers. A more recent study by Johansson and coworkers (Ref. 79) was based upon known abusers of phenacetin compounds (29 men and 33 women) who had been admitted to the hospitals of the renal pelvis (cancer) treated at the hospitals throughout Sweden. All tumors were diagnosed during the years 1968 through 1972. All patients had been abusers of drug products containing phenacetin. The preparation used by 80 percent of the patients contained 0.5 g phenacetin, 0.5 g antipyrine and 0.1 g caffeine. The other patients (20 percent) took compounds of the same composition but containing varying amounts of the same ingredients. In 38 patients, detailed data of drug intake were available. The average total ingestion of phenacetin was estimated to be 9.1 kg. Chronic kidney disease had been established in 33 patients for a period of 3 to 15 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 (permanent kidney injury) was made in all but five of the patients. In two patients, examination was not possible. Of the cases, 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 use.
An enlarged spleen is a common symptom of phenacetin abusers. Duggan (Ref. 96) also reported 10 women with significant enlargement of the spleen which were apparently related to chronic ingestion of phenacetin. He found parallel phenomena in his experimental studies in animals.

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 combinations 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 the chronic abuse (habituation potential) of OTC combinations containing phenacetin. The Panel, therefore, concludes that because the risks of these combinations outweigh any possible benefits, phenacetin in combinations is not safe for OTC use as an analgesic and should be removed from analgesic preparations (Category III).

Several presentations have been made in response to the Panel's conclusion. These presentations are in favor of the retention of phenacetin in OTC analgesic preparations. In making its final decision, the Panel considered the questions submitted by these groups.

1. If phenacetin were removed from the OTC market would the general public be deprived of a useful agent for which alternative drugs are not available?

Unlike other analgesics, such as aspirin and acetaminophen, phenacetin is used primarily in combination with other analgesics. Aspirin and acetaminophen are available in single ingredient products as well as in combinations. These phentermin combinations are no more effective than combination analgesics which do not contain phenacetin, but phentermin combinations are less safe than preparations that do not contain phenacetin.

Therefore, because phenacetin is less safe than other analgesics, the general public would not be deprived of a useful agent for which alternative drugs are available. If phenacetin were removed from the OTC market, the risks from the use of phentermin combinations would be much greater than the risks from the use of analgesic combinations that do not contain phenacetin.

In addition, phenacetin preparations offer no advantages to individuals unable to take other analgesic preparations, i.e., individuals sensitive to aspirin. Phenacetin is virtually never marketed as a single entity, and the substitution of acetaminophen for phenacetin in combination preparations (aspirin-phenacetin-cafFee) are not useful as substitutes for individuals with aspirin sensitivity.

In contrast, acetaminophen has been available alone. Although it is the major metabolite of phenacetin it is safer than the parent compound in many respects. Acetaminophen lacks the intrinsic CNS effects of phenacetin and therefore has less abuse potential. Other minor metabolites of phenacetin associated with discomfort, such as methemoglobinemia, splenomegaly and thrombocytopenia, occur to a lesser extent when acetaminophen is given as such.

2. Is the combination of aspirin and phenacetin as safe as those drugs when used separately?

Experimental evidence available strongly suggests that the potential toxicity may actually be increased for combinations of phenacetin and aspirin. Phenacetin appears to be a major factor in the excessive use of analgesic preparations. Its presence may increase use and thus the incidence of serious toxic effects of aspirin or other agents ingested in large amounts in combination products.

The direct effects of phenacetin, including production of methemoglobinemia and hemolytic anemia may interact with the other effects of aspirin which include effects on platelet function, thrombocytopenia and anemia associated with occult gastric bleeding. These combined effects may be related to gastric and renal hemorrhage, ischemia and focal necrosis.

3. Would the risk potential associated with abuse be greater or less with alternate preparations?

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 protracted renal nephropathy or decreased incidence of severe complications.

Some authors have opposed the removal of phenacetin because acetaminophen may be substituted and the combinations with this agent may be equally nephrotoxic. While there is some evidence that acetaminophen may be nephrotoxic, it is likely to be less so for several reasons:

(iii) The decreased CNS effect of acetaminophen reduces abuse potential.

(iv) Decreased anemia of potentially nephrotoxic metabolites are formed after acetaminophen ingestion compared to phenacetin ingestion.

This is supported by several substitution studies in patients with existing renal papillary necrosis in whom the substitution of acetaminophen for phenacetin produced less renal dysfunction. The questions and the Panel's replies are summarized below.

These presentations are in favor of the retention of phenacetin in OTC analgesic preparations. In making its final decision, the Panel considered the questions submitted by these groups. These presentations are in favor of the retention of phenacetin in OTC analgesic preparations. In making its final decision, the Panel considered the questions submitted by these groups.
associated with aspirin? There is no evidence that the substitution of phenacetin for aspirin in APC preparations decreases the ulcerogenic potential of the product. A review of the medical histories of patients described in the literature shows that large amounts of phenacetin-containing and ulcer symptoms in patients taking phenacetin-containing analgesic preparations.

The incidence of adverse effects of aspirin on the gastrointestinal system may be increased when aspirin is used as a component of mixtures taken primarily for the central nervous system effects. Rapaport, White and Randles (Ref. 100) reported that two patients described in the literature of aspirin are ingested. Large amounts of phenacetin-containing analgesic nephropathy had gastric or duodenal ulcers. Rapaport, White and Randles (Ref. 100) reported that two patients with suspected phenacetin/analgesic nephropathy also exhibited a history of peptic ulcer.

An increase of gastric ulcers in eastern Australia has been attributed to the effects of aspirin. However, the preparations involved in 80 percent of these cases contained aspirin, phenacetin or acetaminophen, and caffeine. There were no reports of a combination of renal, hematologic, gastrointestinal and psychological symptoms which occur so frequently with analgesic abuse that Gault and coworkers (Ref. 17) described such patients with analgesic nephropathy had a history of gastrectomy and peptic ulcer.

Ranbip and Hopper (Ref. 99) reported that 4 of 23 patients with analgesic nephropathy had gastric or duodenal ulcers. Moriel and Ranbip (Ref. 100) reported that two patients with suspected phenacetin/analgesic nephropathy also exhibited a history of peptic ulcer.


(50) Research Triangle Institute, Statistics Research Division, "Renal Nephropathy and Compound Analgesics—Preliminary Conclusions," August, 1972, draft of unpublished paper is included in OTC Volume 030150.

(51) Research Triangle Institute, Statistics Research Division, "Renal Nephropathy and Compound Analgesics—Preliminary Conclusions," August, 1972, draft of unpublished paper is included in OTC Volume 030150.


tion of Peptic Ulceration, Chronic Renal Disease, and Analgesic Abuse." Quarterly Journal of Medicine, 35:69-83, 1968.

e. Quinine. The Panel concludes that quinine is an effective analgesic but that it is not uniformly effective.

(1) Effectiveness. The analgesic and antipyretic properties of quinine have been known since the introduction of cinchona bark into medicine in the 17th Century. Because it lowered the fever of malarial patients it was tried in many 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 antipyretics is based on long experience instead of controlled studies.

In the first edition of the Pharmacological Basis of Therapeutics, published in 1941 (Ref. 1), Goodman and Gilman stated:

"Quinine in children. Doses of 0.3 to 0.5 gram 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 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 0.65 to 0.7 g, 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 theAMA Drug Evaluations (Ref. 3):

"Quinine has been used as an antipyretic and 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 for relief of nocturnal leg cramps was introduced in the 1940's when Moss and Herman (Ref. 4) and Goottick (Ref. 5) reported on the benefit of uncontrolled trials that quinine in the doses of 3 to 5 gr (200 to 325 mg) abolished the spasms. Nicholson and Falk (Ref. 6) reported relief following quinine treatment in about 5% of 36 young men suffering from leg cramps. 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 leg cramps were needed, did recommend trying quinine for nocturnal 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 suggests that no controlled studies are needed. In addition, the recommended dosage varies widely, from 200 mg at bedtime to 5 gr (325 mg) 4 times daily as recommended by Perchuck (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 325 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 may remain uncontrolled. It is to the risk of remote effects that it is now turned.

(a) Toxicity. The toxicity of quinine has been the subject of numerous reports and is well summarized in many modern text books of pharmacology and toxicology. The toxicity of quinidine and its stereochemical quinine is well summarized by Gleason et al. (Ref. 10), and in the fourth edition of Goodman and Gilman, Rollo (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 0.6 g with a total daily dose of not more than 2.0 g, a group of symptoms known as cinchonism appear. These include tinnitus, headache, nausea and vomiting, convulsions and other CNS symptoms which may be involved include the gastrointestinal, nervous and cardiovascular systems, and the skin. Actions on the gastrointestinal tract are evidenced by abdominal pain and diarrhea. Damage to the nervous system is usually manifested by the disturbances in hearing and vision due to actions on the optic and auditory nerves. Other actions on the central nervous system may be expressed by headache, fever, apprehension, confusion, excitement, delirium and syncope. Respiration is stimulated and then depressed. Cardiovascular toxicity may be manifested by hypotension, weakness, shock, coma and death. Renal damage has been reported, as has acute hemolytic anemia and hypoprothrombinemia (Ref. 11).

(b) Toxicity in Man. The toxic symptoms of quinine have been extensively documented (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) Abuse. 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


CATEGORY II LABELING

The Panel has examined the submitted labeling claims for analogies 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 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 containing modifying adjectives associating pain with illnesses, and unacceptable claims related to product performance as follows:

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.
claims are "jumpy nerves", "fretfulness", "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 treatment. There are many examples of such claims such as "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. Examples of such claims are: "pain following dental work", "inoculation", "vaccination". "Pain of teeth" is also included here because the use of OTC drugs in children under 3 years of age requires the advice and supervision of a physician.

Modifying adjectives associating pain with illnesses. In its discussion of the indications and directions for use information on the labeling of OTC drug products, the Panel has examined these terms which in its opinion are unnecessary and misleading. The Panel views the implication that these drugs are to be used for the treatment of diseases should be discouraged. (See part II, paragraph C. above—Labeling of Analgesics, Analgesics—Antipyretic Drug Products.) Although analgesic ingredients may effectively ameliorate the pain due to various physical conditions, disease entities or specific physical sites, the listing of a plethora of conditions and sites in order to be factual and all inclusive would not only result in a lengthy list that would tend to be confusing but would also mislead the consumer by the implied assumption that the product treats the physical conditions and/or disease rather than just temporarily relieves 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 pains, pains due to overexertion" in the labeling of one manufacturer's product and the omission of these claims from the labeling of the same drug by another manufacturer would mislead the user into believing the preparations are different. The misdirection would be even greater if the products were of different ingredients as for example one manufacturer's aspirin tablets versus another manufacturer's acetaminophen tablets.

6. Unacceptable claims submitted for specific analgesics. Examples of unacceptable claims that have been submitted for specific analgesics that are unsupported by scientific data and/or sound theoretical reasoning, and that contain modifying adjectives associating pain with various physical conditions, disease entities or specific physical sites are listed below—Antipyretic Drug Products.


(3) Calcium carbaspirin: "pains due to sinusitis", "minor aches and 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 pains", "overexertion", "fatigue", "minor aches and pains of rheumatism", "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 (salsalate salicylic acid): "minor pains, swelling, stiffness of fibrositis", "minor pains, swelling, stiffness of osteoarthritis", "aspirin—for relief of arthritis".

(b) Unacceptable claims related to product performance. Terms such as "fast pain relief", "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 allude to the beneficial performance of these products as a result of the antacid 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 consistently provide the above-verse 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 more buffered and highly buffered aspirin should be restricted to the following: "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 has discussed this labeling elsewhere in this document. See part V. Panel's Recommendations, B.I.D. below—Labeling claims for marketed products containing analgesics combined with antacid or buffering ingredients.

The Panel further concludes that any other statement(s) are classified as Category II.

5. 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 analgesic active ingredients listed below—Tablets. These claims are not 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 safety data are not obtained within 3 years, however, these ingredients listed in this Category should not longer be marketed in OTC products:

Aluminum aspirin
Salicylate (salsalate salicylic acid)
Antipyrine
Sudafed

A. Aluminum aspirin. The Panel concludes that aluminum aspirin is safe but that there are insufficient data 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 doses in 24 hours for not more than 10 days.

(1) Effectiveness. Aluminum aspirin (aluminum acetylsalicylate) is chemically very similar to aspirin. The aluminum salt has been used because of greater palatability with lessstringency to the taste. Its greater stability gives it 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, 5, and 9). Yet, it is claimed that although this drug is absorbed somehow more slowly than aspirin it apparently produces a satisfactory degree of analgesia similar to that produced by aspirin (Ref. 4).

Levy and Sahli (Ref. 2) compared the effectiveness.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
tion from orally administered aluminum acetylsalicylate (aluminum aspirin) was found to be less rapid than from aspirin, probably due to the very slow dissolution of the aluminum salt in gastrointestinal fluids and perhaps may be due to its water insolubility. The release rate in vivo of several antipyretic and analgesic drugs in man must be carefully evaluated with respect to absorption rate and biological availability.

Nogami and Hanano (Ref. 3) compared the release rate in vivo of several antipyretic and analgesic drugs in humans. They compared six sugar coated analgesic tablets. The ingredients were: sulpyrine, aminopyrine, phenacetin, buacetin, N-acetyl-paminophenol, salicylamide and aluminum aspirin. They concluded that aluminum aspirin release rate was slower than that of any of the others and this difference was statistically significant.

However, one submission cites two bioavailability studies which are pertinent; the first, an oral study in rabbits and the second, absorption and solubility studies compared to aspirin cannot be stated at this time.

(2) Safety. Data reviewed by the Panel indicate that aluminum aspirin is as safe as aspirin in equivalent dosages. Although the evidence is not complete, it seems to indicate that aluminum aspirin is not less effective and is as safe as aspirin. The incidence of adverse reactions, either prior to or after absorption, would be comparable to that of aspirin as discussed previously in this document. (See part III. paragraph B.1.a. above—Safety.) Consequently, all cautions required for aspirin should be required for aluminum aspirin.

(3) Proposed dosage. Adult oral dosage is 350 to 730 mg every 4 hours while symptoms persist not to exceed 4,380 mg in 24 hours for not more than 10 days. Children 11 to under 12 years oral dosage is 350 mg every 4 hours while symptoms persist not to exceed 1,825 mg in 24 hours for not more than 6 days. Children 9 to under 11 years oral dosage is 305 mg every 4 hours while symptoms persist not to exceed 1,075 mg in 24 hours for not more than 5 days. Children 7 to under 9 years oral dosage is 215 mg every 4 hours while symptoms persist not to exceed 800 mg in 24 hours for not more than 4 days. Children 5 to under 7 years oral dosage is 165 mg every 4 hours while symptoms persist not to exceed 660 mg in 24 hours for not more than 3 days. Children 3 to under 5 years oral dosage is 120 mg every 4 hours while symptoms persist not to exceed 450 mg in 24 hours for not more than 2 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 1 labeling for analgesic active ingredients. (See part III. paragraph B.1.b. below—Category 1 Labeling.) In addition, the Panel recommends the following specific labeling: (1) 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."

(5) Analgesic equivalence value. In the previous discussion on "standard 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 containing aluminum aspirin differs per dosage unit from the established standard of 325 mg (5 gr) aspirin. (See part III. paragraph B.1.c. above—Established Standard Dosage Unit and Analgesic 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 "doseage unit" is defined as 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 7.3 mg (0.24 gr) of aspirin per dosage unit".

(6) Evaluation. Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for analgesic drugs. Bioavailability studies of aluminum aspirin in man must show comparable blood levels of salicylates to those 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) Water, R. W., "Clinical Trial of 2% Grain Aluminum Aspirin Dulcet Tablets," draft of unpublished paper is included in OTC Volume 030037.

b. Antipyrine. The Panel concludes that there are insufficient data to determine the effectiveness of antipyrine as an OTC analgesic when, as in the case of aspirin, the term analgesic was first used to describe a drug with analgesic effects, as defined by the Panel. Antipyrine was synthesized in 1883 by Knorr (Ref. 1) after antipyrine as an OTC analgesic when known that aspirin was declining, antipyrine continued to be used for its analgesic effects which were 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 popularity of the salicylates and not because of a demonstrated lesser effectiveness or safety of antipyrine (Ref. 1). In Europe, paracetamol is more commonly used by large segments of the population, it is found mainly in combination with other products. Therefore, there are insufficient data on the safety and effectiveness of antipyrine.
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 properties and side effect liability have been reported. As reviewed by Greenberg (Ref. 1), numerous reports of experimental tests of the pain threshold in man, using mechanical, thermal, or electrical stimulation, describe only moderate or, in most cases, inconsistent and generally inconclusive effects of antipyrine in elevating the pain thresholds. 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 drugs.

The manufacturer of the only product submitted containing antipyrine cites in his labeling and in his submission a study by Ritchie & Splller (1949) who state that "the transformation 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 for hours or more. This is considerably longer than with acetanilide, phenacetin or N-acetyls-p-aminophenol." Thus, from this study it is apparent that the metabolism of antipyrine is slow and therefore it is suspected to provide longer antipyrine 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.)

### Antibody Case Reports

<table>
<thead>
<tr>
<th>Case Report I (Ref. 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Author:</strong> Broc (1944)</td>
</tr>
<tr>
<td><strong>Medication:</strong> Antipyrine</td>
</tr>
<tr>
<td><strong>Patient description:</strong> Three white females</td>
</tr>
</tbody>
</table>
| **Signs and symptoms:** Fixed pigmented erythema.
- Antipyrine test dose: +, +, +
- Other drug test dose: |
| **Outcome:** |

<table>
<thead>
<tr>
<th>Case Report II (Ref. 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Author:</strong> Apolt (1948)</td>
</tr>
<tr>
<td><strong>Medication:</strong> Antipyrine (ointment)</td>
</tr>
<tr>
<td><strong>Patient description:</strong></td>
</tr>
<tr>
<td><strong>Signs and symptoms:</strong> Erythema reappeared after local application of an antipyrine-containing ointment.</td>
</tr>
</tbody>
</table>
| **Antipyrine test dose:** +, +, +
| **Other drug test dose:** |
| **Outcome:** |

<table>
<thead>
<tr>
<th>Case Report III (Ref. 7)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Author:</strong> Ritchie &amp; Spiller (1940)</td>
</tr>
<tr>
<td><strong>Medication:</strong> Antipyrine-containing cold medicine (2 tablets)</td>
</tr>
<tr>
<td><strong>Patient description:</strong> One white male</td>
</tr>
<tr>
<td><strong>Signs and symptoms:</strong> Large, dusky erythematous and scaly macules scattered over shoulders, arms and thighs.</td>
</tr>
</tbody>
</table>
| **Antipyrine test dose:** +, +, +
| **Other drug test dose:** +, +, +
| **Outcome:** Hospitalization. |

1. The term "fixed" was used because once the reaction had occurred it tended to reappear in the same areas of the body where it had occurred previously.
2. Not specified.

*The first sign (+ or —) indicates whether test doses were employed to see if signs and symptoms appeared; the second sign (+ or —) indicates whether the reaction was positive or negative.*

---

**PROPOSED RULES**

**Case Report IV (Ref. 8):**

**Authors:** McDuffie & Rigelman (1951).
**Medication:** Antipyrine-containing cold preparation.
**Patient description:** One black male.
**Signs and symptoms:** Numerous erythematous and hyperpigmented well-demarcated lesions in some of which contained central bullae. They were located in the face, neck, chest, back, arms, buttocks, and lower extremities, scrotum and glans 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 headaches. The lips and the interior portion of the 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:** Kenneth & Ayer (1950).
**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 causing swelling and sometimes pain referred to the genito-urinary system. The mucosa of the eyes, mouth and genitalia, as well as edematous and 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 102° F.
**Antipyrine test dose:**
**Other drug test dose:**
**Outcome:** Hospitalization of various duration.

**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" (dark brown, flat), neurologic symptoms, grand mal seizures, delirium and large, pigmented bullous lesions, of the type seen in erythema multiforme, appeared over the body, particularly on the neck, thighs and genitaiia. Patients were acutely ill and had fever over 102° F.
**Antipyrine test dose:**
**Other drug test dose:**
**Outcome:** Hospitalization; one death.

**Case Report VIII (Ref. 12):**

**Author:** Verboj (1973).
**Medication:** Dichloralphenazone (an antipyrine derivative with hypnotic property).
**Patient description:** One white male.
**Signs and symptoms:** Severe irritation of the upper and lower extremities.
**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 Broc (Ref. 1). The antipyrine-sensitive skin that Broc discovered had been introduced, Broc 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 and that it was in most cases had remained darker in color. He coined the term of "fixed pigmented erythema" which is still used. He prepared an ointment containing 10 percent antipyrine in lanolin. After rubbing this ointment in previously affected areas, he observed that itching occurred at these sites within 10 minutes, and that within 24 hours an erythema, exactly like the original in size but somewhat less in degree, appeared and lasted for about 3 days. Previously unaffected sites did not react to the application of this ointment.

Two articles cited in the table of antipyrine case reports warrant further discussion. Coldman and Rockwell (Ref. 9) have reported a case of a 47-year-old male Negro who was admitted to the hospital with a 7-day history of sore lips and penis, fever and chills, loss of appetite and headache. The patient had ingested 10 grains of a marketed OTC cold remedy containing 3.5 g antipyrine (60 gr). His temperature on admission was 102° F and both his lips and anterior portion of the penis were edematous and denuded with crusting and bleeding. 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 hyper sensivity, 0.2 g (3 gr) antipyrine was administered to the patient. The patient responded with a fever for 4 days, severe abdominal pain and pruritus in the hands, and a papular eruption in the perianal region and in the pigmented lesions on the hands. A week later the patient was given 100 mg cortisone at 2 p.m. and 4:00 p.m. and 8 g antipyrine was administered at 5 p.m. followed by an additional dose of 50 mg cortisone at 5:30 p.m. Only a minimal pruritus in the hands was reported by the patient. This is another case in which hyper sensitivity to antipyrine was proved first with a challenge dose of antipyrine and then the reaction was prevented by the concurrent administration of cortisone.
cemic 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.

The minority of the Panel concludes that antipyrene is unsafe and should be in Category II.

The extensive review of adverse reactions described in this document above leads to the conclusion that antipyrene, typically 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 other case reports suggests 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 authors (14) express a concern, the risk to benefit ratio of such a study of antipyrene toxicity is extremely high. This type of prospective toxicity study should be required if the drug is to move from Category III to Category I. The minority of the Panel feels that if a study has a high risk to benefit ratio and therefore would place antipyrene in Category II.

References
(2) Nelson, J., Letter solicited by the Panel, December 27, 1974, copy is included in OTC Volume 03910.
(7) Ritchie, F. B. and W. F. Spitzer, "Disorders of Drug Metabolism (Fixed Type)." AMA Archives of Dermatology and Syphilology, 59:487-488, 1949.

The Panel concludes 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 while symptoms persist not to exceed 6,000 mg in 24 hours for not more than 10 days) may be effective but has not been tested for safety for OTC use. Therefore, the Panel recommends that salicylamide not be made available for OTC use at the higher dosage range until suitable studies have been completed. Salicylamide is also considered by Panel evaluators for its slight hypnotic properties.

Until a few years ago, it was marketed as a single ingredient in a suspension dosage form (as an OTC analgesic-antipyretic agent. It is used primarily in a wide variety of OTC analgesic combinations in products and cold preparations as an analgesic agent. The amount per dosage unit ranges from 97.2 to 400 mg salicylamide in such combinations. It has also been marketed at higher doses as prescription products for its anti-inflammatory activity. In addition, the Panel has also considered the use of salicylamide in combination as an OTC analgesic-adjuvant elsewhere in this document. (See part II, paragraph B.5. below—Salicylamide.)

1. **Effectiveness.** Salicylamide is currently marketed as an OTC analgesic-antipyretic agent. It is used primarily in a wide variety of OTC analgesic combinations in products and cold preparations as an analgesic agent. The amount per dosage unit ranges from 97.2 to 400 mg salicylamide in such combinations. It has also been marketed at higher doses as prescription products for its anti-inflammatory activity. In addition, the Panel has also considered the use of salicylamide in combination as an OTC analgesic-adjuvant elsewhere in this document. (See part II, paragraph B.5. below—Salicylamide.)

The rate and extent of salicylamide metabolism by the human body varies. Because of the unique characteristics of salicylamide metabolism, it is not possible to compare the rate and extent of salicylamide metabolism to that of another salicylatoid drug. The metabolism of salicylamide, a non-salicylate, is unusual in that virtually no active (unmetabolized) salicylamide is available for therapeutic action. This initial absorption (transit) of the drug before it becomes available in the systemic circulation is called the absorption phase. The rapid rate of elimination noted by earlier authors is due to the metabolism of the drug during the absorption phase by intestinal and/or liver drug conjugating enzymes systems. Once the drug has been metabolized principally to glucuronide and sulfate conjugates by intestinal and primarily hepatic metabolizing systems. The rate and extent of salicylamide metabolism by the human body varies. Because of the unique characteristics of salicylamide metabolism, it is not possible to compare the rate and extent of salicylamide metabolism to that of another salicylatoid drug. The metabolism of salicylamide, a non-salicylate, is unusual in that virtually no active (unmetabolized) salicylamide is available for therapeutic action. The metabolism of salicylamide, a non-salicylate, is unusual in that virtually no active (unmetabolized) salicylamide is 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 metabolites 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 saturable 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 levels are indirectly influenced by the dose given (Ref. 14) as illustrated in the following table:

<table>
<thead>
<tr>
<th>Dose (mg)</th>
<th>200 mg</th>
<th>1,000 mg</th>
<th>2,000 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma levels (micrograms per milliliter) of active (unmetabolized) salicylamide</td>
<td>11.3</td>
<td>2.0</td>
<td>x2.0</td>
</tr>
</tbody>
</table>

1 Plasma levels could not be detected.

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 concentrations (10 to 20 fold) are observed. Based on other information (Refs. 13 and 15), these workers concluded that with smaller doses (300 to 600 mg) the drug was virtually completely absorbed 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) drug would not be evident if only total drug was measured in plasma or urine (Refs. 13 through 15).

Dosage formulation also can influence the systemic availability and plasma blood 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 blood levels of salicylamide plasma concentration reached by the suspension was greatly reduced (2 µg/ml), the tablet reached a higher level (3 µg/ml) and greater area under the plasma time curve but took a longer time for the peak concentration to be reached, whereas the solution provided the highest peak plasma level (13.6 µg/ml), a significantly greater area under the plasma time curve. The following table summarizes the peak plasma concentration of free drug reached with each dosage form:

| Dosage form related effects—comparison of peak plasma concentrations following administration of 1,200 mg of different dosage forms |
|-----------------------------|----------------|----------------|
| Microgram per milliliter    | Solution, aqueous | Tablet (commercial) |
| 13.6                        | 13.0            | 12.0           |

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 are due to increased metabolism during absorption. This is a result of the saturation of free drug from the solid dosage forms.

The salicylamide suspension was quite viscous and the slow release resulted in drastically reduced plasma levels. It is significant that this formulation was used in early clinical trials and illustrates the difficulties in assessing clinical 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 saturable metabolism during the absorptive phase account for earlier difficulties in establishing a safe and efficacious dosage and standard for bioavailability studies. Based upon current understanding, the Panel finds that this remains to be done.

(ii) Effectiveness as a single ingredient.

(a) Analgesic activity in animals.

Several workers noted that the pharmacologically active (unmetabolized) salicylamide is rapidly eliminated from the body by hepatic metabolism (Refs. 5 and 6) to the corresponding glucuronide and sulfate conjugates (Refs. 7 through 12). These water soluble conjugates of salicylamide are considered to be pharmacologically inactive and are rapidly eliminated by the kidney (Refs. 11 and 12).

Very little active (unmetabolized) salicylamide can be detected in the plasma or urine after usual oral single doses of 300 to 600 mg. Most earlier blood level studies, therefore, measured only total drug (active drug plus metabolite). It is now clear that for a drug with nonlinear metabolism, the amount of parent drug not linearly related to the dose, like salicylamide, analytical methods measuring the concentrations of total drug alone provide no information on the bioavailability (systemic availability) of the parent drug, i.e., the amount of unmetabolized drug reaching the systemic circulation after oral administration.

Levy and Matsuwa (Ref. 13) demonstrated that the metabolism of salicylamide was saturable since changes in the ratio of the amounts of sulfate and glucuronide conjugates appearing in the urine occurred with different doses and different dosage forms.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
man by salicylamide may be due to its rapid absorption, early peak blood levels, extensive metabolism and rapid excretion (Refs. 9, 10, and 17). In five healthy subjects administered 2,000 mg salicylamide, 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 the extensive metabolism during the absorptive phase, doses of 600 mg or less would not be expected to have significant analgesic effects; use of dosage forms which have slow drug release characteristics; decreased systemic availability; failure to use more than one dosage level; and failure to show the duration of action.

Clinical studies in humans have not demonstrated any superiority of salicylamide over aspirin. Several studies used low doses and could not distinguish the drug from placebo. Higher doses with higher doses have established analgesic activity. Litter et al. (Ref. 10) reported an analgesic effect of salicylamide in 90 of 118 subjects (75 percent) with a variety of arthritis diseases. The total daily dose found to cause analgesia in these rheumatoid 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 Houde (Ref. 20), and Wallenstein, Houde and Beaver (Ref. 21) compared aspirin, salicylamide and acetaminophen in a double-blind study using placebo, in 27 patients with chronic pain due to advanced cancer. Each patient received at least one dose of each drug and replicated data was obtained on 17 patients. Following the use of salicylamide, pain intensity for a 6-hour period after 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 only. This difference in the activity of salicylamide was explained by the rapid metabolism of salicylamide to an inactive compound resulting in a very short duration of action.

Batterman and Grossman evaluated 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 of the subjects had pain due to osteoarthritis and one subject complained of hematurympathic spasm or strain. They concluded that salicylamide was not an effective analgesic or anti-inflammatory 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 bordermotheroscopy, the poor choice of patient population (pain due to osteoarthritis), and the poor choice of a standard which also has anti-inflammatory effects, this study also failed to statistically distinguish myalgia 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 adequate and consistent analgesic activity. This compound has unique properties that make it mandatory to clearly delineate the dose form relation and the dose effects on systemic availability during such studies using analytical methods and pharmacokinetic studies which measure active (unmetabolized) salicylamide in plasma.

(2) Safety. The Panel concludes that salicylamide is ineffective in currently recommended doses of 300 to 600 mg and therefore, is not indicated for safety and should be placed in Category III. In addition at doses that may be effective, i.e., 1,000 mg every 4 hours not to exceed 6,000 mg in 24 hours for not more than 3 days, salicylamide 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 in dosages that can produce analgesia, 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 decreased hepatic effects. Adequacy of dosage required to reach therapeutic plasma levels. Batterman and Grossman noticed side effects in 31 percent of patients taking 600 mg of salicylamide every four hours for 4 days. These effects, which were evenly distributed between gastrointestinal and central nervous system manifestations (Ref. 26).

Three cases of purpura attributed to salicylamide have been reported. Stettbacher 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).

Greig reported two cases of "black and blue" areas caused by effects on the blood clotting mechanism (thrombocytopenic purpura) in 1955 (Ref. 27). One woman took a total of 300 g orally in 50 days and developed the usual symptoms of thrombocytopenic purpura 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 with hypoplasia of all elements in both women.

Very large doses of salicylamide can produce effects similar to those of the salicylates including ringing of the ears, ecchymoses, hemorrhagic lesions, leukopenia and thrombocytopenia. Barr and Penna (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 were hospital 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 up to 5 years of age received 120 mg/dose and those over 5 years of age received 300 mg/dose. Since the ages of the patients are not specified, the Panel assumes that they are all below 12 years of age. They were compared with 27 patients who received aspirin at the same salicylamide dosage. Salicylamide had "practically no anti-inflammatory or analgesic action. Anderson noted a mild sedative reaction. In addition, however, five patients with no evidence of respiratory disease had a significant blood urea nitrogen rise after 4 days. Another five patients with no demonstrable liver 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. Anderson found these 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 study in older 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 reason 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 information 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 this review, the Panel recommends further studies as to the toxic effect of therapeutic doses on liver and kidney function. It would also be desirable to clarify what, if any, effect formulation has on toxic manifestations.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
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 show that, in contrast to the salicylates, there is 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. 12). Salicylamide has no effect on bleeding time (Ref. 29), 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 is rapidly absorbed 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 ineffective when salicylamide is used as a single analgesic (or antipyretic) agent.

Doses of 600 to 1,000 mg may be effective depending on the characteristics of the dosage form which should be individually evaluated for each product. The true incidence and nature of adverse effects at this dosage level is not well established and must also be characterized by a well-designed study.

Studies to establish safety and/or effectiveness must include an assessment of the systemic availability of the unmetabolized parent drug. Pre and postrenal clearance of renal and intestinal metabolism which have been identified in the literature, are needed including those for CNS, gastrointestinal, hematopoietic and hepatic functions.

RECOMMENDATIONS

I. Use of OTC Product. A single product containing salicylamide alone was submitted to the Panel. Currently marketed products contained 97.5 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 8,000 mg/24 hours or up to 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 conducted 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.

In addition, the Panel has also considered the use of salicylamide as an OTC analgesic adjunct 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.)

Additional information from carefully planned clinical studies is required in order to establish effective dosage, select formulations that provide 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 formulation prior to testing.

(5) 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 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


Salsalate (salicylsalicylic acid) is an ester of salicylic acid and salicylsalicylic acid. The Panel concludes that there are insufficient data to determine that salsalate is either safe or effective as an OTC analgesic. In the recommended dosage range 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.

1. Effectiveness. Salsalate, also known as salicylsalicylic acid, is more closely related to the nonacetylated salicylates than it is to aspirin (an acetylated salicylate). However, unlike most of the other salicylates reviewed by the Panel, this ingredient is highly insoluble (Refs. 1, 2, 3). In fact, Beaver notes that salsalate seems to hydrolyze slowly in the stomach, which may result in slow or incomplete absorption (Ref. 3). Although salsalate is discussed in several standard medical texts, little work has been done on this ingredient (Refs. 2 and 4).

In one uncontrolled, unpublished study, salsalate was compared to aspirin on the basis of analgesic effect in a double-blind comparison of headache treatment in 30 subjects (Ref. 9). Aspirin was given at a dose of 600 mg and salsalate at a dose of 1,000 mg. Aspirin produced a faster onset of analgesia, but the difference did not produce a significant advantage. They also noted that it showed a slight superiority in degree of pain relief. However, they felt this difference in degree of pain relief was not significant. While it is likely that salsalate might be an effective analgesic, the Panel concludes that, because of its insolubility and slow absorption, at least it is only 1/3 as potent as aspirin.

2. Safety. Salsalate (salicylsalicylic acid) is an ester of two molecules that hydrolyzes to yield the parent compound and thus it is considered by some to be pharmacologically indistinguishable from salicylic acid. However, there appears to be no justification in the literature for such a simplistic view of the pharmacokinetic and pharmacologic properties of this compound. Following oral administration of salicylsalicylic acid and calcium carbaspirin in 1925 (Ref. 8), there were apparent no additional published studies on plasma levels until the study of Rudin and colleagues in 1970 (Ref. 7). The study of Rudin (Ref. 7) indicates that a significant amount of unhydrolyzed drug reaches the systemic circula-

PROPOSED RULES
testinal and blood clotting side effects of aspirin or the other salicylates. Until studies showing these effects are complete, it seems that the severity and incidence of adverse reactions, either prior to or after absorption, would be comparable to that of aspirin and other acetylated buffered salicylates discussed previously in this document. Until studies show that salicylate has different absorption characteristics and these characteristics are correlated with greater safety, all manufacturers should put comparable 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

(9) OTC Volume 030156.

CATEGORY III LABELING

The Panel concludes that the Category I labeling claims are sufficiently broad to encompass the various specific types of pain, e.g., "body aches", "muscle aches", etc. As noted above, 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 I Labeling and 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 classified 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. Should be taken by certain individuals with stomach disorders as cautioned elsewhere on the label", and b. "Paster 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 should be 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 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 the stomach distress that aspirin presents since it causes stomach disorders as cautioned elsewhere on the label". The basis for this classification is discussed under analgesics 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 I are in accord with the present state of the art and do not preclude the use and advance of improved methodology in the future.

1. Considerations in designing an experimental protocol for testing analgesic drugs. General Principles. The important Panel has considered 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 in a significant and advanced way. The basis for this classification is discussed under analgesics in this document. (See part III paragraph 1.d.2. above—Safety.)

b. Animal screening tests and most methods employing experimental pain in normal human volunteers have failed to predict with any consistency or performance of analgesic drugs, particularly those used for OTC medication.

c. The most successful efforts to quantitate pain in the clinical situation have been those that have accepted the patient's own report of the magnitude of the pain experience and of the relief resulting from analgesic administration. Various criteria for analgesia may be used successfully, but whichever is used should be well defined, and each should not be confused with analgesia.

2. Determination of the patient population. A large number of appropriate subjects with different types of pain should be studied for the analgesic effect of mild analgesics. The subjective response variable change in pain intensity or pain relief are the usual effects studied. The major criteria for subjects should be those with mild to moderate pain. Subjects who have pain due to inflammatory conditions should be differentiated from those who have pain from other conditions. 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. The study should 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 randomization procedure balances the variables not otherwise controlled in the patients. An example 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 subjects' characteristics is necessary to allow for the adequate interpretation of results. Furthermore, all exclusions from the experimental protocol should be stated.

Allusion 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 and generate a time—response curve that is similar to many of the curves generated by the mild analgesics. However, the active compound will yield significantly more relief.

Much has been written about the placebo responder. The response of patients to an inert compound or a placebo complicates the evaluation of analgesics. It is known that response to placebo is not necessarily consistent within themselves. Some believe that the degree of placebo response among the population is in some respects a measure of the rapport the investigator has with the patients in the population. There is nothing gained from determining who responds to a placebo and from eliminating them from the analysis of the data of the analgesic study. Furthermore, it has been shown that the patients responding to placebo are not necessarily consistent within themselves. That is, if they respond positively to placebo in one trial, in the next trial they may respond negatively and vice versa.

3. Test parameters for study. a. General considerations.—Regardless of the parameters studied to evaluate the effectiveness 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 whenever possible.

(3) Consideration should be given to the type of pain present in the patient populations used in the various studies, since conflicting reports could arise from the fact that certain of the mild analgesics have no effect on their effects to actions directed at relieving the cause of the pain, e.g., anti-inflammatory.

(4) Suitable controls should be introduced, graded doses of an analgesic...
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 test drug and allows for the establishment of a dose-response relationship. 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 assess (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 of drug effects, even if proven, can be virtually meaningless.

(7) Results of single dose studies should not be extrapolated to predict the effect of the chronic use of a drug.

(8) Prior to carrying out an anagelosis 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 analgesic effectiveness. In the case of naloxone or similar variants of an analgesic, e.g. meperidine or morphine, for which effectiveness has been established, crossover bioavailability studies may be used to establish effectiveness. In these studies blood levels 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 parent compound and major active metabolites may be equated with effectiveness.

4. Data interpretation. To establish Category I status for a Category III compound requires at least two studies by 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 90 subjects, placebo and known 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, blood and organ 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 favorable and any unfavorable results.

5. Safety evaluation. An evaluation of the safety of an analgesic ingredient should be based on the usual animal studies and observations in man relevant to the various organs and systems, such as the gastrointestinal system, the kidneys, the effect on 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 aspirin as a 650 mg (10 gr) dose. The scoring of pain and/or relief should be done frequently during the expected duration of action to justify its continued inclusion in combinations.

c. Each component must make a statistically significant contribution to the total effect. For instance, this could be determined by factorially designed studies. 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


IV. ANTIPYRETIC AGENTS

A. GENERAL DISCUSSION.

Antipyretics are used to reduce the body temperature when it is above the normal value of 98.6°F (37°C). The OTC antipyretics are intended primarily for the symptomatic reduction of fever. If the fever is over 103°F (39.5°C), persists for more than 72 hours, or recurs, measures in addition to antipyresis should be considered. The Panel concludes that to specify a specific temperature in the label warning would not be meaningful. A specific temperature above the normal range of 98.6°F to 100.4°F (37°C to 38°C) the patient would be symptomatic of a disease state requiring the diagnosis and treatment of a physician cannot be established by the Panel.

The Panel does not believe that a fever secondary to an undiagnosed condition should be allowed to persist for more than 3 days. The Panel recognizes the long standing use of OTC analgesic-antipyretic products without any specific limitation on the use of them as antipyretics. In most instances, the labeling contains a general warning statement, not specific to fever, for use up to 10 days. In view of the marketing experience with the 10 day warning, the Panel recommends that all future labeling be readily distinguishable and clearly limit use of antipyretic products to 3 days (72 hours) in the presence of fever. The Panel recommends that all future labeling of antipyretic products include the warning: "If fever persists for more than 3 days (72 hours), or recurs, consult your physician.

The Panel believes that it is important to differentiate in the labeling between the use of the product as an antipyretic and its use as an analgesic. It may be that some antipyretics have a relative potency which is less than one would predict from their analgesic relative potency. If a single antipyretic ingredient for which relative potency has been computed in man. For this reason, the Panel recommends that the labeling on all preparations containing analgesic-antipyretic ingredients list the same dose for antipyretic use as that required for the analgesic effect since our present state of knowledge is uncertain as to the optimal dose for antipyretic activity.

The question has properly been raised whether a fever should be treated at all. This subject has been argued at length and the Panel recognizes that not every fever requires immediate treatment. In children especially, febrile convulsions are a concern to the pediatrician and to the parent.

There are some disadvantages to antipyretic therapy, for instance, in the patient who has just been started on an antibiotic for the treatment of an infection. The response to the antibiotic can be judged by the reduction in fever. It is important to recognize the febrile reaction, and not misinterpret it. Some physicians argue that by giving an antipyretic, the one sign, reduction in body temperature, which can be followed easily to determine the effectiveness of the antibiotic for the treatment of an infection has been obscured. It is also possible that in patients with undiagnosed disease, the febrile course may be of diagnostic importance because of its particular characteristics. In a fever, fever may in fact be a progressively rising temperature indicates to the physician that things are not going well and additional examination, diagnostic procedures, treatment or perhaps hospitalization may be necessary. These arguments for and against antipyretic treatment have been discussed by Done (Ref. 1).

The Panel finds that antipyretics fill a role useful in the OTC management of symptomatic relief of fever. The Panel believes that there is a suitable target population that can benefit from the use of such OTC products. However, the fever may be a prodromal indicator that things are not going well and additional examination, diagnostic procedures, treatment, or perhaps hospitalization may be necessary. These arguments for and against antipyretic treatment have been discussed by Done (Ref. 1).

The Panel finds that antipyretics fill a role useful in the OTC management of symptomatolc relief of fever. The Panel believes that there is a suitable target population that can benefit from the use of such OTC products. However, the fever may be a prodromal indicator that things are not going well and additional examination, diagnostic procedures, treatment, or perhaps hospitalization may be necessary. These arguments for and against antipyretic treatment have been discussed by Done (Ref. 1).

The Panel does not believe that a fever secondary to an undiagnosed condition should be allowed to persist for more than 3 days. The Panel recognizes the long standing use of OTC analgesic-antipyretic products without any specific limitation on the use of them as antipyretics. In most instances, the labeling contains a general warning statement, not specific to fever, for use up to 10 days. In view of the marketing experience with the 10 day warning, the Panel recommends that all future labeling be readily distinguishable and clearly limit use of antipyretic products to 3 days (72 hours). In the presence of fever.

b. Combinations should 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 aspirin as a 650 mg (10 gr) dose. The scoring of pain and/or relief should be done frequently during the expected duration of action to justify its continued inclusion in combinations.

c. Each component must make a statistically significant contribution to the total effect. For instance, this could be determined by factorially designed studies. 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


2. CATEGORIZATION OF DATA.

1. Category I conditions under which antipyretic agents are generally recognized as safe and effective and are not misbranded:

Aspirin
Acetaminophen
Acetaminophen
Magnesium salicylate
Calcium salicylate
Calcium salicylate

a. Aspirin. The Panel concludes that aspirin is a safe and effective OTC anti-

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

35445
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 in 24 hours for not more than 3 days. (1) Effectiveness. In animals, as well as in man and findings presented, prove the antipyretic and effective antipyretic. Although many clinical studies are poorly designed and the evidence is often anecdotal, there are well-documented and carefully analyzed studies showing that aspirin is a potent antipyretic agent. (Refs. 1 through 10).

The most carefully conducted study is that of Seed (Ref. 6) 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. 5), 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. Therefore, there is no advantage to giving these drugs in combination for their antipyretic effect. The drugs in this study were used alone and at the same dosage in the combination. Therefore, if an observable interaction is observed, the interaction may be due merely to the increase in dosage because of the presence of both drugs. Statistically, there is no way of calculating the interaction in this study. However, the data of the observed interaction in combination represents a simple addition, potentiation or indeed even antagonism.

(2) Safety. The safety of aspirin has been discussed earlier in this document. (See part III. paragraph B.1.a. above—Safety.)

(3) Dosage. (i) 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 480 mg (7.38 gr) every 4 hours while fever persists not to exceed 2,400 mg (36.9 gr) in 24 hours for not more than 3 days. Children 9 to under 11 years oral dosage is 400 mg (6.15 gr) every 4 hours while fever persists not to exceed 1,200 mg (18.45 gr) in 24 hours for not more than 3 days. Children 7 to under 9 years oral dosage dose is 320 mg (4.92 gr) every 4 hours while fever persists not to exceed 1,000 mg (15.74 gr) in 24 hours for not more than 3 days. Children 4 to under 6 years oral dosage is 240 mg (3.69 gr) every 4 hours while fever persists not to exceed 800 mg (12.3 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.

(ii) For products containing more than 325 mg (5 gr) but not more than 411 mg (6.48 gr) per dosage unit. Adult oral dosage is more than 325 mg (5 gr) but not more than 500 mg (7.69 gr) every 4 hours while fever persists not to exceed 2,437.5 mg (36.9 gr) in 24 hours for not more than 3 days. Children 2 to 4 years oral dosage is 180 mg (2.86 gr) every 4 hours while fever persists not to exceed 800 mg (12.3 gr) in 24 hours for not more than 3 days. Children 6 to under 9 years oral dosage is 145 mg (2.24 gr) every 4 hours while fever persists not to exceed 650 mg (9.76 gr) in 24 hours for not more than 3 days. Children under 6 years 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 3 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 411 mg (6.48 gr) but not more than 455 mg (7.46 gr) per dosage unit. Adult oral dosage is more than 421 mg (6.48 gr) but not more than 500 mg (7.69 gr) every 4 hours while fever persists not to exceed 2,437.5 mg (37.5 gr) in 24 hours for not more than 3 days. Children 9 to under 11 years oral dosage is 400 mg (6.15 gr) every 4 hours while fever persists not to exceed 2,031.5 mg (31.25 gr) in 24 hours for not more than 3 days. Children 6 to under 9 years oral dosage is 320 mg (4.92 gr) every 4 hours while fever persists not to exceed 1,625 mg (25 gr) in 24 hours for not more than 3 days. Children 4 to under 6 years oral dosage is 240 mg (3.69 gr) every 4 hours while fever persists not to exceed 1,205 mg (18.75 gr) in 24 hours for not more than 3 days. Children 2 to under 4 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. Children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

(b) Nonstandard schedule. — Adult oral dosage is 325 mg (5 gr) to 976 mg (15 gr) in 24 hours for not more than 3 days. Children 11 to under 12 years oral dosage is 480 mg (7.38 gr) every 4 hours while fever persists not to exceed 2,400 mg (36.9 gr) in 24 hours for not more than 3 days. Children 9 to under 11 years oral dosage is 400 mg (6.15 gr) every 4 hours while fever persists not to exceed 1,200 mg (18.45 gr) in 24 hours for not more than 3 days. Children 7 to under 9 years oral dosage is 320 mg (4.92 gr) every 4 hours while fever persists not to exceed 1,000 mg (15.7 gr) in 24 hours for not more than 3 days. Children 4 to under 6 years oral dosage is 240 mg (3.69 gr) every 4 hours while fever persists not to exceed 800 mg (12.3 gr) in 24 hours for not more than 3 days. Children under 6 years 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 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 the Category I labeling for antipyretic active ingredients. (See part IV. paragraph E. above—Category I Labeling.) In addition, the Panel recommends the following specific labeling: (1) 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.

(ii) Standard aspirin dosage unit. In the previous discussion on "standard strength" dosage forms, the Panel made clear the need to indicate both the quantity of aspirin per tablet, teaspoon or other dosage unit as well as the quantity by which a particular product containing aspirin differs per dosage unit from the established standard of 325 mg (5 gr) aspirin per dosage unit. (See part II. paragraph E. above—Standard Dosage Unit and Analgesic Equivalence.)

The Panel recommends that all 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 alert those individuals having sensitivity to aspirin.

Product containing aspirin is an amount different than 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.

Product 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 shall state in metric units the quantity of aspirin per dosage unit. The following specific labeling: "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

aspamin 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 therapeutic effective dosage of 325 to 650 mg every 4 hours for symptomatic relief of fever. In addition, acetaminophen is absorbed more rapidly and appears to have a shorter duration of action compared to aspirin when given in 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 acetaminophen has been discussed earlier in this document (see paragraphs 1.1 to 1.2 above—Safety.)
(3) Dosage. (i) 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 487.5 mg (7.5 gr) every 4 hours while fever persists not to exceed 4,375.5 mg (7.5 gr) in 24 hours for not more than 3 days. Children 9 to under 11 years oral dosage is 406.3 mg (6.3 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 6 to under 9 years oral dosage is 320 mg (5 gr) every 4 hours while fever persists not to exceed 1,525 mg (25 gr) in 24 hours for not more than 3 days. Children 4 to under 6 years oral dosage is 243.8 mg (3.75 gr) every 4 hours while fever persists not to exceed 1,119 mg (18.75 gr) in 24 hours for not more than 3 days. Children 2 to under 4 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.
(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. Children 11 to under 12 years initial dosage is 487.5 mg (7.5 gr) every 4 hours while fever persists not to exceed 4,375.5 mg (7.5 gr) in 24 hours for not more than 3 days. Children 9 to under 11 years initial dosage is 406.3 mg (6.3 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 6 to under 9 years initial dosage is 320 mg (5 gr) every 4 hours while fever persists not to exceed 1,525 mg (25 gr) in 24 hours for not more than 3 days. Children 4 to under 6 years initial dosage is 243.8 mg (3.75 gr) every 4 hours while fever persists not to exceed 1,119 mg (18.75 gr) in 24 hours for not more than 3 days. Children 2 to under 4 years initial 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. Children 12 to under 18 years initial dosage is 325 mg (5 gr) every 4 hours while fever persists not to exceed 4,000 mg (61.52 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.

(b) Nonstandard dosage. (i) Oral antipyretic effect of acetaminophen is not significantly different from aspirin. The data of Steele et al. and constructs mean temperature 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.

(b) Nonstandard. (i) Oral antipyretic effect of acetaminophen is not significantly different from aspirin. The data of Steele et al. and constructs mean temperature 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.

(b) Nonstandard. (i) Oral antipyretic effect of acetaminophen is not significantly different from aspirin. The data of Steele et al. and constructs mean temperature 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.


(11) Otga Volume 006050.

c. Calcium carbaspirin. The Panel concludes that calcium carbaspirin is a safe and effective OTC antipyretic when taken in the recommended dosage of 414 to 828 mg every 4 hours while fever persists not to exceed 4,968 mg in 24 hours for not more than 3 days.

(1) Effectiveness. The Panel concludes that calcium carbaspirin is effective, not based on controlled clinical studies, but on the fact that the absorbed moiety is aspirin itself which has been demonstrated to be safe and effective in controlled trials. The adequate bioavailability has been established demonstrating an effect similar to aspirin. (Ref. 1 and 2). (See part III paragraph B.1.c. above—Calcium carbaspirin).

(2) Safety. The safety of calcium carbaspirin has been discussed earlier in this document. (See part III paragraph B.1.c. above—Calcium carbaspirin). The Panel recommends that products containing calcium carbaspirin 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.

(3) Dosage. Adult oral dosage is 435 to 870 mg every 4 hours while fever persists not to exceed 5,220 mg in 24 hours for not more than 3 days. Children 11 to under 12 years oral dosage is 652.5 mg every 4 to 8 hours while fever persists not to exceed 1,275 mg in 24 hours for not more than 3 days. Children 9 to under 11 years oral dosage is 543.8 mg every 4 hours while fever persists not to exceed 2,175 mg in 24 hours for not more than 3 days. Children 7 to under 9 years oral dosage is 435 mg every 4 hours while fever persists not to exceed 1,275 mg in 24 hours for not more than 3 days. Children under 7 years, there is no recommended dosage except under the advice and supervision of a pediatrician.

(4) Labeling. The Panel recommends the Category I labeling for antipyretic active ingredients. (See part IV, paragraph B.1. below—Category I Labeling.) In addition, the Panel recommends the following specific labeling: (1) Warnings.

"Do not take this product if you are allergic to salicylates except under the advice and supervision of a physician.

"Do not take this product if you have asthma except under the advice and supervision of a physician.

"Do not take this product if you have a history of urticaria or urticarial rash except under the advice and supervision of a physician.

"Do not take this product if you have a history of allergy to aspirin or if you have asthma except under the advice and supervision of a physician.

"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.

"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.

"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.

"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."
simple, a product containing 435 mg choline salicylate per tablet (dosage unit) shall be labeled, “Equivalent to 325 mg per tablet, teaspoon containing standard of 325 mg sodium salicylate per tablet.”

REFERENCES

Magnesium salicylate. The Panel concludes that magnesium salicylate is safe and effective as an OTC antipyretic in children under 12 years of age. More than 485 mg but not more than 500 mg of magnesium salicylate per tablet, teaspoon, or other dosage unit as well as the quantity by which a particular product containing magnesium salicylate differs clinically 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 Equivalence Value.) 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 established standard of 325 mg sodium salicylate per dosage unit.”

f. Sodium salicylate. The Panel concludes that sodium salicylate 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 4,000 mg in 24 hours for not more than 3 days. (1) Effectiveness. Although sodium salicylate is 0.6 times as potent as aspirin (Refs. 1 and 2), this is the only controlled study in children under 12 years, there is no recommended dosage except under the advice and supervision of a physician. The safety of sodium salicylate in this population was investigated the antipyretic effects in patients with chronic cancer and associated infectious processes. He determined that sodium salicylate was 0.8 times as potent as aspirin (Refs. 1 and 2). This is the only controlled study in which an assay was carried out so that the relative potency of one antipyretic as compared with the standard, aspirin, could be determined.

(ii) 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 clinically 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 Equivalence Value.)

(iii) Analgesic equivalence value. 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 established standard of 325 mg sodium salicylate per dosage unit.”

(ii) 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 421 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 3 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 421 mg but not more than 485 mg every 3 hours while symptoms persist not to exceed 3,900 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.

(iv) 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 500 mg initially, followed by more than 485 mg every 4 hours while symptoms persist not to exceed 4,880 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.

(v) For products containing more than 500 mg but not more than 650 mg per dosage unit. Adult oral dosage is more than 500 mg but not more than 650 mg initially, followed by more than 650 mg every 4 hours while symptoms persist not to exceed 6,380 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.

(iv) 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 500 mg initially, followed by more than 485 mg every 4 hours while symptoms persist not to exceed 4,880 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.

(v) For products containing more than 500 mg but not more than 650 mg per dosage unit. Adult oral dosage is more than 500 mg but not more than 650 mg initially, followed by more than 650 mg every 4 hours while symptoms persist not to exceed 6,380 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.

Labeling. The Panel recommends the Category I labeling for antipyretic active ingredients. (See Part IV. paragraph B.1.f. 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 0.2 mg (5 mg) or higher of sodium salicylate 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 is 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 of 325 mg sodium salicylate per dosage unit may 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 contain only 325 mg sodium salicylate per dosage unit it is possible for the Food and Drug Administration to be 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 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" 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


CATEGORY I ACTIVE INGREDIENTS

The Panel has classified the following claimed antipyretic active ingredients as not generally recognized as safe and effective or as misbranded:

Acetaminophen
Phenacetin
Iodopyrine
Quinine

b. Acetaminophen. The Panel concludes that acetaminophen is an effective antipyretic when taken in the recommended dosage of 200 to 300 mg but is not safe for OTC use.

(1) Effectiveness. No suitable designed clinical trials on acetaminophen have been reported in the literature. Nevertheless, it is recognized that acetaminophen is an effective antipyretic agent.

In the AMA Drug Evaluations, acetaminophen is listed as having historical interest because it is the first salicylate antipyretic introduced into medicine (Ref. 1). However, it is stated that there is "no justification for using acetaminophen in preference to aspirin and equally effective mild analgesics.

(2) Safety. The Panel concludes after a review of the literature that this drug is not safe for OTC use.

The safety of acetaminophen has been discussed earlier in this document. (See part III, paragraph B.2.a.(2) above—Safety.) The Panel concludes that this drug is not safe for use as an OTC antipyretic.

3. Iodopyrine. The Panel finds that iodopyrine is not safe for OTC use.

(1) Effectiveness. No studies were found concerning the effectiveness of this iodide salt of antipyrine for use as an OTC antipyretic. 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.(3) above—Effectiveness.)

(2) Safety. The safety of iodopyrine has been discussed earlier in this document. (See part III, paragraph B.2.a.(2) above—Safety.) The Panel concludes that iodopyrine is not safe for use as an OTC antipyretic.

c. Phenacetin. The Panel concludes that phenacetin is an effective OTC antipyretic but not safe for OTC use because of the high potential for abuse, the high potential for harm to the kidney through phenaetin or acetaminophen (Ref. 2). Severe methemoglobinemia occurs and possibly sulfhemoglobinemia. The dose required to produce these changes varies from one individual to another, and therefore the risk of dependence on the drug may occur (Ref. 3).

Acetanilid has practically disappeared from use since it is rapidly converted to aniline which causes methemoglobinemia (Ref. 4). Furthermore, it has been implicated in the production of hemolysis in glucose-6-phosphate dehydrogenase deficient individuals who form a significant proportion of the target population (Ref. 5).

Evaluation. The Panel concludes because of the high incidence of toxic effects and the relative unfavorable margin of safety that the risks from use outweigh any benefit and therefore classifies acetanilid not safe for use as an OTC antipyretic.
and the possibility of hemolytic anemia and methemoglobinemia resulting from abuse (Ref. 1), and the lack of compensating benefits of the drug. The benefit to risk ratio of phenacetin compounds compares unfavorably with other single active ingredients to exceed the preparatory preparations available to target populations.

1. Effectiveness. The antipyretic effect of phenacetin has been investigated by Mintz (Ref 2). He studied the comparative antipyretic effects expressed in 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 whether it was expressed as a 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 full doses of phenacetin. Thus, phenacetin appears to be half as effective as aspirin in terms of its antipyretic effects.

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 the use of phenacetin is not safe for OTC use.

a. Aluminum aspirin. The Panel concludes that there are insufficient data to determine effectiveness as an 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. Children 11 to under 12 years oral dosage is 930 mg every 4 hours for not more than 3 days. Children 9 to under 11 years oral dosage is 730 mg every 4 hours for not more than 3 days. Children 6 to under 9 years oral dosage is 530 mg every 4 hours for not more than 3 days. Children 4 to under 6 years oral dosage is 305 mg every 4 hours for not more than 3 days. Children 2 to under 4 years oral dosage is 150 mg every 4 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.

b. "Do not take this product during the last 3 months of pregnancy except under the advice and supervision of a physician.

c. "Do not take this product for at least 7 days after tonsillectomy or oral surgery except under the advice and supervision of a physician.

(ii) Analgesic equivalence value. In the previous discussion on "standard strength" dosage forms 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 2. above—Standard Dosage Unit and Analogous Evaluation 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 and dosage form is to be determined by the manufacturer and listed on the label. The following information is needed: Blood levels of aspirin in human and animal studies, which must be exceeded before any antipyretic effect is seen. The results of these studies and the knowledge of the dose-response relationship must be used to show comparable blood levels of aspirates to those following administration of the standard aspirin, as detailed below. (See part IV. paragraph C. below—Data Required for Evaluation.)

b. Antipyrine. The Panel concludes that there are insufficient data to determine the safety and effectiveness of antipyrine as an OTC antipyretic when, as recommended, the dose is limited to a single 975 mg dose in 24 hours while symptoms persist 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. (1) Effectiveness. As far as effectiveness is concerned, no single controlled clinical study has been found in which the antipyretic properties of antipyrine have been evaluated.

The effectiveness of antipyrine as an analgesic has been discussed earlier in this document. (See part III. paragraph B.3.b.(1) above—Effectiveness.)

(2) Safety. The safety of antipyrine has been discussed earlier in this document. (See part III. paragraph B.3.d.(2) above—Safety.)

3. Proposed dosage. Adult oral dosage is limited to a single 975 mg dose in 24 hours while symptoms persist 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 the following specific labeling: (1) Warnings: (a) "Do not exceed recommended dosage."

(b) "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 antipyretic drugs. (See part IV. paragraph C. below—Data Required for Evaluation.) Data to demonstrate safety should include epidemiological studies, animal studies, and clinical trials taking into consideration the concerns of the Panel. Interested drug manufacturers should consult with the Food and Drug Administration as to the design of such studies. The Panel concludes that salicylamide is either safe or effective when used in combination with acetaminophen or aspirin, and therefore classifies such combinations as Category III. The Panel has discussed the role of salicylamide in clinical trials 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

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
following specific labeling: Analgesic Equivalence Value. In the previous discussion on "standard strength" dosage forms the Panel made clear the need to indicate the quantity of salsalate per tablet, teaspoon or other dosage unit as well as the quantity by which a particular product containing salsalate differs per dosage unit from the established standard of 325 mg sodium salicylate per dosage unit. (See part II, paragraph E. above—Dosage Unit and Analgesic Equivalence Value.)

The Panel recommends that products containing salsalate 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, capsule, etc. For example, a product containing 500 mg salsalate per tablet (dosage unit) shall be labeled, "Equivalent to 325 mg per tablet of the established standard of 325 mg sodium salicylate 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, paragraphs A. 1, 2, below—Data Required for Evaluation.)

CATEGORY III LABELING

The Panel concludes that the Category I labeling claims are sufficiently broad to encompass the various types of fever due to "cold", etc. All other labeling claims relating to fever are unsupported by scientific data or sound theoretical reasoning and are classified Category II. (See part IV, paragraph B.1. above—Category I Labeling and part IV, paragraph B.2. above—Category II Labeling.)

In addition, the Panel has examined the labeling claims for aspirin and has classified 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 aspirin occasionally causes but should not be taken on an empty stomach and may prevent the stomach distress that aspirin occasionally causes but should not be taken on an empty stomach and may prevent the stomach distress that aspirin occasionally causes but should not be taken on an empty stomach and may prevent the stomach distress that aspirin occasionally causes but should not be taken on an empty stomach and may prevent the stomach distress that aspirin occasionally causes but should not be taken on an empty stomach and may prevent the stomach distress that aspirin occasionally causes but should not be taken on an empty stomach and may prevent the stomach distress that aspirin occasionally causes but should not be taken on an empty stomach and may prevent the stomach distress that aspirin occasionally causes but should not be taken on an empty stomach and may prevent the stomach distress that aspirin occasionally causes but should not be taken on an empty stomach and may prevent the stomach distress that aspirin occasionally causes but should not be taken on an empty stomach and may prevent the stomach distress that aspirin occasionally causes but should not be taken on an empty stomach and may prevent the stomach distress that aspirin occasionally causes but should not be taken on an empty stomach and may prevent the stomach distress that aspirin occasionally causes but should not be..."), and b. "Paster to the bloodstream and standard compounds and possibly a placebo.

(2) The patient treatments should be allocated under a randomized scheme to distribute bias evenly.

b. Effects of the drug on the patient. The antipyretic effect of the drug should be evaluated by obtaining the patient's temperature at least every hour for 4 to 6 hours. The difference between the postdrug temperature and the predrug temperature can be used to calculate "the degree minutes" of lowering of the temperature. From the temperature lowering effect of the drug, the antipyretic effect can be done and the relative potency and fiducial limits of the test compound to the standard compound computed (Ref. 1).
You are an individual, not quite like anyone else. Your arthritis is not quite like anyone else's arthritis. How such aspirin you need for your disease, and how much you can safely take, will depend on your particular disease. Make a serious mistake when you act as your own doctor and try to figure out your own dosage 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, with establishment of a personalized treatment program, which may include not only OTC antirheumatic drugs, but also prescription medications (e.g., gold, phenylbutazone, indomethacin, hydroxychloroquine, corticosteroids, etc.), physical therapy, exercise, devices (braces, splints, crutches, etc.) and reconstructive surgical procedures. The Panel is concerned that any labeling conditions that occur if rheumatic diseases mislead the consumer who attempts to self-diagnose and self-treat a serious disease. Terms such as "arthritis," "rheumatism," "pain of arthritis," "minor aches and pains of arthritis," "pain of rheumatism," "minor pain of arthritis," "minor pain of rheumatism," "rheumatism," "rheumatoid arthritis," etc. and "rheum," "arthrod," "arthro-

The mistaken notion that joint aches and pains can be self-treated is instilled in the consumer by current labeling of OTC antirheumatic products, and by misleading advertising. In addition, the consumer is led to believe that there is no distinction between the joint aches and pains of different individuals. The impression is given that all aches, pains and other joint symptoms are medically the same. Consequently, such misleading labeling and advertising can have the proper daily dosage adjusted on an individual basis by a physician.

Because of the widespread current OTC use of aspirin and other salicylates in treating rheumatic diseases, the Panel recommends that all OTC products containing salicylates contain the warning, "Take this product for the treatment of arthritis only under the advice and supervision of a physician." The Panel is of the opinion that such a warning is necessary to inform the consumer not to self-diagnose and self-medicate for arthritis. In addition, the Panel concludes that the nonsalicylate, acetaminophen, is not an effective OTC antirheumatic agent. Consequently, the Panel recommends that no OTC products containing acetaminophen be included on OTC antirheumatic products and by misleading advertising. In addition, the consumer is led to believe that there is no distinction between the joint aches and pains of different individuals. The impression is given that all aches, pains and other joint symptoms are medically the same, and that 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 leave the consumer with the false idea that all joint aches, pains and stiffness are both "minor" and due to a single disease entity when in fact these same symptoms are present in indiduals who have many different rheumatic diseases. As with other rheumatic diseases, many of these rheumatic diseases are very serious and are not amenable to treatment with the OTC antirheumatic products. Although the pain associated with some rheumatic diseases may be relieved by these OTC antirheumatic products, the serious clinical features, which if untreated often lead to progressive degeneration and debilitation, may be unaffected by these products. Also, those inevitable rheumatic diseases that can be treated with these products often require a much higher daily dosage and more prolonged treatment than is required for the relief of pain alone.

There are no labeling claims, i.e., indications for use, for OTC antirheumatic drugs that are suitable for OTC marketed products. Labeling claims are limited to professional labeling (labeling of the products for health professionals but not for the general public). There is no suitable OTC dosage schedule nor directions for use that could be included on OTC antirheumatic products. Each person should therefore talk to their physician about their condition and not act as their own doctor and try to figure out their own dosage schedule.

In the discussion that follows, 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, producing pain (Ref. 3). Rheumatism also covers 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 when the joint itself is the major cause of the rheumatic disease. However, the disease involves much more than just aches and pains around a joint. In fact, inflamed joints may be only one manifestation of the many different diseases that can be termed arthritis. "In some of these conditions rheumatic complaints occur irregularly or constitutively at a single minor problem whereas in others joint disease may play an important role in the patient's illness." Other types of rheumatic diseases involve muscles, tendons, ligaments, or bursae and are referred to as rheumatism. According to the National Health Examination Survey conducted by the National Center for Health Statistics of the Department of Health, Education, and Welfare, more than 16 million people in the United States believed they had "arthritis" (Ref. 4).

2. Classification of rheumatic diseases

In this discussion, the Panel has referred to the classification of rheumatic diseases as proposed by the Nomenclature and Classification Committee of the American Rheumatism Association and officially adopted by that society in 1968 (Ref. 4).

The common property shared by most of the diseases and syndromes is that of an inflammatory involvement of the joints (chiefly the synovial joints) and/or para-articular structures. The three most common diseases in the U.S. are osteoarthritis, rheumatoid arthritis, and gout. Each disease is different, with different causes and different prospects for recovery depending upon the specialized 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:

**Classification of the Rheumatic Diseases**

**T. Polyarthritis of Unknown Etiology**

1. A. Rheumatoid arthritis
2. B. Juvenile rheumatoid arthritis (including Still's disease)
3. C. Ankylosing spondylitis
4. D. Psoriatic arthritis
5. E. Reiter's syndrome
6. F. Others

**II. "Connective Tissue" Disorders (Acquired)**

1. A. Systemic lupus erythematosus
2. B. Progressive systemic sclerosis (scleroderma)
3. C. Polymyositis and dermatomyositis
4. D. Necrotizing arteritis and other forms of vasculitis (polyarteritis nodosa, hyper-
sensitivity arthritides, Wegener's granulomatosis, Takayasu's (pulseless) disease, Cogan's syndrome and giant cell arteritis (including polyglandular rheumatism)

E. Amyloidosis
F. Others (See also rheumatoid arthritis, L. above; Sjogren's syndrome, VI. G. below).

III. RHEUMATIC FEVER

A. Primary
B. Secondary

V. NONARTICULAR RHEUMATISM

A. Fibrositis
B. Intervertebral disk and low back syndromes
C. Myositis and myalgia
D. Tendinitis and peritendinitis (bursitis)
E. Tenosynovitis
F. Fasciitis
G. Carpal tunnel syndrome
H. Others (See also shoulder-hand syndrome, VIII. A. below)

VI. DISEASES WITH WHICH ARTHRITIS IS FREQUENTLY ASSOCIATED

A. Sarcoidosis
B. Relapsing polychondritis
C. Schönlein-Henoch purpura
D. Ulcerative colitis
E. Others (See also inherited and congenital disorders, XII. below)

X. NEUROPATHIES
A. Synovial
B. Primary intra-articular bone tumors
C. Metastatic malignant tumors
D. Leukemia
E. Multiple myeloma
F. Benign tumors of articular tissue
G. Others (See also hypertrophic ostearthropathy, XIII. I. below).

III. INFECTION AND/or NEUROPATHIC DISORDERS

A. Traumatic arthritis (the result of direct trauma)
B. Neurologic arthropathy (charcot joints), syphils (tabes dorsalis), diabetes mellitus (diabetic neuropathy), syringomyelia, myelomeningocoele, congenital insensitivity to pain (including familial dysautonomia) and others
C. Shoulder-hand syndrome
D. Mechanical derangement of joints
E. Osteoarthrosis (see also degenerative joint disease, IV. above; carpal tunnel syndrome, V. above)

XII. INHERITED AND CONGENITAL DISORDERS

A. Marfan syndrome
B. Homocystinuria
C. Ehlers-Danlos syndrome
D. Osteogenesis imperfecta
E. Ehlers-Danlos syndrome
F. Osteogenesis imperfecta
G. Cutis laxa
H. Musculoskeletal dysplasias (including Hunter's syndrome)
I. Arthrogyrosis multiplex congenita
J. Hypertrophic osteoarthropathy
K. Familial Mediterranean fever
L. Werner's syndrome
M. Congenital dysplasia of the hip
N. Others (See also arthropathy associated with known biochemical or endocrine abnormalities, IX. above).

XIII. MISCELLANEOUS DISORDERS

A. Pigmented villonodular synovitis and tenosynovitis
B. Behcet's syndrome
C. Erythema nodosum
D. Relapsing panniculitis (Weber-Christian disease)
E. Avascular necrosis of bone
F. Juvenile osteochondritis
G. Osteochondritis dissecans
H. Erythema nodule (Stevens-Johnson syndrome)
I. Hypertrophic osteoarthropathy
J. Multicentric reticulohistiocytosis
K. Disseminated lipogranulomatosis (Furber's disease)
L. Familial lipochrome pigmentary arthritis
M. Tietze's syndrome
N. Thrombotic thrombocytopenic purpura
O. Others

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. 2), 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 of a population that the results can only be applied to the general population. In spite of the handicap, the realization that rheumatic diseases form a tremendous segment of chronic disability is becoming more widespread in recent years.

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.)

From the data of a U.S. survey (Ref. 7), Hollander (Ref. 3) further states that:

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.

The Panel finds that the insidiousness of this group of diseases makes it all the more important that extraneous factors be eliminated so as to not 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 lead to recovery, are clearly misleading.

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:

**Incidence of rheumatic diseases in the United States during 1974**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Number of persons (millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rheumatic disease</td>
<td>12</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>6</td>
</tr>
<tr>
<td>Gout</td>
<td>1</td>
</tr>
<tr>
<td>Systemic lupus erythematous</td>
<td>4.2 x 10^5</td>
</tr>
</tbody>
</table>

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.


(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 symptomatic by evidence of inflammation in and around the joints, yet pain and swelling of the joints are present due to destruction of
calls cartilage on the joint. This condition which is very common among elderly individuals is an ubiquitous condition which increases in frequency with aging.

The joints most frequently involved are those of the distal interphalangeal joint (joint near fingernail), first carpo-
metacarpal joint (joint at base of thumb), hips and knees. Degenerative disease of the knee alone is estimated to be present in at least 175,000 Americans age 65 or older (Ref. 9). The lower spine and joints of the neck may also be involved frequently.

Approximately 50 percent of those persons having osteoarthritis have moderate or severe disease (Ref. 10).

Clinical features of the disease (Ref. 11) include pain, crunching 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 for fluid in the joint which may be present after episodes of trauma following unusually vigorous usage of the involved joint.

The Primer on the Rheumatic Diseases has described the clinical features as follows (Ref. 11):

Special forms of degenerative disease involve particular joints in a characteristic manner.

Bony nodes, termed Heberden's nodes, are commonly found; they consist of a deforming bone protuberance at the margins and on the dorsal surface of the distal interphalangeal joint. The joint next to the nail of the finger, and are often associated with deformity 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 joint and the distal metacarpophalangeal joint are described, and all are associated with osteoarthritis, and may give rise to confusion with rheumatoid arthritis.

Involvement 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, and this generally becomes 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 limited range of motion of the involved hip.* * *

The changes (in the knee) may involve the softening of the posterior surface of the patella, as well as the weight-bearing surfaces of the femoral and tibial condyles. The femur and tibia are prominent bony nodes, termed Heberden's nodes, are commonly found; they consist of a deforming bone protuberance at the margins and on the dorsal surface of the distal interphalangeal joint. The joint next to the nail of the finger, and are often associated with deformity 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 joint and the distal metacarpophalangeal joint are described, and all are associated with osteoarthritis, and may give rise to confusion with rheumatoid arthritis.

Degenerative disease of the spine affects both the vertebrae and the intervertebral articulations, which may be extremely effective in severe hip disease. Many patients accept pain as inevitable. Individuals who self-medicate with analgesics to relieve their pain may delay consulting a physician and thus unwittingly contribute to the progressive degeneration of their joint disease.

The Primer on the Rheumatic Diseases (Ref. 11) also notes that:

Corticosteroids should not be used with the excess of intra-articular injections which may provide relief of symptoms for weeks and months. Therapy must 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, since these agents have been found to inhibit the synthesis of proteoglycanic cartilage by articular cartilage. It has been stated by Christian (Ref. 13):

It remains to be determined whether drug therapy can slow the development of progression of early degenerative joint diseases. There are some preliminary findings from experimental studies. Saliylates seem to prevent the development of degenerative changes in scars of the flexion deformity. 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."

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 further 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.

1. 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 further 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."

"..."
tients is undesirable because they will thus deny themselves proper medical management. Self-medicating patients will not receive proper treatment for their disease because they will not receive treatment such as physical therapy and psychological 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. Adult cases occur typically as early as 6 weeks of age. The disease is characterized by inflammation of the synovial joints (moveable joints which possess a cavity lined with a synovium) 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 joint. The cartilage of the joint may then become eroded by the inflammatory process, 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): Rheumatoid arthritis is defined clinically by joint involvement but this is often preceded by constitutional symptoms alone 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 labeling and mass media advertising of aspirin as a specialized connective tissue. Inflammation of the synovium in the form of pain, swelling, redness, warmth, and tenderness. Stiffness of the joints on waking after a period of joint. 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 with shock advertising or the subjective feeling of pain may give these consumers the belief that the OTC dosage of aspirin is the recommended therapy for their symptoms. The Panel is concerned that the label 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 safe and effective in individuals with rheumatoid arthritis. Consumers are deluged with such advertisements daily on a massive scale, leading to a general misconception in the minds of many patients with rheumatoid arthritis that aspirin in OTC doses is as effective for rheumatoid arthritis, as it is for headaches and minor pains, and that this is a disease which is simply managed by an OTC product without medical supervision. As will be discussed below, the Panel’s recommended OTC analgesic dosage of aspirin provides inadequate management for rheumatoid arthritis. (See part V. B.I.b. below—Aspirin.)

The Arthritis Foundation in its Primer on the Rheumatic Diseases (Ref. 16) gives the following additional description of the clinical features of rheumatoid arthritis:

In adults joint symptoms usually originate in the hands and feet. Rheumatoid arthritis also attacks the large peripheral joints, including the knees, ankles, wrists, and elbows. In some cases virtually all the peripheral joints may be involved, including the jaw, the spine, and intervertebral discs. Even such fine structures as the carpal and facet joints of the larynx may be involved.

Tenosynovitis (inflammation of the tendon sheath) is common, most frequently affecting the extensor and flexor tendon sheaths about the wrists. Inflammation of the bursa is often associated with the development of the carpal tunnel syndrome (median neuropathy), bringing about aching and stiffness in the initial distribution of affected joints, rheumatoid arthritis tends to be more variable. A monosynovitis, usually one knee, is noted frequently. It is often associated with the development of prior trauma to the joint. In these patients, particular attention must be given to differential diagnosis since it may especially infectious arthritis and gout.

Thus, it is important for the patient with pain and some swelling in one knee to see a physician rather than to self-medicate. Although a delay of 10 days may not lead to serious consequences in a patient with rheumatoid arthritis, this patient may actually have infectious arthritis which needs immediate therapy with antibiotics to prevent spread of the infection and destruction of the cartilage, which can occur during the recommended 10 days of self-medication for OTC indications). Changes observable by x-ray can occur 3 weeks after the onset of infectious arthritis consisting of loss of cartilage. Chondrocalcinosis is often present in the initial distribution of affected joints, rheumatoid arthritis tends to be more variable. A monosynovitis, usually one knee, is noted frequently. It is often associated with the development of prior trauma to the joint. In these patients, particular attention must be given to differential diagnosis since it may especially infectious arthritis and gout.

As has been stated in the Primer on the Rheumatic Diseases (Ref. 16): The period from the onset of symptoms to the time the patient consults a physician is highly variable. When there are only mild symptoms, i.e., pain limited to the hands, it is understandable why a patient may not seek medical advice; indeed, she may dose herself with aspirin, or the symptoms may disappear spontaneously. Swelling and pain of the larger joints, however, are likely to lead to prompt medical attention. Evaluation by the physician in the early stages of the disease is important in order to exclude other diagnostic possibilities that will be especially helpful in management in the event of prolonged active disease, and this may be accomplished by x-ray examination of the bones at the stage in which improvement and even remission is likely to occur in the majority of cases.

The Panel concurs with the above statement regarding the need for evaluation by a physician in the early stages of the disease. Since self-medicating patients may, in some instances, experience relief of pain, they may tend to 
time to self-medicate intermittently for a prolonged time as 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 stated. But self-medication by the patient will be relieved of pain but will not be taking aspirin at the dosage required for an anti-inflammatory action. During this period of intermittent self-medication, 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 aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.

The Panel also is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician. In addition, the Panel is aware that at least three-quarters of the patients with rheumatoid arthritis who have aspirin in their cabinets never have been changed by a physician because the pain will have been relieved.
by industry spokesmen that arthritic patients will be better off self-medicating than going to a physician because the physician will treat them with corticosteroids. However, the Panel concurs with the statement in the Primer on the Rheumatic Diseases, prepared by leading rheumatologists of the American Rheumatism Association, that "the prudent physician avoids promises of quick relief or perhaps even cures, and usually refrains from precribing any antirheumatic medication except aspirin" (Ref. 18). The use of corticosteroids in the treatment of rheumatic diseases is limited to specific indications. This is because corticosteroids in the treatment of arthritis has been well documented over the past 15 years.

Proper therapy includes the use of aspirin in adequate doses to control the inflammation of the synovial membrane. As noted 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 3.0 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 upset, blood dyscrasia, or tinnitus. With active disease aspirin should be taken on a regular basis rather than at will. There is considerable variation among patients in the minimum aspirin level of serum salicylate when following the OTC dosages. Since the majority of patients will use corticosteroids at very high dosage levels as anti-inflammatory agents the mainstay of therapy. The Panel concludes that intermittent self-medication for the patient with the necessary anti-inflammatory levels of salicylate. This unique safety feature of salicylates, particularly aspirin, was discussed in more detail earlier in this section (III. paragraph B.2. above—Safety.)

Clearly, OTC dosages of 12 tablets daily are rarely capable of achieving anti-inflammatory levels of salicylate. Thus, it is unwise for patients to self-medicate therapy in the Primer on the Rheumatic Diseases (Ref. 22) in that "patients with progressive deformities, disease activity and incapacity. Various surgical procedures have also been used for correcting or compensating for joint deformity."

It is clear that the management of patients with rheumatoid arthritis is a complicated therapeutic situation which must include the family physician or internist. These physicians may request consultation in the complicated patient situation which may persist with incapacitating symptoms. As an example of manifestations (Ref. 22). As an anti-inflammatory disease which is accompanied by pain, the use of aspirin or other salicylates at very high dosage levels as analgesics and as anti-inflammatory agents is the mainstay of therapy. The treatment of rheumatoid arthritis requires the use of corticosteroids for the patient with joint pain and muscle spasm. These exercises are designed to preserve the range of motion and self-medicate, the diagnosis and treatment. The daily dosage of aspirin or other salicylates needed to reach an anti-inflammatory effect may be higher and the duration of therapy greatly differs from the OTC dosage level. Only a physician can individualize the salicylate dosages needed for anti-inflammatory effectiveness.

1. 1977710 (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 older adults, with a peak incidence between the ages of 40 and 50 years. The Primer on the Rheumatic Diseases (Ref. 24) has described gout and its clinical features as follows:

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 gouty arthritis. Gouty arthritis is typically associated with a rheumatologist and/or orthopedic surgeon. These physicians may request consultation when patients are self-medicating with corticosteroids for the patient with joint inflammation and arthritis. The daily dosage of aspirin or other salicylates needed to achieve an anti-inflammatory effect is frequently greater than the OTC dosage level. Only a physician can individualize the salicylate dosages needed for anti-inflammatory effectiveness.

1. 1977710 (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 older adults, with a peak incidence between the ages of 40 and 50 years. The Primer on the Rheumatic Diseases (Ref. 24) has described gout and its clinical features as follows:

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 gouty arthritis. Gouty arthritis is typically associated with a rheumatologist and/or orthopedic surgeon. These physicians may request consultation when patients are self-medicating with corticosteroids for the patient with joint inflammation and arthritis. The daily dosage of aspirin or other salicylates needed to achieve an anti-inflammatory effect is frequently greater than the OTC dosage level. Only a physician can individualize the salicylate dosages needed for anti-inflammatory effectiveness.

1. 1977710 (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 older adults, with a peak incidence between the ages of 40 and 50 years. The Primer on the Rheumatic Diseases (Ref. 24) has described gout and its clinical features as follows:

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 gouty arthritis. Gouty arthritis is typically associated with a rheumatologist and/or orthopedic surgeon. These physicians may request consultation when patients are self-medicating with corticosteroids for the patient with joint inflammation and arthritis. The daily dosage of aspirin or other salicylates needed to achieve an anti-inflammatory effect is frequently greater than the OTC dosage level. Only a physician can individualize the salicylate dosages needed for anti-inflammatory effectiveness.

1. 1977710 (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 older adults, with a peak incidence between the ages of 40 and 50 years. The Primer on the Rheumatic Diseases (Ref. 24) has described gout and its clinical features as follows:

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 gouty arthritis. Gouty arthritis is typically associated with a rheumatologist and/or orthopedic surgeon. These physicians may request consultation when patients are self-medicating with corticosteroids for the patient with joint inflammation and arthritis. The daily dosage of aspirin or other salicylates needed to achieve an anti-inflammatory effect is frequently greater than the OTC dosage level. Only a physician can individualize the salicylate dosages needed for anti-inflammatory effectiveness.
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 a correct diagnosis has been made, treatment is aimed at 1) immediate control of the acute joint inflammation and 2) prevention of future attacks and the long term reduction in hyperuricemia so as to prevent formation of uric acid crystals and promote resolution of those tophi already present (Refs. 24 and 25). With the medications currently available it is possible to achieve both of these objectives and to attain normal levels of uric acid in the blood in the vast majority of gouty subjects. The maintenance of normal serum uric acid levels and prevention of tophaceous gout require long treatment which is seldom successful unless the patient is well informed concerning the nature of this disease (Ref. 24).

Several drugs are used to treat gout, some of which lower the amount of uric acid in the blood. Dietary management is also important in helping to reduce the body burden of uric acid. Especially to be avoided are foods high in purines. Surgery has been used in the management of gout. Surgical excision is indicated for large tophi, particularly so, if there is external drainage, infection, or ulceration. Joint replacement surgery and other procedures may be helpful in selected cases of severe or crippling gouty arthritis.

The objectives of treatment cannot be met by the use of any of the OTC analgesics. Aspirin given in amounts of 3 g or more daily exerts a uricosuric effect (increased amount of uric acid excretion into the urine). The Primer on the Rheumatic Diseases notes that “Since uricosuric therapy must be continued indefinitely, however, and since the frequency of toxic reaction to the large doses of aspirin required for effective uricosuric therapy is comparable to that of the method today for the use of aspirin to control serum urate levels” (Ref. 24). Probenecid and sulfinpyrazone are prescribed for many patients with gout. It should also be noted that, in order to achieve maximum quantities of aspirin counteract the uricosuric effects of the agents sulfinpyrazone and probenecid and, hence, should be avoided by patients taking these drugs (Ref. 24). In addition, small doses of aspirin may lead to the inhibition of uric acid excretion resulting in elevation of serum urate levels which may bring on an attack of gout (Ref. 24).

The drugs that will effectively control acute gouty arthritis are prescription drugs. They can only be obtained with a physician’s prescription. It is therefore important to avoid the use of nonprescription medications for gouty arthritis that may be due to gout, consult a physician for diagnosis and treatment.

(3) Summary and conclusions. If the patient self-medicates with OTC analgesics for painful acute attacks, which would subside within a few days without any treatment at all, he will never have seen a physician and therefore no diagnosis will have been made. With increasing numbers of attacks over the years, serious complications will arise unless proper medical management is received which is directed at lowering the serum urate level rather than withholding uricosuric agents. 50 to 60 percent of patients with gouty arthritis develop visible tophi and permanent joint damage (Refs. 24 and 26). The development of tophi is correlated with the height of the serum uric acid concentration. These patients, in addition to developing severe joint destruction, may also develop renal disease due to the deposition of urate in the kidney. Mortality from the eventuality of death in from 22 to 25 percent of gouty subjects who have not received proper medical management to reduce their uric acid levels (Ref. 27 and 28).

The Panel concludes that self-medication with OTC analgesics, such as aspirin, by individuals with joint inflammation that may be due to gouty arthritis, is medically unwise, possibly hazardous. It delays proper diagnosis and treatment which may lead to serious complications.

d. Arthritis associated with known infectious agents. Arthritis may be caused by many different infectious agents. The following bacterial agents may produce arthritis: Gonococcus (gonorrhea), meningococcus, pneumococcus, Streptococcus, Staphylococcus, Salmonella, Brucella, Streptobacillus moniliformis, Mycobacterium tuberculosis, Treponema pallidum (syphilis), Treponema pertenue (yaws) and others. Rickettsial agents may also produce arthritis. Viruses such as rubella, mumps, viral hepatitis and others may cause arthritis. Occasionally, arthritis due to fungal and parasitic agents may occur (Ref. 29). Bacterial arthritis is caused by the invasion of the synovial membrane by living microorganisms. Infectious arthritis may present minimal signs of inflammation and need not be confined to a single joint. Between 75 and 85 percent of gonococcal infections involve two or more joints (Refs. 36 and 31).

Bacterial arthritis may cause pain in the joint which is perceived by the individual and noted by others as being localized in the region of the joint involved. Signs 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 that “effective treatment of septic arthritis should not be encouraged to self-medicate 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 spread of the disease.” 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 is well documented 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 joint (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 an antibiotic chosen on the basis of sensitivity tests on the infection organism. Treatment should be initiated as soon as adequate cultures are obtained and antibiotic sensitivities are available” (Ref. 35).
Rheumatic fever may treat the arthritic age limit of 4g/24 hours for aspirin. The 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 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). 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). Daily dose of approximately 0.1 g/kg of 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 be under prompt physician's care and are managed and treated with aspirin even for 10 days.

(2) "Connective tissue" disorders. Another group of rheumatic diseases is the "connective tissue" disorders which are acquired rather than congenitally inherited diseases. These disorders include systemic lupus erythematosus, progressive systemic sclerosis, polymyositis, necrotizing arteritis and other forms of vasculitis, and are systemic diseases in which the joints may be life-threatening. These patients must be under the care of the physician and should not self-medicate. Since arthritis or muscle pain is a feature of all of these diseases, the patient should be diagnosed by a physician, and such patients should not self-medicate for their "arthritis" since this will prolong the period before they eventually seek a physician's aid and are 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 tests are essential for diagnosis and subsequent assessment of the patient's status and response to treatment.

(3) Miscellaneous diseases. Other diseases with which arthritis may be associated include sarcoidosis, relapsing polychondritis, ulcerative colitis, and regional enteritis.

Nonarticular rheumatism involves structures around joints and includes such disorders as osteoarthritis, peripheral neuritis, gout, diabetes mellitus, and various other disorders. These common conditions 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. Mucous may occur in the heart muscle, severely impairing the heart and contributing to the heart manifestations described above. It is clear that patients with this type of arthritis should be under prompt physician's care and are managed and treated with aspirin even for 10 days.

Another group of rheumatic diseases is the "connective tissue" disorders which are acquired rather than congenitally inherited diseases. These disorders include systemic lupus erythematosus, progressive systemic sclerosis, polymyositis, necrotizing arteritis and other forms of vasculitis, and are systemic diseases in which the joints may be life-threatening. These patients must be under the care of the physician and should not self-medicate. Since arthritis or muscle pain is a feature of all of these diseases, the patient should be diagnosed by a physician, and such patients should not self-medicate for their "arthritis" since this will prolong the period before they eventually seek a physician's aid and are 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 tests are essential for diagnosis and subsequent assessment of the patient's status and response to treatment.

(3) Miscellaneous diseases. Other diseases with which arthritis may be associated include sarcoidosis, relapsing polychondritis, ulcerative colitis, and regional enteritis.

Nonarticular rheumatism involves structures around joints and includes such disorders as osteoarthritis, peripheral neuritis, gout, diabetes mellitus, and various other disorders. These common conditions 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. Mucous may occur in the heart muscle, severely impairing the heart and contributing to the heart manifestations described above. It is clear that patients with this type of arthritis should be under prompt physician's care and are managed and treated with aspirin even for 10 days.

Another group of rheumatic diseases is the "connective tissue" disorders which are acquired rather than congenitally inherited diseases. These disorders include systemic lupus erythematosus, progressive systemic sclerosis, polymyositis, necrotizing arteritis and other forms of vasculitis, and are systemic diseases in which the joints may be life-threatening. These patients must be under the care of the physician and should not self-medicate. Since arthritis or muscle pain is a feature of all of these diseases, the patient should be diagnosed by a physician, and such patients should not self-medicate for their "arthritis" since this will prolong the period before they eventually seek a physician's aid and are 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 tests are essential for diagnosis and subsequent assessment of the patient's status and response to treatment.

(3) Miscellaneous diseases. Other diseases with which arthritis may be associated include sarcoidosis, relapsing polychondritis, ulcerative colitis, and regional enteritis.

Nonarticular rheumatism involves structures around joints and includes such disorders as osteoarthritis, peripheral neuritis, gout, diabetes mellitus, and various other disorders. These common conditions 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. Mucous may occur in the heart muscle, severely impairing the heart and contributing to the heart manifestations described above. It is clear that patients with this type of arthritis should be under prompt physician's care and are managed and treated with aspirin even for 10 days.
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 most frequently recommended analgesic for 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, "The patient does not take aspirin to fight arthritis. It is not the way you take it for a headache or the common cold."

The Arthritis Foundation has published in the leaflet (Ref. 2) five important recommendations for the treatment of arthritis. The Panel fully concurs with these recommendations which are as follows:

1. DO see a qualified physician for diagnosis and treatment of arthritis. Proper treatment can control the disease and prevent crippling.
2. DO take aspirin, if the doctor prescribes it, according to the 'aspirin program' he gives you.
3. DON'T change your aspirin dosage schedule without consulting your physician.
4. DON'T try to diagnose your own arthritis problem or pick your own remedies from non-prescription medicines available at the local drug store.
5. DON'T be lured by aspirin advertising into self-treatment and doing 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 analgesic-antipyretic-anterheumatic products be classified by the Panel as Category II for self-treatment because of its potential for abuse. It should not be permitted.

The labeling and advertising of OTC aspirin products to avoid the false impression that the consumer can self-diagnose and self-treat rheumatoid diseases.

REFERENCES

(1) Diffew Publication, National Institute of Arthritis, Metabolic and Digestive Diseases, "How to Diagnose with Arthritis," National Institutes of Health (NIH) 76-1096, Bethesda, 1976, copy is included in OTC Volume 030150.

(2) "Aspirin for Arthritis," The Arthritis Foundation, copy is included in OTC Volume 030150.


(8) "The Arthritis Foundation, Personal Communication to Lee Geismer, copy is included in OTC Volume 030150.


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 equal doses is required (Ref. 14).

Aspirin is also recommended in the treatment of osteoarthritis (Ref. 15). Harth and Bondy performed a crossover trial using objective measurements rather than relief of pain scores. This study compared 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, knee, and ankle strength and isometric strength of knee muscles were evaluated prior to 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 antacid buffering agents such as aluminum hydroxides has not specifically been among others to reduce gastrointestinal irritation. The Panel has discussed the effects of finished dosage forms on the therapeutic activity of the active ingredients elsewhere in this document. (See part II. paragraph J. above—Effects of Product Formulations on Drug Absorption and Pharmacologic Effect. Below). 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 (5 gr) aspirin it should be considered to be as effective as aspirin at the same dosage.

Fremont-Smith (Ref. 17) analyzed the analgesic but not the antirheumatic effect of aspirin plus magnesium and aluminum hydroxides on patients with arthritis. Feinblatt et al. (Ref. 18) measured the effect of aspirin plus magnesium and aluminum hydroxides in 20 patients with arthritis of unclear etiology. The mobility improved in all but one patient (Ref. 16). Unfortunately, the exact disease and the method of measurement of limitation of joint motion were poorly described.

Sandoe and Schwartz (Ref. 19) studied the analgesic effect of aspirin and magnesium and aluminum hydroxides in patients with arthritis. No attempt to measure antirheumatic efficacy was made.

A buffered aspirin tablet was studied regarding its analgesic effect on patients with rheumatoid arthritis and osteoarthritis (Ref. 20).

Similarly, Giovino (Ref. 21) studied the analgesic effect of an enteric coated aspirin tablet on rheumatoid arthritis and osteoarthritis patients. If the enteric-coated aspirin can be shown to prove blood salicylate levels similar to that of uncoated aspirin, then it should be recommended that the coated tablet is effective as an antirheumatic agent in all diseases in which aspirin is effective.

(2) Safety.

The safety of aspirin has been thoroughly reviewed in this document. (See part III, paragraph B.1.a. above—Safety)

The Panel concludes that it is generally not safe for the general public to self-medicate for joint pain perceived as "arthritis". Since the antirheumatic daily dose is much greater than that recommended for OTC use, side effects are more severe. In addition, the duration of therapy is much longer than that recommended for OTC use, and therefore, prolonged high daily doses of aspirin are less safe.

The OTC consumer is unable to differentiate the various forms of arthritis due to the large variety of diseases associated with pain in joints. Diagnosis should be made by a physician so that appropriate and adequate treatment of the arthritis can be instituted. It is not safe for individuals to self-medicate using antirheumatic doses of aspirin.

Patients with a history of gastritis or duodenal ulcers or those with symptoms of ulcers should be under the care of a physician and antirheumatic therapy prescribed by the physician. These patients are at risk of 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 measure 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 or subtract other therapeutic measures. These results revealed that aspirin is effective in the treatment of osteoarthritis (Refs. 2 and 4).


dosage except 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.1. below—Category I Labeling.)
Calcium carbaspirin. The Panel concludes that calcium carbaspirin 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 (1,900 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, as discussed earlier in this document, its dissolution rate and analgesic activity in human studies found to be similar in action to aspirin. (See part III, paragraph B.1.c.(1) above—Effectiveness.)

(2) **Safety.** The safety of calcium carbaspirin has been previously discussed earlier in this document. (See part III, paragraph B.1.c.(2) above—Safety.)

The Panel concludes that calcium carbaspirin 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.1.b. below—Category I Labeling.)

REFERENCES


(3) Golden, H. E., J. T. Tesser and P. R. Schmid, "Quantitation of Gastrointestinal Side Effects with the Efficacy of Para-Aminobenzoic Acid at a Daily Dose of 4 g Daily for 1 week. Antirheumatic Efficacy was Measured by Subjective Parameters such as Relief of Stiffness and Measurement of the Erythrocyte Sedimentation Rate before and after 1 week of Therapy. No Change in the Sedimentation Rate was observed, while Relief of Stiffness Occurred. The Data Were Compared with the Efficacy of Para-Aminobenzoic Acid at a Daily Dose of 4 g Daily for 1 Week. Sulfonamide Salicylate was found to give substantially more Relief of Stiffness than Para-Aminobenzoic Acid. The Study, However, Did Not Actually Measure Antirheumatic Efficacy on Cysts of the Inflamed Joints. The Results, Therefore, Do Not Permit a Conclusion as to the Efficacy of Sodium Salicylate as an Antirheumatic.

A similarly inconclusive study was conducted by Brown (Ref. 1) 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 antirheumatic efficacy 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 salicylate.
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 placebo. Sodium salicylate 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 margin (0 = no pain, +1 = patient complains of pain, 2+= patient complains of pain, winses and withdraws). The maximal score is +78. The mean intra-observer error difference (difference between observers examining the same joint) is 1.2 score units and the standard error is 1.1 score units. In addition to the Ritchie index, pain, tenderness, stiffness and swelling in one knee was noted. A total of 10 patients received placebo and 9 received sodium salicylate. Each was given a 0 to +3 scale. The results revealed that the knee score was significantly higher as tested by a paired Students t test while the patients received placebo than when they were treated with either sodium salicylate (p is less than 0.001) or indomethacin (p is less than 0.001).

The antirheumatic index of Ritchie was significantly higher while patients received placebo than when they were treated with either sodium salicylate (p is less than 0.001) or indomethacin (p is less than 0.001). The arthritic index of Ritchie was significantly higher while patients received placebo than when they were treated with either sodium salicylate (p is less than 0.001) or indomethacin (p is less than 0.001). Thus, this study clearly demonstrated the antirheumatic efficacy in a well-designed study.

A similarly well-designed study was carried out by Dick, Greyson, Woodburn et al. (Ref. 7). In this study, which may be used as a model for future studies on arthritis, the following parameters were measured: Ritchie index (Ref. 4); grip strength (Ref. 9); (mechanical measurement of the strength of a patient's grip); measurements of circumference of finger joints using a millimeter gauge (Ref. 10); and knee score (Ref. 6). In addition to the above, the accumulation of radioactive technetium within the knee joint after intravenous administration was studied by joint scanning. Ten patients with rheumatoid arthritis were studied in a triple crossover clinical trial using 5 mg sodium salicylate daily, 100 mg indomethacin daily and placebo, each administered for 1 week. Sodium salicylate was shown to be significantly better than placebo according to articular index (Ritchie index), knee score, and technetium peak count. No significant difference was noted when using the grip strength. The results reveal that sodium salicylate has antirheumatic efficacy.

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 earlier in this document. (See part III, page 201, para 5.7.2.5.1.3.)

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.

(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.1. below—Category I Labeling.) In addition, the Panel recommends the following specific labeling:

a. Indications. For rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, osteoarthritis, degenerative joint disease, anklyosing spondylitis, psoriatic arthritis, Reiter's syndrome and fibrositis.

b. Category II conditions under which antirheumatic agents are not generally recognized as safe and effective or are misbranded.

The Panel classifies the following active ingredients as not generally recognized as safe and effective or are misbranded:

Acetaminophen Phenacetin
Acetanilid Quinine
Ibuprofen Salicylamide

a. Acetaminophen. The Panel concludes that acetaminophen is not an effective OTC antirheumatic.

(1) Effectiveness. Acetaminophen is not considered to have effective antirheumatic properties (Refs. 1 and 2). A study by Boardman and Hart compared the efficacy of 6 g acetaminophen daily administered as 3 tablets given 4 times daily 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 jewelers' rings 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 classic or definite rheumatoid arthritis of at least 1 year's duration, had synovitis of the small joints of the hands and in all cases it was possible to stop all treatment for 14 days before the trial. The results showed that there was no significant difference of joint size in patients on acetaminophen compared with placebo. Patients had a mean improvement of grip strength from 303 mm Hg on placebo to 326 mm Hg on acetaminophen. This difference was not significant (t = 0.57, n=26; 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.d.1) above—Safety.

- Evaluation. The Panel concludes that there are no data demonstrating the effectiveness of acetaminophen as an antirheumatic that the ingredient is not effective 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 effectiveness of acetanilid earlier in this document. (See part III, paragraph B.2.a.(1) above—Effectiveness.)

- Evaluation. The Panel concludes that acetanilid is not safe 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.)

The Panel concludes that acetanilid is not safe for use as an OTC antirheumatic.

(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


d. Iodopyrine. The Panel notes that "Acetaminophen and phenacetin have analgesic and antipyretic 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


e. Salicylamide. The Panel concludes that salicylamide is not an effective OTC antirheumatic.

(1) Effectiveness. Calabro and Paulus compared the efficacy of aspirin, salicylamide and succrose placebo given as three 0.3 g tablets every 4 hours for 24 hours (Ref. 1). The double-blind crossover study included in each of its three phases, 8 weeks of drug-testing of aspirin, salicylamide or placebo daily, and 2 weeks of interval therapy when all patients took only 2.6 g aspirin daily. The patients were evaluated every 2 weeks using the Lansbury indices. This index evaluates five criteria: Duration of morning stiffness; time of onset of fatigue; aspirin need; grip strength; and the Western Gastrointestinal Sedimentation Rate. Using Lansbury's Tables, individual findings are converted to a percentage equivalent. When the percentages are added together they constitute a final score. In this study the data were analyzed by the Wilcoxon signed-rank test and found to be statistically significant. No differences were found between the effects of aspirin and salicylamide. The results of this study using the Wilcoxon signed-rank test revealed that salicylamide was not effective as placebo in only two subjective parameters of the ten parameters evaluated. Therefore, time of onset of fatigue and the need for additional aspirin. All of the eight other parameters showed no statistically significant difference between salicylamide and placebo. Statistically significant differences between placebo and aspirin were shown by all criteria.

Batterman and Grossman (Ref. 2) studied the analgesic effect of salicylamide on patients with osteoarthritis, but did not measure anti-inflammatory effects.

Similarly, Litter, Moreno and Donin (Ref. 3) studied the analgesic efficacy of salicylamide on a large group of arthritic patients, but did not measure anti-inflammatory effects.

(2) Safety. The Panel notes that salicylamide is not effective for use as an OTC antirheumatic.

(3) Evaluation. The Panel concludes that salicylamide is not effective for use as an OTC antirheumatic.
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. Claims should be deleted if inadequate testing is undertaken in the development of the claim or if adequate testing is undertaken 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 believes it reasonable to provide 3 years for the development and review of such data, the ingredients listed in this document for the safety evaluation of antirheumatic drugs. The studies should be double-blind crossover in design with aspirin as the standard drug and the patients treatment should be randomized. Objective indices of joint inflammation should be measured (Ref. 1), e.g., grip strength measured by manometer, circumference of the proximal interphalangeal joints, measurement of the time taken to walk a certain distance and the number of swollen or tender joints.

Prior to carrying out an antirheumatic assay, the appropriate statistical analysis should be defined. Unless the above points have been considered, any statistical analysis would only impart a false sense of confidence in the results.

4. Data interpretation. 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 and types of studies required for compounds questioned because of safety, will be the same as outlined for Category III 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 antirheumatic ingredient should be based on the studies and observations discussed earlier in this document for the safety evaluation of analogics. (See part III, paragraph C.5.—Safety evaluation.)
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 may affect the activity or safety of the analgesic components (a) of the submitted preparation(s).

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 either derives from or modifies the activity of the analgesic, antipyretic or antirheumatic agents reviewed. More specifically, this group may be divided into three categories to include adjuvants which may be directly or indirectly acting, corrective and excipients.

The components of the drug delivery system can be defined as follows:

1. **Adjutants.** Adjutants are agents whose activity is not inherent to the active ingredient. Examples include benzoic and salicylamide, which are claimed to compete for metabolizing systems affecting the disposition (absorption, metabolism, excretion or distribution) of the active agent. Examples include benzoic acid and salicylamide, which are claimed to modify 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 claim since the mechanism of action and the clinical endpoint are likely to be different.

2. **Correctives.** A corrective is an agent in the drug delivery system intended to reduce some undesirable 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.** In the course of the manufacture of the finished dosage form, many inert ingredients are required, such as starch or other agents to aid in dispersion, or magnesium stearate as a lubricant in the tableting process. Only when these agents are inert pharmacologically but inactive should they be considered a separate claim since the point of view of adversely affecting the rate and extent of the 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 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 claim 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 (aluminum glycinate)
   - Dihydroxyaluminum sodium carbonate
   - 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:

   - **MARKETED PRODUCTS CONTAINING ANALGESIC COMBINED WITH ANTACID OR BUFFERING INGREDIENTS**

   a. **Analgesic-antacid products.** Products containing nonaspartamylate ingredients combined with antacids.

   b. **Buffered aspirin products.** Products containing aspirin combined with buffering ingredients (correctives).

   c. **Highly buffered aspirin.** Products containing aspirin combined with buffering ingredients (correctives).

   The Panel notes that these ingredients are identified in § 331.11 of the OTC antacid monograph such that the finished product meets the following minimum requirements: Each dosage unit contains antacid active ingredients identified in § 331.11 of the OTC antacid monograph which the finished product contains at least 1.9 mEq of acid neutralizing capacity per 325 mg (5 gr) aspirin. Buffered aspirin products are labeled as an analoges (for "headache", "pain", etc.) accounting for the recognized activity of aspirin, but in addition, are labeled with terms such as "buffering agents to help make the pain reliever more gentle to the system", or "buffers prevent the pain which is often caused by pain aspirin". The Panel has discussed such labeling more fully below.

   Buffered aspirin is defined in the document as a solid dosage form which consists of aspirin plus a sufficient quantity of buffered aspirin to 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 labeling for buffered aspirin be reviewed through appropriate testing procedures, that each product shall meet in order to be recognized as a safe and effective "buffered aspirin" preparation.

   The Panel concludes that the aspirin tablets may be labeled as "buffered aspirin" providing they meet the following minimum requirements: Each dosage unit contains antacid active ingredients. The finished product contains at least 1.9 mEq 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 § 331.25 of the OTC antacid monograph.

   The product should show dissolution characteristics equivalent to the buffered aspirin tablet that has been used in most comparative clinical studies (Refs. 1 through 5). 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 devising suitable dissolution methodology is likely to involve significant experimental development to establish in vivo correlations and therefore, beyond the scope of this Panel. The conditions of the dissolution tests should be established by the appropriate compendial and/or Governmental Agency. A dissolution methodology is described below for illustrative purposes. (See part VI.)
lished. (See part II. paragraph J.4.e. above—Onset, duration and intensity of adverse effects) has not been definitively established in improved clinical effectiveness or that 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 aspirin tablets, when 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; (2) decrease the incidence of objective gastrointestinal intolerance in some of the relatively small percentage of persons in the general population who regularly experience gastric intolerance with aspirin tablets; and (3) decrease the incidence of gastrointestinal absorption of salicylates, such as the tablet compression and capacity and show similar dissolution characteristics and appropriately designed dissolution procedures as determined by this Panel.

Evaluation of individual formulations is beyond the scope of the Panel's review. Claims do not imply that increased rate of dissolution of aspirin from the particular 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 the 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


(4) Paul, W. D., "Bufferin and Neolin Demonstration of Gastric Tolerance," draft of unpublished paper is included in OTC Volume 030137.


c. Products containing aspirin combined with antacids—(1) Introduction. Highly buffered aspirin for solution contains a sufficient quantity of buffers to conform to the specifications for antacid established in the antacid monograph (21 CFR Part 331) and therefore, will increase the pH of the gastric fluid. Such products, which are not the currently available buffered aspirin products, will reduce gastric distress and a history of peptic ulcer, gastritis or previous episodes of gastrointestinal hemorrhage.

Contrary to the assertions in the data submitted by the manufacturer, there is no evidence to support their argument that aspirin acts through only one single localized mechanism. In fact, the submitted studies and references support the view that several different mechanisms may be involved in the potentiation of bleeding from acute lesions by the local and/or systemic effects of aspirin and salicylates on hemostasis as well as on mucosal blood flow. These lesions are not only caused by aspirin in the presence or absence of gastric acid but may also be caused by other factors.

The claims for highly buffered aspirin solutions have been quite controversial. The Panel in its examination of these claims has had the advantage of extensive published conclusions of others (Refs. 6, 7, and 8). The Panel has also had the advantage of several new epidemiological studies (Refs. 9 and 10) and experimental studies (Refs. 11 through 13) not referred to in the data submitted by the manufacturer, there is no evidence to support the concurrent use of aspirin and an antacid for concurrent symptoms requiring both an antacid and an analgesic-antipyretic.

The Panel finds it irrational to include aspirin in the treatment regimen intended to provide claims for an antacid effect, e.g., "For the treatment of heartburn, sour stomach and acid indigestion," since aspirin in any dosage form, e.g., tablet, highly buffered aspirin solution, etc., can pass through the gastric mucosal barrier 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 gastrointestinal symptoms described above.

Therefore, the Panel concludes that it is rational to market such an aspirin product for use only as an analgesic-antipyretic and not for concurrent symptoms requiring an antacid. The Panel has identified such products as highly buffered aspirin for solution. The Panel has discussed products as highly buffered aspirin for solution. The Panel has 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, paragraph B.l.a. (2)(i))—Adverse effects on the gastrointestinal tract.

The highly buffered aspirin for solution products discussed above contain aspirin combined with antacid active ingredient(s) identified in § 331.11 of the OTC antacid monograph such that the final finished product contains at least 20 mEq of acid neutralizing capacity per 24 hour period as measured by the method described in § 331.25 of the OTC antacid 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 headache, and general aches and pains". In addition, claims such as "Provides ingredients that may prevent the stomach upset that plain aspirin occasionally causes", and/or "Gives to the bloodstream faster than plain aspirin", are possibly more valid 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 preparations as for other buffered aspirin preparations and must therefore be considered as Category III.

Currently marketed highly buffered aspirin for solution preparations are claimed by the drug manufacturer to be safe for self-medication by individuals with symptoms of stomach distress, indigestion and heartburn and to be safe for concurrent symptoms requiring both an antacid and an analgesic, both for individuals with normal gastrointestinal function and those who may have peptic ulcer.

The following categories of products have also been made by them (Refs. 1 and 2).

(2) General. Evidence is presented indicating that blood loss occurring after the ingestion of aspirin, whether occult or overt, is due to the action of the proton gradient across the gastric mucosal barrier, permitting back diffusion of aspirin into the gastric mucosa. In the absence of acid there will be no blood loss from the stomach. The demonstrable increase in blood loss occurring after the ingestion of aspirin is due not only to the action of un-ionized aspirin in breaking the gastric mucosal barrier but in the absence of acid there will be no blood loss from the stomach and (Ref. 7) to induce major gastrointestinal hemorrhage from acute lesions by the local and/or systemic effects of aspirin and salicylates on hemostasis as well as on mucosal blood flow. These lesions are not only caused by aspirin in the presence or absence of gastric acid but may also be caused by other factors.

The claims for highly buffered aspirin solutions have been quite controversial. The Panel in its examination of these claims has had the advantage of extensive published conclusions of others (Refs. 6, 7, and 8). The Panel has also had the advantage of several new epidemiological studies 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 including "normal" (unbuffered 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 high alcohol consumption, such as the habitual consumption of alcoholic beverages 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 warning which states: "Caution: Do not take this product if you have stomach 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 the large number of 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 incidence and, most importantly, studies on occult bleeding in normal and peptic ulcer patients; on the analysis of published epidemiological studies; and on marketing experience data.

The Panel concluded that 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 did not involve the following contentions: (i) The acid-mediated single mechanism theory. The primary 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 is considered. In opposition to this mechanism, the presence of gastric acid is required for aspirin to produce the primary lesion involved in massive or occult bleeding. The primary lesion is manifested by the penetration of unionized aspirin into the mucosal cell and at some critical concentration increases the permeability of the gastric barrier which facilitates backflux of hydrogen ions, causes mucosal erosion and hemorrhage. This postulate is referred to by the Panel as the "acid-mediated single mechanism theory." (ii) The alleged distinctive 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 (which is chemically and pharmacologically distinct from aspirin, is a neutral or "sluggish" form of aspirin, is not absorbed into the mucosal cell. Therefore, critical concentrations are not reached in the cell for local effect. Also, the gastric acid is neutralized and therefore, 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 symptoms, i.e., for use as an analgesic and analgesic, is dependent on an unproven argument that there is only one single mechanism involved in massive bleeding. Virtually all other 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 sequence of arguments which have been used to justify the proposed use of highly buffered aspirin for solution preparations for concurrent symptoms in individuals with stomach distress, gastritis, peptic ulcer, etc.

(i) The allegation that occult bleeding studies demonstrate the safety of highly buffered aspirin for solution. In the data submitted to the Panel, it is contended that since aspirin-induced massive bleeding and occult bleeding involve the same mechanism, studies of occult bleeding are assumed to be valid for massive bleeding. The major academic gastroenterologists (Refs. 1, 2, and 3) have concluded that since massive bleeding not involving 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. Thus, the Panel concludes that aspirin can produce acute erosions and occult bleeding by the acid-mediated mechanism, but that gastric acid is not essential for this effect. 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 by 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) which may be simply triggered or potentiated by aspirin. This mechanism(s) explains and correlates many otherwise inconsistent clinical and experimental observations.

(iv) 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 type of evidence which has been inadequately used to show that highly buffered aspirin for solution cannot produce massive bleeding. The argument that massive gastrointestinal bleeding must occur is not triggered or potentiated 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, that therefore, all gastric bleeding involves erosions produced by the Davenport mechanism and that there is evidence that only one possible mechanism exists for each of the three observed events.
Although morphologically different, these lesions have the same clinical characteristics and prognosis in cases of massive bleeding. These lesions may be chronic or acute, gastric or intestinal, and may best be explained for the absence of gastric acid (Refs. 24 and 25). The feature they have in common, however, is an abraded mucosa with an exposed engorged capillary bed which by virtue of the close 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.1.a.2) above—Relation between systemic platelet 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 involving irreversible platelet damage and there may possibly be other effects on platelet function, although this has not been proven.

The submission dismisses the effect of aspirin on hemostasis as a factor in massive bleeding on the basis of the study by Leonard, Levy, and Stenestrand (Ref. 17) which showed that aspirin given intravenously increased template bleeding time but did not increase occult bleeding. The lack of correlation between bleeding time and occult bleeding has also been rejected by the Panel. (See part III, paragraph B.1.a.2) above—Occult bleeding.)

The use of this study as evidence to conclude that the systemic aspirin hemostatic effect does not relate to massive bleeding, again results from the unwarranted adherence to the unproven 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 Leonards and Levy had pre-existing lesions which predisposed them to massive bleeding episodes, effects observed as realistic models to determine the effects of the increase in bleeding time on gastric bleeding from preexisting potentially bleeding sites.

The Panel emphasizes that a study which shows no difference should not be accepted unless there is evidence that the study was properly designed relative to the question at hand and that the study had statistical power 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 bleeding time will potentiate bleeding in patients who have existing potentially hemorrhagic gastrointestinal lesions. Indeed, the studies of Grossman showed that intravenous aspirin caused significant gastrointestinal bleeding 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 potentializing role rather than the initiating role of aspirin in bleeding from existing erosions is reviewed below.

Finally, the Panel concludes that there is now significant evidence from experimental and clinical studies strongly supporting a mechanism in which aspirin can potentiate major gastrointestinal bleeding in certain individuals with pre-existing 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 is therefore a potential mechanism which explains and correlates many otherwise inconsistent clinical and experimental observations.

1. Evidence for multiple mechanisms of aspirin-induced massive bleeding. The Panel concludes that current evidence indicates that aspirin may contribute to the increased incidence of massive gastric bleeding caused by direct products of the bleeding lesion and/or by potentiating bleeding from existing lesions. (a) Direct production of acute mucosal lesions. In some cases it is possible that repetitive dosing of aspirin may produce acute necrotizing gastritis which becomes the bleeding lesion. Supporting evidence, discussed elsewhere in this document, is the extensive clinical and experimental data showing that aspirin reproduces produces gastric erosions and occult bleeding in normal subjects. Massive bleeding, however, is more likely in individuals with existing gastrointestinal disease (Refs. 28, 29, and 30). (See part III, paragraph B.1.a.2) above—Massive gastrointestinal bleeding.) However, when a 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 chronic aspirin ingestion, the occult bleeding and gastric damage produced is no different than that produced in normal control subjects (Ref. 31).

Those who contend that aspirin contributes to massive bleeding only by its direct mucosal effects would have to agree that 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 common to occult bleeding must be considered as evidence that the contribution 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 unifying 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 directly cause erosions by the same mechanism that it causes occult bleeding. An important part of their basic assertion is that this common mechanism requires the involvement of gastric acid since part of the proof 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 (Refs. 24 and 26).

While there is no reason to rule out the possibility that aspirin may initiate acute erosions or increase the bleeding from existing erosions by direct mucosal effects, there is no reason to assume that this is the only mechanism possible or that aspirin requirement is gastric since massive bleeding following aspirin ingestion may occur in patients with achlorhydria (Refs. 25 and 34). The prediction of bleeding from existing erosions following aspirin at times causes acute mucosal erosions, in many cases reported bleeding took place after only a few aspirin ingestions in patients with bleeding in which acute lesions 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 these acute erosive bleeding cases is described by Katz and Siegel (Ref. 29).

Katz and Siegel (Ref. 26) have discussed the relationship between gastrointestinal hemorrhage and the occurrence of acute gastric mucosal lesions 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 the epithelium, hemorrhage in 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 detection of involvement of endoscopic or biopsy categories may not be evident unless multiple biopsies are made. In 93 patients with upper gastrointestinal bleeding, the acute mucosal erosions were present in histological studies in 68.6 percent of patients with gastroscopically observed localized erosions, in 69.7 percent of patients with diffuse gastric erosions (localized or diffuse), in whom the cause of upper gastrointestinal hemorrhage was undiagnosed by gastroscopic examination indicating to the authors the possible involvement of antral and gastric erosions.

The histological acute mucosal lesion is thus the common denominator for a variety of gastric conditions associated with massive gastrointestinal bleeding. The diagnosis may not be 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 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 without bleeding. Furthermore, characterization of the lesion depends upon whether single or multiple biopsies were taken for histological studies (Refs. 24 and 26). Finally, recent studies show that similar types 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 are not easily seen unless special endoscopic procedures (duodenoscopy or esophagoscopy) or surgery are performed.

Several authors have 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. In 80 percent of patients in whom the cause of upper gastrointestinal hemorrhage was undiagnosed by gastroscopic examination indicating to the authors the possible involvement of antral and gastric erosions.

<table>
<thead>
<tr>
<th>Type of erosion, gastroscopic diagnosis</th>
<th>Number of cases</th>
<th>Cases with acute gastric mucosal lesion (In percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Localized gastric erosions</td>
<td>35</td>
<td>86.6</td>
</tr>
<tr>
<td>Diffuse erosive gastritis</td>
<td>33</td>
<td>80.7</td>
</tr>
<tr>
<td>Indiscernible gastritis (aspirin and x-ray negative)</td>
<td>25</td>
<td>80.0</td>
</tr>
<tr>
<td>Total</td>
<td>93</td>
<td>83.3</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 active 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 small in this group which biased some of his further conclusions.

Acute peptic ulcer bleeding and other x-ray positive conditions. Even when a positive radiological diagnosis of a chronic ulcer is made, further gastroscopic 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 bleeding 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 output gastric acid (Ref. 26).

The etiology of acute mucosal lesions is apparently the end product of several possible interacting endogenous and exogenous factors which can directly or indirectly affect the mucosal blood supply. However, acute mucosal lesions are 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. 33).
It has also been shown that the assumption that alcohols 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. 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 gastroscopic examinations. Erosions and histology returned to normal after abstinence. It is claimed that the erosions can probably develop in the absence of gastric acid. The net result is that any agent which will decrease 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, occurred presumably due to venous congestion and arterial hypotension. Although aspirin apparently is not the end product of a variety of other inter- acting endogenous and exogenous potential etiological variables which directly or indirectly affect the mucosal circulation, they also occur in chronic alcoholics in whom exhibited abnormal mucosa on histological examination in 15 percent of the patients. Histological examination of the lamina propria as a factor in the development of gastric erosions (Ref. 26).

Katz and Siegel (Ref. 26). Although this aspirin effect persists turned to normal after abstinence. It is evidenced that aspirin has an additional effect that is different from the gastric barrier. (See part III. Discussion theory and the hypothesis that aspirin and salicylic acid can produce this effect (the 50 percent effective dose (ED50)). The ED50 for salicylic acid is 40 ± 10 mg/dL, whereas the ED50 for aspirin is 50 ± 15 mg/dL. 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 which 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 ED50 for aspirin and salicylic acid 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).

Nineteen percent of salicylic acid patients with bleeding (primed) lesions.

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 however greatly increase blood loss in the "primed" patients bleeding from duodenal ulcer and esophageal varices. Oral aspirin greatly increased bleeding in jejunial ulcer, duodenal ulcer and esophageal varices. It is obvious that this effect is not dependent upon the acid-mediated mechanism (Kaplan's) in the jejunum or esophagus. Thus, part of the action of aspirin appears to be due to local effects of salicylic acid on existing erosions. There is an additional effect which occurs after intravenous administration of aspirin but not 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.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
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 not be observed in healthy 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 occult bleeding in normal subjects appear different than potentiation of bleeding from acute mucosal lesions.

Aspirin-induced occult bleeding in normal subjects can be decreased 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 findings made by others (Ref. 30). Many people do not realize the analgesic and anti-inflammatory effects of aspirin. In existing acute lesions histamine has probably already been stimulated by other factors, the most likely being stress according to some authors (Refs. 5, 16, 26, and 32). Increased occult bleeding is produced by aspirin in patients with achlorhydria which is further evidence that some effects of aspirin on abnormal gastric mucosal lesions may act independently of 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 although normal patients gave higher values of blood loss (4.29 ml daily) than patients with achlorhydria showing significant blood loss (1.9 ml daily). There are several possible mechanisms by which aspirin can precipitate or 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.

Of 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 gastric mucosal lesions 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 effects 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 of increased occult bleeding (Ref. 31) listed below. These contentions are not consistent with experimental data from animals or occult bleeding studies in man. These erroneous allegations are: "Aspirin which is completely contained in the double-act of [an effervescent aspirin preparation] is entirely converted to the water soluble salt, sodium acetylsalicylate;" "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. 38) in which it was stated that: "most 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 statements that the absorption rate of aspirin was found to increase in occult bleeding continues to occur even with highly buffered aspirin for solution is physico-chemically or pharmacologically different from any other aspirin. This assumption is scientifically unsound and clinically misleading.

All aspirin whether administered as an effervescent buffered solution, tablet, or sodium salt always exists in solution as an equilibrium mixture of both the ionized (acetylsalicylic acid) and the ionized species (acetylsalicylate). Both species are always present. The relative abundance of each being determined solely by the pH (a measure of acidity) of the solution and, therefore, changes almost instantly whenever the pH of the solution changes. If the pH of the solution is lowered to a pH of 1 to 2 (the usual gastric pH) the ionized acetylsalicylic acid is reduced to about 1,000-fold. When the pH is raised to pH 6 to 7 (the initial pH after highly buffered aspirin for solution is given) the ratio of unionized to ionized is only 0.001. It is important to emphasize that when aspirin is administered as an effervescent drug 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 ionized 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 occurs with aspirin (unionized) 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 reduced. He states that "most of the dog on the absorption rate of aspirin was found to decrease from 342 μml/30 min at pH 1 to 65 μml/30 min at pH 6.5 even though the fraction of aspirin unionized is reduced from 0.997 to 0.001, an 1,000-fold decrease. He suggests that absorption of the ionized species may occur or that there is an acidic microenvironment at the cell surface. Aspirin damages the gastric mucosa only after being absorbed into the cell at sufficient concentration to alter the gastric barrier and result in bleeding. In the normal state the gastric barrier prevents diffusion of hydrogen ions into the cell and to the capillaries.

Morrish et al. (Ref. 39) correlated gastric lesions with the absorption of radioactive (C) sodium acetylsalicylate administered to albino rats at a dose of 0.25 μmol/kg of body weight dissolved in 0.15 M citrate buffer. The final pH was 4.6 which is about that usually obtained with highly buffered aspirin for solution. Bleeding occurred in the corpus region only by sodium acetylsalicylate and not by sodium salicylate which was absorbed more rapidly than sodium acetylsalicylate.

Anderson (Ref. 40) also found that the addition of buffering did not preclude gastric absorption and gastric erosions when gastric emptying was prevented, concluding that 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 from a solution of pH 7.0 was only 50 percent less than that absorbed when the pH was 1 to 3. Most important, lesions were also produced at the high pH (7.0).

Anderson concludes that the critical rate of absorption is of low order in the guinea pig and if a similarly low rate occurs in man the avoidance of gastric erosions would be different with any formulation which has a high rate of absorption. These considerations are acidic because of the higher gradient of unionized aspirin outside the cell to the unionized aspirin inside 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 the effects of gastric lesions persist, but they might persist after the buffering capacity of highly buffered aspirin for solution is gone. This might be particularly true for hypersecreters of gastric acid. As is discussed in the next section, the effects of aspirin may persist for several days after dosing has stopped. In prolonged effect cases, the immediate buffering capacity of highly buffered aspirin for solution was not statistically of no value if, as the submission contends, that all 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 hydrochloric acid which is a necessary component of gastric erosions and bleeding. Therefore, the argument continues, "highly buffered acetylsalicylate causes no damage." The Panel finds that although gastric acid is reduced by aspirin, the postulate that the buffering capacity of gastric acid is not essential for aspirin to cause gastric erosions or occult bleeding as has been discussed earlier. (See part III, paragraph B.1.a.(2) ii.) Other mechanisms of aspirin damage.

The study of Dagle et al. (Ref. 22) in vagotomized rats indicates that microscopical 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 ulcer disease and the next section considers the role of causes including pernicious anemia and atrophic gastritis (Ref. 25 and 34).

(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 occurring 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, 19, 43 and 46).

However, analysis of submitted data show that average occult bleeding 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 differences from a clinical point of view. They are significant, however, from the point of view of evaluating mechanistic assumptions. Of additional importance in these studies are certain patterns observed 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 seen 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 studies represent the response of most of the normal subjects (70 to 80 percent). It is not likely, therefore, to provide useful information on mechanisms related to the topical maxill and quick bleeding. An occasional subject has shown excessive occult bleeding. These individuals may be two standard deviations higher than others of the group and in some studies these cases have been identified from statistical evaluation as "outliers." The mean blood loss of the occult bleeding is not predictive of massive bleeding. However, in several studies in animals and humans, there were subjects who constantly showed an increased pattern of blood loss. It is the opinion of the Panel that these outliers may have some unknown predisposing factors and should be studied further to see if these outliers could provide a possible model for massive bleeding. In the Panel's opinion, it is significant that these outliers occurred most often in subjects who are likely to have acute mucosal lesions, e.g., patients with peptic ulcer, and are therefore subjects with potential or potentially critical bleeding sites. These outliers or "excessive occult bleeders" have occurred with all types of aspirin solutions including highly buffered aspirin for solution (Refs. 3 and 4) and enteric-coated preparations (Ref. 19).

The potential for increased occult bleeding in patients receiving highly buffered aspirin for solution is shown in the Goulston study (Ref. 11). Multiple doses of highly buffered aspirin (effervescent) solution were given to apparently healthy volunteers (19 males and 1 female). Ten subjects were given two tablet doses in 200 ml water 4 times daily for the first 8 days followed by a control period of 8 days (Group A). The reverse order was given for the second 10 subjects (Group B) resulting in average occult bleeding losses shown below:

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly buffered aspirin for solution (milliliter)</td>
<td>1.7</td>
<td>1.3</td>
</tr>
<tr>
<td>Control (milliliter)</td>
<td>1.1</td>
<td>1.3</td>
</tr>
</tbody>
</table>

In the initial submission to the Panel, it was stated that "* * * subjects 8, 11, 12 on some days had fecal blood loss well in excess of the range of the other subjects. Applying statistical analysis ("Uni- States Pharmacopeia," 16th Ed., p. 873) to these aberrant results, the average blood loss was projected. As a result it was claimed that no statistical difference existed. The notion of omitting the "outliers" which were excessively bleeding therefore atypical, in a study conducted to show the potential following drug treatment is in the Panel's view 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 the 8 day control period and average occult bleeding losses during the 8 days were 0.0 to 0.9 ml daily but on the 4th, 5th, and 6th day of drug treatment experienced daily blood losses 17.9, 24.9 and 13.5 ml, respectively.

In the Panel's view no conclusion can be concluded for the population studied in the Goulston study: (1) Highly buffered aspirin for solution given chronically 4 times daily for 8 days increases fecal occult blood loss; this loss is probably less than would have been produced by aspirin tablets and is not significant clinically.

(2) One subject had a loss of over 50 ml during 3 successive days which is not only clinically significant but suggests that highly buffered aspirin for solution may produce excessive bleeding in an unpredictable abrupt manner similar to that seen in massive (major) gastrointestinal bleeding. Three other subjects had blood losses of 8.6 ml or more in 1 day during drug treatment only.

(3) There is a temporal pattern 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 drug dosing stops. When one 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 only by 3 of 10 subjects in the first 2 days of the second 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 blood losses over a period of time, this pattern is obviously wrong.

(4) Review of new studies on occult bleeding in subjects and animal preparations with existing lesions. The Rider study (Ref. 14) measured average daily occult blood loss in subjects receiving the Rider drug (12 day control period), a placebo (7 days) and a highly buffered aspirin for solution for 12 days. Occult bleeding in the placebo group increased from 0.1 to 1.7 ml daily. In the study of Dagle et al. (Ref. 22), blood loss was significant in 7 of 11 animals in whom bleeding was noted. The Rider study was limited in that bleeding was not noted until after 500 mg of aspirin was given. 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 drug dosing stops. When one 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 only by 3 of 10 subjects in the first 2 days of the second 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 blood losses over a period of time, this pattern is quite obvious.
solution product (7 days), and a post-treatment period (6 days).

The average data are shown below:

<table>
<thead>
<tr>
<th></th>
<th>Average range milliliters per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control period (7 d)</td>
<td>0.57 (0.28-1.94)</td>
</tr>
<tr>
<td>Post placebo period (6 d)</td>
<td>0.67 (0.32-1.22)</td>
</tr>
<tr>
<td>Highly buffered aspirin</td>
<td>1.58 (0.97-4.18)</td>
</tr>
<tr>
<td>Post highly buffered</td>
<td>2.17</td>
</tr>
</tbody>
</table>

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 0.67 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.

Other studies 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 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.

Epidemiological studies on massive bleeding. Two epidemiologic studies, the Brown and Mitchell study and the Jennings study do not show that there is any difference between the role of regular aspirin and highly buffered aspirin for solution in potentiating massive bleeding. These two studies 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 bleed from duodenal ulcers whereas regular aspirin is more often used in those who bleed from acute gastritis. Langman concluded from this study that since bleeding from gastritis is more frequently associated with aspirin the types of aspirin dosage forms which have the greatest 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 greater incidence of gastric distress than individuals with only acute gastritis, particularly of the atrophic variety. Since at the time of the Brown and Mitchell study (1956), highly buffered aspirin for solution preparations claimed and were promoted for the symptoms of gastric distress, in the Paper it is unlikely that a greater number of individuals with duodenal ulcer ingested this type of preparation. Second, the potention of aspirin induced bleeding by alcohol is matched shown for the duodenal ulcer 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 promoted for use for concomitant symptoms of headache and gastritis related to overindulgence with alcohol. Therefore, when alcohol ingestion is a factor, these preparations would more 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 aspirin can potentiate bleeding, especially since industry contends that this product can be used safely by ulcer patients.

Langman implies that the epidemiological study of Brown and Mitchell (Ref. 15) in which 83 percent of patients who bled had taken "insoluble" (regular) aspirin and 14 percent of such patients had taken a buffered effervescent preparation, supports only the role of the "insoluble" aspirin product forms in potentiating massive bleeding. The conclusion drawn from this study is not warranted as the 40 percent figure referred to individuals who might have ingested highly buffered effervescent aspirin as long as several months before the study. The period of aspirin ingestion by the individuals who bled in the last 48 hours just prior to the study. The latter group of individuals would have been the proper control upon which Langman should have based his conclusions.

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 total population takes one brand of buffered effervescent aspirin from "time to time". This is consistent with the control group suggested by Brown and Mitchell (Ref. 15). However, calculations from the industry data also show 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 content 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 preparations are not implicated in massive gastrointestinal bleeding. It is to the "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 presented on specific types of aspirin used, including highly buffered aspirin. The distribution of aspirin products in patients with over gastrointestinal bleeding was as follows: In the radiologically negative group, 42 percent of patients took a buffered effervescent aspirin. In 29 percent of the chronic ulcer patients took a buffered aspirin. In 18 percent took soluble aspirin, 7 percent took a buffered aspirin preparation. In 23 percent, 29 percent of the chronic ulcer patients took an ordinary aspirin. In 14 percent took soluble aspirin, and 21 percent took the highly buffered effervescent preparation. Langman in his report noted that the highly buffered effervescent preparation was the cause of bleeding the incidence of use would be higher in the chronic ulceration group which is most often associated with gastrointestinal bleeding. There are several reasons for questioning the validity of this contention. First, patients with chronic ulcer generally have a higher incidence of gastrointestinal 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 expected that the group with the highest incidence of gastric distress would have the highest incidence of highly buffered effervescent aspirin use. Second, evidence that the use is associated with acute ulcer (to a higher proportion) than with chronic ulcer. It has nevertheless been associated with bleeding in chronic ulcer patients. In fact in his review in 1958 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, Jennings's data, which were claimed by the author to suggest synergistic effects of alcohol and aspirin, show that the coincident alcohol usage is a common and perhaps less common in the acute lesion group than in those with bleeding due to chronic ulcers although the treatment of aspirin is generally considered to be an option for the treatment of gastritis. The data of Jennings (Ref. 16), showing a higher incidence of aspirin and alcohol associated with hemorrhage in patients with chronic ulcer including duodenal ulcer, are consistent with other recent studies.

Therefore, the Panel concludes that arguments of Langman cannot be used to dismiss in a variety of different conditions, evidence that highly buffered effervescent aspirin is as likely to be associated with gastric bleeding as any other form of aspirin.

**Benefit to risk considerations.**
Several benefit to risk considerations were involved in the Panel's recommendation not to allow highly buffered aspirin for solution to be indicated for use in individuals with any history of symptoms of gastrointestinal bleeding, ulcer or symptoms of gastric distress with or without concurrent headache. The Panel's conclusions regarding the mechanisms involved in current-induced major gastrointestinal bleeding were a significant factor in this decision, particularly the fact that the "primed" bleeding lesion may be caused by factors other than direct gastric erosion induced by aspirin. It was concluded that bleeding can be precipitated by aspirin from existing mucosal lesions which can subsequently produce symptoms of concomitant headache and gastric distress. Highly buffered aspirin solution has been claimed for use to relieve the concurrent conditions.

The Panel is concerned that the same conditions, alcohol and stress, which frequently "prime" the gastrointestinal tract for massive bleeding, are also those which may frequently produce symptoms of concomitant headache and gastric distress. Highly buffered aspirin solution has been claimed for use to relieve the concurrent conditions.

A further concern of the Panel is that if an antacid (highly buffered)-aspirin combination product is promoted for use in gastric distress, even if the concurrent claim of a headache is allowed, the public should regard these products as safer than unbuffered (plain) or slightly buffered butalbital with aspirin but also somewhat different. The Panel feels that this is misleading.

The Panel is concerned that in cases where concurrent gastritis and headache occur, individuals will usually take some analgesia, probably containing aspirin, and that they may assume that the availability of highly buffered aspirin for solution is offered as protection of the safest aspirin product that could be taken. However, if as the new information suggests, the primary role of aspirin is the initiation of the bleeding lesion but the promotion of bleeding from existing lesions by systemic effects, then the dosage form is irrelevant and highly buffered aspirin for solution offers no advantage over unbuffered (plain) aspirin. Thus, the Panel feels 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 based on marketing history (Ref 2), such products could be more likely to be used in instances involving gastric symptoms only. When one considers that massive gastric hemorrhage related to aspirin involves a 10 percent mortality rate this is much too severe a risk relative to the minimal, if any, benefit derived (Ref. 49).

The Panel concludes that it is unproven, and unlikely that highly buffered aspirin for solution can prevent major gastrointestinal hemorrhage than regular aspirin. Neither is there evidence to show that it would be safer to use this product rather than regular aspirin for the prevention of gastric erosion associated with analgesic gastric distress. Current evidence suggests that alcohol gastritis and stress are the two most likely causes of concomitant symptoms of headache and gastric distress. Alcoholic gastritis and stress are also the 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 current evidence warrants an exemption from the labeling recommendation for any form of aspirin for persons with gastric distress 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."

**References**

(1) OTC Volume 030008.
(2) OTC Volume 030104.
(3) OTC Volume 030150.
(4) OTC Volume 030162.
(8) Wolfe, S. M., "Comment to the Food and Drug Administration Concerning the Recommendations of the Panel," is included in OTC Volume 030150.
(11) Goulston, K., "Alka Seltzer and Gastrointestinal Bleeding," draft of unlisted paper is included in OTC Volume 030122.
(13) Rider, "The Effect of Alka-Seltzer on Peptic Ulcer (Full report)," included in OTC Volume 030162.
(14) Rider, "The Effect of Alka-Seltzer on Peptic Ulcer," Summary provided to Panel on April 22, 1973 and presented to Panel during open session on March 11, 1974 and included in OTC Volume 030150.
(18) Presentation to Panel during open session on March 11, 1974 and included in OTC Volume 030150.
(23) Cooke, A. R., Presentation to Panel during open session on July 30, 1973 and included in OTC Volume 030150.
(24) Dagnall, A. E. R. Lee, D. Bosco and S. J. 8 ' "Alka Seltzer and Gas­

(25) Winawer, S. J., J. Bejar and M. Zau­
(26) Katz, D. and H. Sleijfer, "Erosive Gas­

(32) Kossower, M. and M. H. Kaslan, "The Role of Salicylates in Massive Gastrointes­

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
These advantages have been, in various ways, stated to be due to a 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 aspirin. These 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 “Firmly in the bloodstream” or “Gentle 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 well as by 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 Category III statements:

- Faster to the bloodstream than plain aspirin
- 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 as a result of the antacid or buffering ingredients in the product be classified as Category II.

(2) Effect of rate of absorption into the bloodstream. The Panel has reviewed data, opinions and recommendations from both sides of the controversy regarding absorption claims that buffered aspirin has therapeutic advantages over plain aspirin due to a more rapid rate of drug absorption into the bloodstream.

The problem is complex 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 absorbed more rapidly 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 20 minutes correlate quite well with the amount of drug absorbed (Ref. 4). Therefore, the Panel concludes 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. This second question pertained to divergent opinions regarding the validity and value to the public of statements regarding differences in drug absorption with no mention of therapeutic advantages. 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 concluded 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 interpretation 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 in the future regarding prolonged blood levels produced with some dosage forms and the inference that prolonged duration of effect will occur.

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 assessment of current scientific information and the development of methodology to determine the validity of the claims. Category III should be used to classify claims which cannot be fully evaluated with present data but have some reasonable basis for belief but can be evaluated by further testing, perhaps involving more sensitive methodology. Second is to establish a policy that allows the maximum amount of information to be given to the public provided that in-dated scientific studies not only to validate the clinical significance of differences in blood level data but also to accurately communicate them to the public.

While current studies have failed to show a direct one-to-one correlation between the serum level of an analgesic drug and pharmacologic response, there is some evidence that a complex nonlinear relationship between these two variables undoubtedly does exist. While this involves highly nonlinear complex functions and time lags. These reasons include the fact that
a nonlinear dose-response function has been shown by different methods and that a greater degree of pain relief has also been shown (see part III. paragraph B.i.a. (1) above—Effectiveness). There are known relationships between dose and plasma concentration of aspirin, but few effects have been demonstrated by kinetic modeling, analytical methodology and clinical-testing will probably allow validation 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 insensitive methods cannot determine differences between the two. In the absence of other evidence, no means of validating claims are available.

There is other evidence to indicate potential clinical differences due to rate of absorption. First, from a theoretical point of view, it can be shown by mathematical analysis that because the rate of elimination of aspirin is much more rapid than that of any other drug (90 percent is eliminated in 15 to 20 minutes), changes in rates of absorption within normal ranges can result in two-fold changes in the peak plasma concentration (Ref. 1). Experimental data on the blood levels of aspirin by LeBards (Ref. 5) have shown that the peak blood level and relative amount of aspirin absorbed as assessed by the areas under the blood level-versus-time curves is very great for an effervescent preparation as for a simple aspirin tablet. Even greater peak blood levels were observed when the sodium salt of aspirin was administered.

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. 6) compared the salicylate levels attained in human aspirin products with an unspecified plain aspirin product. The initial plasma levels and, therefore, the rate of absorption of the buffered products were from 1 1/2 to 2 1/2 times greater than those aspirin preparations.

One of the buffered products was tested against the plain aspirin in two crossover studies comparing time of onset for 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 formulation 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 rate of onset of pain relief cannot be further evaluated. However, because two preparations were evaluated with two types of pain, the data can be analyzed to see if they are consistent with the possibility that the rate of absorption could affect the rate of onset. Preliminary 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 products is not too 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 by some 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 given to make an informed decision. Claims such as "faster acting" may be scientifically accurate but misleading for example, if the difference is 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 a disproportionately higher rate of absorption may be moved from Category III to Category I if the claimed differences of analgesic effect can be quantitatively established and the average 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 based on the 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.

The Panel suggests once the clinical studies are available to adequately demonstrate quantitative 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 should be accompanied by clear concise statements regarding the quantitation, significance and degree of the difference. The specific information that should be conveyed is the average difference in magnitude of effect that has been proven and what percent of the usual target population will be involved.

In the Panel's view, value judgments on comparative claims are best left to the consumer provided all the pertinent facts are conveyed. In the absence of available information on the relative degree of effect or incidence of effect in the target population, comparative statements are of limited value and even potentially misleading. Indeed, the Panel notes that statements such as "safe to the stomach" may be taken as a comparative judgment involving properties not possessed by other agents.

(3) Validation of Category III labeling. The Panel notes that clinical or blood level studies showing an increased rate of absorption for one buffered product are not necessarily valid for other buffered products, or even different products lots of the same product. There is also ample evidence that some buffered products have formulation, such that, they are more slowly absorbed than regular aspirin. (See part VI. paragraph B.i.b. above—Products containing aspirin combined with buffering ingredients (corrective)). For these reasons, the term buffered aspirin has limited value as a general labeling term in identifying or assuring particular performance characteristics. The Panel, therefore, considered the need for in vivo and in vitro standards to define the therapeutically significant characteristics of the dosage form.

The Panel does not believe this to be a high priority until the claims for buffered aspirin have been validated and, accordingly, justify a special designation. It does not seem justified to expend considerable time and money to define the in vivo blood level characteristics at this point. Methodology for the stomach safety claims is difficult to evaluate and certain properties that relate to absorption and stomach safety claims should probably have a lower priority at this point in time. There will be other needs, however, that may be expediently met in in vivo neutralization standards as a more expedient means to routinely evaluate products and lots.

In addition to serving as a means of simulating in vivo performance of the dosage form, in vitro procedures 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.I. below—Aspirin standard testing procedures.) This methodology must be evaluated 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 FDA 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


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 adjuvant and classifies it as Category II. The Panel further concludes that the combination of para-aminobenzoic acid (PABA) or sodium aminobenzoate with any ingredients discussed above in the antirheumatic section of this report is also classified as Category II. (See part V. above—ANTIRHEUMATIC AGENTS.) There is no evidence that para-aminobenzoic acid or sodium aminobenzoate contribute to the antirheumatic action of known antirheumatic agents.

In 1947, Rosenthal and Fraser studied the efficacy of para-aminobenzoic 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, Hollander and Harris studied 27 patients with acute 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. No patient experienced relief of pain and stiffness; note that 4 g of sodium salicylate daily 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 which excretively 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 diseases. In large doses, PABA can increase the blood level of salicylate by competing for glycine and thereby slowing the rate of conversion of salicylate to salicylic acid, as shown by studies of Salassa et al., who demonstrated that PABA in doses of 24 g daily along 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 550 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 either salicylate alone (Ref. 2). However, analgesic effectiveness could not be related to the level of salicylate achieved.

The studies on the antirheumatic effects of PABA do not provide objective evidence of effectiveness.

Analgesic effectiveness in relief of arthritis pain is claimed by Barden and Cuneo (Ref. 6), Cass et al. (Ref. 7), Smith (Ref. 8) and Hebert and Reuzi (Ref. 9). Only clinical impressions of effectiveness are given.

Ford and Blanchard compared the functional capacity of arthritic patients before and after the treatment with physical therapy and the combination (sodium salicylate plus PABA) (Ref. 10). Some patients were also given the combination plus 2.5 mg cortisone. No conclusions regarding the antirheumatic or analgesic effectiveness of the combination could 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.

The enteric-coated combination of aspirin and PABA may be excrated intact as described by Smith in three patients (Ref. 8). Studies of the blood salicylate levels of aspirin alone and with PABA reveal no significant differences when taken in a dose of 900 mg aspirin every 6 hours for 12 doses as compared to 900 mg aspirin plus 900 mg PABA every 6 hours for 12 doses (Ref. 11). The combination was found to produce a greater number of mild gastrointestinal side effects.

Taylor (Ref. 12) studied the antirheumatic effectiveness of the combination in osteoarthritis patients by observing activity status and early morning pain. No details are provided regarding the definition of these parameters and therefore no conclusions can be reached.

b. Safety. PABA has been shown to be goutogenic in large doses (Ref. 13).

REFERENCES


(2) Hollander, J. L. and T. N. Harris, "Combination of Sodium Aminobenzoic Acid (Pabulacte) in the Treatment of Rheumatoid Arthritis," American Journal of the Medical Sciences, 221:308-401, 1951.


(5) Carski, "Combination of Individual Active Components: Controlled Study No. 8201," draft of unpublished paper is included in OTC Volume 82004.


(11) Anonymous, "Comparative Plasma Levels of Salicylate After the Administration of Aspirin, Pabulacte or Buffered Pabulacte," draft of unpublished paper is included in OTC Volume 900503.


3. Caffeine (citrate caffeine). The Panel concludes that caffeine (citrate caffeine) when used alone in an adult oral dose of 65 mg not to exceed 600 mg in 24 hours is safe but ineffective as an OTC analgesic and/or antirheumatic ingredient and is classified as Category II. However, there are insufficient data available to classify the adjuvant effect of caffeine (citrate caffeine) when used in combination with aspirin as Category I analgesic, antipyretic and/or antirheumatic adjuvant and it is therefore classified in combination as Category III.

The Panel notes that the Advisory Review Panel on OTC Sedative, Tranquilizer and Sleep-Aid Drug Products, in their report published in the Federal Register, Vol. 42, No. 131—Friday, July 8, 1977, (Ref. 2) concluded that caffeine is safe and effective for use as an OTC stimulant when used in the recommended oral dosage of 100 to 200 mg not more often than every 4 hours. However, the United States Pharmacopeia XIX also categorizes caffeine as a stimulant whereas a former edition of another official compendium, National Formulary XIII, categorizes caffeine in combination with aspirin and phenacetin (widely known as APC compound) as an analgesic mixture. This combination is no longer found in current official compendia. However, caffeine is still widely used in analgesic-antipyretic preparations. In fact, several of the submissions submitted to the Panel for review contained combination products which included caffeine, aspirin and phenacetin ranging from 15 to 65 mg per dosage unit. Unfortunately, the information and data submitted, fail to demonstrate conclusively that caffeine as a combination is effective as an analgesic, antipyretic and/or antirheumatic ingredient. The Panel finds there is little evidence to show that this ingredient even contributes to these pharmacologic effects in the clinical situation.
The pharmacologic rationale for the long accepted use of caffeine in APC compound and in other similar products is not clearly understood. The Panel recognizes the known pharmacologic 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 ineffective clinical use for these preparations containing caffeine has been for the treatment of certain types of headache. There is some evidence that caffeine may contribute to the effectiveness of other analgesics and, therefore, the Panel has categorized this possible contributory effect as a potential adjuvant action of caffeine.

### Effectiveness

1. **Caffeine as an Analgesic Adjunct**

   As noted above, the Panel finds that there is some inconclusive evidence to suggest that caffeine may exert additional analgesia when used in combination with other analgesics. The Panel recognizes 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 combinations in terms of their systemic and antipyretic effects. As will be discussed below, there is only one well-controlled clinical study to determine whether aspirin plus caffeine is more effective than aspirin alone and whether aspirin and caffeine are equi-effective (Ref. 1). Several other clinical studies provide some support for this hypothesis, and there are also supporting 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 mild analgesics are many and include the difficulty of carrying out controlled clinical assays 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 determined in clinical trials, prompt relief of headache which results from the hypertensive state. There was immediate relief of headaches following administration of caffeine 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 other analgesics. It has been known for many years and shown by the work of Leake et al. (Ref. 5) that the production of experimental headache by nitrates was accompanied by dilatation of the meningeal blood vessels. Leake et al. performing experiments in 1939 (Ref. 6) studied headache produced by intravenous injections of small amounts of histamine. These studies were enlarged by Clark et al. (Ref. 7), and by Schumacher et al. in 1940 (Ref. 8) who demonstrated that this experimental headache was accompanied by increased amplitude of pulsation of the cerebral blood vessels. Thus there is good evidence to support the theory that some headaches are related to cerebral vascular dilatation.

   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) (Ref. 9). Caffeine (an inhibitor of phosphodiesterase) decreases cyclic AMP to be increased and act as a second messenger to increase vascular tone. This mechanism 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, Dresbach and Pfeiffer (Ref. 10) showed that caffeine could be important in the treatment of caffeine withdrawal headache. The authors recognized that many people ascribe an occasional headache to lack of morning coffee and the "letdown" which may result if this stimulant is withdrawn from habitual consumers. Caffeine withdrawal was accompanied by nausea in four of the five migraine subjects, and vomiting in one of them. The investigators found that in 55 percent of 38 trials in 22 subjects, a headache as extreme and severe as the subject had ever experienced was produced by the sudden withdrawal of caffeine. This headache responded to treatment by caffeine or aspirin. The authors concluded that this study also provides a plausible explanation for the infrequent empirical addition of caffeine to many headache remedies.

   The psychophysiologic 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 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 physiologically active. There was a strong positive association between the subjects' sensitivity to mood elevating effects of caffeine, and a sensitivity to the wakefulness effects of this stimulant. The central nervous system stimulant effects of caffeine have been discussed in detail in the OTC Sedative, Tranquilizer and Sleep-Aid Panel report published in the Federal Register of December 8, 1975 (40 FR 37292).

   The Panel finds these studies tend to demonstrate that the habitual use of caffeine for central nervous system effects may make caffeine dependent. Hence, the likelihood of headache associated with the use of analgesic agents in combination with caffeine may be increased without proven compensatory analgesic or sedative effects. It is important to remember that caffeine 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 significantly higher for aspirin alone (Refs. 1 and 12). Although the difference was not statistically significant in the study of DeKornfeld et al. (Ref. 12), it seemed to suggest that caffeine was contributing to the pain relief observed. However, this study was not designed to test the hypothesis that caffeine augments the effect of the analgesic(s), and the higher scores could have been due to the inordinantly potent dosage of analgesic or indeed, as the authors interpreted, due to chance.

   In a study presented by Houde (Ref. 1), the effect of caffeine is statistically significant. Houde found that a com-
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 concluded by recommending that aspirin, as well as caffeine and analgesic preparations containing caffeine be used during relief. 105 mg/kg for rats 105 mg/kg. The minimal lethal intravenous dose for cats is 80 to 100 mg/kg. It is believed that human subjects may be more sensitive to the lethal effects of caffeine, but extrapolating from the animal data, it appears that the therapeutic doses used in combination with analgesics are safe. Although low and fatalities extremely rare, they are not unheard of (Refs. 21 and 22). In his excellent review, Peters (Ref. 20) pointed out that it has been shown for humans that the absorption of caffeine after oral administration is faster than after intramuscular administration, where the peak plasma level occurs after 30 minutes to 1 hour. Thus, orally administered caffeine is very quickly taken up and has a half-life of 3 to 3½ hours in the body. The stimulant effects and toxicity of caffeine have also been reviewed extensively by the OTC Sedative, Tranquilizer and Sleep-Aid Panel. A report published in the Federal Register of December 8, 1975 (40 FR 57292). They discussed, in addition, the mutagenic effects in detail. This Panel agrees with their conclusions regarding the safety of caffeine. Chronic toxicity has not been observed in humans, but some resistance to the drug does develop. In animals, the dose that killed 50 percent of young adult female rats in 100 days, or which, if their life span, was estimated to be 150 mg/kg daily. The maximal dose that was estimated to produce no death in 100 days was 110 mg/kg daily. The figure of 110 mg/kg daily extrapolated to man corresponds to drinking 60 to 100 cups of coffee daily. Thus, caffeine consumption by man, in the most readily available form, is not likely to cause death in young healthy persons. Relatively chronic toxicity is the factor of tolerance to caffeine. Tolerance appears to develop within 2 to 3 days after the daily dosage. Tolerance to the hypertensive effects of caffeine has also been demonstrated to develop in cats. Thus, in man it is likely that some tolerance to caffeine develops with daily use. In the rat, sensitivity to the toxic dose for caffeine intravenously is not increased. There is little information available on the biochemical effects of caffeine on blood glucose level or the sugar tolerance curve. In high doses, caffeine produces a sharp rise in the pressure level of blood, an action similar to the effect of stress. Caffeine increases lipolysis by direct action on the adipose tissue (Ref. 23). These actions, like other pharmacologic actions of caffeine, resemble those of the catecholamines. Ingestion of caffeine in some patients resembles the effects of catecholamines on the heart, too, in that it induces a rise in cardiac output, increased heart rate, mean arterial pressure and ventricular filling pressure (Ref. 24). In some individuals the use of coffee causes an increase in premature ventricular contractions and in platelet aggregation (Refs. 28 and 29). Recently Jick et al. (Ref. 25) reported a positive association between coffee consumption and acute myocardial infarction but no association between tea consumption and acute myocardial infarction. There is no available information that inclusion of caffeine in OTC analgesic preparations may lead to their consumption.
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

(1) Houde, R. W., "Study of Aspirin, N-Acetyl-p-Aminophenol and Caffeine Combination Toxicity," "Enhancement of Human Performance by Caffeine and the Anabolics," "Acetyl-p-Aminophenol and Caffeine Com- for dramatic effect, the Panel has classified the following in combination as Category C. The Panel notes that the Advisory Review Panel on OTC Antihistamine, in their report published in the Federal Register of September 9, 1976 (41 FR 38312) concluded that pheniramine maleate is safe and effective as an OTC antihistamine. The Panel concluded that pheniramine maleate was used alone in the currently marketed OTC adult oral dosage of 30 mg not to exceed 240 mg in 24 hours is safe but ineffective as an OTC analgesic, antipyretic and/or antirheumatic ingredient and is classified as Category H. However, there are insufficient data available to classify the adjuvant effect of phenyltoloxamine dihydrogen citrate with Category I analogues, antpyretic and/or antirheumatic adjuvant and it is therefore classified in combination as Category III.

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, 1975 (40 FR 57292) concluded that the available data were insufficient to justify a warning at the present time and the potential benefits outweigh this risk. The Panel recommended a proposed dosage of up to a maximum 100 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.

b. Phenyltoloxamine dihydrogen citrate. The Panel concludes that phenyltoloxamine dihydrogen citrate when used alone in the currently marketed OTC adult oral dosage of 30 mg not to exceed 240 mg in 24 hours is safe but ineffective as an OTC analgesic, antipyretic and/or antirheumatic ingredient and is classified as Category H. However, there are insufficient data available to classify the adjuvant effect of phenyltoloxamine dihydrogen citrate when used in combination with Category I analogues, antpyretic and/or antirheumatic agents such as effective analgesic, antipyretic and/or antirheumatic adjuvant and it is therefore classified in combination as Category III.
Phenyltoloxamine belongs to the ethereal 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 rhinitis, hay fever, pruritus, eczema, urticaria, asthma and certain other allergic drug reactions. Animal studies have shown that the drug is one of the least toxic phenyltoloxamines. However, it may cause drowsiness, dizziness, insomnia, nervousness and epigastric distress in some people.

The Panel is unaware of any OTC marketing of phenyltoloxamine alone as an analgesic, antipyretic and/or antihistamine. However, the Panel did receive submissions of the use of phenyltoloxamine as an analgesic, antipyretic and/or antihistamine. The Panel finds these data insufficient to classify phenyltoloxamine as an analgesic, antipyretic and/or antihistamine. Labeling for these marketed products include phrases such as "for enhanced relief of pain and anxiety", "relief of mild to moderate pain and anxiety", "for enhanced relief of pain and anxiety", "analgesic, antipyretic and/or antihistamine in combination with acetaminophen, phenylpropanolamine, and with acetaminophen and caffeine. Labeling for these marketed products include phrases such as "for enhanced relief of pain and anxiety", "for enhanced relief of pain and anxiety", and "for enhanced relief of pain and anxiety". The Panel notes that the Advisory Review Panel published in the Federal Register, Vol. 42, No. 8, July 7, 1977, has provided a complete list of all OTC products containing phenyltoloxamine. The Panel further concludes that the available data are insufficient to support the conclusion that the combination is more effective than acetaminophen alone. The Panel has classified the potential adjuvant effect of phenyltoloxamine in combination as Category III.

4. Pyrilamine maleate. The Panel concludes that pyrilamine maleate when used alone in the currently marketed OTC adult oral dosage of 12.5 mg not to exceed 60 mg in 24 hours is safe but ineffective as an OTC analgesic, antipyretic and/or antihistamine ingredient and is classified as Category II. However, there are insufficient data available to classify the adjuvant effect of pyrilamine maleate when used in combination with acetaminophen, phenylpropanolamine, and/or phenyltoloxamine was significantly more effective than acetaminophen alone in the treatment of headache.

The Panel carefully reviewed this study and the additional data submitted (Refs. 1 and 5). 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 was significantly more effective than acetaminophen alone in the treatment of headache.

In the other double-blind study on relief of muscularkeletal 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 nonrheumatic muscularkeletal pain associated with anxiety were included. There were 73 females and 67 males in the study. Subjects were divided into four treatment groups. Each patient received two tablets 3 times daily for 3 days.

Both were found to be effective, 325 mg acetaminophen in relieving pain and 80 mg phenyltoloxamine. According to the study, the combination, i.e., 325 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 effect of the combination was significantly greater than the effect of acetaminophen alone (p is less than 0.01). The Panel carefully evaluated this study and the additional data submitted (Refs. 2 and 5) and found that while the double-blind combination of acetaminophen and phenyltoloxamine produced more pain relief than acetaminophen alone, this was statistically significant only at 2 days. Therefore, the Panel concludes that pyrilamine maleate is classified as "evidence that salicylamide may be effective in relieving anxiety, both acetaminophen and phenyltoloxamine in the treatment of simple nervous tension accompanied by headache and the second study was designed to determine the effectiveness of the combination in relief of muscularkeletal pain associated with anxiety.

In the single-dose, double-blind cross-over study of 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 and discomfort due to simple headaches; for temporary relief of such pain associated with muscle and joint soreness, neuritis, sinusitis, minor menstrual cramps, premenstrual cold or sore throat, and minor aches and pains of rheumatism and arthritis and "produces mild sedation and tranquilization."

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-calming effects of a currently marketed combination product containing acetaminophen and phenyltoloxamine in the treatment of simple nervous tension accompanied by headache and the second study was designed to determine the effectiveness of the combination product in relief of muscularkeletal pain associated with anxiety.

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 of 97.5 to 400 mg. The Panel finds that salicylamide was effective at a higher dosage (1,000 mg every 4 hours while symptoms persist not to exceed 6,000 mg in 24 hours for not more than 10 days) may be effective but has not been demonstrated to be safe as an 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.

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 either as an adjuvant to directly enhance the pharmacological activity of analgesic agents, that is, the usual hypnotic activity of acetaminophen, or possibly indirectly by increasing the amount of the aspirin absorbed possibly by competition or inhibition of metabolism in the duodenum or liver. This mechanism provides one possible explanation for the "aspirin sparing" claim submitted for one analgesic combination (Ref. 4).

Salicylamide has been demonstrated to inhibit salicylate metabolism competing with aspirin for the glucuronidation pathway. It has also been shown that salicylamide inhibits the metabolism of acetaminophen in the glucuronidate and sulfate formation (Refs. 2 and 3).

The mechanisms involved, doses required and effects of formulation variables are not well defined. Claims for additive 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 crosses the systemic circulation. In most clinical studies, these doses of salicylamide have provided little or no effect compared to that obtained with placebo. Doses of 1 to
2 g and higher are usually required to show analgesic effects. Based on the knowledge of single doses of salicylamide alone, it would seem unlikely that the small oral doses of 300 to 600 mg found in most combination products would result in effective plasma levels of salicylamide. There is accumulating evidence, however, that combinations of salicylamide with salicylic acid and sodium salicylate (Ref. 2) and also a combination of salicylamide and acetaminophen (Ref. 3). This was not the case, however, with the combination of acetaminophen and salicylate (Ref. 2). When 2.32 g sodium salicylate was given to healthy adults 2 hours before the administration of 600 mg salicylamide, there was a mutual inhibition of glucuronidation of both drugs with the suggestion of a salicylate-induced inhibition of salicylamide sulfate formation (Ref. 2). Such inhibitory action would be expected to result in higher blood levels of the free unmetabolized drugs with a concomitant increased pharmacologic action. 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 salicylamide was given 1.5 hours after the administration of 4 g acetaminophen in the form of acetaminophen sulfate, acetaminophen glucuronide and salicylamide sulfate was observed as evidenced by the decreased excretion rates of these metabolites in the urine. The inhibition of sulfate formation was counteracted by L-cysteine, a source of sulfate, administered concomitantly with salicylamide (Ref. 3). On the other hand, when sodium salicylate was given 5 times a day for 10 days in conjunction with a standard phosphatase administration, there was no apparent mutual inhibition of the formation of the major metabolites (glucuronides and sulfates) of acetaminophen or the formation of the sulfate of salicylamide. The inhibition of sulfate formation was limited to the production of free unmetabolized salicylamide (Ref. 4). This is in contrast to the mutual metabolic inhibition that occurred when acetaminophen was administered with salicylamide (Ref. 3). The results of the metabolic studies using combinations of salicylamide and acetaminophen, salicylamide and sodium salicylate, and acetaminophen and sodium salicylate, indicate that salicylamide is the major determinant in the metabolic inhibitory interactions between acetaminophen and salicylamide and between sodium salicylate and salicylamide. This pronounced competitive inhibitory effect of salicylamide on glucuronide and sulfate formation is most likely due to its very rapid metabolism. Available data indicate that the formation of salicylamide glucuronide and sulfate proceeds about 10 times more rapidly than the formation of acetaminophen glucuronide and sulfate at body levels of 1 g of these drugs (Ref. 4).

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 vitro intestinal microsomal system in a 50 percent increase in free salicylamide transfer across the everted intestine.

The extent to which combinations of these analgesics may interact in man at 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 experimental animals (Refs. 3, 6, and 7).

Berger (Ref. 6) in 1954 reported that salicylamide had a hypnotic effect that was enhanced by phenacetin which has no sedative effect of its own. The finding that salicylamide is more sedative corroborated by the studies in mice by White et al. (Ref. 7) who in 1956 found sedative effects of several combinations at doses which had no effect when given separately, the combination of acetaminophen, salicylamide-acetaminophen and salicylamide-acetanilide. These workers also found that with a mixture of 240 mg acetaminophen and 300 mg salicylamide, 76 of 108 patients noted a sedative effect and some patients commented on the analgesic effect of the mixture. The same dose given 4 times daily to 15 subjects resulted in mild sedation in 14 patients and in 7 patients receiving a placebo. No other adverse reactions were noted.

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. The treatment was administered in a double-blind Latin-square design (Ref. 8). In a total of 94 subjects with 229 headaches, relief was obtained in 46 percent by placebo, 78 percent by aspirin and 76 and 69 percent 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 different from each other.

It is reasonable to conclude that in considering the dose of each individual ingredient in a combination product that includes salicylamide, reliance cannot be placed upon using the same dose of the ingredients that is contained in single ingredient products. The inhibitory action on the metabolism of the ingredients in the combination, by the presence of salicylamide, might be expected to increase the amounts of the free unmetabolized drugs to levels that would otherwise occur if each ingredient were administered alone at the same dose. Such increased levels might result in overdose and toxic effects. It is possible that competition for metabolism either at intestinal or hepatic sites during absorption will provide a "sparing" effect.

REFERENCES

(1) OTC Volume 0575, 1971.

C. DATA REQUIRED FOR EVALUATION

1. Aspirin standard testing procedures. The studies cited above have shown that buffered aspirin products vary among themselves with respect to dissolution rate, rate of absorption and effect on gastric tolerance. (See part II, paragraph J above—Effects of Product Formulation on Drug Absorption and Pharmacologic Effectiveness.) Variations in these characteristics, are also found in plain aspirin products. Although buffered aspirin products generally have faster dissolution rates, are better tolerated and are absorbed faster than plain aspirin products, all buffered aspirin products cannot be equated to have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time.
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) Standardizing reagents. (i) pH meter, equipped with glass and saturated calomel electrodes.
(2) Magnetic stirrer. (ii) Magnetic stirring bars (about 40 mm long and 10 mm in diameter).
(3) Tablett disintegration apparatus. (iii) 0.1 N, 0.5 N and 1.0 N hydrochloric acid.
(4) 0.05 M potassium hydrogen phthalate.
(5) Buret stand. (v) 50 ml buret.
(6) Magnetic stirrer. (vi) 100 ml beakers.
(7) Pipette 30.0 ml of 1.0 N HCl into the sample solution while stirring on the magnetic stirrer at 30 ± 30 r.p.m.
(8) Stir for exactly 15 minutes after addition.
(9) 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. (x) Check the sample solution 10 to 15 seconds after obtaining pH 3.5 to make sure the pH is stable.
(10) Calculate the number of mEq of acid neutralized by the sample as follows:

Total mEq = (30.0 ml) (normality of HCl) - (ml of NaOH) (N of NaOH)

Use appropriate factors, i.e., density, average tablet weight, etc., to calculate the total mEq of acid neutralized per minimum labeled dosage.

(5) Test modification. The formulation and/or mode of administration of certain products may require modification of this in vitro test. Any proposed modification and the data to support it shall 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 the equivalent of 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 167.5 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, then with alcohol, and carefully dried. Take precautions to prevent contamination from airborne, fluorescent particles and from metal and rubber surfaces.

(2) Dissolution test apparatus. The apparatus consists of a suitable water bath, a 500 ml round bottom glass vessel (Kimble Glass No. 33710-S1, or equivalent), a motor, and a stirring blade (Sargent-S-76637, size B, 3-in length; Hancock-65-700-300, or equivalent) on a stirring ring (Sargent-S-76634, 14, 5-in length; Hancock-65-700-001, or equivalent). The water bath may be of any convenient size that permits keeping the water temperature uniformly at 37°C ± 0.5°C throughout the test. The water bath must not transmit perceptible vibration to the sample vessel, which is cylindrical, with a spherical bottom. It is 19 cm high and is 10 cm in inside diameter. Its sides are flanged near the top. The vessel is positioned so that the stirring shaft from the motor is perpendicular to the vessel's cylindrical axis. The motor is fitted with a speed-regulating device that allows the motor speed to be held at 50 r.p.m. ± 1 r.p.m. The motor is suspended above the vessel in such a way that it will be raised or lowered to position the stirring blade. The stirring shaft is 10 mm in diameter and about 37 cm in length. It must run true on the motor axis without perceptible wobble. The stirring blade is 4 mm thick and forms a section of a circle whose diameter is 83 mm and which is subtended by parallel chords of 42 and 77 mm. The blade is positioned horizontally, with the 42 mm diameter at the center of the vessel, so that the lowest edge of the blade is 2.5 cm ± 0.2 cm above the lowest inner surface of the vessel.

(3) Dissolution medium. Use a reagent containing 2.0 g sodium chloride, 2.2 g papain, 5.0 g mucin and 10 ml 51 N hydrochloric acid (HCl) combined and diluted with distilled water per each 1,000 ml solution.

(6) Procedure. Place 500 ml of dissolution medium in the vessel. Place 500 mg of aspirin into the flask. After 5, 20, and 60 minutes, accurately timed, withdraw 10 ml, using a glass syringe connected to a glass sampling tube, of solution from a point midway between the stirring shaft and the wall of the vessel and approximately midway in depth. Filter the solution promptly after withdrawal, using a suitable membrane filter of not greater than 0.8 micron porosity. This is the test solution. Repeat the dissolution procedure on 5 additional tablets containing the equivalent of 325 mg (5 gr) buffered aspirin per tablet.

(7) Measurement of acetylsalicylic acid. The amount of acetylsalicylic acid in the test solution at the time of sampling is determined by comparing their absorbancies with standard curves prepared for the two acids from known solutions. The solutions from which the standard curves are prepared should contain a known amount of acid dissolved in reagent dissolution medium and their absorbancies should be read immediately after preparation. The amount of the acids in the test solution at the time of sampling are expressed in mg. The decreasing volume of the test solution after repeated samplings, as well as the amounts of acetylsalicylic acid and salicylic acid removed in each sample should be considered in deter-
PROPOSED RULES

Sec. 343.3 Definitions.

Subpart A--Active Ingredients

§ 343.1 Scope.

An over-the-counter internal analgesic, antipyretic, or antirheumatic product in a form suitable for oral administration 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 established in § 331.1 of this chapter.

Subpart B--Active Ingredients

§ 343.3 Definitions.

(a) Acetaminophen analgesic equivalence value. The analgesic effectiveness for a product containing acetaminophen when compared to the standard acetaminophen 325 mg (5 gr) dosage unit.

(b) Acetaminophen (pediatric dosage unit). A single dosage unit containing 80 mg (1.23 gr) acetaminophen for children under 12 years.

Subpart C--(Reserved)

Subpart D--Labeling

§ 343.30 Permitted combinations of active ingredients.

Subpart E--Labeling

§ 343.343-INTERNAL ANALGESIC, ANTIPYRETIC AND ANTIINFLAMMATORY PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

PART 343--INTERNAL ANALGESIC, ANTIPYRETIC AND ANTIINFLAMMATORY PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A--General Provisions

§ 343.1 Scope.

The active ingredients of the product consist of the following within the dosage limit established for each ingredient:

(a) Aspirin.—(1) For products containing 325 mg (5 gr) per dosage unit.

§ 343.10 Analgesics.

§ 343.343.14 Antihistamines.

§ 343.343.30 Permitted combinations of active ingredients.

Subpart C--(Reserved)

Subpart D--Labeling

§ 343.330 Labelling of analgesic and antipyretic products.

§ 343.340 Professional labelling.


Subpart A--General Provisions

§ 343.1 Scope.

An over-the-counter internal analgesic, antipyretic, or antirheumatic product in a form suitable for oral administration 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 established in § 331.1 of this chapter.

§ 343.3 Definitions.

(a) Acetaminophen analgesic equivalence value. The analgesic effectiveness for a product containing acetaminophen when compared to the standard acetaminophen 325 mg (5 gr) dosage unit.

(b) Acetaminophen (pediatric dosage unit). A single dosage unit containing 80 mg (1.23 gr) acetaminophen for children under 12 years.

(c) Adjulant. 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.

(1) Direct acting. An adjulant which enhances the pharmacologic response directly by synergistic or additive effects at the site of action.

(2) Indirect acting. An adjulant 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.

(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) Antiinflammatory 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 carbasi­

Subpart B--Active Ingredients

§ 343.20 Analgesics.

§ 343.22 Antipyrines.

§ 343.14 Antihistamines.

§ 343.343.30 Permitted combinations of active ingredients.

Subpart C--(Reserved)

Subpart D--Labeling

§ 343.330 Labelling of analgesic and antipyretic products.

§ 343.340 Professional labelling.


Subpart A--General Provisions

§ 343.1 Scope.

An over-the-counter internal analgesic, antipyretic, or antirheumatic product in a form suitable for oral administration 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 established in § 331.1 of this chapter.

§ 343.3 Definitions.

(a) Acetaminophen analgesic equivalence value. The analgesic effectiveness for a product containing acetaminophen when compared to the standard acetaminophen 325 mg (5 gr) dosage unit.

(b) Acetaminophen (pediatric dosage unit). A single dosage unit containing 80 mg (1.23 gr) acetaminophen for children under 12 years.

(c) Adjulant. 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.

(1) Direct acting. An adjulant which enhances the pharmacologic response directly by synergistic or additive effects at the site of action.

(2) Indirect acting. An adjulant 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.

(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) Antiinflammatory 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 carbasi­
(7.69 gr) every 3 hours or 970 mg (15.38 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 (15.38 gr) initially, followed by more than 325 mg (5 gr) but not more than 500 mg (8.47 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 under 11 years oral dosage is 487.5 mg (7.5 gr) every 4 hours while symptoms persist not to exceed 2,031.5 mg (31.5 gr) in 24 hours for not more than 10 days. Children 9 to under 11 years oral dosage is 325 mg (5 gr) every 4 hours while symptoms persist not to exceed 1,035 mg (16.5 gr) in 24 hours for not more than 10 days. Children 4 to under 6 years oral dosage is 207 mg every 4 hours while symptoms persist not to exceed 947.5 mg (15.38 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.

(d) Choline salicylate. Adult oral dosage is 435 to 870 mg every 4 hours while symptoms persist not to exceed 2,175 mg in 24 hours for not more than 5 days. Children 4 to under 6 years oral dosage is 316.5 mg every 4 hours while symptoms persist not to exceed 1,035 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.

(e) Magnesium salicylate. Adult oral dosage is 325 mg (5 gr) to 750 mg (12.5 gr) initially, followed by 325 mg (5 gr) every 4 hours while symptoms persist not to exceed 1,632.5 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 2,719 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.

For products containing 80 mg (1.25 gr) per dosage unit. Children 11 to under 12 years oral dosage is 160 mg (2.46 gr) every 4 hours while symptoms persist not to exceed 800 mg (12.5 gr) in 24 hours for not more than 10 days. Children 11 to under 12 years oral dosage is 652.5 mg every 4 hours while symptoms persist not to exceed 3,282.5 mg in 24 hours for not more than 5 days. Children 9 to under 11 years oral dosage is 517.5 mg per dosage unit. Children 9 to under 11 years oral dosage is 487.5 mg (7.5 gr) initially, followed by more than 487.5 mg but not more than 500 mg (8.47 gr) every 3 hours or 970 mg (15.38 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.

(3) For products containing 500 mg (7.69 gr) per dosage unit. Adult oral dosage is 500 mg (7.69 gr) to 1,000 mg (15.38 gr) initially, followed by more than 500 mg (7.69 gr) every 4 hours while symptoms persist not to exceed 800 mg (12.5 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.

(4) For products containing more than 500 mg (7.69 gr) but not more than 650 mg (10 gr) per dosage unit. Adult oral dosage is 543 mg every 4 hours while symptoms persist not to exceed 2,719 mg in 24 hours for not more than 5 days. Children 6 to under 9 years oral dosage is 320 mg (4.92 gr) every 4 hours while symptoms persist not to exceed 1,200 mg (18.45 gr) in 24 hours for not more than 5 days. Children 2 to under 4 years oral dosage is 160 mg (2.46 gr) every 4 hours while symptoms persist not to exceed 800 mg (12.5 gr) in 24 hours for not more than 10 days. Children 2 to under 4 years oral dosage is 160 mg (2.46 gr) every 4 hours while symptoms persist not to exceed 800 mg (12.5 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.
(§ 343.12 Antipyretics.

The active ingredients of the product consist of the following within the dosage limit established for each ingredient:

(1) 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 1,200 mg (1.8 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) Nonstandard schedule. Adult oral dosage is 325 mg to 650 mg (5 to 10 gr) per dosage unit. Adult oral dosage is more than 500 mg (7.69 gr) but not more than 650 mg (9.78 gr) per dosage unit. For products containing more than 650 mg (9.78 gr) per dosage unit, adult oral dosage is more than 500 mg (7.69 gr) but not more than 650 mg (9.78 gr) per dosage unit.

(b) Aspirin.—(1) For products containing 325 mg (5 gr) per dosage unit—

(i) Standard schedule. Adult oral dosage is 325 mg (5 gr) to 650 mg (10 gr) every 4 hours while fever persists not to exceed 3,000 mg (45 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) Nonstandard schedule. Adult oral dosage is more than 500 mg (7.69 gr) but not more than 650 mg (9.78 gr) per dosage unit. Adult oral dosage is more than 650 mg (9.78 gr) per dosage unit. For products containing more than 650 mg (9.78 gr) per dosage unit, adult oral dosage is more than 500 mg (7.69 gr) but not more than 650 mg (9.78 gr) per dosage unit.

3. For products containing more than 243.8 mg but not more than 485 mg per dosage unit. Oral dosage is more than 421 mg per dosage unit. Children under 6 years oral dosage is 325 mg (5 gr) every 4 hours while fever persists not to exceed 1,625 mg (24.6 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.

4. For products containing more than 485 mg but not more than 590 mg per dosage unit. Adult oral dosage is more than 485 mg but not more than 1,000 mg (15.38 gr) per dosage unit. Adult oral dosage is more than 1,000 mg (15.38 gr) per dosage unit. For products containing more than 1,000 mg (15.38 gr) per dosage unit, adult oral dosage is more than 1,000 mg (15.38 gr) per dosage unit. For products containing more than 1,000 mg (15.38 gr) per dosage unit, adult oral dosage is more than 1,000 mg (15.38 gr) per dosage unit.

5. For products containing more than 1,200 mg (18.45 gr) per dosage unit. Adult oral dosage is more than 1,200 mg (18.45 gr) per dosage unit. Adult oral dosage is more than 1,200 mg (18.45 gr) per dosage unit. For products containing more than 1,200 mg (18.45 gr) per dosage unit, adult oral dosage is more than 1,200 mg (18.45 gr) per dosage unit.

6. For products containing more than 590 mg (8.85 gr) but not more than 650 mg (9.78 gr) per dosage unit. Adult oral dosage is more than 590 mg (8.85 gr) but not more than 650 mg (9.78 gr) per dosage unit. Adult oral dosage is more than 650 mg (9.78 gr) per dosage unit. For products containing more than 650 mg (9.78 gr) per dosage unit, adult oral dosage is more than 650 mg (9.78 gr) per dosage unit.
under 12 years oral dosage is 487.5 mg (7.5 gr) every 4 hours while fever persists not to exceed 2,437.5 mg (37.5 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 2,031.5 mg in 24 hours for not more than 3 days. Children 6 to under 9 years oral dosage is 325 mg (5 gr) every 4 hours while fever persists not to exceed 1,632.5 mg in 24 hours for not more than 3 days. Children 4 to under 6 years oral dosage is 310.5 mg every 4 hours while fever persists not to exceed 1,532.5 mg in 24 hours for not more than 3 days. Children 2 to under 4 years oral dosage is 207.5 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.

(d) Choline salicylate. Adult oral dosage is 435 to 870 mg every 4 hours while fever persists not to exceed 5,220 mg in 24 hours for not more than 3 days. Children 11 to under 12 years oral dosage is 414 to 828 mg every 4 hours while fever persists not to exceed 3,880 mg in 24 hours for not more than 3 days. Children 9 to under 11 years oral dosage is 325 mg to 650 mg every 4 hours while fever persists not to exceed 2,437.5 mg in 24 hours for not more than 3 days. Children 7 to under 9 years oral dosage is 315 mg to 630 mg every 4 hours while fever persists not to exceed 2,031.5 mg in 24 hours for not more than 3 days. Children 5 to under 7 years oral dosage is 305 mg to 615 mg every 4 hours while fever persists not to exceed 1,632.5 mg in 24 hours for not more than 3 days. Children 4 to under 6 years oral dosage is 310.5 mg to 621 mg every 4 hours while fever persists not to exceed 1,530 mg in 24 hours for not more than 3 days. Children 3 to under 4 years oral dosage is 305 mg to 610 mg every 4 hours while fever persists not to exceed 1,035 mg in 24 hours for not more than 3 days. Children 2 to under 2 years oral dosage is 295 mg to 590 mg every 4 hours while fever persists not to exceed 812.5 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.

(ii) Nonstandard schedule. Adult oral dosage is more than 970 mg every 4 hours when fever persists not to exceed 3,900 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.

(2) For products containing more than 325 mg but not more than 421 mg per dosage unit. Adult oral dosage is more than 812.5 mg but not more than 1,000 mg every 4 hours. Initially, followed by more than 325 mg but not more than 421 mg every 4 hours while fever persists not to exceed 3,880 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.

(e) Magnesium salicylate. Adult oral dosage is 325 to 650 mg every 4 hours while fever persists not to exceed 3,880 mg in 24 hours for not more than 3 days. Children 11 to under 12 years oral dosage is 325 mg (5 gr) every 4 hours while fever persists not to exceed 2,437.5 mg in 24 hours for not more than 3 days. Children 9 to under 11 years oral dosage is 315 mg (5 gr) every 4 hours while fever persists not to exceed 2,031.5 mg in 24 hours for not more than 3 days. Children 7 to under 9 years oral dosage is 305 mg (5 gr) every 4 hours while fever persists not to exceed 1,632.5 mg in 24 hours for not more than 3 days. Children 5 to under 7 years oral dosage is 305 mg (5 gr) 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 305 mg (5 gr) every 4 hours while fever persists not to exceed 812.5 mg in 24 hours for not more than 3 days. Children 2 to under 2 years oral dosage is 295 mg (5 gr) every 4 hours while fever persists not to exceed 621 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.

(f) Calcium carbaspirin. Adult oral dosage is 414 to 828 mg every 4 hours while fever persists not to exceed 3,880 mg in 24 hours for not more than 3 days. Children 11 to under 12 years oral dosage is 621 mg every 4 hours while fever persists not to exceed 3,165 mg in 24 hours for not more than 3 days. Children 9 to under 11 years oral dosage is 517.5 mg every 4 hours while fever persists not to exceed 2,587.5 mg in 24 hours for not more than 3 days. Children 7 to under 9 years oral dosage is 414 mg every 4 hours while fever persists not to exceed 2,031.5 mg in 24 hours for not more than 3 days. Children 5 to under 7 years oral dosage is 315 mg every 4 hours while fever persists not to exceed 1,532.5 mg in 24 hours for not more than 3 days. Children 4 to under 6 years oral dosage is 310.5 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.

(1) Sodium salicylate.—(1) For products containing 325 mg per dosage unit.—(1) Standard schedule. Adult oral dosage is more than 325 mg but not more than 421 mg every 4 hours. Initially, followed by more than 325 mg but not more than 421 mg every 4 hours while symptoms persist not to exceed 3,900 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.

§ 343.14 Antirheumatics.

The active ingredients of the product consist of the following:

(a) Aspirin. There is no recommended dosage except under the advice and supervision of a physician.

(b) Calcium carbamazepine. There is no recommended dosage except under the advice and supervision of a physician.

(c) Calcium 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 the combination product consist of any two of the following at the dosage limit established for each ingredient:

1. Aspirin 325 mg (5 gr) per dosage unit.
2. Acetaminophen 325 mg (5 gr) per dosage unit.
3. Calcium carbamazepine 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 antihypertensive 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 nonasartan and/or nonantipyrine ingredients. (1) Any single active ingredient identified in § 343.10 or § 343.12 or any combination of active ingredients identified in § 343.10 or § 343.12 may be combined with generally recognized as safe and effective antihypertensive 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 for the temporary relief of nasal congestion due to the common cold (cold)".

(2) Any single active ingredient identified in § 343.10 or § 343.12 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 for the temporary relief of nasal congestion due to the common cold (cold)".

(3) Any single active ingredient identified in § 343.10 or § 343.12 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 for the temporary relief of nasal congestion due to the common cold (cold)"

(4) 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 for the temporary relief of nasal congestion due to the common cold (cold)"

(5) 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 § 351.10 of this chapter or § 351.20(b), or § 351.10(a) of this chapter.

(6) Aspirin identified in § 343.10(a) or § 343.12(a) may be combined with antacid active ingredient(s) identified in § 351.10 or § 351.20 of this chapter and provided the product is labeled as highly buffered aspirin with aspirin only as identified in § 343.50(a).

(7) Aspirin identified in § 343.10(a) or § 343.12(a) may be combined with antacid active ingredient(s) identified in § 351.10 or § 351.20 of this chapter and provided the product is labeled as highly buffered aspirin with aspirin 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 to the appropriate definition(s) established in § 343.3 and shall contain the following:

(1) For products containing antipyretic 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 § 343.10 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 or § 343.20 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, followed by "or as directed by a physician."
(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 for at least 7 days after tonsillectomy or oral surgery except under the advice and supervision of a physician".

(iv) For products containing creatinine or magnesium identified in §343.10 (b), §343.12 (b) or §343.20 if applicable:

(i) "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".

(v) For products containing any antiseptic or any anthipyretic ingredient identified in §343.10 (d), (e), (f), §343.12 (d), (e) 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".

(vi) For products containing magnesium salicylate identified in §343.10 (e), §343.12(e) or §343.20 if applicable in an amount more than 50 mEq of magnesium salicylate per dosage unit: "Do not take this product if you have kidney disease except under the advice and supervision of a physician".

(vii) For products containing sodium salicylate identified in §343.10 (f), §343.12 (f), §343.20 if applicable:

(i) 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), (b), (c), (d) or §343.12 (a), (b), (c), (d), (e) or (f) or §343.20 if applicable: "Do not take this product if you are allergic to aspirin except under the advice and supervision of a physician".

(2) Statement on equivalent value. (1) For products containing calcium asparin identified in §343.10 (a), (b), (c), (d), (e) or §343.12 (a), (b), (c), (d), (e), (f) shall be clearly labeled on the principal display panel: "Contains the standard strength 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.

(2) For products containing choline salicylate identified in §343.10 (d) or §343.12 (d) 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.

(3) For products containing magnesium salicylate identified in §343.10 (e) or §343.12 (e) 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.
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Office of the Secretary

MEDICARE

Limitations on Provider Costs
Effective July 1, 1977
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Health Care Financing Administration

SCHEDULE OF LIMITS ON HOSPITAL IN-PATIENT GENERAL ROUTINE SERVICE COSTS UNDER THE MEDICARE 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 estimated or prospective costs of 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 23622) published 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, this Notice 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 20168) 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 23622) 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 26992) 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, 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 system, a hospital located in the part of the county not included in OMB in the SMSA/SCSA would be subject to a nonmetropolitan limit even though the per capita 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 for 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 description 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 in 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, the entire county would be deemed to be part of the SMSA whose major city it encompasses. Where a county contains a county city and any SMSA's and does not contain the major city of any SMSA, 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 county with a limit lower than the limit to which the provider has been subject without change, the higher 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 nonmetropolitan areas. 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 reflect the trend in 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 modified the classification of State nonmetropolitan areas on a 5-year per capita average income instead of 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 nonmetropolitan 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 for SMSA/SCSA areas.

The revised Schedule of Limits retains the provision to protect metropolitan area providers, for the period in which this schedule is in effect from the effects of lower limits that may 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 group or the immediately preceding year group. This provision will lessen the effect of unusual short-term fluctuations in area per capita income on reimbursement to individual providers.

The period in which this schedule is in effect the same provision will be applied to nonmetropolitan providers which have been placed in a lower group as a result of the new classification methodology. SMSA/SCSA 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 national 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 to Provider A beginning July 1, 1977, is the higher of the Group II limit or the Group III limit.

An additional refinement has been divided into the following five groups based on per capita income. Counties, rather than SMSA/SCSA areas, are listed for New England States.
SMSA/SCSA Group I

Alaska
Anchorage

California
Los Angeles-Long Beach-Anaheim (SCSA)
Los Angeles-Long Beach
Anaheim-Santa Ana-Garden Grove
Oxnard-Simi Valley-Ventura
Riverside-San Bernardino-Ontario
San Francisco-Oakland-San Jose (SCSA)
San Francisco-Oakland
San Jose
Vallejo-Fairfield-Napa

Colorado
Denver-Boulder
Fairfield County
Burlington County
Litchfield County
Middlesex County
Tolland County

District of Columbia
Washington, DC, DC-MD-VA

Florida
Miami-Port Lauderdale (SCSA)
Fort Lauderdale-Boca Raton

Illinois
Chicago-Gary, IL-IN (SCSA)
Chicago, IL
Gary-Hammond-East Chicago, IN
Peoria
Springfield

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
SEE NEW YORK SCSA

New York
New York-Newark-Jersey City, NY-NJ-CT (SCSA)
New York, NY-NJ
Newark, NJ
Jersey City, NJ
Paterson-Clifton-Passaic, NJ
Nassau-Suffolk, NY
Long Branch-Asbury Park, NJ
New Brunswick-Peapack-Netcong, NJ
Rochester
<table>
<thead>
<tr>
<th>State</th>
<th>Cities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ohio</td>
<td>Cleveland, Akron-Lorain, (SCSA)</td>
</tr>
<tr>
<td></td>
<td>Cleveland</td>
</tr>
<tr>
<td></td>
<td>Akron</td>
</tr>
<tr>
<td></td>
<td>Lorain-Elyria</td>
</tr>
<tr>
<td></td>
<td>Virginia</td>
</tr>
<tr>
<td></td>
<td>Richmond</td>
</tr>
<tr>
<td></td>
<td>Washington</td>
</tr>
<tr>
<td></td>
<td>Richland-Kennewick</td>
</tr>
<tr>
<td></td>
<td>Wisconsin</td>
</tr>
<tr>
<td></td>
<td>Milwaukee-Racine (SCSA)</td>
</tr>
<tr>
<td></td>
<td>Milwaukee</td>
</tr>
<tr>
<td></td>
<td>Racine</td>
</tr>
<tr>
<td></td>
<td>Kenosha</td>
</tr>
<tr>
<td></td>
<td>SMSA/SCSA Group II</td>
</tr>
<tr>
<td></td>
<td>Arizona</td>
</tr>
<tr>
<td></td>
<td>Phoenix</td>
</tr>
<tr>
<td></td>
<td>California</td>
</tr>
<tr>
<td></td>
<td>Bakersfield</td>
</tr>
<tr>
<td></td>
<td>Santa Barbara-Santa Maria-Lompoc</td>
</tr>
<tr>
<td></td>
<td>San Diego</td>
</tr>
<tr>
<td></td>
<td>Stockton</td>
</tr>
<tr>
<td></td>
<td>Connecticut</td>
</tr>
<tr>
<td></td>
<td>New Haven County</td>
</tr>
<tr>
<td></td>
<td>New London County</td>
</tr>
<tr>
<td></td>
<td>Delaware</td>
</tr>
<tr>
<td></td>
<td>SEE PHILADELPHIA SCSA</td>
</tr>
<tr>
<td></td>
<td>Georgia</td>
</tr>
<tr>
<td></td>
<td>Atlanta</td>
</tr>
<tr>
<td>Hawaii</td>
<td>#Honolulu</td>
</tr>
<tr>
<td></td>
<td>Idaho</td>
</tr>
<tr>
<td></td>
<td>Boise City</td>
</tr>
<tr>
<td></td>
<td>Illinois</td>
</tr>
<tr>
<td></td>
<td>Bloomington-Normal</td>
</tr>
<tr>
<td></td>
<td>Decatur</td>
</tr>
<tr>
<td></td>
<td>Kankakee</td>
</tr>
<tr>
<td></td>
<td>*Rockford</td>
</tr>
<tr>
<td></td>
<td>Indiana</td>
</tr>
<tr>
<td></td>
<td>Fort Wayne</td>
</tr>
<tr>
<td></td>
<td>Indianapolis</td>
</tr>
<tr>
<td></td>
<td>Iowa</td>
</tr>
<tr>
<td></td>
<td>Cedar Rapids</td>
</tr>
<tr>
<td></td>
<td>Des Moines</td>
</tr>
<tr>
<td></td>
<td>Waterloo-Cedar Falls</td>
</tr>
<tr>
<td></td>
<td>Kansas</td>
</tr>
<tr>
<td></td>
<td>Topeka</td>
</tr>
<tr>
<td></td>
<td>Wichita</td>
</tr>
<tr>
<td></td>
<td>Kentucky</td>
</tr>
<tr>
<td></td>
<td>Louisville, KY-IN</td>
</tr>
<tr>
<td></td>
<td>Maryland</td>
</tr>
<tr>
<td></td>
<td>Baltimore</td>
</tr>
<tr>
<td></td>
<td>Massachusetts</td>
</tr>
<tr>
<td></td>
<td>Berkshire County</td>
</tr>
<tr>
<td></td>
<td>*Essex County</td>
</tr>
<tr>
<td></td>
<td>*Middlesex County</td>
</tr>
<tr>
<td></td>
<td>*Norfolk County</td>
</tr>
<tr>
<td></td>
<td>*Plymouth County</td>
</tr>
<tr>
<td></td>
<td>*Suffolk County</td>
</tr>
<tr>
<td></td>
<td>Worcester County</td>
</tr>
</tbody>
</table>
Michigan

*Flint
Grand Rapids
Jackson
Kalamazoo-Portage
Saginaw

Missouri

Kansas City, MO-KS
St. Louis, MO-IL

Lincoln

New Hampshire

Rockingham County

New Jersey

SEE PHILADELPHIA SCSA

Nevada

*Las Vegas

New York

*Albany-Schenectady-Troy
Buffalo
Poughkeepsie

North Carolina

Greensboro-Winston-Salem-High Point

North Dakota

*Fargo-Moorhead, ND-MN

Ohio

Dayton
Lima
Toledo, OH-MI
Youngstown-Warren

Oregon

Portland, OR-WA

Pennsylvania

Philadelphia-Wilmington-Trenton, PA-DE-NJ-MD (SCSA)

Philadelphia, PA-NJ
Trenton, NJ
Wilmington, DE-NJ-MD

Allentown-Bethlehem-Easton, PA-NJ
Harrisburg
Lancaster
Pittsburgh
Reading

Rhode Island

Washington County

New Hampshire

Rockingham County

New Jersey

SEE PHILADELPHIA SCSA

Nevada

*Las Vegas

New York

*Albany-Schenectady-Troy
Buffalo
Poughkeepsie

North Carolina

Greensboro-Winston-Salem-High Point

North Dakota

*Fargo-Moorhead, ND-MN

Ohio

Dayton
Lima
Toledo, OH-MI
Youngstown-Warren

Notices
<table>
<thead>
<tr>
<th>State</th>
<th>Cities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arizona</td>
<td>Tucson</td>
</tr>
<tr>
<td>Arkansas</td>
<td>Little Rock-North Little Rock</td>
</tr>
<tr>
<td>California</td>
<td>Fresno, Modesto, Sacramento, Santa Cruz, Santa Rosa</td>
</tr>
<tr>
<td>Colorado</td>
<td>Greeley</td>
</tr>
<tr>
<td>Florida</td>
<td>Jacksonville, Orlando, Tampa-St. Petersburg</td>
</tr>
<tr>
<td>Illinois</td>
<td>Champaign-Urbana-Rantoul</td>
</tr>
<tr>
<td>Indiana</td>
<td>*Anderson, Evansville, IN-KY, South Bend</td>
</tr>
<tr>
<td>Iowa</td>
<td>Dubuque, Sioux City, IA-MI</td>
</tr>
<tr>
<td>Kentucky</td>
<td>Lexington-Fayette</td>
</tr>
<tr>
<td>Louisiana</td>
<td>New Orleans</td>
</tr>
<tr>
<td>Maine</td>
<td>Cumberland County, York County</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>Hampden County, Hampshire County</td>
</tr>
<tr>
<td>Michigan</td>
<td>*Battle Creek, Bay City, *Lansing-East Lansing</td>
</tr>
<tr>
<td>Minnesota</td>
<td>*Rochester</td>
</tr>
<tr>
<td>Mississippi</td>
<td>Jackson</td>
</tr>
<tr>
<td>Montana</td>
<td>Billings</td>
</tr>
<tr>
<td>Nebraska</td>
<td>Omaha, NE-IA</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>Hillsborough County, Merrimack County</td>
</tr>
<tr>
<td>New Jersey</td>
<td>Atlantic City, Vineland-Millville-Bridgeton</td>
</tr>
<tr>
<td>New York</td>
<td>Binghamton, NY-PA, Elmira, Syracuse</td>
</tr>
<tr>
<td>North Carolina</td>
<td>Charlotte-Gastonia, Raleigh-Durham</td>
</tr>
<tr>
<td>State</td>
<td>Cities</td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>Ohio</td>
<td>Cincinnati-Hamilton, OH-KY-IN</td>
</tr>
<tr>
<td></td>
<td>Cincinnati, OH-KY-IN</td>
</tr>
<tr>
<td></td>
<td>Hamilton-Middletown, OH</td>
</tr>
<tr>
<td></td>
<td>Canton</td>
</tr>
<tr>
<td></td>
<td>Columbus</td>
</tr>
<tr>
<td></td>
<td>Mansfield</td>
</tr>
<tr>
<td></td>
<td>Springfield</td>
</tr>
<tr>
<td></td>
<td>Steubenville-Weirton, OH-WV</td>
</tr>
<tr>
<td></td>
<td>Oklahoma</td>
</tr>
<tr>
<td></td>
<td>Tulsa</td>
</tr>
<tr>
<td></td>
<td>Oregon</td>
</tr>
<tr>
<td></td>
<td>Salem</td>
</tr>
<tr>
<td></td>
<td>Pennsylvania</td>
</tr>
<tr>
<td></td>
<td>Erie</td>
</tr>
<tr>
<td></td>
<td>York</td>
</tr>
<tr>
<td></td>
<td>Rhode Island</td>
</tr>
<tr>
<td></td>
<td>Bristol County</td>
</tr>
<tr>
<td></td>
<td>Kent County</td>
</tr>
<tr>
<td></td>
<td>Newport County</td>
</tr>
<tr>
<td></td>
<td>Providence County</td>
</tr>
<tr>
<td></td>
<td>Sioux Falls</td>
</tr>
<tr>
<td></td>
<td>Tennessee</td>
</tr>
<tr>
<td></td>
<td>Memphis, TN-AR-MS</td>
</tr>
<tr>
<td></td>
<td>Nashville-Davidson</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>State</td>
<td>Cities</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Kentucky</td>
<td>Owensboro</td>
</tr>
<tr>
<td>Louisiana</td>
<td></td>
</tr>
<tr>
<td>Baton Rouge</td>
<td></td>
</tr>
<tr>
<td>Shreveport</td>
<td></td>
</tr>
<tr>
<td>Bristol County</td>
<td>Michigan</td>
</tr>
<tr>
<td>Muskegon-Norton Shores-Muskegon Heights</td>
<td>Minnesota</td>
</tr>
<tr>
<td>Duluth-Superior, MN-WI</td>
<td></td>
</tr>
<tr>
<td>St. Joseph</td>
<td>Missouri</td>
</tr>
<tr>
<td>Great Falls</td>
<td>Montana</td>
</tr>
<tr>
<td>Albuquerque</td>
<td>New Mexico</td>
</tr>
<tr>
<td>New York</td>
<td></td>
</tr>
<tr>
<td>Utica-Rome</td>
<td>North Carolina</td>
</tr>
<tr>
<td>Asheville</td>
<td>Burlington</td>
</tr>
<tr>
<td>Oklahoma City</td>
<td>Oklahoma</td>
</tr>
<tr>
<td>Eugene-Springfield</td>
<td>Oregon</td>
</tr>
<tr>
<td>Johnnytown</td>
<td></td>
</tr>
<tr>
<td>Wilkes Barre-Scranton-Hazleton (Northeast PA)</td>
<td></td>
</tr>
<tr>
<td>Williamsport</td>
<td>South Carolina</td>
</tr>
<tr>
<td>Columbia</td>
<td>Greenville-Spartanburg</td>
</tr>
<tr>
<td>Chattanooga, TN-GA</td>
<td>Tennessee</td>
</tr>
<tr>
<td>Clarksville-Hopkinsville, TN-KY</td>
<td>Knoxville</td>
</tr>
<tr>
<td>Austin</td>
<td>Texas</td>
</tr>
<tr>
<td>Abilene</td>
<td></td>
</tr>
<tr>
<td>Austin - Temple</td>
<td></td>
</tr>
<tr>
<td>Lubbock</td>
<td></td>
</tr>
<tr>
<td>Odessa</td>
<td></td>
</tr>
<tr>
<td>San Angelo</td>
<td></td>
</tr>
<tr>
<td>San Antonio</td>
<td></td>
</tr>
<tr>
<td>Sherman-Denison</td>
<td></td>
</tr>
<tr>
<td>Tyler</td>
<td></td>
</tr>
<tr>
<td>Waco</td>
<td>Utah</td>
</tr>
<tr>
<td>Salt Lake City-Ogden</td>
<td>Virginia</td>
</tr>
<tr>
<td>Lynchburg</td>
<td></td>
</tr>
<tr>
<td>Wheeling, WV-OH</td>
<td>West Virginia</td>
</tr>
<tr>
<td>Parkersburg-Maritza, WV-OH</td>
<td></td>
</tr>
<tr>
<td>Oregon</td>
<td></td>
</tr>
<tr>
<td>Green Bay</td>
<td></td>
</tr>
<tr>
<td>La Crosse</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td>Cities</td>
</tr>
<tr>
<td>-------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Alabama</td>
<td>Anniston, Florence, Gadsden, Honeville, Tuscaloosa</td>
</tr>
<tr>
<td>Arkansas</td>
<td>Fayetteville-Springdale, Fort Smith, AR-OK, Pine Bluff</td>
</tr>
<tr>
<td>Florida</td>
<td>Pensacola</td>
</tr>
<tr>
<td>Georgia</td>
<td>Albany</td>
</tr>
<tr>
<td>Indiana</td>
<td>Bloomington, *Terre Haute, Bloomington, Terre Haute</td>
</tr>
<tr>
<td>Louisiana</td>
<td>Alexandria, Lafayette, Lake Charles, Monroe</td>
</tr>
<tr>
<td>Maine</td>
<td>Androscoggin County, Androscoggin County, St. Cloud</td>
</tr>
<tr>
<td>Minnesota</td>
<td>St. Cloud</td>
</tr>
<tr>
<td>Mississippi</td>
<td>Biloxi-Gulfport, Pascagoula-Moss Point</td>
</tr>
<tr>
<td>North Carolina</td>
<td>Fayetteville, Wilmington</td>
</tr>
<tr>
<td>Oklahoma</td>
<td>Lawton</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>Altoona</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>Caguas, Mayaguez, Ponce, San Juan</td>
</tr>
<tr>
<td>South Carolina</td>
<td>Charleston-North Charleston</td>
</tr>
<tr>
<td>Tennessee</td>
<td>Johnson City-Kingsport-Bristol, TN-VA</td>
</tr>
<tr>
<td>Texas</td>
<td>Brownsville-Harlingen-San Benito, Bryan-College Station, Corpus Christi, El Paso, Laredo, McAllen-Pharr-Edinburg, Texarkana, TX-AR</td>
</tr>
<tr>
<td>Utah</td>
<td>Provo-Orem</td>
</tr>
<tr>
<td>West Virginia</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
Massachusetts
New Jersey

Iowa
Nebraska
Washington

Kansas
Nevada
Wyoming

Group II

California
Connecticut
Delaware

Hawaii
Illinois
Indiana

Maryland
North Dakota

Group III

Colorado
Florida
Idaho

Minnesota
Montana
New Hampshire

New York
Ohio

Group IV

Arizona
Maine

Missouri
North Carolina

Oklahoma
Texas

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
405-684
685 and above

Non-Standard Metropolitan Statistical Areas

Less than 100
100-169
170 and above
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(v) 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)

<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>89</td>
<td>87</td>
<td>109</td>
<td>109</td>
</tr>
</tbody>
</table>

(B) Limits 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>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>
</tr>
<tr>
<td>Honolulu</td>
<td>164</td>
<td>170</td>
<td>188</td>
</tr>
</tbody>
</table>

HOSPITALS LOCATED OUTSIDE SMSA's (NONMETROPOLITAN)

<table>
<thead>
<tr>
<th>State group</th>
<th>Less than 100</th>
<th>100 to 169</th>
<th>170 and above</th>
</tr>
</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>
</tr>
<tr>
<td>III</td>
<td>100</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>

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.

(A) The schedule of limits and adjustment factor 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 factor.

(Dated: June 30, 1977.

DAVID N. WEINMAN,
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]
DEPARTMENT OF LABOR

Employment Standards Administration

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions
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 from 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 (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following the Secretary of Labor's Orders 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 (37 FR 21138) and of Secretary of Labor's Orders 13-71 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.

Modifications and Supersedeas 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. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

Modifications and Supersedeas Decisions to General Wage Determination Decisions

Modifications and Supersedeas Decisions to General Wage Determination Decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued. The determinations of prevailing rates and fringe benefits made in the Modifications and Supersedeas Decisions 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 (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following the Secretary of Labor's Orders 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 13-71 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.

Modifications and Supersedeas 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. Accordingly, the applicable decision together with any modifications issued subsequently to its publication shall be made a part of the every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR, Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

NOTICES

The numbers of the decisions being modified and their dates of publication in the Federal Register are listed with each State.

Arizona:
AZ77-5868; AZ77-5869 _______ June 17, 1977.
California:
CA77-5039; CA77-5040; __________ Apr. 22, 1977.
Florida:
FL77-1065; __________ May 13, 1977.
Georgia:
AR-4038; __________ Sept. 27, 1976.
Idaho:
ID77-5045; __________ May 13, 1977.
Illinois:
IL76-2138; IL76-2139; __________ Oct. 29, 1976.
IL76-2142; __________ Dec. 10, 1976.
IL76-2144; __________ Dec. 12, 1976.
IL76-2145; __________ Dec. 14, 1976.
IL77-2029; __________ Feb. 25, 1977.
IL77-2058; __________ June 10, 1977.
Indiana:
IN77-4075; __________ Apr. 8, 1977.
Kentucky:
KY77-4075; __________ Apr. 8, 1977.
Louisiana:
LA77-4074; __________ May 20, 1977.
Maryland:
MD77-3077; __________ June 3, 1977.
Michigan:
MI77-2140; __________ Nov. 19, 1976.
MI77-2050; MI77-2053; __________ June 6, 1977.
MI77-2054; __________ June 3, 1977.
MI77-2071; __________ June 3, 1977.
Minnesota:
MN77-2047; __________ May 6, 1977.
MN77-2048; __________ May 20, 1977.
Mississippi:
MS77-1033; __________ Mar. 26, 1977.
Montana:
MT77-2037; __________ June 3, 1977.
Nevada:
NV77-5031; __________ Mar. 18, 1977.
NV77-5061; __________ June 17, 1977.
New Mexico:
NM77-4116; __________ Do.
Pennsylvania:
PAT7-3029; PAT7-3030; __________ Feb. 18, 1977.
PAT7-3031; PAT7-3039; __________ Apr. 8, 1977.
PAT7-3050; PAT7-3055; __________ Mar. 13, 1977.
PAT7-3054; PAT7-3055; __________ Mar. 13, 1977.
PAT7-3057; __________ June 10, 1977.
PAT7-3061; __________ June 17, 1977.
South Dakota:
SD77-3093; __________ June 17, 1977.
Texas:
TX77-4097; TX77-4098; __________ May 6, 1977.
TX77-4101; __________ May 13, 1977.
TX77-4108; __________ June 3, 1977.
Washington:
WA77-5085; __________ June 17, 1977.

SUPERSEDEAS 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.

Supersedeas Decision numbers are in parentheses following the numbers of the decisions being superseded.
### Alabama
- Decision No.: AL77-1090
- Date: 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>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>H &amp; W Pensions</td>
<td>Vacation</td>
</tr>
<tr>
<td>Air conditioning mechanics</td>
<td>4.58</td>
</tr>
<tr>
<td>Bricklayers</td>
<td>6.75</td>
</tr>
<tr>
<td>Carpenters</td>
<td>5.56</td>
</tr>
<tr>
<td>Cement masons</td>
<td>5.56</td>
</tr>
<tr>
<td>Drywall finisher</td>
<td>5.00</td>
</tr>
<tr>
<td>Drywall hanger</td>
<td>5.00</td>
</tr>
<tr>
<td>Electricians</td>
<td>5.41</td>
</tr>
<tr>
<td>Insulators</td>
<td>4.65</td>
</tr>
<tr>
<td>Laborers:</td>
<td></td>
</tr>
<tr>
<td>Laborers, unskilled</td>
<td>3.00</td>
</tr>
<tr>
<td>Mason tenders</td>
<td>3.75</td>
</tr>
<tr>
<td>Laborers</td>
<td>3.00</td>
</tr>
<tr>
<td>Painters, brush</td>
<td>4.00</td>
</tr>
<tr>
<td>Plumbers &amp; pipefitters</td>
<td>4.21</td>
</tr>
<tr>
<td>Roofers</td>
<td>5.50</td>
</tr>
<tr>
<td>Sheet metal workers</td>
<td>3.75</td>
</tr>
<tr>
<td>Soft floor layers</td>
<td>6.00</td>
</tr>
<tr>
<td>Tile setters</td>
<td>5.00</td>
</tr>
<tr>
<td>Tile setters' helpers</td>
<td>3.00</td>
</tr>
<tr>
<td>Truck drivers</td>
<td>3.00</td>
</tr>
</tbody>
</table>

### Montana
- Decision No.: MT77-3089
- Date: Mar. 11, 1977
- Description of Work: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.

### New Mexico
- Decision No.: NM77-3090
- Date: Aug. 8, 1975
- Description of Work: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.

### New Jersey
- Decision No.: NJ77-3090
- Date: Aug. 8, 1975
- Description of Work: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.

### Puerto Rico
- Decision No.: PR77-3090
- Date: Aug. 8, 1975
- Description of Work: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.
### New Decision

**State:** Michigan  
**County:** Ionia  
**Decision No.:** MI77-2106  
**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>Carpenters</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N &amp; W Pensions</td>
<td>Vacation</td>
</tr>
<tr>
<td><strong>Carpenters</strong></td>
<td>5.50</td>
<td></td>
</tr>
<tr>
<td>Cement Masons</td>
<td>5.00</td>
<td></td>
</tr>
<tr>
<td>Drywall Hanglers</td>
<td>8.00</td>
<td></td>
</tr>
<tr>
<td>Drywall Tapers</td>
<td>6.00</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>
</tr>
<tr>
<td>Roofers</td>
<td>4.81</td>
<td></td>
</tr>
<tr>
<td>Soft Floor Layers</td>
<td>7.08</td>
<td></td>
</tr>
</tbody>
</table>

### New Decision

**State:** North Carolina  
**County:** Orange  
**Decision No.:** NC77-1092  
**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>Bricklayers</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N &amp; W Pensions</td>
<td>Vacation</td>
</tr>
<tr>
<td><strong>Bricklayers</strong></td>
<td>$6.25</td>
<td></td>
</tr>
<tr>
<td>Carpenters</td>
<td>4.83</td>
<td></td>
</tr>
<tr>
<td>Cement Masons</td>
<td>5.00</td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td>5.00</td>
<td></td>
</tr>
<tr>
<td>Glaziers</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>3.67</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>4.50</td>
<td></td>
</tr>
<tr>
<td>Sheet metal workers</td>
<td>4.50</td>
<td></td>
</tr>
<tr>
<td>Tile setters</td>
<td>6.50</td>
<td></td>
</tr>
<tr>
<td>Truck drivers</td>
<td>3.73</td>
<td></td>
</tr>
</tbody>
</table>

### Power Equipment Operators:
- Backhoe: 4.37
- Front end loader: 4.25
- Roller: 3.75
- Welders - rate for craft.
### Basic Hourly Rates and Fringe Benefits Payments

#### Statewide, Arizona

<table>
<thead>
<tr>
<th>Change</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bricklayers (Tucson Area): Bricklayers, Stonemasons:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone A</td>
<td>$10.82</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone B</td>
<td>11.19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone C</td>
<td>11.56</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone D</td>
<td>12.02</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manhole Builders:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone A</td>
<td>11.07</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone B</td>
<td>11.44</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone C</td>
<td>11.81</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone D</td>
<td>12.57</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians (Phoenix; Flagstaff, Globe, Kingman, Prescott and Yuma 10 mile radius from center of town):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone A</td>
<td>12.24</td>
<td>3%+.78</td>
<td>3/4%</td>
</tr>
<tr>
<td>Zone B</td>
<td>14.38</td>
<td>3%+.78</td>
<td>3/4%</td>
</tr>
<tr>
<td>Zone C</td>
<td>15.46</td>
<td>3%+.78</td>
<td>3/4%</td>
</tr>
</tbody>
</table>

#### Maricopa County, Arizona

<table>
<thead>
<tr>
<th>Change</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electricians:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone A</td>
<td>$10.51</td>
<td>3%+.78</td>
<td>1/2%</td>
</tr>
<tr>
<td>Zone B</td>
<td>11.94</td>
<td>3%+.78</td>
<td>1/2%</td>
</tr>
<tr>
<td>Zone C</td>
<td>13.42</td>
<td>3%+.78</td>
<td>1/2%</td>
</tr>
</tbody>
</table>

#### Pima County, Arizona

<table>
<thead>
<tr>
<th>Change</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electricians:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone A</td>
<td>$12.24</td>
<td>3%+.78</td>
<td>1/2%</td>
</tr>
<tr>
<td>Zone B</td>
<td>14.38</td>
<td>3%+.78</td>
<td>1/2%</td>
</tr>
<tr>
<td>Zone C</td>
<td>15.48</td>
<td>3%+.78</td>
<td>1/2%</td>
</tr>
</tbody>
</table>

### Line Construction:

#### Line I (Phoenix and Tucson 10 mile radius from center of town)

<table>
<thead>
<tr>
<th>Change</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Groundmen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment Operators:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone A</td>
<td>9.67</td>
<td>3%+.78</td>
<td>1/2%</td>
</tr>
</tbody>
</table>

#### Line II (Other areas)

<table>
<thead>
<tr>
<th>Change</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Groundmen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment Operators:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone A</td>
<td>11.29</td>
<td>3%+.78</td>
<td>1/2%</td>
</tr>
</tbody>
</table>

---

**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
### Decision No. CA77-5039

#### (42 FR 20994 - April 22, 1977)

**Modifications**


#### Changes

**Bricklayers; Stonemasons**
- Del Norte, Humboldt, Lake, Marin, Mendocino, Napa, San Francisco, San Mateo, Siskiyou, Solano, Sonoma, and Trinity Counties
  - Electricians: $14.42 $1.50 $1.10 $1.00 .05
- Fresno, Kings, Madera, Mariposa and Merced Counties
  - Brick Tenders: 11.55 .95 1.00
- Fresno, Kings, Madera, and Tulare Counties
  - Electricians: 10.25 .80 1.40
- Alameda County
  - Electricians: 12.91 1.05 3+.12.15 .03
  - Cable Splicers: 14.52 1.05 3+.12.15 .03

**Electricians**
- Del Norte and Humboldt Cos.
  - Electricians: 15.20 .70 3+.12.00
  - Cable Splicers: 16.70 .70 3+.12.00
- Alameda County
  - Electricians: 12.81 1.05 3+.12.15 .03
  - Cable Splicers: 14.52 1.05 3+.12.15 .03

**Other Counties**
- Del Norte, Humboldt Cos.
  - Electricians: 15.20 .70 3+.12.00
  - Cable Splicers: 16.70 .70 3+.12.00
- Butte, Glenn, Lassen, Modoc, Plumas, Shasta, Siskiyou, Tehama and Trinity Counties
  - Electricians: 13.16 .87 3+.12.00
  - Cable Splicers: 13.16 .87 3+.12.00
- Lake Tahoe Area
  - Electricians: 13.98 .67 3+.12.00
  - Cable Splicers: 15.28 .67 3+.12.00
- Those portions of Alpine, El Dorado, Nevada, Placer, and Sierra Counties West of the Sierra Mountain Watershed
  - Electricians: $14.39 .95 3+.05 .045
  - Cable Splicers: 15.83 .95 3+.05 .045
- Tunnels:
  - Electricians: 14.52 .95 3+.05 .045
  - Cable Splicers: 15.97 .95 3+.05 .045

**Cable Splicers**
- Lake Tahoe Area
  - Electricians: 13.98 .67 3+.12.00
  - Cable Splicers: 15.28 .67 3+.12.00
- Butte, Glenn, Lassen, Modoc, Plumas, Shasta, Siskiyou, Tehama and Trinity Counties
  - Electricians: 13.16 .87 3+.12.00
  - Cable Splicers: 13.16 .87 3+.12.00
- Lake Tahoe Area
  - Electricians: 13.98 .67 3+.12.00
  - Cable Splicers: 15.28 .67 3+.12.00
- Those portions of Alpine, El Dorado, Nevada, Placer, and Sierra Counties West of the Sierra Mountain Watershed
  - Electricians: $14.39 .95 3+.05 .045
  - Cable Splicers: 15.83 .95 3+.05 .045
- Tunnels:
  - Electricians: 14.52 .95 3+.05 .045
  - Cable Splicers: 15.97 .95 3+.05 .045
- Calaveras and San Joaquin Cos.
  - Electricians: 12.15 .92 3+.12.25 .01
  - Cable Splicers: 13.67 .92 3+.12.25 .01
- Contra Costa County
  - Electricians: 15.20 .70 3+.12.00
  - Cable Splicers: 16.70 .70 3+.12.00
- Tuolumne, Yolo and Yuba Counties, California

### Fringe Benefits Payments

<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>$14.42</td>
<td>$1.50</td>
<td>$1.10</td>
<td>$1.00</td>
<td>.05</td>
</tr>
<tr>
<td>11.55</td>
<td>.95</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.25</td>
<td>.80</td>
<td>1.40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.91</td>
<td>1.05</td>
<td>3+.12.15</td>
<td>.03</td>
<td></td>
</tr>
<tr>
<td>14.52</td>
<td>1.05</td>
<td>3+.12.15</td>
<td>.03</td>
<td></td>
</tr>
<tr>
<td>13.16</td>
<td>.87</td>
<td>3+.12.05</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>13.84</td>
<td>.87</td>
<td>3+.12.05</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>12.58</td>
<td>.87</td>
<td>3+.12.05</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>3.84</td>
<td>.87</td>
<td>3+.12.05</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>12.15</td>
<td>.92</td>
<td>3+.12.25</td>
<td>.03</td>
<td></td>
</tr>
<tr>
<td>13.67</td>
<td>.92</td>
<td>3+.12.25</td>
<td>.03</td>
<td></td>
</tr>
<tr>
<td>15.20</td>
<td>.70</td>
<td>3+.12.00</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>16.70</td>
<td>.70</td>
<td>3+.12.00</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>11.25</td>
<td>.80</td>
<td>3+.12.05</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>12.15</td>
<td>.80</td>
<td>3+.12.05</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>15.97</td>
<td>.95</td>
<td>3+.12.05</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>15.28</td>
<td>.67</td>
<td>3+.12.77</td>
<td>.08</td>
<td></td>
</tr>
<tr>
<td>13.98</td>
<td>.67</td>
<td>3+.12.77</td>
<td>.08</td>
<td></td>
</tr>
<tr>
<td>14.39</td>
<td>.95</td>
<td>3+.05</td>
<td>.045</td>
<td></td>
</tr>
<tr>
<td>15.83</td>
<td>.95</td>
<td>3+.05</td>
<td>.045</td>
<td></td>
</tr>
<tr>
<td>14.52</td>
<td>.95</td>
<td>3+.05</td>
<td>.045</td>
<td></td>
</tr>
<tr>
<td>15.97</td>
<td>.95</td>
<td>3+.05</td>
<td>.045</td>
<td></td>
</tr>
<tr>
<td>13.98</td>
<td>.67</td>
<td>3+.12.77</td>
<td>.08</td>
<td></td>
</tr>
<tr>
<td>15.28</td>
<td>.67</td>
<td>3+.12.77</td>
<td>.08</td>
<td></td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
<table>
<thead>
<tr>
<th>Area</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>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
</tr>
<tr>
<td>Lake, Marin, Mendocino and Sonoma Counties</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td>$12.09</td>
<td>.75</td>
<td>3%+.95</td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>12.65</td>
<td>.75</td>
<td>3%+.95</td>
</tr>
<tr>
<td>Mariposa, Merced, Stanislaus and Tuolumne Counties</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td>9.83</td>
<td>.62</td>
<td>3%</td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>10.01</td>
<td>.62</td>
<td>3%</td>
</tr>
<tr>
<td>Monterey County Electricians</td>
<td>12.50</td>
<td>1.10</td>
<td>3%+.30</td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>13.91</td>
<td>1.10</td>
<td>3%+.30</td>
</tr>
<tr>
<td>Lake and Solano Counties Electricians</td>
<td>12.07</td>
<td>.68</td>
<td>3%+.85</td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>12.75</td>
<td>.68</td>
<td>3%+.85</td>
</tr>
<tr>
<td>San Benito, Santa Clara and Santa Cruz Counties</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td>12.88</td>
<td>.77</td>
<td>3%+1.50</td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>15.53</td>
<td>.77</td>
<td>3%+1.50</td>
</tr>
<tr>
<td>San Francisco County Electricians</td>
<td>15.25</td>
<td>1.04</td>
<td>3%+2.90</td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>17.53</td>
<td>1.04</td>
<td>3%+2.90</td>
</tr>
<tr>
<td>San Mateo County Electricians</td>
<td>11.77</td>
<td>.82</td>
<td>3%+5.50</td>
</tr>
<tr>
<td>Lathers: Calaveras and San Joaquin Counties</td>
<td>13.26</td>
<td>.68</td>
<td>.55</td>
</tr>
<tr>
<td>Line Construction: Contra Costa County Groundmen</td>
<td>4.50</td>
<td>.70</td>
<td>3%+1.00</td>
</tr>
<tr>
<td>Groundmen Operators</td>
<td>4.50</td>
<td>.70</td>
<td>3%+1.00</td>
</tr>
<tr>
<td>Mensa</td>
<td>13.20</td>
<td>.70</td>
<td>3%+1.00</td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>15.70</td>
<td>.70</td>
<td>3%+1.00</td>
</tr>
<tr>
<td>Plasterers: Del Norte, Humboldt, Lassen (Northwestern half), Marin, Modoc, Napa, Shasta, Siskiyou, Solano, Sonoma, Tehama and Trinity Counties</td>
<td>10.25</td>
<td>.98</td>
<td>.50</td>
</tr>
</tbody>
</table>
### Soft Floor Layers:
Alpine, Amador, Butte, Calaveras, Colusa, El Dorado, Glenn, Lassen (excluding Honey Lake Area), Merced (west of San Joaquin River), Plumas, San Joaquin, Siskiyou, Sacramento, Shasta, Siskiyou, Stanislaus, Tuolumne, Yolo and Yuba Counties and those portions of El Dorado, Placer and Sierra Counties (excluding Lake Tahoe Area)

### Terrazzo Workers:
Alameda, Contra Costa, Del Norte, Humboldt, Lake, Marin, Mendocino, Napa, San Francisco, San Mateo, Siskiyou, Solano, Sonoma and Trinity Counties

### Tile Setters:
Fresno, Kings, Madera, Mariposa, Merced and Tulare Counties

### Laborers (Gunnite):

<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>$9.235</td>
<td>$1.25</td>
<td>$1.70</td>
<td>$1.10</td>
</tr>
<tr>
<td>2</td>
<td>8.645</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
<tr>
<td>3</td>
<td>8.525</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
</tbody>
</table>

### Tunnel and Shaft work:

<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10.545</td>
<td>1.75</td>
<td>1.10</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>10.535</td>
<td>1.75</td>
<td>1.10</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>9.855</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
<tr>
<td>4</td>
<td>9.705</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
</tbody>
</table>

### Wrecking work:

<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>9.775</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
<tr>
<td>2</td>
<td>8.625</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
<tr>
<td>3</td>
<td>8.525</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
</tbody>
</table>

### Monterey and Santa Cruz Counties Laborers:

<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8.775</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
<tr>
<td>2</td>
<td>9.000</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
<tr>
<td>3</td>
<td>9.375</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
<tr>
<td>4</td>
<td>8.825</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
<tr>
<td>5</td>
<td>8.725</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
<tr>
<td>6</td>
<td>8.975</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
<tr>
<td>7</td>
<td>8.675</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
<tr>
<td>8</td>
<td>8.725</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
<tr>
<td>9</td>
<td>8.025</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
<tr>
<td>10</td>
<td>8.025</td>
<td>1.25</td>
<td>1.70</td>
<td>1.10</td>
</tr>
</tbody>
</table>
**DECISION NO. CA77-5040 - Mod. #2**

(42 FR 21012 - April 22, 1977)


**Change:**

*Bricklayers; Stonemasons:*

- Del Norte, Humboldt, Marin, Napa, San Francisco, San Mateo, Solano and Sonoma Counties
- Fresno, Mariposa and Merced Counties

*Brick Tenders:*

- Fresno County

*Electricians:*

- Alameda County
- Calaveras and San Joaquin Counties
- Contra Costa County
- Del Norte and Humboldt Counties
- Marin and Sonoma Counties
- Monterey County
- Napa and Solano Counties
- San Benito, Santa Clara and Santa Cruz Counties
- San Francisco County
- Tehama County
- Tehama County (Family residences, limited to 3 stories)

<table>
<thead>
<tr>
<th>Basic Rates</th>
<th>Hourly Education Rates</th>
<th>Fringe Benefits Payments</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship Tr.</th>
</tr>
</thead>
</table>
| **Electricians (4 stories):**
| Electricians | $11.98 | .87 | 3%+1.705 | .04 |
| Cable Splicers | 13.18 | .87 | 3%+1.705 | .04 |
| Calaveras and San Joaquin Counties Electricians | 12.15 | .92 | 3%+1.25 | .01 |
| Cable Splicers | 13.09 | .92 | 3%+1.25 | .01 |
| Contra Costa County Electricians | 15.28 | .70 | 3%+1.00 | .04 |
| Cable Splicers | 16.19 | .70 | 3%+1.00 | .04 |
| Del Norte and Humboldt Counties Electricians | 11.25 | .80 | 3%+1.00 | .04 |
| Cable Splicers | 12.15 | .80 | 3%+1.00 | .04 |
| Marin and Sonoma Counties Electricians | 12.65 | .81 | 3%+1.00 | .04 |
| Cable Splicers | 13.01 | .81 | 3%+1.00 | .04 |
| Monterey County Electricians | 13.50 | 1.10 | 3%+2.30 | .06 |
| Cable Splicers | 13.81 | 1.10 | 3%+2.30 | .06 |
| Napa and Solano Counties Electricians | 15.30 | .68 | 3%+2.30 | .06 |
| Cable Splicers | 15.58 | .68 | 3%+2.30 | .06 |
| San Benito, Santa Clara and Santa Cruz Counties Electricians | 13.80 | .77 | 3%+1.50 | .05 |
| Cable Splicers | 15.53 | .77 | 3%+1.50 | .05 |
| San Francisco County Electricians | 15.58 | 1.04 | 3%+3.90 | .06 |
| Cable Splicers | 17.55 | 1.04 | 3%+3.90 | .06 |

Lathers:

- Calaveras and San Joaquin Counties

Plasterers:

- Del Norte, Humboldt, Marin, Napa, Sonoma and Tehama Counties

| Lathers | $17.53 | 1.04 | 3%+3.90 | .06 |
| Plasterers | $17.53 | 1.04 | 3%+3.90 | .06 |

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
| Soft Floor Layers: Alpine, Amador, Calaveras, | Basic | Fringe Benefits Payments |
| Merced [East of the San Joaquin River], San Joaquin, Sacramento, Butte, Tehama, Trinity, Yolo and Yuba Counties; and those portions of El Dorado, Nevada and Placer Counties (excluding Lake Tahoe Area) | H & W | Pensions | Vacation | Education and/or Apprenticeship |
| | $10.73 | .84 | $1.30 | $1.00 | .10 |

| Terrazzo Workers: Alameda, Contra Costa, | Basic | Fringe Benefits Payments |
| Del Norte, Humboldt, Marin, Napa, San Francisco, San Mateo, Solano and Sonoma Counties | H & W | Pensions | Vacation | Education and/or Apprenticeship |
| | $11.42 | 1.00 | 1.10 | 1.00 |

| Tile Setters: Fresno, Mariposa and Madera Counties, Monterey, and Santa Cruz Counties | Basic | Fringe Benefits Payments |
| | H & W | Pensions | Vacation | Education and/or Apprenticeship |
| | $13.41 | 1.09 | 1.18 |

| Laborers: | Basic | Fringe Benefits Payments |
| Group 1 | H & W | Pensions | Vacation | Education and/or Apprenticeship |
| Group 1(a) | 8.775 | 1.25 | 1.70 | 1.10 | .10 |
| Group 1(b) | 8.775 | 1.25 | 1.70 | 1.10 | .10 |
| Group 1(c) | 8.725 | 1.25 | 1.70 | 1.10 | .10 |
| Group 1(d) | 8.725 | 1.25 | 1.70 | 1.10 | .10 |
| Group 1(e) | 8.725 | 1.25 | 1.70 | 1.10 | .10 |
| Group 1(f) | 8.725 | 1.25 | 1.70 | 1.10 | .10 |
| Group 2 | 8.975 | 1.25 | 1.70 | 1.10 | .10 |
| Group 3 | 8.975 | 1.25 | 1.70 | 1.10 | .10 |

| Laborers (Gunite): | Basic | Fringe Benefits Payments |
| Group 1 | H & W | Pensions | Vacation | Education and/or Apprenticeship |
| Group 1 | 8.715 | 1.25 | 1.70 | 1.10 | .10 |
| Group 2 | 8.665 | 1.25 | 1.70 | 1.10 | .10 |
| Group 3 | 8.525 | 1.25 | 1.70 | 1.10 | .10 |
### Basic Hourly Rates Compared

#### Decision #IL76-2015 - Mod. 65

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Rate</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bricklayers &amp; Stonemasons</td>
<td>$11.06</td>
<td>60</td>
<td>85</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>Carpenters:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residential</td>
<td>11.11</td>
<td>50</td>
<td></td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Tazewell County &amp; the remainder of Peoria County</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial</td>
<td>11.11</td>
<td>50</td>
<td></td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Tazewell County &amp; the remainder of Peoria County</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Millwrights &amp; Piledrivermen</td>
<td>11.61</td>
<td>50</td>
<td></td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Cement Masons</td>
<td>10.71</td>
<td>50</td>
<td></td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Laborers: Peoria Co., the City of East Peoria in Tazewell County</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 1</td>
<td>9.85</td>
<td>40</td>
<td>60</td>
<td>0.03</td>
<td></td>
</tr>
<tr>
<td>Class 2</td>
<td>9.975</td>
<td>40</td>
<td>60</td>
<td>0.03</td>
<td></td>
</tr>
<tr>
<td>Class 3</td>
<td>10.10</td>
<td>40</td>
<td>60</td>
<td>0.03</td>
<td></td>
</tr>
<tr>
<td>Class 4</td>
<td>10.025</td>
<td>40</td>
<td>60</td>
<td>0.03</td>
<td></td>
</tr>
<tr>
<td>Class 5</td>
<td>10.225</td>
<td>40</td>
<td>60</td>
<td>0.03</td>
<td></td>
</tr>
<tr>
<td>Class 6</td>
<td>9.975</td>
<td>40</td>
<td>60</td>
<td>0.03</td>
<td></td>
</tr>
<tr>
<td>Class 7</td>
<td>10.10</td>
<td>40</td>
<td>60</td>
<td>0.03</td>
<td></td>
</tr>
<tr>
<td>Plasterers</td>
<td>10.60</td>
<td>40</td>
<td>60</td>
<td>0.03</td>
<td></td>
</tr>
<tr>
<td>Sheet Metal Workers</td>
<td>11.22</td>
<td>50</td>
<td>75</td>
<td>0.08</td>
<td></td>
</tr>
<tr>
<td>Bridging Construction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>10.57</td>
<td>45</td>
<td>55</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>10.37</td>
<td>45</td>
<td>55</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td>9.495</td>
<td>45</td>
<td>55</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Group 4</td>
<td>9.72</td>
<td>45</td>
<td>55</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Group 5</td>
<td>9.41</td>
<td>45</td>
<td>55</td>
<td>0.05</td>
<td></td>
</tr>
</tbody>
</table>

#### Decision #IL76-2120 - Mod. 65

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Rate</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carpenters:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residential</td>
<td>99.75</td>
<td>55</td>
<td>55</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Millwrights &amp; Piledrivermen</td>
<td>10.40</td>
<td>55</td>
<td>55</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Cement Masons</td>
<td>9.40</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laborers: Peoria Co., the City of East Peoria in Tazewell County</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasterers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sheet Metal Workers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bridging Construction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Decision #IL76-2121 - Mod. 65

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Rate</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carpenters:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residential</td>
<td>11.39</td>
<td>55</td>
<td>55</td>
<td>0.12</td>
<td></td>
</tr>
<tr>
<td>Millwrights &amp; Piledrivermen</td>
<td>11.80</td>
<td>55</td>
<td>55</td>
<td>0.12</td>
<td></td>
</tr>
<tr>
<td>Cement Masons</td>
<td>11.65</td>
<td>55</td>
<td>55</td>
<td>0.12</td>
<td></td>
</tr>
<tr>
<td>Laborers: Peoria Co., the City of East Peoria in Tazewell County</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasterers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sheet Metal Workers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bridging Construction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Decision #IL76-2126 - Mod. 65

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Rate</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carpenters:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residential</td>
<td>11.11</td>
<td>50</td>
<td>50</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Millwrights &amp; Piledrivermen</td>
<td>11.41</td>
<td>50</td>
<td>50</td>
<td>0.05</td>
<td></td>
</tr>
</tbody>
</table>
MODIFICATIONS P. 15

DECISION #11,76-2127 - Mod. #3
(41 FR 44627 - October 8, 1976)
McLean County, Illinois

CHANGE:
Carpenters:
Carpenters & Soft Floor Layers
Millwrights & Piledrivermen
Painters:
Brush
Structural Steel & Spray
Cement Masons & Plasterers
Bricklayers:
Millwrights & Piledrivermen
Brush
Structural Steel & Spray
Cement Masons & Plasterers

DECISION #11,76-2128 - Mod. #6
(41 FR 46823 - October 22, 1976)
Christian, DeWitt, Macon, Macoupin, Moultrie, Piatt & Shelby Counties, Illinois

CHANGE:
Cement Masons: Remainder of Christian County
Electricians:
Macon & Christian Cos, DeWitt Co., (Townships of Pana, Assumption & Radford in Christian Co; West of Rt. 105 in Piatt County)

DECISION #11,76-2129 - Mod. #6 (CONT'D)

DECISION #11,76-2130 - Mod. #5
(41 FR 47724 - October 29, 1976)

CHANGE:
Cement Masons: Remainder of Christian County

DECISION #11,76-2131 - Mod. #4
(41 FR 48093 - October 22, 1976)
Sangamon County, Illinois

CHANGE:
Bricklayers:
Bricklayers, Stonemasons, Marble-Tile-Terrazzo Workers-Pointers-Caulkers & Cleaners

DECISION #11,76-2132 - Mod. #6 (CONT'D)

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### MODIFICATIONS P. 17

#### DECISION 0IL76-2132 - Mod. 07

- **Alexander, Franklin, Gallatin, Hamilton, Hardin, Jackson, Jefferson, Johnson, Morgan, Massac, Perry, Pope, Pulaski, Saline, Union, White & Williamson Counties, Illinois**

**CHANGE:**
- **Bricklayers & Stonemasons:**
  - Jackson & Perry Counties: Bricklayers, Stonemasons, Terrazzo & Tile Workers
- **Cement Masons & Plasterers:**
  - Alexander, Jackson, Perry, Pulaski & Union Counties
- **Plumbers & Steamfitters:**
  - Alexander, Hardin, Massac, Jackson, Johnson, Perry, Pope, Pulaski & Union Cos.

---

### MODIFICATIONS P. 18

#### DECISION 0IL76-2133 - Mod. 06 (CONT'D)

**Electricians (Cont'd):**
- Pleasant Valley, Barrampom Twp, Co; Whiteside (Geneva, Jordan, Hopkins, Pearson, Eum, Montgomery, Tampio, Buffalo & Tamps County
- Sheet Metal Workers:
  - Boone, DeKalb, Lee, Ogle, Whiteside, Winnebago, Carroll (Eastern 1/3 of Co.)
- Truck Drivers:
  - Boone, Stephenson, Winnebago Co; Carroll (North of Rt. 64 & East of Co. Wabash East of Rt. 64 - except city of Rockton Co. 2-3 Axle Trucks: 9.75
  - 4-Axle Trucks: 10.10
  - 5-Axle Trucks: 10.35
  - 6-Axle Trucks: 10.60

**ADD:**
- Under Counties DeKalb Co; East of Rte. 31 in Lee & Ogle Counties:
  - 2-3 Axle Trucks: 9.80
  - 4-Axle Trucks: 10.15
  - 5-Axle Trucks: 10.35
  - 6-Axle Trucks: 10.60

---

### NOTICES

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

---

### MODIFICATIONS P. 18

#### DECISION 0IL76-2333 - Mod. 06 (CONT'D)

<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>
</tbody>
</table>

**Electricians:**
- Boone, DeKalb, Winnebago, Stephenson, Ogle, Lee, Jo Davies, Warren, Rock, Sear, Stockton, Wards Grove,
- Boone, DeKalb, Winnebago, Stephenson, Ogle, Lee, Jo Davies, Warren, Rock, Sear, Stockton, Wards Grove,
### MODIFICATIONS P. 19

<table>
<thead>
<tr>
<th>DECISION 0176-2142 - Mod. 03</th>
</tr>
</thead>
<tbody>
<tr>
<td>(41 FR 50126 - November 12, 1976)</td>
</tr>
<tr>
<td>Bureau, Carroll, Henry, Lee,</td>
</tr>
<tr>
<td>Jo Daviess, Ogle, Rock Island,</td>
</tr>
<tr>
<td>Stephenson, Whiteside &amp; Winnebago</td>
</tr>
<tr>
<td>Counties, Illinois</td>
</tr>
<tr>
<td><strong>CHANGE:</strong></td>
</tr>
<tr>
<td>Carpenters &amp; Piledrivermen:</td>
</tr>
<tr>
<td>Winnebago County; North of</td>
</tr>
<tr>
<td>Oregon in Ogle County</td>
</tr>
<tr>
<td><strong>Basic Hourly Rates</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>$10.33</td>
</tr>
</tbody>
</table>

### MODIFICATIONS P. 20

<table>
<thead>
<tr>
<th>DECISION 0176-2144 - Mod. 03</th>
</tr>
</thead>
<tbody>
<tr>
<td>(41 FR 52247 - November 25, 1976)</td>
</tr>
<tr>
<td>Fulton, Hancock, Henderson,</td>
</tr>
<tr>
<td>Knox, McLean, Mercer, Peoria,</td>
</tr>
<tr>
<td>Stark, Tazewell &amp; Warren Counties,</td>
</tr>
<tr>
<td>Illinois</td>
</tr>
<tr>
<td><strong>CHANGE:</strong></td>
</tr>
<tr>
<td>Carpenters &amp; Piledrivermen:</td>
</tr>
<tr>
<td>Unskilled</td>
</tr>
<tr>
<td>Semi-Skilled</td>
</tr>
<tr>
<td>Skilled</td>
</tr>
<tr>
<td><strong>Basic Hourly Rates</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>$9.85</td>
</tr>
<tr>
<td>$10.05</td>
</tr>
<tr>
<td>$10.25</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DECISION 0176-2145 - Mod. 03</th>
</tr>
</thead>
<tbody>
<tr>
<td>(41 FR 53251 - December 3, 1976)</td>
</tr>
<tr>
<td>Champaign, Clark, Coles,</td>
</tr>
<tr>
<td>Champaign, Clark, Coles,</td>
</tr>
<tr>
<td>Cumberland, DeWitt, Douglas,</td>
</tr>
<tr>
<td>Edgar, Hancock, Shelby, Tazewell,</td>
</tr>
<tr>
<td>Winnebago &amp; Whiteside Counties,</td>
</tr>
<tr>
<td>Illinois</td>
</tr>
<tr>
<td><strong>CHANGE:</strong></td>
</tr>
<tr>
<td>Carpenters &amp; Piledrivermen:</td>
</tr>
<tr>
<td>Champaign County; North of</td>
</tr>
<tr>
<td>Oregon in Ogle County</td>
</tr>
<tr>
<td><strong>Basic Hourly Rates</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>$11.11</td>
</tr>
<tr>
<td>$11.41</td>
</tr>
<tr>
<td>$11.71</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DECISION 0176-2146 - Mod. 03</th>
</tr>
</thead>
<tbody>
<tr>
<td>(41 FR 53251 - December 3, 1976)</td>
</tr>
<tr>
<td>Fulton, Hancock, Henderson,</td>
</tr>
<tr>
<td>Knox, McLean, Mercer, Peoria,</td>
</tr>
<tr>
<td>Stark, Tazewell &amp; Warren Counties,</td>
</tr>
<tr>
<td>Illinois</td>
</tr>
<tr>
<td><strong>CHANGE:</strong></td>
</tr>
<tr>
<td>Carpenters &amp; Piledrivermen:</td>
</tr>
<tr>
<td>Western 1/3 of Hancock County:</td>
</tr>
<tr>
<td>Unskilled</td>
</tr>
<tr>
<td>Semi-Skilled</td>
</tr>
<tr>
<td>Skilled</td>
</tr>
<tr>
<td><strong>Basic Hourly Rates</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>$11.11</td>
</tr>
<tr>
<td>$11.41</td>
</tr>
<tr>
<td>$11.71</td>
</tr>
<tr>
<td><strong>NOTICES</strong></td>
</tr>
<tr>
<td>FEDERAL REGISTER, VOL. 42, NO. 131---FRIDAY, JULY 8, 1977</td>
</tr>
</tbody>
</table>
#11.76-2145

## MODIFICATIONS P. 22

## MODIFICATIONS P. 21

### DECISION #11.76-2145 - Mod. 4

(41 FR 54128 - December 10, 1976)


### CHANGE:

<table>
<thead>
<tr>
<th>County</th>
<th>Unskilled</th>
<th>Semi-Skilled</th>
<th>Skilled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adams County: (North of Petersburg):</td>
<td>9.26</td>
<td>.35</td>
<td>.40</td>
</tr>
<tr>
<td>Semi-skilled</td>
<td>9.46</td>
<td>.35</td>
<td>.40</td>
</tr>
<tr>
<td>Skilled</td>
<td>9.66</td>
<td>.35</td>
<td>.40</td>
</tr>
<tr>
<td>Christian County:</td>
<td>9.21</td>
<td>.45</td>
<td>.40</td>
</tr>
<tr>
<td>Semi-skilled</td>
<td>9.41</td>
<td>.45</td>
<td>.40</td>
</tr>
<tr>
<td>Skilled</td>
<td>9.61</td>
<td>.45</td>
<td>.40</td>
</tr>
<tr>
<td>Menard County (Petersburg &amp; South):</td>
<td>9.21</td>
<td>.35</td>
<td>.40</td>
</tr>
<tr>
<td>Semi-skilled</td>
<td>9.41</td>
<td>.35</td>
<td>.40</td>
</tr>
<tr>
<td>Skilled</td>
<td>9.61</td>
<td>.35</td>
<td>.40</td>
</tr>
</tbody>
</table>

### Previous Decision #11.76-2149 - Mod. 4

(41 FR 54128 - December 10, 1976)


### CHANGE:

<table>
<thead>
<tr>
<th>County</th>
<th>Unskilled</th>
<th>Semi-Skilled</th>
<th>Skilled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shelby County:</td>
<td>10.05</td>
<td>.35</td>
<td>.40</td>
</tr>
<tr>
<td>Semi-Skilled</td>
<td>10.25</td>
<td>.35</td>
<td>.40</td>
</tr>
<tr>
<td>Skilled</td>
<td>10.40</td>
<td>.35</td>
<td>.40</td>
</tr>
<tr>
<td>DeWitt County:</td>
<td>10.30</td>
<td>.30</td>
<td>.30</td>
</tr>
<tr>
<td>Semi-Skilled</td>
<td>10.40</td>
<td>.30</td>
<td>.30</td>
</tr>
<tr>
<td>Skilled</td>
<td>10.55</td>
<td>.30</td>
<td>.30</td>
</tr>
<tr>
<td>Macon County:</td>
<td>9.95</td>
<td>.35</td>
<td>.50</td>
</tr>
<tr>
<td>Semi-Skilled</td>
<td>10.15</td>
<td>.35</td>
<td>.50</td>
</tr>
<tr>
<td>Skilled</td>
<td>10.30</td>
<td>.35</td>
<td>.50</td>
</tr>
<tr>
<td>Vermillion County:</td>
<td>9.75</td>
<td>.45</td>
<td>.40</td>
</tr>
<tr>
<td>Semi-Skilled</td>
<td>9.85</td>
<td>.45</td>
<td>.40</td>
</tr>
<tr>
<td>Skilled</td>
<td>10.10</td>
<td>.45</td>
<td>.40</td>
</tr>
</tbody>
</table>

### Table:

<table>
<thead>
<tr>
<th>Scale Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unskilled</td>
<td>.35</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Semi-Skilled</td>
<td>.35</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Skilled</td>
<td>.35</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Unskilled</td>
<td>.30</td>
<td>.30</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Semi-Skilled</td>
<td>.30</td>
<td>.30</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Skilled</td>
<td>.30</td>
<td>.30</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Unskilled</td>
<td>.35</td>
<td>.50</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Semi-Skilled</td>
<td>.35</td>
<td>.50</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Skilled</td>
<td>.35</td>
<td>.50</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Unskilled</td>
<td>.45</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Semi-Skilled</td>
<td>.45</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Skilled</td>
<td>.45</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Unskilled</td>
<td>.45</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Semi-Skilled</td>
<td>.45</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Skilled</td>
<td>.45</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Unskilled</td>
<td>.45</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Semi-Skilled</td>
<td>.45</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Skilled</td>
<td>.45</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Unskilled</td>
<td>.35</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Semi-Skilled</td>
<td>.35</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
<tr>
<td>Skilled</td>
<td>.35</td>
<td>.40</td>
<td>.035</td>
<td></td>
</tr>
</tbody>
</table>
### Modifications P. 23

<table>
<thead>
<tr>
<th></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bricklayers:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hancock &amp; McDonough Counties:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bricklayers, Stonemasons, Cement Blocklayers, Marble-Tile, Terrazzo Workers</td>
<td>$11.65</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carpenters:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>McDonough Co &amp; Eastern 1/3 of Hancock County</td>
<td>11.11</td>
<td>.40</td>
<td>.50</td>
</tr>
<tr>
<td>Carpenters &amp; SFL</td>
<td></td>
<td></td>
<td>.05</td>
</tr>
<tr>
<td>Millwrights &amp; Piledrivermen</td>
<td>1.61</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Painters:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remainder of Counties</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brush Structural Steel &amp; Spray</td>
<td>9.85</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structural Steel &amp; Spray</td>
<td>10.30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cement Masons &amp; Plasterers:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hancock, McDonough &amp; Schuyler Counties:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cement Masons</td>
<td>11.65</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasterers</td>
<td>11.40</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Modifications P. 24

<table>
<thead>
<tr>
<th></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bricklayers:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hancock &amp; McDonough Counties:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bricklayers, Stonemasons, Cement Blocklayers, Marble-Tile, Terrazzo Workers</td>
<td>$11.65</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carpenters:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>McDonough Co &amp; Eastern 1/3 of Hancock County</td>
<td>11.11</td>
<td>.40</td>
<td>.50</td>
</tr>
<tr>
<td>Carpenters &amp; SFL</td>
<td></td>
<td></td>
<td>.05</td>
</tr>
<tr>
<td>Millwrights &amp; Piledrivermen</td>
<td>1.61</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Painters:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remainder of Counties</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brush Structural Steel &amp; Spray</td>
<td>9.85</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structural Steel &amp; Spray</td>
<td>10.30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cement Masons &amp; Plasterers:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hancock, McDonough &amp; Schuyler Counties:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cement Masons</td>
<td>11.65</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasterers</td>
<td>11.40</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### DECISION

**FRIDAY, JULY 2, 1977**
## DECISION #MQ77-4075 - Mod. #4

April 8, 1977

**Cass, Clay, Jackson, Platte, Ray, Henry, Johnson & Lafayette Counties, Missouri; Johnson & Wyandotte Counties, Kansas**

### Change:

- **Cement Masons (Heavy & Highway Construction):**
  - Johnson & Wyandotte Counties, Kansas
  - Change:
    - **Electricians**
      - Zones:
        - **Zone 1:**
          - Hourly Rates: 11.22, .39, 38.51, .80, .06
        - **Zone 2:**
          - Hourly Rates: 13.22, .39, 38.51, .80, .06
        - **Zone 3:**
          - Hourly Rates: 13.67, .39, 38.51, .80, .06
        - **Zone 4:**
          - Hourly Rates: 11.22, .39, 38.51, .80, .06
  - **Electricians (contracts over $5,000):**
    - Hourly Rates: 11.22, .39, 38.51, .80, .06
  - **Electricians (contracts $5,000 and under):**
    - Hourly Rates: 10.06, .39, 38.51, .80, .06
  - **Electricians (contracts over $5,000):**
    - Hourly Rates: 11.22, .39, 38.51, .80, .06
  - **Electricians (contracts $5,000 and under):**
    - Hourly Rates: 10.06, .39, 38.51, .80, .06

- **Line Construction:**
  - **Zone 1:**
    - Linemen: 11.39, .45, 38.15, .06
    - Lineman operator: 10.60, .45, 38.15
    - Groundman: 7.26, .45, 38.15
    - Groundman 1st & 2nd mos.: 6.43, .45, 38.15
    - Groundman-powderman: 7.90, .45, 38.15
  - **Zone 2:**
    - Linemen: 10.00, .45, 38.00, .06
    - Cable splicers: 10.56, .45, 38.00
    - Groundman, over 1 year: 6.33, .45, 38.00
    - Groundman, 1st year: 6.71, .45, 38.00
    - Powderman: 8.29, .45, 38.00
    - Line truck and equipment operators:
      - 1st year: 6.37, .45, 38.00
      - 2nd year: 7.02, .45, 38.00
      - Over 2 years' experience: 8.29, .45, 38.00

### Fringe Benefits Payments:

- **Fringe Benefits Payments**
  - **Hourly Rates:**
    - **Vacation:**
      - **H & W:**
        - **Pensions:**
          - **Vacation:**
            - **Education and/or Appr. Tr.:**

- **Pipefitters**
  - Hourly Rates:
    - **Vacation:**
      - **H & W:**
        - **Pensions:**
          - **Vacation:**
            - **Education and/or Appr. Tr.:**

- **Soft Floor Layers**
  - Hourly Rates:
    - **Vacation:**
      - **H & W:**
        - **Pensions:**
          - **Vacation:**
            - **Education and/or Appr. Tr.:**
### Basic Hourly Rates and Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Zone</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>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
</tr>
</tbody>
</table>

#### Zone 4:
- **Bricklayers & stonemasons:**
  - Zone 1: $10.42, $.35, $.20, $.035
  - Zone 2: $9.00, $.01

#### Zone 4:
- **Laborers (Building Construction):**
  - Group 1: $6.87, $.15, $.27, $.05
  - Group 2: $6.97, $.15, $.27, $.05
  - Group 3: $7.02, $.15, $.27, $.05

#### Zone 5:
- **Marble setters:**
  - Zone 1: $10.42, $.35, $.20, $.035
  - Zone 2: $9.00, $.01

#### Zone 6:
- **Elec. fitters:**
  - Zone 3: $10.42, $.35, $.20, $.035

#### Zone 7:
- **Plumbers & pipe fitters:**
  - Zone 1: $10.42, $.35, $.20, $.035
  - Zone 2: $10.50, $.35, $.20, $.035

---

#### Changes:
- **Cement Masons:**
  - Zone 1: $10.00, $.60, $.50, $.02
  - Zone 2: $10.43, $.60, $.50, $.02

#### Change:
- **Truck Drivers (Excavation):**
  - Dump truck: $7.74, $.93, $.70, T
  - End dump wagons & dumpsters: $8.05, $.93, $.70, T
  - Drop-frame, goose-neck, & trailers: $7.94, $.95, $.70, T
  - Pickups: $7.50, $.93, $.70, T

---

#### Modifications P. 28

<table>
<thead>
<tr>
<th>Zone</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>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
</tr>
</tbody>
</table>

#### Zone 1:
- **Concrete Masons:**
  - Zone 1: $10.42, $.35, $.20, $.035

#### Change:
- **Truck Drivers (Excavation):**
  - Dump truck: $7.74, $.93, $.70, T
  - End dump wagons & dumpsters: $8.05, $.93, $.70, T
  - Drop-frame, goose-neck, & trailers: $7.94, $.95, $.70, T
  - Pickups: $7.50, $.93, $.70, T

---

#### Modifications P. 27

<table>
<thead>
<tr>
<th>Zone</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>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
</tr>
</tbody>
</table>

#### Zone 4:
- **Bricklayers & stonemasons:**
  - Zone 1: $10.42, $.35, $.20, $.035
  - Zone 2: $9.00, $.01

#### Zone 4:
- **Laborers (Building Construction):**
  - Group 1: $6.87, $.15, $.27, $.05
  - Group 2: $6.97, $.15, $.27, $.05
  - Group 3: $7.02, $.15, $.27, $.05

#### Zone 5:
- **Marble setters:**
  - Zone 1: $10.42, $.35, $.20, $.035
  - Zone 2: $9.00, $.01

#### Zone 6:
- **Elec. fitters:**
  - Zone 3: $10.42, $.35, $.20, $.035

#### Zone 7:
- **Plumbers & pipe fitters:**
  - Zone 1: $10.42, $.35, $.20, $.035
  - Zone 2: $10.50, $.35, $.20, $.035

---

#### Changes:
- **Cement Masons:**
  - Zone 1: $10.00, $.60, $.50, $.02
  - Zone 2: $10.43, $.60, $.50, $.02

#### Change:
- **Truck Drivers (Excavation):**
  - Dump truck: $7.74, $.93, $.70, T
  - End dump wagons & dumpsters: $8.05, $.93, $.70, T
  - Drop-frame, goose-neck, & trailers: $7.94, $.95, $.70, T
  - Pickups: $7.50, $.93, $.70, T

---

**Federal Register, Vol. 42, No. 131—Friday, July 8, 1977**
<table>
<thead>
<tr>
<th>DECISION #1177-2053 - Mod. P2</th>
<th>Rate</th>
<th>Rate</th>
<th>Rate</th>
<th>Rate</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allegan, Barry, Calhoun, Clinton, Eaton, Ingham, Jackson &amp; Kalamazoo Counties, Michigan</td>
<td><strong>Electricians:</strong></td>
<td><strong>Ironworkers:</strong></td>
<td><strong>Painters:</strong></td>
<td><strong>Plumbers:</strong></td>
<td></td>
</tr>
<tr>
<td>11.04</td>
<td>10.70</td>
<td>11.49</td>
<td>10.09</td>
<td>8.30</td>
<td></td>
</tr>
<tr>
<td>11.01</td>
<td>10.70</td>
<td>11.49</td>
<td>10.09</td>
<td>8.30</td>
<td></td>
</tr>
<tr>
<td>10.70</td>
<td>10.49</td>
<td>11.27</td>
<td>10.09</td>
<td>8.30</td>
<td></td>
</tr>
<tr>
<td>10.44</td>
<td>10.24</td>
<td>11.03</td>
<td>10.09</td>
<td>8.30</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DECISION #1177-2054 - Mod. P3</th>
<th>Rate</th>
<th>Rate</th>
<th>Rate</th>
<th>Rate</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allegan, Barry, Calhoun, Clinton, Eaton, Ingham, Jackson &amp; Kalamazoo Counties, Michigan</td>
<td><strong>Bricklayers:</strong></td>
<td><strong>Glaziers:</strong></td>
<td><strong>Marble-Tile-Terrazzo Workers:</strong></td>
<td><strong>Plumbers:</strong></td>
<td></td>
</tr>
<tr>
<td>Genesee, Lapeer &amp; Shiawassee Cos</td>
<td>Genesee, Lapeer &amp; Shiawassee Cos</td>
<td>Genesee, Lapeer &amp; Shiawassee Cos</td>
<td>Genesee, Lapeer &amp; Shiawassee Cos</td>
<td>Genesee, Lapeer &amp; Shiawassee Cos</td>
<td></td>
</tr>
<tr>
<td>$10.09</td>
<td>10.44</td>
<td>8.75</td>
<td>10.09</td>
<td>11.47</td>
<td></td>
</tr>
<tr>
<td>9.70</td>
<td>10.09</td>
<td>8.55</td>
<td>10.09</td>
<td>11.47</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DECISION #1177-2055 - Mod. P3</th>
<th>Rate</th>
<th>Rate</th>
<th>Rate</th>
<th>Rate</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allegan, Barry, Calhoun, Clinton, Eaton, Ingham, Jackson &amp; Kalamazoo Counties, Michigan</td>
<td><strong>Glaziers:</strong></td>
<td><strong>Marble-Tile-Terrazzo Workers:</strong></td>
<td><strong>Plumbers:</strong></td>
<td><strong>Steeplejack:</strong></td>
<td></td>
</tr>
<tr>
<td>Genesee, Lapeer &amp; Shiawassee Cos</td>
<td>Genesee, Lapeer &amp; Shiawassee Cos</td>
<td>Genesee, Lapeer &amp; Shiawassee Cos</td>
<td>Genesee, Lapeer &amp; Shiawassee Cos</td>
<td>Genesee, Lapeer &amp; Shiawassee Cos</td>
<td></td>
</tr>
<tr>
<td>8.75</td>
<td>8.75</td>
<td>10.44</td>
<td>8.75</td>
<td>10.12</td>
<td></td>
</tr>
<tr>
<td>8.55</td>
<td>8.55</td>
<td>10.44</td>
<td>8.75</td>
<td>10.12</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DECISION #1177-2055 - Mod. P3</th>
<th>Rate</th>
<th>Rate</th>
<th>Rate</th>
<th>Rate</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allegan, Barry, Calhoun, Clinton, Eaton, Ingham, Jackson &amp; Kalamazoo Counties, Michigan</td>
<td><strong>Plasterers:</strong></td>
<td><strong>Steeplejack:</strong></td>
<td><strong>Steeplejack:</strong></td>
<td><strong>Steeplejack:</strong></td>
<td></td>
</tr>
<tr>
<td>Saginaw County</td>
<td>Saginaw County</td>
<td>Saginaw County</td>
<td>Saginaw County</td>
<td>Saginaw County</td>
<td></td>
</tr>
</tbody>
</table>

**NOTICES 35525**
### DECISION #KI77-2071 - Mod. 41

(42 FR 28763 - June 3, 1977)

**Electricians:**
- Remainder of Counties:
  - Basic Hourly Rates: $11.40
  - Fringe Benefits Payments:
    - H & W: 1.95
    - Pensions: 12.1
    - Vacation: 1.96
  - Education and/or Apprenticeship: 1.00

### DECISION #MN77-2047 - Mod. 2

(42 FR 23412 - May 6, 1977)

**Sheet Metal Workers:**
- Carlton Co.; Southern 1/2 of St. Louis County:
  - Basic Hourly Rates: $10.35
  - Fringe Benefits Payments:
    - H & W: 1.40
    - Pensions: 14.4

### DECISION #MN77-2048 - Mod. 2

(42 FR 26157 - July 29, 1977)

**Well Drilling:**
- Construction or Repair of Water Wells & appurtenances:
  - Metropolitan Area:
    - Hennepin, Ramsey, Washington, Anoka, Carver, Scott & Dakota Counties; That part of Wright County east of T-34, 25, Sherburne County south of T-34 & east of R-278 & that part of Chisago Co., south of T-34:
      - Driller-Pumpman: $8.50
      - General Helper: $6.90
      - Mechanic-Welder: $7.85
      - Driver or Service Man: $6.90
  - Rural Area:
    - Hennepin, Carver, Scott, Dakota Counties: That part of Wright County east of T-34, 25, Sherburne County south of T-34 & east of R-278 & that part of Chisago Co., south of T-34:
      - Driller-Pumpman: $8.50
      - General Helper: $6.90
      - Mechanic-Welder: $7.85
      - Driver or Service Man: $6.90
### Decision # MS77-1033 - Mod. #2

**Warren County, Mississippi**

**Basic Hourly Rates**

<table>
<thead>
<tr>
<th>Trade</th>
<th>Basic Rate</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electricians</td>
<td>9.25</td>
<td>.35</td>
<td>3%</td>
<td>.50</td>
<td>.04</td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>9.50</td>
<td>.35</td>
<td>3%</td>
<td>.50</td>
<td>.04</td>
</tr>
<tr>
<td>Ironworkers</td>
<td>8.95</td>
<td>.30</td>
<td>.35</td>
<td></td>
<td>.04</td>
</tr>
<tr>
<td>Lathers</td>
<td>8.45</td>
<td>.30</td>
<td>.35</td>
<td></td>
<td>.03</td>
</tr>
<tr>
<td>Plasterers</td>
<td>7.60</td>
<td>.25</td>
<td>.50</td>
<td></td>
<td>.05</td>
</tr>
<tr>
<td>Roofers</td>
<td>8.25</td>
<td></td>
<td></td>
<td>.20</td>
<td></td>
</tr>
</tbody>
</table>

### Decision # MS77-5031 - Mod. #4

**Warren County, Mississippi**

**Basic Hourly Rates**

| Zone 1: In Warren County, the area within 5 road miles of the following communities: Carson City, Lawrence, also area within 10 road miles of Reno, Nevada, and Warren Valley between Reno, Nevada, and Carson City, Nevada, but not including any area further than the foot of the mountains to the east or west side of Washoe Valley; also the area of Stead Air Force Base. **Change:**

<table>
<thead>
<tr>
<th>Trade</th>
<th>Basic Rate</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electricians</td>
<td>9.25</td>
<td>.35</td>
<td>3%</td>
<td>.50</td>
<td>.04</td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>9.50</td>
<td>.35</td>
<td>3%</td>
<td>.50</td>
<td>.04</td>
</tr>
<tr>
<td>Ironworkers</td>
<td>8.95</td>
<td>.30</td>
<td>.35</td>
<td></td>
<td>.04</td>
</tr>
<tr>
<td>Lathers</td>
<td>8.45</td>
<td>.30</td>
<td>.35</td>
<td></td>
<td>.03</td>
</tr>
<tr>
<td>Plasterers</td>
<td>7.60</td>
<td>.25</td>
<td>.50</td>
<td></td>
<td>.05</td>
</tr>
<tr>
<td>Roofers</td>
<td>8.25</td>
<td></td>
<td></td>
<td>.20</td>
<td></td>
</tr>
</tbody>
</table>

### Decision # MS77-1033 - Mod. #2

**Cascade, Deer Lodge, Gallatin, Glacier, Hill, Missoula, Silver Bow and Valley Counties, Montana**

**Electricians:**

<table>
<thead>
<tr>
<th>Trade</th>
<th>Basic Rate</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cascade and Glacier Counties: <strong>Electricians:</strong></td>
<td>9.10</td>
<td>.55</td>
<td>3%</td>
<td>.70</td>
<td>.44</td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>11.00</td>
<td>.55</td>
<td>3%</td>
<td>.70</td>
<td>.44</td>
</tr>
<tr>
<td>Deer Lodge and Silver Bow Counties: <strong>Electricians:</strong></td>
<td>9.90</td>
<td>.50</td>
<td>3%</td>
<td>.70</td>
<td>.44</td>
</tr>
<tr>
<td>Missoula County: <strong>Electricians:</strong></td>
<td>10.70</td>
<td>.50</td>
<td>3%</td>
<td>.70</td>
<td>.44</td>
</tr>
<tr>
<td>Cascade and Glacier Counties: <strong>Cable Splicers:</strong></td>
<td>11.10</td>
<td>.42</td>
<td>3%</td>
<td></td>
<td>.44</td>
</tr>
<tr>
<td>Deer Lodge and Silver Bow Counties: <strong>Electricians:</strong></td>
<td>11.10</td>
<td>.42</td>
<td>3%</td>
<td></td>
<td>.44</td>
</tr>
<tr>
<td>Missoula County: <strong>Electricians:</strong></td>
<td>11.35</td>
<td>.40</td>
<td>3%</td>
<td></td>
<td>.44</td>
</tr>
<tr>
<td>Cascade and Glacier Counties: <strong>Electricians:</strong></td>
<td>10.35</td>
<td>.40</td>
<td>3%</td>
<td>.50</td>
<td>.44</td>
</tr>
<tr>
<td>Missoula County: <strong>Electricians:</strong></td>
<td>8.70</td>
<td>.55</td>
<td>3%</td>
<td>.50</td>
<td>.44</td>
</tr>
<tr>
<td>Painters: <strong>Missoula County:</strong></td>
<td>7.48</td>
<td>.46</td>
<td>.40</td>
<td></td>
<td>.06</td>
</tr>
<tr>
<td>Plumbers: <strong>Cascade, Glacier, Hill and Valley Counties:</strong></td>
<td>11.60</td>
<td>.65</td>
<td>.95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roofers: <strong>Cascade, Glacier, Hill and Valley Counties:</strong></td>
<td>9.70</td>
<td>.60</td>
<td>.95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missoula County: <strong>Sheet Metal Workers:</strong></td>
<td>20.23</td>
<td>.82</td>
<td>.25</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Change (Cont'd):</td>
<td>Fringe Benefits Payments</td>
<td>Minions H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
<td>Education and/or App. Tr.</td>
</tr>
<tr>
<td>-----------------</td>
<td>--------------------------</td>
<td>---------------</td>
<td>----------</td>
<td>----------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Laborers (Cont’d):</td>
<td>Basic Hourly Rates</td>
<td>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
<td>Education and/or App. Tr.</td>
</tr>
<tr>
<td>Zone 3: Area over 20 and not more than 40 road miles from the above communities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>9.00</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>9.15</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td>9.25</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 4</td>
<td>9.30</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 5</td>
<td>9.40</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 6-A</td>
<td>9.60</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 6-B</td>
<td>9.50</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 6-C</td>
<td>9.70</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Zone 4: Area over 40 road miles from the above communities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>9.70</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>9.80</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td>9.95</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 4</td>
<td>10.20</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 5</td>
<td>10.40</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 6-A</td>
<td>10.60</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 6-B</td>
<td>10.50</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 6-C</td>
<td>9.85</td>
<td>.70</td>
<td>.90</td>
<td>.10</td>
<td></td>
</tr>
</tbody>
</table>

Sheet Metal Workers: 10.34 1.04 .90

Carpenters: $11.51 1.05 .90 .10

<table>
<thead>
<tr>
<th>Change:</th>
<th>Fringe Benefits Payments</th>
<th>Minions H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or App. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laborers (Cont’d):</td>
<td>Basic Hourly Rates</td>
<td>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
<td>Education and/or App. Tr.</td>
</tr>
<tr>
<td>Zone 1: Area within the City Limits of Henderson, 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 spur track and on the west by the train line of the Union Pacific Railroad:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>11.36</td>
<td>.65</td>
<td>.90</td>
<td>$1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 2</td>
<td>11.36</td>
<td>.65</td>
<td>.90</td>
<td>$1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 3</td>
<td>11.36</td>
<td>.65</td>
<td>.90</td>
<td>$1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 4</td>
<td>11.36</td>
<td>.65</td>
<td>.90</td>
<td>$1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 5</td>
<td>11.36</td>
<td>.65</td>
<td>.90</td>
<td>$1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 6-A</td>
<td>11.36</td>
<td>.65</td>
<td>.90</td>
<td>$1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 6-B</td>
<td>11.36</td>
<td>.65</td>
<td>.90</td>
<td>$1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 6-C</td>
<td>11.36</td>
<td>.65</td>
<td>.90</td>
<td>$1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Zone 2: Area outside of Zone 1 and not more than 20 miles from the communities described above:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>11.86</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 2</td>
<td>11.86</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 3</td>
<td>11.86</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 4</td>
<td>11.86</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 5</td>
<td>11.86</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 6-A</td>
<td>11.86</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 6-B</td>
<td>11.86</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 6-C</td>
<td>11.86</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Zone 3: Area over 20 miles and not more than 40 miles from the communities described in Zone 1:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>12.11</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 2</td>
<td>12.11</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 3</td>
<td>12.11</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 4</td>
<td>12.11</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 5</td>
<td>12.11</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 6-A</td>
<td>12.11</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 6-B</td>
<td>12.11</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Group 6-C</td>
<td>12.11</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
</tbody>
</table>
### DECISION NO. NM77-5061 (Cont'd)

**Carpenters (Cont'd):**
- Zone 4: Area over 40 miles from the communities described in Zone 1:
  - Carpenters:
  - Floor layers; Patent scaffold erectors;
  - Power saw operators:
  - Piledrivermen:
  - Millwrights:
  - Glaziers:
  - Soft Floor Layers

### DECISION NO. NM77-4116 - Mod. #2

(42 FR 31094 - June 17, 1977)
Statewide, New Mexico

**CHANGE:**
**Carpenters:**
- General Building and Heavy Engineering and Residential Construction (Dwelling Houses and apartments over two stories in height)

### Basic Hourly Rates

<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>Zone 4-A</td>
<td>13.36</td>
<td>.65</td>
<td>.90</td>
<td>$1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Zone 4-B</td>
<td>13.51</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Zone 4-C</td>
<td>13.56</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Zone 4-D</td>
<td>14.06</td>
<td>.65</td>
<td>.90</td>
<td>1.00</td>
<td>.10</td>
</tr>
<tr>
<td>Classless</td>
<td>13.50</td>
<td>.90</td>
<td>.40</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Soft Floor Layers</td>
<td>12.67</td>
<td>.65</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### MODIFICATIONS P. 38

### DECISION NO. NJ77-3029 - Mod. #4

(42 FR 10263 - February 18, 1977)
Berks County, Pennsylvania

**Bricklayers & Stonemasons**

<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>Zone VIII</td>
<td>$9.30</td>
<td>.60</td>
<td>.75</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone IX</td>
<td>10.45</td>
<td>.73</td>
<td>.15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone XI</td>
<td>11.80</td>
<td>.84</td>
<td>1.26</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>Zone XII</td>
<td>11.80</td>
<td>.84</td>
<td>1.26</td>
<td>.02</td>
<td></td>
</tr>
</tbody>
</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>Zone VIII</td>
<td>9.40</td>
<td>.40</td>
<td>.25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone IX</td>
<td>6.87</td>
<td>.40</td>
<td>.25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone XI</td>
<td>8.03</td>
<td>.40</td>
<td>.25</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

###虚空机 operators:

- General Laborers
- Operators of jackhammer, paving breaking and other pneumatic, electrical and mechanical tools, coming under the jurisdiction of laborer; laying of all clay, terra cotta, stone, vitrified concrete or non-metallic pipe and the making of joints for same, wagon drill operators and concrete power buggies, gas and slab placers, signal men, brick, stone, plasterers and cement masons tenders, machine mixers, stockers, scaffold buildings, plaster pump and conveyors, blasters, caisson workers, wagon and track, diamond point drill operators, burning torches, green cutting machine, steam jenny and blast.

### Line Construction:

- Cable splicers & Lineman
- Groundmen
- Winch truck operators
### Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Fringe Benefits Payments</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>Painters:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brush</td>
<td>7.50</td>
<td>.70</td>
<td>.35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bridge, tower, stacks &amp; tanks</td>
<td>10.40</td>
<td>.70</td>
<td>.35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spray &amp; steel</td>
<td>10.00</td>
<td>.70</td>
<td>.35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plumbers &amp; Steamfitters</td>
<td>11.76</td>
<td>.60</td>
<td>1.45</td>
<td></td>
<td>.15</td>
</tr>
</tbody>
</table>

### DECISION NO. PA77-3029 - Mod. #4

**Cont'd.**

**Cumberland, Dauphin, Perry, Juniata, New Cumberland, Army Depot & York County, Pa.**

**Change:**
- Cement masons: $10.035
- Electricians: 10.36
- Ironworkers: Structural, ornamental, & reinforcing: 11.28
- Line Construction:
  - Linemen: 10.82
  - Cable splicer: 10.82
  - Groundmen: 6.45
  - Winch truck operators: 7.34
- Pile drivers: 10.77

### DECISION PA77-3030 - Mod. #4

**Lebanon County, Pennsylvania**

**Change:**
- Electricians: Lawn, East Hanover & Indiantown Gap Military Reservation: $10.36, .65, .94, .31, 2/6%
- Ironworkers: 11.28, .84, 1.36, .63
- Laborers:
  - General Laborers: 6.70, .40, .75
  - Operators of jackhammers, paving breaking and other pneumatic, electrical and mechanical tools coming under the jurisdiction of laborers, laying of all clay, terra cotta, brick, stone, plasterers and cement masons tenders, machine mixers, stockers, scaffolding building, plastering, pump and conveyors, blasters, casing workers, wagon air track and diamond point drill operators, burning torches, green cutting machine, steam jenny and blasting, cofferdam, (below 10') tunnel free air and muckers, handling and using cutting or burning torches in the wrecking of buildings, plasterers tenders, scaffold building and removal for plasterers: 6.94, .40, .25
### DECISION NO. PA-77-3031 - Mod. 5

**Line Construction:**

- Linemen & cable splicer
- Groundmen
- Winch truck operator
- Filedrivermen

<table>
<thead>
<tr>
<th></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>Linemen &amp; cable splicer</td>
<td>$11.51</td>
<td>.40</td>
<td>3%</td>
<td>.3/4%</td>
<td></td>
</tr>
<tr>
<td>Groundmen</td>
<td>8.97</td>
<td>.40</td>
<td>3%</td>
<td>.3/4%</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>
</tr>
<tr>
<td>Filedrivermen</td>
<td>10.77</td>
<td>2.13</td>
<td>1.30</td>
<td>.12</td>
<td></td>
</tr>
</tbody>
</table>

**Footnote:**
- Paid Holidays: Washington’s Birthday; Good Friday; Memorial Day; Labor Day; Presidential Election Day; Veterans Day; Thanksgiving Day, and Christmas Day.

### DECISION NO. PA-77-3039 - Mod. 5

**Fringe Benefits Payments**

**Asbestos Workers**
- Zone 1
- Zone 4

**Bricklayers & Stonemasons**
- Zone 1
- Zone 4

**Carpenters & Soft Floor Layers**
- Zone 1
- Zone 4

**Cement Masons**
- Zone 3

**Carpenters & Soft Floor Layers**
- Zone 1
- Zone 4

**Electricians**
- Zone 1
- Zone 2
- Zone 3

**Ironworkers**
- Zone 1
- Zone 2
- Zone 3

**Line Construction:**
- Zone 1
- Zone 3

**Line Men:**
- Zone 1
- Zone 3

**Groundmen:**
- Zone 1
- Zone 3

**Winch Truck Operators:**
- Zone 1
- Zone 3

**Plumbers & Steamfitters:**
- Zone 1

**Change:**
- Asbestos Workers
- Bricklayers & Stonemasons
- Carpenters & Soft Floor Layers
- Cement Masons
- Electricians
- Ironworkers
- Line Construction
- Line Men
- Groundmen
- Winch Truck Operators
- Plumbers & Steamfitters
### DECISION OP77-3049 - Mod. # 3
(42 FR 21043 - April 22, 1977)
Northumberland County, Pennsylvania

<table>
<thead>
<tr>
<th>Fringe Benefits Payments</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>Asbestos workers</td>
<td>$20.70</td>
<td>.45</td>
<td>.60</td>
<td>.01</td>
<td></td>
</tr>
<tr>
<td>Cement masons</td>
<td>10.10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delaware, Lewis &amp; Trubuc</td>
<td>5.46</td>
<td>.50</td>
<td>324.60</td>
<td>.60</td>
<td>.02</td>
</tr>
<tr>
<td>Remainder of County</td>
<td>10.95</td>
<td>.35</td>
<td>.32</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Ironworkers</td>
<td>13.28</td>
<td>.34</td>
<td>1.36</td>
<td>.03</td>
<td></td>
</tr>
</tbody>
</table>

### DECISION OP77-3050 - Mod. # 2
(42 FR 24669 - May 13, 1977)
Lackawanna, Susquehanna, Wayne, and Wyoming Counties, Pennsylvania

<table>
<thead>
<tr>
<th>Fringe Benefits Payments</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>Asbestos workers</td>
<td>$10.70</td>
<td>.65</td>
<td>.60</td>
<td>.01</td>
<td></td>
</tr>
<tr>
<td>Electricians:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lackawanna, Susquehanna and Wayne Counties</td>
<td>9.75</td>
<td>.50</td>
<td>324.50</td>
<td>.50</td>
<td>.10</td>
</tr>
<tr>
<td>Wyoming County:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>East of Susquehanna River</td>
<td>9.75</td>
<td>.50</td>
<td>324.50</td>
<td>.50</td>
<td>.10</td>
</tr>
<tr>
<td>West of Susquehanna River</td>
<td>10.74</td>
<td>.50</td>
<td>324.73</td>
<td>.03</td>
<td></td>
</tr>
<tr>
<td>Glaziers</td>
<td>9.65</td>
<td>.60</td>
<td>.70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ironworkers:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lackawanna, Wayne &amp; Wyoming Counties:</td>
<td>11.90</td>
<td>e</td>
<td></td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Structural &amp; ornamental</td>
<td>11.90</td>
<td>e</td>
<td></td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Painters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brush &amp; Rollers</td>
<td>8.40</td>
<td>1.20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spray</td>
<td>9.90</td>
<td>1.20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steel</td>
<td>9.60</td>
<td>1.20</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### DECISION #PA77-3054 - Mod. # 2

**Bedford, Cambria, Cameron, Clarion, Elk, Forest, Jefferson, Crawford & Venango Counties, Pennsylvania**

#### Change:
- Bricklayers & Stonemasons:
  - Zone 1
  - Zone 2
  - Zone 3
  - Zone 4
- Carpenters & Soft Floor Layers:
  - Zone 1
  - Zone 2
  - Zone 3
  - Zone 4
- Cement Masons:
  - Zone 1
  - Zone 2
  - Zone 3
  - Zone 4
- Electricians:
  - Zone 1
  - Zone 2
  - Zone 3
  - Zone 4

### DECISION #PA77-3055 - Mod. # 2

**Greene, Somerset & Potter Counties, Pennsylvania**

#### Change:
- Bricklayers & Stonemasons:
  - Zone 1
  - Zone 2
  - Zone 3
- Electricians:
  - Zone 1
  - Zone 2
- Lineman:
  - Groundman
- Winch truck operators
- Painters:
  - Zone 1
  - Zone 2
  - Zone 3
  - Zone 4

### DECISION #PA77-3057 - Mod. # 1

**Sullivan County, Pennsylvania**

#### Change:
- Asbestos Workers
- Bricklayers
- Electricians:
  - Western part of County
- Glaziers
- Plasterers
- Soft floor layers
- Plumbers & Steamfitters
- Stonemasons

### Basic Hourly Rates

<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 1</td>
<td>$10.35, $10.65, $10.91, $12.00</td>
</tr>
<tr>
<td>Zone 2</td>
<td>$9.60, $9.91, $10.20, $10.50</td>
</tr>
<tr>
<td>Zone 3</td>
<td>$8.85, $9.10, $9.35, $9.65</td>
</tr>
<tr>
<td>Zone 4</td>
<td>$8.10, $8.35, $8.60, $8.85</td>
</tr>
</tbody>
</table>

### Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Category</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### DECISION #PA77-3058 - Mod. # 2

**(42 FR 24877 - May 13, 1977)**

<table>
<thead>
<tr>
<th>Category</th>
<th>Basic Hourly Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 1</td>
<td>$10.35, $10.65, $10.91, $12.00</td>
</tr>
<tr>
<td>Zone 2</td>
<td>$9.60, $9.91, $10.20, $10.50</td>
</tr>
<tr>
<td>Zone 3</td>
<td>$8.85, $9.10, $9.35, $9.65</td>
</tr>
<tr>
<td>Zone 4</td>
<td>$8.10, $8.35, $8.60, $8.85</td>
</tr>
</tbody>
</table>

### Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Category</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### DECISION #PA77-3061 - Mod. # 1
(42 FR 30133 - June 10, 1977)

<table>
<thead>
<tr>
<th>Trade</th>
<th>Basic Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Armstrong, Allegheny, Beaver, Butler, Fayette, Indiana, Washington &amp; Westmoreland Counties, Pennsylvania</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bricklayers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 3</td>
<td>$12.125</td>
<td>.45</td>
<td>.60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 2</td>
<td>$11.40</td>
<td>.40</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 3</td>
<td>$12.30</td>
<td>.45</td>
<td>.65</td>
<td>.2%</td>
<td></td>
</tr>
<tr>
<td>Landscape Laborers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Landscape Laborer</td>
<td>$6.50</td>
<td>.40</td>
<td>.60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skilled Landscape Laborer</td>
<td>$6.65</td>
<td>.40</td>
<td>.60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Landscape Tractor Operator</td>
<td>$7.00</td>
<td>.40</td>
<td>.60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lineman</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Winch Truck operator</td>
<td>$8.40</td>
<td>.40</td>
<td>.35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Groundman</td>
<td>$7.20</td>
<td>.40</td>
<td>.35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marble Setters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 2</td>
<td>$12.125</td>
<td>.45</td>
<td>.60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Painters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial Brush</td>
<td>$9.00</td>
<td>.45</td>
<td>.35</td>
<td>.60</td>
<td></td>
</tr>
<tr>
<td>Industrial Brush</td>
<td>$10.25</td>
<td>.45</td>
<td>.35</td>
<td>.60</td>
<td></td>
</tr>
<tr>
<td>Roller</td>
<td>$10.75</td>
<td>.45</td>
<td>.35</td>
<td>.60</td>
<td></td>
</tr>
<tr>
<td>Zone 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brush &amp; Roller</td>
<td>$8.50</td>
<td>.45</td>
<td>.35</td>
<td>.60</td>
<td></td>
</tr>
<tr>
<td>Spray</td>
<td>$9.475</td>
<td>.45</td>
<td>.35</td>
<td>.60</td>
<td></td>
</tr>
<tr>
<td>Plumbers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 2</td>
<td>$11.71</td>
<td>.40</td>
<td>.35</td>
<td>.65</td>
<td></td>
</tr>
<tr>
<td>Zone 3</td>
<td>$11.07</td>
<td>.45</td>
<td>1.20</td>
<td>.67</td>
<td></td>
</tr>
<tr>
<td>Steamfitters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 4</td>
<td>$11.71</td>
<td>.40</td>
<td>.35</td>
<td>.65</td>
<td></td>
</tr>
<tr>
<td>Stone Masons</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 4</td>
<td>$12.125</td>
<td>.45</td>
<td>.60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 1</td>
<td>$10.63</td>
<td>.73</td>
<td>1.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Terrazzo workers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 2</td>
<td>$12.125</td>
<td>.45</td>
<td>.60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tile Setters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 2</td>
<td>$12.125</td>
<td>.45</td>
<td>.60</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### DECISION NO. SD77-3065 - Mod. #1
(42 FR 31114 - June 17, 1977)

<table>
<thead>
<tr>
<th>Trade</th>
<th>Basic Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meade and Pennington Counties, South Dakota</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 15 mile radius of Rapid City Post Office</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td>$9.05</td>
<td>.40</td>
<td>.35</td>
<td>.60</td>
<td></td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>10.05</td>
<td>.40</td>
<td>.35</td>
<td>.60</td>
<td></td>
</tr>
<tr>
<td>Within 15 to 35 mile radius of Rapid City Post Office</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td>10.05</td>
<td>.40</td>
<td>.35</td>
<td>.60</td>
<td></td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>10.60</td>
<td>.40</td>
<td>.35</td>
<td>.60</td>
<td></td>
</tr>
<tr>
<td>Outside a 35 mile radius of Rapid City Post Office</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td>10.85</td>
<td>.40</td>
<td>.35</td>
<td>.60</td>
<td></td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>11.45</td>
<td>.40</td>
<td>.35</td>
<td>.60</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Basic Hourly Rates</td>
<td>Fringe Benefits Payments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>--------------------</td>
<td>--------------------------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td>H &amp; W Pensions</td>
<td>Vacation</td>
<td>Education and/or Appr. Tr.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MODIFICATIONS P. 49</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Carpenters</strong>:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 1</td>
<td>8.925</td>
<td>.30</td>
<td>.30</td>
<td>.005</td>
<td></td>
</tr>
<tr>
<td>Millwrights</td>
<td>9.125</td>
<td>.30</td>
<td>.30</td>
<td>.005</td>
<td></td>
</tr>
<tr>
<td><strong>Electricians</strong>:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 2 - Collin, Dallas, Ellis, Grayson, Hunt, Kaufman &amp; Rockwall Co.:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Area A - All work performed in Dallas &amp; Grayson Co.:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td>10.43</td>
<td>.45</td>
<td>.35</td>
<td>7/10%</td>
<td></td>
</tr>
<tr>
<td>Cable splicers</td>
<td>11.47</td>
<td>.45</td>
<td>.35</td>
<td>7/10%</td>
<td></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>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td>10.66</td>
<td>.45</td>
<td>.35</td>
<td>7/10%</td>
<td></td>
</tr>
<tr>
<td>Cable splicers</td>
<td>11.73</td>
<td>.45</td>
<td>.35</td>
<td>7/10%</td>
<td></td>
</tr>
<tr>
<td>Area C - All work performed outside of Area A &amp; B:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td>10.83</td>
<td>.45</td>
<td>.35</td>
<td>7/10%</td>
<td></td>
</tr>
<tr>
<td>Cable splicers</td>
<td>12.02</td>
<td>.45</td>
<td>.35</td>
<td>7/10%</td>
<td></td>
</tr>
<tr>
<td><strong>Painters</strong>:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 2 - Collin, Dallas, Ellis, Grayson, Hunt, Kaufman &amp; Rockwall Co.:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricals</td>
<td>10.43</td>
<td>.60</td>
<td>.75</td>
<td>.70 of 1%</td>
<td></td>
</tr>
<tr>
<td><strong>Laborers</strong>:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>6.91</td>
<td>.28</td>
<td>.40</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>6.96</td>
<td>.28</td>
<td>.40</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td>7.01</td>
<td>.28</td>
<td>.40</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>Group 4</td>
<td>7.01</td>
<td>.28</td>
<td>.40</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>Group 5</td>
<td>7.16</td>
<td>.28</td>
<td>.40</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>Group 6</td>
<td>7.265</td>
<td>.28</td>
<td>.40</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>Electricians</strong>:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 2 - Collin, Dallas, Ellis, Grayson, Hunt, Kaufman &amp; Rockwall Co.:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td>8.25</td>
<td>.28</td>
<td>.35</td>
<td>.40%</td>
<td></td>
</tr>
<tr>
<td><strong>Painters</strong>:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 2 - Collin, Dallas, Ellis, Grayson, Hunt, Kaufman &amp; Rockwall Co.:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricals</td>
<td>10.43</td>
<td>.60</td>
<td>.75</td>
<td>.70 of 1%</td>
<td></td>
</tr>
<tr>
<td><strong>Electricians</strong>:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 2 - Collin, Dallas, Ellis, Grayson, Hunt, Kaufman &amp; Rockwall Co.:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td>10.43</td>
<td>.60</td>
<td>.75</td>
<td>.70 of 1%</td>
<td></td>
</tr>
</tbody>
</table>
### Fringe Benefits Payment

**Decision No. WA77-5055 - Mod. il**

**(42 FR 31115 - June 17, 1977)**

Statewide, Washington Hourly & W Pensions Vacation Education and/or Appr. Tr.

**Change:**

- **Laborers (Area 3)**: Clark, Cowlitz, Klickitat, Skamania, Wahkiakum and the Southern portion of Pacific Counties—

<table>
<thead>
<tr>
<th>Group 1:</th>
<th>Zone A</th>
<th>Zone B</th>
<th>Zone C</th>
<th>Zone D</th>
<th>Zone E</th>
<th>Zone F</th>
</tr>
</thead>
<tbody>
<tr>
<td>H &amp; W</td>
<td>8.29</td>
<td>8.69</td>
<td>9.04</td>
<td>9.29</td>
<td>9.54</td>
<td>9.79</td>
</tr>
<tr>
<td>Rates</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
</tr>
<tr>
<td>Pension</td>
<td>1.10</td>
<td>1.10</td>
<td>1.10</td>
<td>1.10</td>
<td>1.10</td>
<td>1.10</td>
</tr>
<tr>
<td>Vacation</td>
<td>0.65</td>
<td>0.65</td>
<td>0.65</td>
<td>0.65</td>
<td>0.65</td>
<td>0.65</td>
</tr>
<tr>
<td>Education and/or Appr. Tr.</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
</tr>
</tbody>
</table>

- **Group 2:**

<table>
<thead>
<tr>
<th>Zone A</th>
<th>Zone B</th>
<th>Zone C</th>
<th>Zone D</th>
<th>Zone E</th>
<th>Zone F</th>
</tr>
</thead>
<tbody>
<tr>
<td>H &amp; W</td>
<td>8.64</td>
<td>9.04</td>
<td>9.39</td>
<td>9.64</td>
<td>9.89</td>
</tr>
<tr>
<td>Rates</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
</tr>
<tr>
<td>Pension</td>
<td>1.10</td>
<td>1.10</td>
<td>1.10</td>
<td>1.10</td>
<td>1.10</td>
</tr>
<tr>
<td>Vacation</td>
<td>0.65</td>
<td>0.65</td>
<td>0.65</td>
<td>0.65</td>
<td>0.65</td>
</tr>
<tr>
<td>Education and/or Appr. Tr.</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
</tr>
</tbody>
</table>

- **Group 3:**

<table>
<thead>
<tr>
<th>Zone A</th>
<th>Zone B</th>
<th>Zone C</th>
<th>Zone D</th>
<th>Zone E</th>
<th>Zone F</th>
</tr>
</thead>
<tbody>
<tr>
<td>H &amp; W</td>
<td>8.94</td>
<td>9.34</td>
<td>9.69</td>
<td>9.94</td>
<td>10.19</td>
</tr>
<tr>
<td>Rates</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
</tr>
<tr>
<td>Pension</td>
<td>1.10</td>
<td>1.10</td>
<td>1.10</td>
<td>1.10</td>
<td>1.10</td>
</tr>
<tr>
<td>Vacation</td>
<td>0.65</td>
<td>0.65</td>
<td>0.65</td>
<td>0.65</td>
<td>0.65</td>
</tr>
<tr>
<td>Education and/or Appr. Tr.</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
</tr>
</tbody>
</table>

- **Group 4:**

<table>
<thead>
<tr>
<th>Zone A</th>
<th>Zone B</th>
<th>Zone C</th>
<th>Zone D</th>
<th>Zone E</th>
<th>Zone F</th>
</tr>
</thead>
<tbody>
<tr>
<td>H &amp; W</td>
<td>9.19</td>
<td>9.59</td>
<td>9.94</td>
<td>10.19</td>
<td>10.44</td>
</tr>
<tr>
<td>Rates</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
</tr>
<tr>
<td>Pension</td>
<td>1.10</td>
<td>1.10</td>
<td>1.10</td>
<td>1.10</td>
<td>1.10</td>
</tr>
<tr>
<td>Vacation</td>
<td>0.65</td>
<td>0.65</td>
<td>0.65</td>
<td>0.65</td>
<td>0.65</td>
</tr>
<tr>
<td>Education and/or Appr. Tr.</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
<td>0.10</td>
</tr>
</tbody>
</table>
**SUPERDEED DECISION**

**STATE:** Alabama  
**COUNTIES:** See below

SUPERDEED Decision No.: AL77-1089 dated January 16, 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>
<thead>
<tr>
<th>Craft/Position</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Air conditioning mechanic</td>
<td>4.85</td>
<td>6.00</td>
</tr>
<tr>
<td>Bricklayers</td>
<td>6.00</td>
<td>4.00</td>
</tr>
<tr>
<td>Carpenters</td>
<td>4.00</td>
<td>4.00</td>
</tr>
<tr>
<td>Cement masons</td>
<td>4.62</td>
<td>4.50</td>
</tr>
<tr>
<td>Dry wall hangers</td>
<td>4.50</td>
<td>4.85</td>
</tr>
<tr>
<td>Dry wall finishers</td>
<td>4.85</td>
<td>4.85</td>
</tr>
<tr>
<td>Dry wall sanders</td>
<td>2.00</td>
<td>4.66</td>
</tr>
<tr>
<td>Electricians</td>
<td>4.66</td>
<td>2.30</td>
</tr>
<tr>
<td>Laborers: Unskilled</td>
<td>2.30</td>
<td>3.00</td>
</tr>
<tr>
<td>Mason tenders</td>
<td>2.30</td>
<td>3.00</td>
</tr>
<tr>
<td>Painters</td>
<td>5.00</td>
<td>4.85</td>
</tr>
<tr>
<td>Plumbers</td>
<td>6.00</td>
<td>2.30</td>
</tr>
<tr>
<td>Roofers</td>
<td>4.65</td>
<td>2.30</td>
</tr>
<tr>
<td>Sheet metal workers</td>
<td>3.50</td>
<td>2.30</td>
</tr>
<tr>
<td>Soft floor layers</td>
<td>4.00</td>
<td>2.30</td>
</tr>
<tr>
<td>Tile setters</td>
<td>4.00</td>
<td>2.30</td>
</tr>
<tr>
<td>Truck drivers</td>
<td>2.76</td>
<td>2.30</td>
</tr>
</tbody>
</table>

**POWER EQUIPMENT OPERATORS:**

<table>
<thead>
<tr>
<th>Craft/Position</th>
<th>Basic Hourly Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Backhoe</td>
<td>4.00</td>
</tr>
<tr>
<td>Bulldozers</td>
<td>4.00</td>
</tr>
<tr>
<td>Dragline</td>
<td>3.75</td>
</tr>
<tr>
<td>Asphalt spreader</td>
<td>4.25</td>
</tr>
<tr>
<td>Roller</td>
<td>3.25</td>
</tr>
<tr>
<td>Front and Loader</td>
<td>4.50</td>
</tr>
</tbody>
</table>

*NOTES*

**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
## SUPERSEDES DECISION

**STATE:** Florida  
**COUNTY:** Broward  
**DECISION NO.:** FL77-1091  
**DATE:** Date of Publication  
**Supersedes Decision No.:** FL77—1015 dated February 18, 1977 in 42 FR-10224  
**DESCRIPTION OF WORK:** Building Construction (excludes single family homes and garden type apartments of 4 stories) and Heavy Construction (excludes sewer and water line construction)

<table>
<thead>
<tr>
<th>Fringe Benefits Payments</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asbestos workers</td>
<td>.50</td>
<td>.65</td>
<td>.04</td>
</tr>
<tr>
<td>Drywall workers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bricklayers:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blocklayers, bricklayers, cement masons, marble setters, plasterers, stone masons, terra cotta mechanics, and tile setters</td>
<td>.50</td>
<td>.60</td>
<td>.03</td>
</tr>
<tr>
<td>Carpenters:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carpenters, soft floor layers</td>
<td>.70</td>
<td>.45</td>
<td>.06</td>
</tr>
<tr>
<td>Electricians:</td>
<td>.63</td>
<td>3+.40</td>
<td>.41</td>
</tr>
<tr>
<td>Cable splicers</td>
<td>.63</td>
<td>3+.40</td>
<td>.41</td>
</tr>
<tr>
<td>Elevator Constructors:</td>
<td>.545</td>
<td>.35</td>
<td>.4+.4½</td>
</tr>
<tr>
<td>Elevator Constructors</td>
<td>.545</td>
<td>.35</td>
<td>.4+.4½</td>
</tr>
<tr>
<td>Elevator constructor helpers:</td>
<td>704.38</td>
<td>.35</td>
<td>.4+.4½</td>
</tr>
<tr>
<td>Elevator constructor helpers:</td>
<td>504.03</td>
<td>.35</td>
<td>.4+.4½</td>
</tr>
<tr>
<td>Ironworkers:</td>
<td>.75</td>
<td>.50</td>
<td>.08</td>
</tr>
<tr>
<td>Laborers:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General laborers</td>
<td>1.00</td>
<td>.30</td>
<td></td>
</tr>
<tr>
<td>Mason tenders, Mortar mixers, vibrator operators:</td>
<td>1.00</td>
<td>.30</td>
<td></td>
</tr>
<tr>
<td>Planterer tenders</td>
<td>1.00</td>
<td>.30</td>
<td></td>
</tr>
<tr>
<td>Laborers:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concrete mixers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elevator Constructors:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elevator constructors:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elevator constructor helpers:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating Engineers:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group I:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All tower cranes, cranes with boom length over 250 ft., derricks, helicopters, all types of flying cranes, all nuclear powered equipment.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group II:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All cranes with boom length of 150 ft., to 250 ft., cranes of 150 tons and over with boom length of under 250 ft., gantry and overhead cranes.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group III:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All hydro cranes, cranes with boom length of under 150 ft., clamshell, shovel, backhoe, gradall, cherry picker, dragline, pile driver, drilling of piling, tagger, hoist, motor grader, (finish), mechanic, side boom, tractor boom, concrete mixer, cableway.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group IV:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boring &amp; drilling machine, concrete pump machine, batching plant, inside elevator, forklift with vert. lift of over 20 ft.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group V:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Locomotive, motor mixing pump, winch truck, A-frame truck, greaser truck, front end loader, bulldozer, pan, motor grader, forklift.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group VI:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trenching and ditching machine, roller, fireman, distributor (bituminous), finish machine (paving), wellpoint system (installation and/or operation), siphon vacuum pump, tractor, conveyor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group VII:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Utility operator (any combination of equipment up to and including 4 pieces listed in Group VIII), welding machine (3 or 4)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group VIII:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pump (over 24 inches), conveyor (over 125 c.f.m.), generator (over 5 kW) welding machines (2).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group IX:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Giler, fuel truck, mechanic helper, boom hauling truck, lowboy truck</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**FOOTNOTES:**


b. Four per cent of basic hourly rate for employees who have worked in business more than five years; two percent for employees who have worked less than five years.

---

**NOTICES**
### OPERATING ENGINEERS (CONT'D)

<table>
<thead>
<tr>
<th></th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>H &amp; W Pensions</td>
<td>Vacation</td>
<td></td>
</tr>
<tr>
<td>Basic Hourly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group I</td>
<td>9.40</td>
<td>0.50</td>
</tr>
<tr>
<td>Group II</td>
<td>9.25</td>
<td>0.50</td>
</tr>
<tr>
<td>Group III</td>
<td>8.75</td>
<td>0.80</td>
</tr>
<tr>
<td>Group IV</td>
<td>8.30</td>
<td>0.80</td>
</tr>
<tr>
<td>Group V</td>
<td>8.15</td>
<td>0.80</td>
</tr>
<tr>
<td>Group VI</td>
<td>7.80</td>
<td>0.80</td>
</tr>
<tr>
<td>Group VII</td>
<td>7.55</td>
<td>0.80</td>
</tr>
<tr>
<td>Group VIII</td>
<td>7.45</td>
<td>0.80</td>
</tr>
<tr>
<td>Group IX</td>
<td>7.05</td>
<td></td>
</tr>
</tbody>
</table>

### HEAVY CONSTRUCTION (CONT'D)

<table>
<thead>
<tr>
<th></th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>H &amp; W Pensions</td>
<td>Vacation</td>
<td></td>
</tr>
<tr>
<td>Basic Hourly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group I</td>
<td>7.60</td>
<td>0.50</td>
</tr>
<tr>
<td>Group II</td>
<td>7.45</td>
<td>0.80</td>
</tr>
<tr>
<td>Group III</td>
<td>6.95</td>
<td>0.80</td>
</tr>
<tr>
<td>Group IV</td>
<td>6.80</td>
<td>0.80</td>
</tr>
<tr>
<td>Group V</td>
<td>6.65</td>
<td>0.80</td>
</tr>
<tr>
<td>Group VI</td>
<td>6.55</td>
<td>0.80</td>
</tr>
<tr>
<td>Group VII</td>
<td>6.45</td>
<td>0.80</td>
</tr>
<tr>
<td>Group VIII</td>
<td>6.35</td>
<td>0.80</td>
</tr>
<tr>
<td>Group IX</td>
<td>6.25</td>
<td>0.80</td>
</tr>
</tbody>
</table>
### SUPERSEDES DECISION

**STATE:** Illinois  
**COUNTY:** Cook  
**DECISION NUMBER:** IL77-2100  
**DATE:** Date of Publication  
**SUPERSEDES DECISION PAGE 2**  
**DESCRIPTION OF WORK:** Building (Including Residential), Heavy and Highway Construction

#### Basic Hourly Rates

<table>
<thead>
<tr>
<th>Occupation/Role</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASBESTOS WORKERS</strong></td>
<td>$11.51</td>
<td>.81</td>
<td>.72</td>
<td>.12</td>
</tr>
<tr>
<td><strong>MASON WORKERS</strong></td>
<td>$10.55</td>
<td>.65</td>
<td>1.00</td>
<td>.09</td>
</tr>
<tr>
<td><strong>BRICKLAYER &amp; STONEMAKERS</strong></td>
<td>$13.21</td>
<td>.80</td>
<td>.78</td>
<td>.04</td>
</tr>
<tr>
<td><strong>Carpenters:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Building, Heavy &amp; Highway</td>
<td>$10.50</td>
<td>.78</td>
<td>.88</td>
<td>.04</td>
</tr>
<tr>
<td>Carpenters &amp; Soff: Floor Layers</td>
<td>$10.50</td>
<td>.78</td>
<td>.88</td>
<td>.04</td>
</tr>
<tr>
<td><strong>Cement Masons:</strong></td>
<td>$10.55</td>
<td>.78</td>
<td>.88</td>
<td>.04</td>
</tr>
<tr>
<td><strong>Boilermakers</strong></td>
<td>$10.55</td>
<td>.78</td>
<td>.88</td>
<td>.04</td>
</tr>
<tr>
<td><strong>Bricklayers &amp; Stonemasons</strong></td>
<td>$13.21</td>
<td>.80</td>
<td>.78</td>
<td>.04</td>
</tr>
<tr>
<td><strong>Carpenters:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Electricians</strong></td>
<td>$11.75</td>
<td>8.243</td>
<td>.80</td>
<td>.88</td>
</tr>
<tr>
<td><strong>Elevator Constructors:</strong></td>
<td>$11.91</td>
<td>.545</td>
<td>.35</td>
<td>.02</td>
</tr>
<tr>
<td><strong>Certified Operators</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Helpers</strong></td>
<td>$10.78</td>
<td>.533</td>
<td>.35</td>
<td>.02</td>
</tr>
<tr>
<td>** Helpers (Prob.)**</td>
<td>$50.82</td>
<td>.533</td>
<td>.35</td>
<td>.02</td>
</tr>
<tr>
<td><strong>Glassers</strong></td>
<td>$12.23</td>
<td>.28</td>
<td>.79</td>
<td>.01</td>
</tr>
<tr>
<td><strong>Ironworkers:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Fencing Erector</td>
<td>$8.30</td>
<td>.56</td>
<td>.575</td>
<td>.10</td>
</tr>
<tr>
<td>Structural &amp; Reinforcing</td>
<td>$11.80</td>
<td>1.14</td>
<td>1.32</td>
<td>.09</td>
</tr>
<tr>
<td>Ornamental</td>
<td>$11.60</td>
<td>.65</td>
<td>.805</td>
<td>.10</td>
</tr>
<tr>
<td>Rigging &amp; Machinery Movers</td>
<td>$9.45</td>
<td>.65</td>
<td>1.325</td>
<td>.15</td>
</tr>
<tr>
<td>Red Book Fence Erector</td>
<td>$8.62</td>
<td>.65</td>
<td>.805</td>
<td>.10</td>
</tr>
<tr>
<td><strong>Lathers</strong></td>
<td>$9.82</td>
<td>.58</td>
<td>.445</td>
<td>.05</td>
</tr>
<tr>
<td><strong>Lead Workers</strong></td>
<td>$9.25</td>
<td>.35</td>
<td>.01</td>
<td>.01</td>
</tr>
<tr>
<td><strong>Line Construction:</strong></td>
<td>$11.80</td>
<td>.54</td>
<td>.68</td>
<td>.850%</td>
</tr>
<tr>
<td>Lineman</td>
<td>$9.05</td>
<td>.54</td>
<td>.68</td>
<td>.850%</td>
</tr>
<tr>
<td>Groundman</td>
<td>$11.50</td>
<td>.70</td>
<td>.70</td>
<td>.00</td>
</tr>
<tr>
<td><strong>Marble Setters</strong></td>
<td>$9.00</td>
<td>.62</td>
<td>.33</td>
<td></td>
</tr>
<tr>
<td><strong>Marble Setters' Helpers &amp; Polishers</strong></td>
<td>$9.00</td>
<td>.62</td>
<td>.33</td>
<td></td>
</tr>
<tr>
<td><strong>Painters:</strong></td>
<td>$9.65</td>
<td>.575</td>
<td>.40</td>
<td>.013</td>
</tr>
<tr>
<td><strong>Plasterers</strong></td>
<td>$9.60</td>
<td>.60</td>
<td>.81</td>
<td>.048</td>
</tr>
<tr>
<td><strong>Pile Drivers</strong></td>
<td>$11.90</td>
<td>.80</td>
<td>1.00</td>
<td>.02</td>
</tr>
<tr>
<td><strong>Pointers</strong></td>
<td>$11.92</td>
<td>.75</td>
<td>.75</td>
<td>.10</td>
</tr>
<tr>
<td><strong>Pointers, Chippers &amp; Cleaners</strong></td>
<td>$11.10</td>
<td>.95</td>
<td>.85</td>
<td>.10</td>
</tr>
</tbody>
</table>

#### Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Occupation/Role</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Roofers:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Composition &amp; Waterproofer</td>
<td>1.20</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>Slate &amp; Tile</td>
<td>1.06</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>Sheet Metal Workers</strong></td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>Sprinkler Fitters</strong></td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>Survey Crews:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Instrument Man</td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>Rodman</td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>Teal sign Workers</strong></td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>Tile Setters</strong></td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>Tile Setters' Helpers</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Truck Drivers:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Building &amp; Residential</td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>2-3 Axle Trucks</strong></td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>4 Axle Trucks</strong></td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>5 Axle Trucks</strong></td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>6 Axle Trucks</strong></td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>Heavy &amp; Highway</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>2-3 Axle Trucks</strong></td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>4 Axle Trucks</strong></td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>5 Axle Trucks</strong></td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>6 Axle Trucks</strong></td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>Well Driller:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Driller, Pump Installer, Welder &amp; Mechanic</td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>Tool Dresser, Helper</td>
<td>1.00</td>
<td>.02</td>
<td></td>
</tr>
</tbody>
</table>

#### Paid Holidays (Where Applicable)

- A-New Year's Day  
- B-Memorial Day  
- C-Independence Day  
- D-Labor Day  
- E-Thanksgiving Day  
- F-Christmas Day

### Footnotes:

- a. Six paid 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. Nine paid holidays: A through F plus Washington's Birthday, Good Friday & 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
### Decision No. IL77-2100

#### Laborers:

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class I</strong></td>
<td>Common Laborers, Planters, Laborers, Pumps for Debabeling &amp; other Unclassified Laborers</td>
<td>7.80</td>
<td>.57</td>
<td>1.10</td>
</tr>
<tr>
<td><strong>Class II</strong></td>
<td>Cement Gun Laborers</td>
<td>7.875</td>
<td>.57</td>
<td>1.10</td>
</tr>
<tr>
<td><strong>Class III</strong></td>
<td>Scaffold Laborers &amp; Chimney Laborers over 40'</td>
<td>7.90</td>
<td>.57</td>
<td>1.10</td>
</tr>
<tr>
<td><strong>Class IV</strong></td>
<td>Masons &amp; Cement Gun Nozzle Laborers - Gunite</td>
<td>7.95</td>
<td>.57</td>
<td>1.10</td>
</tr>
<tr>
<td><strong>Class V</strong></td>
<td>Stone Handlers &amp; Derrickmen</td>
<td>8.00</td>
<td>.57</td>
<td>1.10</td>
</tr>
<tr>
<td><strong>Class VI</strong></td>
<td>Jackhammers</td>
<td>8.025</td>
<td>.57</td>
<td>1.10</td>
</tr>
<tr>
<td><strong>Class VII</strong></td>
<td>Concrete Vibrator, Plumbers' Laborer &amp; Chain Saw Operator</td>
<td>8.05</td>
<td>.57</td>
<td>1.10</td>
</tr>
<tr>
<td><strong>Class VIII</strong></td>
<td>Pilebrake &amp; Boiler Setters' Laborers</td>
<td>8.125</td>
<td>.57</td>
<td>1.10</td>
</tr>
<tr>
<td><strong>Class IX</strong></td>
<td>Chimney Laborers on Firebrick, Caisson Diggers &amp; Well Point System Men</td>
<td>8.15</td>
<td>.57</td>
<td>1.10</td>
</tr>
<tr>
<td><strong>Class X</strong></td>
<td>Boiler Setters Plastic Laborers</td>
<td>8.25</td>
<td>.57</td>
<td>1.10</td>
</tr>
<tr>
<td><strong>Class XI</strong></td>
<td>Air Compressor on Firebrick Only</td>
<td>8.30</td>
<td>.57</td>
<td>1.10</td>
</tr>
</tbody>
</table>

#### Power Equipment Operators:

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class I</strong></td>
<td>Asphalt plant, asphalt spreader, auto-grad, batch plant, Benotto (requires two engineers), boiler &amp; throttle, valve, cement mixer, central red-mix plant, combination backhoe breaker (truck-mounted), conveyor, concrete paver, concrete placer, concrete tower, cranes (all), derricks (all), grader, elevating, grading machines, highlift cranes or front end loaders 24 yd. &amp; over, hoists, one, two &amp; three drum, hoists, two &amp; three, drum, hoists, two tugger one floor, hydraulic boom trucks, locomotives (all), mechanical, motor patrol, pile drivers &amp; paid rig, post-hole digger, pre-stress machine, pump cretes dual ram (requiring frequent lubrication &amp; water), pumpcretes, squeeze cretes, screw types pumps, gypsum bolier &amp; pump, rock drill (self-propelled), rock drill (truck mounted), scoops - tractor drawn, slipform paver, straddle buggies, tournapull, tractor with boom &amp; side boom, trenching machines</td>
<td>11.85</td>
<td>.75</td>
<td>.85</td>
</tr>
<tr>
<td><strong>Class II</strong></td>
<td>Boiler, bulldozers, boom all power propelled, concrete mixer (2 bag &amp; over), conveyor portable, forklift truck grease engineer, highlift cranes or front end loaders 24 yd. &amp; over, hoists, one, two &amp; three drum, hoists, two &amp; three, drum, hoists, two tugger single floor, hydraulic boom trucks, locomotives (all), mechanical, motor patrol, pile drivers &amp; paid rig, post-hole digger, pre-stress machine, pump cretes dual ram (requiring frequent lubrication &amp; water), pumpcretes, squeeze cretes, screw types pumps, gypsum, bolier &amp; pump, rock drill (self-propelled), rock drill (truck mounted), scoops - tractor drawn, slipform paver, straddle buggies, tournapull, tractor with boom &amp; side boom, trenching machines</td>
<td>10.55</td>
<td>.75</td>
<td>.85</td>
</tr>
<tr>
<td><strong>Class III</strong></td>
<td>Air compressors - small 150 &amp; under (11 to 5 not to exceed a total of 300 ft.), Air compressor - large over 150, combination - small equipment opr., generators under 1 over 50 kw, heaters, mechanical pumps, over 3&quot; (1 to 3 not to exceed a total of 300 ft.), pumps, wall points, welding machines (2 through 5), winches, 4 small electric drill winches</td>
<td>9.40</td>
<td>.75</td>
<td>.85</td>
</tr>
<tr>
<td><strong>Class IV</strong></td>
<td>-Oilers</td>
<td>8.15</td>
<td>.75</td>
<td>.85</td>
</tr>
<tr>
<td>CLASS</td>
<td>Basic Hourly Rates</td>
<td>Fringe Benefits Payments</td>
<td>Education and/or Appr. Tr.</td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>--------------------</td>
<td>--------------------------</td>
<td>-----------------------------</td>
<td></td>
</tr>
<tr>
<td>CLASS I</td>
<td>11.50</td>
<td>.75</td>
<td>.85</td>
<td>.40</td>
</tr>
<tr>
<td>CLASS II</td>
<td>10.95</td>
<td>.75</td>
<td>.85</td>
<td>.40</td>
</tr>
<tr>
<td>CLASS III</td>
<td>10.20</td>
<td>.75</td>
<td>.85</td>
<td>.40</td>
</tr>
<tr>
<td>CLASS IV</td>
<td>9.10</td>
<td>.75</td>
<td>.85</td>
<td>.40</td>
</tr>
<tr>
<td>CLASS V</td>
<td>8.10</td>
<td>.75</td>
<td>.85</td>
<td>.40</td>
</tr>
</tbody>
</table>

CLASS I - Asphalt plant, asphalt heater & planer combination, asphalt spreader, autograde, Bell loader, classon rips, central reddisht plant, concrete breaker (truck mounted), concrete conveyor, concrete pump; over 778 cu. ft., concrete placer, concrete tube float, cranes, all attachments, cranes, Linden, Peco & machines of alike nature, derricks, traveling, dredges, euclid loader, elevating type, gradall, & mechanics of a like nature, derricks, all derrick boats, derricks, traveling, dredges, euclid loader, elevating type gradall, and machines of a like nature, 1 cu. yd. & over, mucking machine, under: 1 cu. yd. P&H; pale drivers' side rig, pre-stress machine, pump cretes dual req (requiring frequent lubrication & water), rock drill cranes; bridge, tunnel, etc. self-propelled scoops; tractor drawn, self-propelled compactors, spreaders, chipper, etc. scraper, tank cars, Hudson, tractor, push, pulling sheeps foot, disc., compactors, etc. tug boats.

CLASS II - Mechanic-welder, batch plant, bituminous mixer, bulldozer, combination backhoe; front endloader machine, concrete breaker; or hyd-ro-hammer, concrete grinding machine, concrete mixer; or pave 72 Series 10 incl. including 27 cu. ft., concrete spreader, concrete cutting machine, backfill machine, belting machine & scaling machine, finishing machine, concrete grader, motor petrol, auto petrol, forklift, pull grader, subgrader, highlift shovels or front endloader, hydraulic boom trucks (all attachments), locomotives,insky, pump cretes; Squeeze cretes; crew type pumps Cypess Bulker & pump, rock drill (self-propelled), roto-tiller, reamer, etc. self-propelled mowers; tractor drawn, self-propelled compactors, spreaders, chipper, etc. scraper, tank cars, Hudson, tractor, push, pulling sheeps foot, disc., compactors, etc. tug boats.

CLASS III - Boilers, boiler & throttle valve, brooms, all power propelled, cement supply tender, compressor throttle valve, concrete mixer (2 bags & over) conveyor, portable, fireman on boiler, forklift trucks; grasper engineer, grouting machine hoists, automatic, hoists, all elevators, hoists, tugger, single drum, jeep diggers, pipe pump saw, concrete, power-driven, pug mills, rollers, all, steam generators, stone crushers, stump machine, winch truck with "A" frame, work boats, tugger, form motor driven.

CLASS IV - Air Compressors, all, generators, heaters, mechanical, light plants, all (1 through 5), pumps, all, pumps well points, tractaire, welding machines (2 through 6).

CLASS V - Oilers.
SUPERSEDES DECISION

STATE: Kansas
COUNTIES: Douglas, Jefferson, Leavenworth, Miami & Shawnee

DECISION NO.: KS77-4161

DATE: Date of Publication

Supersedes Decision No. KS77-4084 dated April 15, 1977 in 42 FR 20059

DESCRIPTION OF WORK: Highway Construction

<table>
<thead>
<tr>
<th></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>H &amp; W Pensions</td>
<td>Vacation</td>
</tr>
<tr>
<td><strong>Carpenters and Piledrivermen:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 1</td>
<td>$8.60</td>
<td>.45</td>
<td>.30</td>
</tr>
<tr>
<td>Zone 2</td>
<td>8.60</td>
<td>.45</td>
<td>.30</td>
</tr>
<tr>
<td>Zone 3</td>
<td>11.00</td>
<td>.50</td>
<td>.30</td>
</tr>
<tr>
<td>Zone 4</td>
<td></td>
<td>.50</td>
<td>.30</td>
</tr>
<tr>
<td>Carpenters</td>
<td>10.75</td>
<td>.50</td>
<td>.30</td>
</tr>
<tr>
<td>Piledrivermen</td>
<td>11.00</td>
<td>.50</td>
<td>.30</td>
</tr>
<tr>
<td>Zone 5</td>
<td>5.375</td>
<td>1.75</td>
<td>.25</td>
</tr>
</tbody>
</table>

**Areas Covered by Carpenters and Piledrivermen Zones**

Zone 1 - Douglas and Shawnee Counties (Includes Forbes Air Force Base and within the City of Topeka and the City of Lawrence and with 3 miles of the city limits of these cities)
Zone 2 - Remainder of Douglas and Shawnee Counties
Zone 3 - Leavenworth County
Zone 4 - Miami County
Zone 5 - Jefferson County

**Cement Masons:**

Zone 1 - Leavenworth and Miami Counties
Zone 2 - Douglas and Shawnee Counties
Zone 3 - Jefferson County

**Electricians:**

Zone 1 - Leavenworth County (Delaware, High Prairie, Kickapo and Leavenworth) Townships
Zone 2 - Douglas, Jefferson, Miami, Shawnee and the remainder of Leavenworth County

**Gross Mixers:**

Zone 1 - 10.20
Zone 2 - 6.80
Zone 3 - 6.85

**Laborers:**

Group 1 - Board mat weavers and cable tiers; georgia buggy (manually operated); mixers-no skip lift; nailers; salamander tenders; track men; tractor swampers; truck dumpers; wire mesh setters; water pump to 4 inches and all other general laborers including flagman
Group 2 - Air tool operators; cement handlers (bulk); chain saw; georgia buggy (mechanically operated); grade men; hot mastic ketttlen; crusher feeders; joint men; jute man; mason tender; material batch hopper and scale men; mixer men; pile hole man working 10 feet deep; pipe layer-drainage (concrete and/or corrugated metal); signal man (crane); truck dumper-dry batch; vibratory operators; wagon and churn drill operator
Group 3 - Asphalt raker, barco tamper; concrete saw; errator operator, spreader; nozzle man; concrete paving; paver man; sandblasting and grouters mixer; sanitary sewer piper; paver man
Group 5 - Leadmen or piper

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

POWER EQUIPMENT OPERATORS:

Group 1 - Asphalt paver and spreader, asphalt plant console operator, auto grader, back hoe, blade operators, all types. hoist. - 2; booster pump on derrick, hoist, aerial device operator, crane mounted; bolster operator, clamshell operator, compressor maintenance operator - 2; concrete plant operators. central mix, concrete mixer-paver, crane operators; Derrick or Derrick trucks; Derrick, Derrick operator, Derrick crane operator, Derrick crane. Derrick crane. Derrick. Derrick mounted on cat driller or hoisting machine, rotary, self-propelled, high loader fork lift; Locomotive operator, standard gauge, Mechanical and welders, maintenance operators, mechanical machine, pile driver operator. pile driver at operator, pumper, quad-trac, scoop operators - all types; scoop in tandem, self-propelled rotary drill (Leary or equal - not air track); booster operator, side discharge spreader; sideboom cats, skimmer. scoop operator, slip-form paver (CM, REX, or equal); shovel man, shovel crane, welding equipment maintenance operator - 2; hoisting engine - 2 active drums.

Group 2 - "A" frame truck, asphalt hot mix silos, asphalt plant mixer, drum or hoist, asphalt plant mixer operators, asphalt plant man, asphalt mixer, buckn live operator; chip spreader, concrete batch plant, dry-drop operator, concrete pump operator, crushing operator; elevating grader operator, greater, hoisting engine - 1 drum. latraine rooter, multiple compactor, pavement breaker, self-propelled of the hydra-hammer or similar type, power shield, pug mill operators, stomp cutting machine, tombstone operator, tractor operator - over 50 HP.

Group 3 - Boilers - 1; chip spreader (front man) chow drill bid operator, compressor maintenance operator - 1; concrete saws, self-propelled, conveyor operator, distributor operators, finishing machine operator, fireman, rig. float operator, form grader operator, pump, pump maintenance operator, other than elevated grader; roller operator, other than high type graders; operators and washing plant operator; self-propelled street broom or plow; street washing plant operator, sub-grading machine operator, tank car heater operator - combination boiler and booster, tractor- 50 HP or less without attachments; vibrating machine operator, but tank; welding equipment maintenance operator - 1.

Group 4 - Mechanic's helper. oiler

Group 5 - Clamshells, 3 yd. capacity or under; crane or rig, 30 ft. of boom or over (including jib); drill rig, 3 yd. capacity or over; pile drivers, 30 ft. of boom or over (including jib); shoeholes, 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 - Oilers, all types

Men working in tunnels or shafts (not air shafts or coffer dams) 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**
- Asphalt paver and spreader, backhoe, boring machine, blades, all types, clamshell, concrete mixer paver operator, concrete central plant operator (automatic), crane, truck crane, pitman crane, hydro crane or any machine with power swing, derrick or derrick truck, derrick operator, derrick operator, derrick, derrick truck, load, load, load - 2 active drum loaders, all types, mechanic or welder, mixer/mill, multi-unit scraper, pile driver operator, power shovel operator, quad truck; scoop operators, all types; side boom car; cherry picker; skidder scoop operator.

**Group 2 - Asphalt plant operator, elevating grader operators, pushcat operator**
- Group 3 - Asphalt plant operator, elevating grader operators, pushcat operator.

**Group 4 - A-frame truck; asphalt roller operator; asphalt plant boiler fireman, backhoe operator, boiler green loader, bomber - other than asphalt, bulk float operator, choker drill operator, compressor operator (1); concrete central plant operator, concrete mixer operator, skip concrete pump operator, crusher operator, distributor operator, finish machine operator; concrete fireman other than asphalt, flex frame operator, fork lift, form grader operator; grease shop 1 - 1 drum, jeep, bituminous, cement, power shovel one, 2+; mulch operator, other than derrick; screening and wash plant operator, small machine operator; spreader box operator, self-propelled; tractor operator over 50 h.p., self-propelled roller operator, other than asphalt; siphon and jets; subgrader machine operator, tank car heater operator, combination booster and boiler, towboat operator, vibrating machine operator, woolEnc.

**Group 5 - Concrete gang saw, self-propelled (con-cut); conveyor operator; hoist, disc, scissor, hoist, tractor operator, 50 h.p., or less; without attachments.

**Group 6 - Oilier, motor crane**

### Truck Drivers

**Group 1 - One tone; station wagons; pickup trucks; material trucks, single axle; tank wagon drivers, single axle**
- Group 2 - Material trucks, tandem, two teams, semi-trailers, which truck dock trucks; distributor drivers and operators; agitator and transit mix tank wagon drivers, single axle; tank wagon drivers; tandem or semi-trailer; small wagons, dump trucks, excavator 5 cu. yds. and over; dumpsters; half-trucks; speedsters; euclids and other similar excavating equipment.

**Group 3 - A-frame, lowboy, boom truck drivers**
- Group 4 - Mechanics and welders.

**Group 5 - Mechanics' helpers, oilers, and greasers**
- Group 6 - Oilier, motor crane.
### Truck Drivers (Cont'd)

<table>
<thead>
<tr>
<th>Zone 1 - Douglas and Shawnee Cos.</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>6.90</td>
<td>.40</td>
<td>.35</td>
</tr>
<tr>
<td>Group 2</td>
<td>7.00</td>
<td>.40</td>
<td>.35</td>
</tr>
<tr>
<td>Group 3</td>
<td>7.15</td>
<td>.40</td>
<td>.35</td>
</tr>
</tbody>
</table>

### 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 partsmen, mechanic helpers and servicemen
- **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; tournatockers; atheys; dumpsters and similar off-road equipment and mechanics on such equipment

### Zone 3 - Miami County

<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>8.15</td>
<td>.75</td>
<td>1.00</td>
</tr>
</tbody>
</table>

### Classification Definitions

**Truck Drivers:**
- **Group 1:** Pickups, panel trucks, station wagons
- **Group 2:** Flat beds, dump and batch trucks, single axle
- **Group 3:** Tandem trucks
- **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; tournatockers; atheys; dumpsters and similar off-road equipment and mechanics on such equipment
- **Group 6:** Watchmen or partsmen; mechanic helpers; servicemen
SUPERSEDES DECISION

STATE: Missouri & Kansas
COUNTIES: Cass, Clay, Jackson, Platte & Ray Counties, Missouri; Johnson & Wyandotte, Kansas

DECISION NO.: M077-4160 DATED: Date of Publication
Supersedes Decision No. M077-4076 dated April 8, 1977, in 42 FR 18820

DESCRIPTION OF WORK: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.

<table>
<thead>
<tr>
<th>Fringe Benefits Payments</th>
<th>Hourly Rates</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprentice</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASBESTOS WORKERS</td>
<td>$11.52</td>
<td>.50</td>
<td>.80</td>
<td>.65</td>
</tr>
<tr>
<td>STEELMAKERS</td>
<td>10.50</td>
<td>.83</td>
<td>.90</td>
<td>.62</td>
</tr>
<tr>
<td>BRICKLAYERS and STONEMASON</td>
<td>9.725</td>
<td>.50</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>CARPENTERS, KLEENMAINTS,</td>
<td>10.50</td>
<td>.83</td>
<td>.90</td>
<td>.62</td>
</tr>
<tr>
<td>PLUMBERS</td>
<td>9.425</td>
<td>.40</td>
<td>.50</td>
<td>.50</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fringe Benefits Payments</th>
<th>Hourly Rates</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprentice</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELECTRICIANS (Up to and including 3 stories):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ZONE 1 - Johnson County, Kansas (that portion of Johnson County west of Aubry, Oxford and Shawnee Townships)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>8.40</td>
<td>.45</td>
<td>.40</td>
<td>.50</td>
</tr>
<tr>
<td>Group 2</td>
<td>8.49</td>
<td>.45</td>
<td>.40</td>
<td>.50</td>
</tr>
<tr>
<td>Group 3</td>
<td>8.58</td>
<td>.45</td>
<td>.40</td>
<td>.50</td>
</tr>
<tr>
<td>Group 4</td>
<td>8.67</td>
<td>.45</td>
<td>.40</td>
<td>.50</td>
</tr>
<tr>
<td>Group 5</td>
<td>8.76</td>
<td>.45</td>
<td>.40</td>
<td>.50</td>
</tr>
<tr>
<td>ZONE 2 - Remainder of Johnson County, Kansas</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>7.80</td>
<td>.45</td>
<td>.40</td>
<td>.50</td>
</tr>
<tr>
<td>Group 2</td>
<td>7.90</td>
<td>.45</td>
<td>.40</td>
<td>.50</td>
</tr>
<tr>
<td>Group 3</td>
<td>8.00</td>
<td>.45</td>
<td>.40</td>
<td>.50</td>
</tr>
<tr>
<td>Group 4</td>
<td>8.10</td>
<td>.45</td>
<td>.40</td>
<td>.50</td>
</tr>
<tr>
<td>Group 5</td>
<td>8.20</td>
<td>.45</td>
<td>.40</td>
<td>.50</td>
</tr>
</tbody>
</table>

FOOTNOTE: a. Employer contributes 4% basic hourly rate for over 5 yrs. service, and 3% of basic hourly rate for 6 mos. to 5 yrs. as Vacation Pay Credit.

b. Paid Holidays: New Year’s Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; Christmas Day.

NOTES
CLASSIFICATION DEFINITIONS

LABORERS:

Group 1 - General labor; Wire mesh handlers or setters; Carpenter tenders; Track men; Plumeo; Signalmen; Salamander tenders; Window cleaners; Floor cleaners; Landscape men; Sed 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; Flax hole diggers (over 10 ft.); Vibrators, jackhammers, and chipping hammer operators; Chain saw operators; Concrete saw operators; Brush feeders on pulverizers; Reinforcing steel handlers; Air tamp operators; Ditch witch operators; Swing ing scaffolds

Group 3 - Cutting torch or burner men; Georgia buggies (self-propelled); Fork lift; Hoseman; Insulation men

Group 4 - Fork lift (masonry); Brick tenders; Plasterer tenders; Stonemason tender (includes all hod-carrier classifications previously shown as mason men and scaffolding)

Group 5 - Barco, Jackson or similar tamp operators; Asphalt rakers; Feeder men; Mastic hot kettle men; Sandblasting and grumite nozzlemen; Wagon and charm drill operators

Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pension</th>
<th>Vacation</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
</table>

LABORERS: (Cont'd)

Site Preparation and Grading

ZONE 3 - Johnson and Wyandotte Counties; Kansas City; Preparation, Incidental Paving and Utilities

Clay; Jackson, Platte and Ray Counties, Missouri

Group 1 | 8.50 | 50 | 50 | 75 | 10
Group 2 | 8.05 | 50 | 50 | 75 | 10
Group 3 | 9.10 | 50 | 50 | 75 | 10
Group 4 | 9.50 | 50 | 50 | 75 | 10
Group 5 | 9.90 | 50 | 50 | 75 | 10
<table>
<thead>
<tr>
<th>CLASSIFICATION DEFINITIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Zone 1</strong></td>
</tr>
<tr>
<td>Group 1: Asphalt paver and spreader; Asphalt plant mixer operator; Asphalt plant operator; Back fillers; Backhoe, all types; Barber-green loaders (similar types); blade-power, all types; Boats-power; Rollers (2); Boring machines (all types); Cableway; Cherry picker (all types); Chip spreader; Clamshells; Combination concrete hoist and mixer such as mixermobile (with tower, 500 per hour additional); Compressors (2) 105 ft. or over not more than 200 apart; Compressors tandem (any size); Compressors single, truck mounted; Concrete mixer pavers; Crane-overhead; Crusher, rock; Derrick and derrick cars (power operated); Pitching machines; Pavers; Draglines; Dredge-oary type power; Grader-all similar type; Hoist, endless chain - power operated with power travel; hoists, all types; Locomotives all types; Mechanic and welders; Rocking machine; Orange peelers, file drivers - all types; Pumps - material all types; Push type Scoops all types; Self-propelled rotary drill; Shovel, power, Slide boom; Skimmer scoop; Telescopic; Throttle; man</td>
</tr>
<tr>
<td>Group 2: A-frame trucks; Rollers (2); Rammers-power operated (all types); Chip spreader (front man); Crane operator; Compressors (1) 105' or over; Concrete saws, self-propelled; Conveyor operator; Crab-power operated; Corp finishing machine; Firemen on rigs; Firemen; Power operated; Fork lift-all types and sizes (except masonry); Greaser; Hoist; Hoist, endless chain - power operated; Hopper - power operated; Hydra hammer (all types); Lad-o-car - similar type; Women with side loaders; Pumps (with well points); Pump Rollers - all types; Siphons, jets and jennies; Sub-graders; Tractors over 50 h.p.</td>
</tr>
<tr>
<td>Group 3: Other</td>
</tr>
<tr>
<td>Group 4: Fork lift-masonry</td>
</tr>
<tr>
<td>Group 5: Other driver all types</td>
</tr>
<tr>
<td>Group 6: Tractors (except when hauling material less than 50 h.p.</td>
</tr>
<tr>
<td>Group 7: Clamshells, 80 ft. of boom or over (including jib); Crane or rig; 80 ft. or boom pc over (including jib); Draglines, 80 ft. of boom or over (including jib); Piledriver, 80 ft. of boom or over (including jib)</td>
</tr>
<tr>
<td>Group 8: Crane or rig, over 200 ft. of boom</td>
</tr>
<tr>
<td>Group 9: Hoists each additional drum over 1 drum</td>
</tr>
<tr>
<td>Group 10: Master Mechanic</td>
</tr>
<tr>
<td>Group 11: Crane - tower or climbing</td>
</tr>
<tr>
<td>Group 12: Ready Mix Concrete Plants: (a) Crane operator; (b) Loader operator; (c) Plant man; (d) Concrete operator</td>
</tr>
</tbody>
</table>
## 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>
<thead>
<tr>
<th>Group</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></td>
<td>10.10</td>
<td>.50</td>
<td>1.00</td>
<td>.75</td>
<td>.10</td>
</tr>
<tr>
<td>Group 1</td>
<td>9.85</td>
<td>.50</td>
<td>1.00</td>
<td>.75</td>
<td>.10</td>
</tr>
<tr>
<td>Group 2</td>
<td>9.60</td>
<td>.50</td>
<td>1.00</td>
<td>.75</td>
<td>.10</td>
</tr>
<tr>
<td>Group 3</td>
<td>8.60</td>
<td>.50</td>
<td>1.00</td>
<td>.75</td>
<td>.10</td>
</tr>
<tr>
<td>Group 4</td>
<td>8.30</td>
<td>.50</td>
<td>1.00</td>
<td>.75</td>
<td>.10</td>
</tr>
<tr>
<td>Group 5</td>
<td>10.35</td>
<td>.50</td>
<td>1.00</td>
<td>.75</td>
<td>.10</td>
</tr>
<tr>
<td>Group 6</td>
<td>10.60</td>
<td>.50</td>
<td>1.00</td>
<td>.75</td>
<td>.10</td>
</tr>
<tr>
<td>Group 7</td>
<td>10.10</td>
<td>.50</td>
<td>1.00</td>
<td>.75</td>
<td>.10</td>
</tr>
<tr>
<td>Group 8</td>
<td>10.10</td>
<td>.50</td>
<td>1.00</td>
<td>.75</td>
<td>.10</td>
</tr>
</tbody>
</table>

### CLASSIFICATION DEFINITIONS

#### Group 1: Asphalt paver and spreader; Asphalt plant console operator; Auto grader; Backhoe; Blade operator, all types; Boilers-2; Boom crane
- Mechanics and welders, field or shop; Maintenance operators; Pile driver operators; Priming machine operators; Power shield; Pugmill operator; Paving machine operators; Paving machine operators in tandem; Self-propelled rotary drill (less than equal - not all tree); Shear operators; Side discharge spreader; Sideboom cats; Skimmer scoop operators; Slif-form paver (CON, OCT, or equal); Throttle man; Truck crane; Welding machine maintenance operators;

#### Group 2:
- A-frame truck; Asphalt hot mix silo; Asphalt plant fireman, drum or boiler; Asphalt plant mixer operators; Asphalt plant operators; Backhoe operator; Chip spreader; Concrete batch plants, dry-power operated; Concrete mixer operators; Skip loader; Concrete pump operators; Crusher operators; Elevating grader operators; Greaser; Hoisting engine-1 drum; Latourneau rooter; Multiple compactors; Pavement breakers, self-propelled, of the hydro-hammer or similar type; Power shields; Pugmill operator; Paving machine operators; Paving machine operators in tandem; Self-propelled street broom or sweeper; Sideloader and jet; Sub-graded machine operators; Tank car handlers; operator-combination boiler and booster; Tractor; 50 h.p. or less VWD/6 attachments; Vibrating machine operators, not hand; Welding machine maintenance operators—1

#### Group 3:
- Bolters-1; Chip spreader (front man); Churn drill operators; Compressor maintenance operators-1; Concrete saws, self-propelled; Concrete saws; Distributor operators; Finishing machine operators; Fireman; Rigs; Float operators; Foreman, distributor operators; Pump; Pump maintenance operators, other than derrick; Rigger operators, other than high type asphalt; Screening and washing plant operators; Self-propelled street broom or sweeper; Sideloader and jet; Sub-graded machine operators; Tank car handlers; operator-combination boiler and booster; Tractors, 50 h.p. or less VWD/6 attachments; Vibrating machine operators, not hand; Welding machine maintenance operators—1

#### Group 4:
- Field mechanics; Oilers

#### Group 5:
- Oilers, drivers, all types

#### Group 6:
- Clamshells, 3 yds. capacity or over; Crane or rig; 80 ft. of boom or over (including jib); Draglines, 3 yds. capacity or over; Pile-drivers; 80 ft. of boom or over (including jib); Shovels, 3 yds. capacity or over
### ROOFERS:

<table>
<thead>
<tr>
<th></th>
<th>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>Basic</td>
<td></td>
<td>.45</td>
<td>.60</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>Roofers</td>
<td>9.89</td>
<td>.45</td>
<td>.60</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>Helpers</td>
<td>6.37</td>
<td>.45</td>
<td>.60</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>1st 6 months</td>
<td>5.88</td>
<td>.45</td>
<td>.60</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>2nd 6 months</td>
<td>6.37</td>
<td>.45</td>
<td>.60</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>3rd 6 months</td>
<td>6.86</td>
<td>.45</td>
<td>.60</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>4th 6 months</td>
<td>7.35</td>
<td>.45</td>
<td>.60</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>5th 6 months</td>
<td>7.86</td>
<td>.45</td>
<td>.60</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>6th 6 months</td>
<td>8.33</td>
<td>.45</td>
<td>.60</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>7th 6 months</td>
<td>8.82</td>
<td>.45</td>
<td>.60</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>SHEET METAL WORKERS</td>
<td>11.35</td>
<td>.50</td>
<td>.75</td>
<td>.06</td>
<td></td>
</tr>
<tr>
<td>SOFT FLOOR LAYERS</td>
<td>6.71</td>
<td>.45</td>
<td>.75</td>
<td>.06</td>
<td></td>
</tr>
<tr>
<td>SPRINKLER FITTERS</td>
<td>11.63</td>
<td>.60</td>
<td>.90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TERRAZZO WORKERS</td>
<td>10.48</td>
<td>3.67%</td>
<td>3.25%</td>
<td>.06</td>
<td></td>
</tr>
</tbody>
</table>

### TRUCK DRIVERS:

#### BUILDING CONSTRUCTION

<table>
<thead>
<tr>
<th>Zone</th>
<th>Group</th>
<th>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></td>
<td>1</td>
<td>8.525</td>
<td>.50</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>8.595</td>
<td>.50</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>8.685</td>
<td>.50</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>8.785</td>
<td>.50</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>8.875</td>
<td>.50</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>8.975</td>
<td>.50</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>8.675</td>
<td>.50</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>8.635</td>
<td>.50</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### CLASSIFICATION DEFINITIONS

**TRUCK DRIVERS:**

**CLASSIFICATION DEFINITIONS**

<table>
<thead>
<tr>
<th>Group</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Warehousemen and stockmen</td>
</tr>
<tr>
<td>2</td>
<td>Dispatchers, dispatching trucks, under 10 yds.</td>
</tr>
<tr>
<td>3</td>
<td>Truck drivers, tandem or semi-trailer, single axle</td>
</tr>
<tr>
<td>4</td>
<td>Material trucks, tandem or semi-trailer, single axle</td>
</tr>
<tr>
<td>5</td>
<td>Distributor drivers and operators, single axle</td>
</tr>
<tr>
<td>6</td>
<td>Mechanics, and welders</td>
</tr>
</tbody>
</table>

**WELDERS:** Receive rate prescribed for craft performing operation to which welding is incidental.
### Supplemental Decision

**State:** Montana  
**Counties:** Statewide

**Decision No.:** MT77-5074  
**Date:** Date of Publication

**Description of Work:** Heavy and Highway Construction

<table>
<thead>
<tr>
<th>Fringe Benefits Payments</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>Carpenters:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carpenters</td>
<td>$9.08</td>
<td>.55</td>
<td>.75</td>
<td>.02</td>
</tr>
<tr>
<td>Pile drivers, sawyers,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carpenters on charred and</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>creosote wood</td>
<td>9.23</td>
<td>.55</td>
<td>.75</td>
<td>.02</td>
</tr>
<tr>
<td><strong>Cement Masons:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cement Masons</td>
<td>8.90</td>
<td>.75</td>
<td>.25</td>
<td></td>
</tr>
<tr>
<td>Grinders, bush hammer and</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clipping fan preparing</td>
<td>9.08</td>
<td>.75</td>
<td>.25</td>
<td></td>
</tr>
<tr>
<td>finished surfaces, epoxy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Electricians:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beaverhead, Deer Lodge,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Granite, Jefferson, Madison, Silver Bow and Powell Counties</td>
<td>9.90</td>
<td>.50</td>
<td>.34+.35</td>
<td></td>
</tr>
<tr>
<td>Gallatin County</td>
<td>10.35</td>
<td>.40</td>
<td>.34</td>
<td>1/24</td>
</tr>
<tr>
<td>Broadwater, Lewis and Clark and Meagher Counties</td>
<td>9.55</td>
<td>.55</td>
<td>.34</td>
<td>1/24</td>
</tr>
<tr>
<td>Electricians</td>
<td>10.35</td>
<td>.40</td>
<td>.34</td>
<td>1/24</td>
</tr>
<tr>
<td>Cascade, Chouteau, Glacier, Judith-Basin, Powder, Teton and Tula Counties</td>
<td>10.75</td>
<td>.55</td>
<td>.34+.75</td>
<td>1/24</td>
</tr>
<tr>
<td>Electricians</td>
<td>11.00</td>
<td>.55</td>
<td>.34+.75</td>
<td>1/24</td>
</tr>
<tr>
<td>Flathead, Lake, Lincoln, Mineral, Missoula, Ravalli and Sanders Counties</td>
<td>10.68</td>
<td>.42</td>
<td>.34</td>
<td>1/24</td>
</tr>
<tr>
<td>Electricians</td>
<td>12.18</td>
<td>.42</td>
<td>.34</td>
<td>1/24</td>
</tr>
<tr>
<td>Big Horn, Carbon, Golden Valley, Musselshell, Powder River, Rosebud, Stillwater, Treasure and Yellowstone Counties</td>
<td>9.37</td>
<td>.40</td>
<td>.34+.50</td>
<td>1/24</td>
</tr>
<tr>
<td>Electricians</td>
<td>10.47</td>
<td>.40</td>
<td>.34+.50</td>
<td>1/24</td>
</tr>
<tr>
<td><strong>Ironworkers:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beaverhead, Brodawater, Deer Lodge, Gallatin, Granite, Jefferson, Madison, Silver Bow (Southern half including Wolf Creek), Madison, Park, Powell, Ravalli and Silver Bow Can.</td>
<td>10.66</td>
<td>.65</td>
<td>1.15</td>
<td>.05</td>
</tr>
<tr>
<td>Flathead, Glacier, Lake, Lincoln, Mineral, Missoula and Sanders Counties</td>
<td>11.15</td>
<td>.58</td>
<td>1.00</td>
<td>.05</td>
</tr>
<tr>
<td>Remaining Counties (including Northern half of Lewis and Clark County)</td>
<td>10.66</td>
<td>.65</td>
<td>1.15</td>
<td>.05</td>
</tr>
<tr>
<td><strong>Painters:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beaverhead, Jefferson (Southern area, south of the City of Boulder ), Madison (West of a line running north-south through the west limits of Harrison and Silver Bow Counties)</td>
<td>7.60</td>
<td>.25</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Spray</td>
<td>10.40</td>
<td>.25</td>
<td>.10</td>
<td></td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### PAINTERS: (Cont'd)

**Big Horn, Carbon, Custer, Crossing, Dawson, Fallon, Golden Valley, Musselshell, Powder River, Prairie, Rosebud, Stillwater, Sweetgrass, Treasure, Wheatland (south of the City of Harlowtown), Wibaux and Yellowstone Counties:**

- **Brush:** $8.33, .49, .20
- **Steel:** $8.38, .49, .20
- **Spray:** $9.56, .49, .20

**Brushing:**
- Deer Lodge County and the southern part of Granite County from a line east-west through the southern limits of Philipsburg Painter and perfataper
  - Application of cold tar products, epoxies, polyurethanes and acid resistant paints; Water sandblasting and steam cleaning; Stacks and steeples; Brushing of steel; Spraying and airless spraying; Work over 30 feet

**Cascade, Chouteau (south of the line running east and west through the southern limits of Big Sandy), Daniels, Garfield, Glacier, (excluding Glacier National Park), Grainfield, Judith Basin, Lewis and Clark, (northern portion from a line running East and West through the southern limits of Craig), Madison (east of the west city limits of Harlowton), Meagher, Park, Powell (northern area from a line running east and west through the southern limits of Harlowton), Blaine, Hill, Liberty and Chouteau (north of the southern limits of the City of Big Sandy), Counties:**

<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>
<tr>
<td>Paperhanger, Brush on steel</td>
<td>$8.44</td>
<td>.25</td>
</tr>
<tr>
<td>Water and sandblasting, Application of cold tar products, epoxies, polyurethanes and acid resistant paints, Spraying and airless spray</td>
<td>$9.19</td>
<td>.25</td>
</tr>
<tr>
<td>Roller over 9&quot; long</td>
<td>$12.54</td>
<td>.25</td>
</tr>
<tr>
<td>Taper</td>
<td>$9.94</td>
<td>.25</td>
</tr>
</tbody>
</table>

**PAINTERS: (Cont'd)**

<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>
<tr>
<td>Big Horn, Carbon, Custer, Crossing, Dawson, Fallon, Golden Valley, Musselshell, Powder River, Prairie, Rosebud, Stillwater, Sweetgrass, Treasure, Wheatland (south of the City of Harlowtown), Wibaux and Yellowstone Counties: Painter, brush, preparatory work, Pot Tender, Parking lot and related work, Roller up to 9 inches</td>
<td>$8.94</td>
<td>.49</td>
</tr>
<tr>
<td>State/County Description</td>
<td>Basic Hourly Rates</td>
<td>Fringe Benefits Payments</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td><strong>Painters</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flathead, Granite (north area) north limits of Phillipsburg, Lake (north area including the City of Ronan), Lincoln, Mineral, Missoula, Powell (north area through south limits of Helena), Ravalli and Sanders Counties</td>
<td>9.35</td>
<td>.44</td>
</tr>
<tr>
<td>** Plumbers**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flathead, Lake, Lincoln, Mineral, Missoula and Sanders Counties</td>
<td>10.53</td>
<td>.35</td>
</tr>
<tr>
<td>Blaine, Cascade, Chouteau, Fergus, Glacier, Hill, Judith-Basin, Liberty, McConaughy, Phillips, Pondera, Roosevelt, Teton, Toole and Valley Counties</td>
<td>11.60</td>
<td>.65</td>
</tr>
<tr>
<td>Beaverhead, Broadwater, Deer Lodge, Gallatin, Granite, Jefferson, Lewis and Clark, Madison, Park, Powell, Silver Bow and Sweetgrass Counties</td>
<td>11.70</td>
<td>.60</td>
</tr>
<tr>
<td>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</td>
<td>11.25</td>
<td>.40</td>
</tr>
</tbody>
</table>

**Sheet Metal Workers**

Broadwater, Jefferson (including north half of the City of Boulder), Lewis and Clark and Meagher Counties

<table>
<thead>
<tr>
<th>State/County Description</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flathead, Lake, Lincoln, Mineral, Missoula, Ravalli and Sanders Counties</td>
<td>10.23</td>
<td>.77</td>
</tr>
<tr>
<td>Blaine, Cascade, Chouteau, Glacier, Hill, Judith-Basin, Liberty, Pondera, Teton and Toole Counties</td>
<td>10.27</td>
<td>.66</td>
</tr>
<tr>
<td>Beaverhead, Deer Lodge, Granite, Jefferson (southern half), Madison, Powell and Silver Bow Counties</td>
<td>11.25</td>
<td>.37</td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
<table>
<thead>
<tr>
<th>LABORERS</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefit Payments</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$</td>
<td>H &amp; W</td>
<td>Positions</td>
</tr>
<tr>
<td>Asphalt Raker</td>
<td>8.35</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Aurora</td>
<td></td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Car and Truck Loaders, Boxman</td>
<td>8.10</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Caulkers Workers (Free air)</td>
<td>8.26</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Cement Handlers</td>
<td>8.20</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Cement Mason Tender</td>
<td>8.26</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Choker Better</td>
<td>8.30</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Choker Tender and Nipper (above ground)</td>
<td>8.10</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Concrete Labors (wet or dry)</td>
<td></td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Concrete or Asphalt Saw</td>
<td>8.20</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Concrete Vibrator (5&quot; and over)</td>
<td>8.40</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Concrete applying and removing</td>
<td>8.10</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Core Drill</td>
<td>8.10</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Drill, Air-tract, self-propelled, Cat or Truck mounted air operated</td>
<td>8.20</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Drill, Air-tract, with Dual Mast</td>
<td>8.40</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Drill, Air-tract, self-propelled, Mustang type or similar</td>
<td>8.20</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Dumpman (Spotter)</td>
<td>8.30</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Dumpman (Grademan)</td>
<td>8.20</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Force Erector and Installer</td>
<td></td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Force Erector and Installer</td>
<td></td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Force Erector and Installer</td>
<td></td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>Grade Setter</td>
<td>8.45</td>
<td>.55</td>
<td>.45</td>
</tr>
<tr>
<td>General Laborer</td>
<td>8.10</td>
<td>.55</td>
<td>.45</td>
</tr>
</tbody>
</table>
### POWER EQUIPMENT OPERATORS

<table>
<thead>
<tr>
<th>Description</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-Frame Truck Crane, Winch Truck and similar</td>
<td>$ 9.05</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Air Compressor, single</td>
<td>9.54</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Air Compressor, two or more</td>
<td>9.71</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Air Driller</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Asphalt Paving Machine</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Asphalt Paving Machine Screed</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Automatic Pile Digger, Gravel and other similar</td>
<td>9.15</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Belt Finish Machine</td>
<td>9.71</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Bit Grader</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Bituminous Mixer Paving, Travel Plant</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Boring Machine (small), Jeep, Pickup or Farm Tractor mounted</td>
<td>9.60</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Boring Machine (large)</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Broom, Self-propelled</td>
<td>9.68</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Cableway Highline</td>
<td>10.52</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Cement Silo</td>
<td>9.68</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Central Mixing Plants, Concrete dam and stationary</td>
<td>10.26</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Chain Bucket Loader</td>
<td>9.71</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Chip or Gravel Spreader, Self-propelled</td>
<td>9.73</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Concrete Batch Plant, one and two mixers</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Concrete Batch Plant, three and four mixers</td>
<td>10.32</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Concrete Batch Plant, five mixers and over</td>
<td>10.45</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Concrete Batch Plant Oiler, up to 10 ft and including two mixers</td>
<td>9.53</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Concrete Batch Plant Oiler, three mixers and over</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Concrete Bucket Dispatcher</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Concrete Finishing Machine</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Concrete Float-Spreader</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Concrete mixer, three bags and under</td>
<td>9.90</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td>Concrete mixer, four bags and over</td>
<td>9.87</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
</tr>
</tbody>
</table>
### Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Power Equipment Operators</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></td>
<td>Appr. Tr.</td>
<td></td>
</tr>
</tbody>
</table>

#### Fringe Benefits Payments

<table>
<thead>
<tr>
<th></th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacations</th>
<th>Education</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Appr. Tr.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Power Equipment Operators (Cont'd)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>
### Fringe Benefit Payments

<table>
<thead>
<tr>
<th>Equipment Type</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>Shovels, including all attachments, under 1 cu. yd.</td>
<td>$10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Shovels, including all attachments, 1 cu. yd. to and including 3 cu. yds.</td>
<td>10.19</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Shovels, including all attachments, over 3 cu. yds. to and including 5 cu. yds.</td>
<td>10.46</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Shovels, including all attachments, over 5 cu. yds.</td>
<td>10.59</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Shovel Oiler, 3 yards and under</td>
<td>9.50</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Shovel Oiler, over 3 cu. yds.</td>
<td>9.91</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Slip Form Paver</td>
<td>10.14</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Stiff Leg Derrick and Guy Derrick</td>
<td>10.46</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Track-type Front End Loaders, up to and including 5 cu. yds.</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Track-type Front End Loaders, over 5 cu. yds. to and including 10 cu. yds.</td>
<td>10.24</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Track-type Front End Loaders, over 10 cu. yds. to and including 15 cu. yds.</td>
<td>10.34</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Track-type Front End Loaders, over 15 cu. yds.</td>
<td>20.44</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Track-type Tractor w/wo attachments</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Track-type Tractor, on Euclid Loader</td>
<td>10.19</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Trenching Machine</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Turnhead Conveyor, or Head Tower on Batch Plant</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Wagner Roller and similar type</td>
<td>10.01</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Whirley Crane</td>
<td>10.54</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Whirley Crane Oiler</td>
<td>9.81</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Water Pull when used for Compaction</td>
<td>10.04</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Washing and Screening Plant</td>
<td>10.04</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Washing and Screening Plant Oiler</td>
<td>9.30</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>To-to Car, both ends</td>
<td>9.34</td>
<td>.55</td>
<td>.35</td>
<td>.05</td>
<td></td>
</tr>
</tbody>
</table>

### Truck Drivers

<table>
<thead>
<tr>
<th>Equipment Type</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>Concrete Mixer and Transit Mixer: 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>
<td></td>
</tr>
<tr>
<td>Over 10 cu. yds. - additional 9.08 per hour each additional 2 cu. yds. increment</td>
<td>9.08</td>
<td>.65</td>
<td>.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distributor Driver and Helper</td>
<td>8.99</td>
<td>.65</td>
<td>.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dry Batch Trucks:</td>
<td>8.76</td>
<td>.65</td>
<td>.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Batch or under</td>
<td>8.76</td>
<td>.65</td>
<td>.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 3 Batch to and including 5 Batch</td>
<td>8.89</td>
<td>.65</td>
<td>.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 5 Batch to and including 10 Batch</td>
<td>9.05</td>
<td>.65</td>
<td>.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 10 Batch to and including 15 Batch</td>
<td>9.21</td>
<td>.65</td>
<td>.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 15 Batch - additional .15 per hour each additional 5 Batch increment</td>
<td>9.35</td>
<td>.65</td>
<td>.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pickup Driver, Hauling Materials</td>
<td>8.86</td>
<td>.65</td>
<td>.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment, Gravel Spreader Box Operator: Pilot Car Driver, Teamsters and Helpers</td>
<td>8.76</td>
<td>.65</td>
<td>.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warehousemen, Partsmen, Cardex Men, Warehouse Expediter</td>
<td>8.96</td>
<td>.65</td>
<td>.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic Hourly Rates</td>
<td>Fringe Benefits Payments</td>
<td>Education and/or Apprenticeship</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------</td>
<td>--------------------------</td>
<td>-------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TRUCK DRIVERS (Cont'd)**

### DUMP TRUCKS AND SIMILAR EQUIPMENT:

#### Pulling P.R. 21 or Similar Dump Wagons:

- **Water Level Capacity, Including Sideboards**
  - 7 cu. yds. or less: $9.76
  - Over 7 cu. yds. to and including 10 cu. yds.: $9.89
  - Over 10 cu. yds. to and including 15 cu. yds.: $9.95
  - Over 15 cu. yds. to and including 20 cu. yds.: $10.19
  - Over 20 cu. yds. to and including 25 cu. yds.: $10.25
  - Over 25 cu. yds. to and including 30 cu. yds.: $10.31
  - Over 30 cu. yds. to and including 35 cu. yds.: $10.37
  - Over 35 cu. yds. to and including 40 cu. yds.: $10.43
  - Over 40 cu. yds. to and including 45 cu. yds.: $10.45
  - Over 45 cu. yds. - additional 8.10 per hour each additional 5 cu. yds. increment.

### DUMPSITERS

- $8.89

### SERVICEMEN

- $9.60

### POWER TRUCK DRIVER (Bulk unloader type)

- $9.94

### FLAT TRUCKS:

- To and including 3 tons: $9.91
- Over 3 tons Factory rating: $10.11

---

**SERVICE TRUCK DRIVERS; FUEL TRUCK DRIVERS; TIREMEN**

- $9.35

**LOWBOYS, FOUR-WHEEL TRAILER, FLOAT SEMI-TRAILER**

- $9.01

**LUMBER CARRIERS, LIFT TRUCKS**

- $8.85

**POWER BROOM**

- $8.85

**WATER TANK DRIVERS, PETROLEUM PRODUCTS DRIVERS:**

- 2,500 gallons and under: $8.76
- Over 2,500 gallons to and including 4,500 gallons: $9.05
- Over 4,500 gallons to and including 6,000 gallons: $9.25
- Over 6,000 gallons to and including 8,000 gallons: $9.31
- Over 8,000 gallons to and including 10,000 gallons: $9.39
- Over 10,000 gallons - additional 8.10 per hour each additional 2,000 gallons increment.

**TRUCK WITH POWER EQUIPMENT IF UNDER TRANSFERS JURISDICTION SUCH AS:**

- Winch, A-frame, Swedish Crane, Spica-lift, Groutcrete, and Combination mulching, seeding and fertilizing: $9.01

**TRUCK MECHANIC**

- $9.75
### Fringe Benefits Payments

#### Basic Hourly Rates

<table>
<thead>
<tr>
<th>Job Category</th>
<th>Hourly Rate</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Approx. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lineman</td>
<td>10.29</td>
<td>.45</td>
<td>1%</td>
<td>1/26</td>
<td></td>
</tr>
<tr>
<td>Cable Splicer</td>
<td>11.44</td>
<td>.45</td>
<td>1%</td>
<td>1/26</td>
<td></td>
</tr>
<tr>
<td>Powderman, Jackhammer, Compressor</td>
<td>7.60</td>
<td>.45</td>
<td>1%</td>
<td>1/26</td>
<td></td>
</tr>
<tr>
<td>Line Equipment Operators</td>
<td>8.26</td>
<td>.45</td>
<td>1%</td>
<td>1/26</td>
<td></td>
</tr>
<tr>
<td>Groundman</td>
<td>6.13</td>
<td>.45</td>
<td>1%</td>
<td>1/26</td>
<td></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 "A"

- **Lineman**: $9.19, H & W = .45, Pensions = 1%, Vacation = 1/26
- **Cable Splicer**: $10.22, H & W = .45, Pensions = 1%, Vacation = 1/26
- **Pole Sprayer**: $9.08, H & W = .45, Pensions = 1%, Vacation = 1/26
- **Line Equipment Operators**: $8.97, H & W = .45, Pensions = 1%, Vacation = 1/26
- **Powderman, Jackhammer, Compressor**: $6.94, H & W = .45, Pensions = 1%, Vacation = 1/26
- **Groundman**: $6.52, H & W = .45, Pensions = 1%, Vacation = 1/26
- **Tree Trimmer**: $9.64, H & W = .45, Pensions = 1%, Vacation = 1/26

### Lines Construction (Cont'd)

#### Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Job Category</th>
<th>Hourly Rate</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Approx. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lineman</td>
<td>9.31</td>
<td>.35</td>
<td>1%</td>
<td>1/26</td>
<td></td>
</tr>
<tr>
<td>Cable Splicer</td>
<td>9.60</td>
<td>.35</td>
<td>1%</td>
<td>1/26</td>
<td></td>
</tr>
<tr>
<td>Powderman</td>
<td>8.53</td>
<td>.35</td>
<td>1%</td>
<td>1/26</td>
<td></td>
</tr>
<tr>
<td>Groundman</td>
<td>7.94</td>
<td>.35</td>
<td>1%</td>
<td>1/26</td>
<td></td>
</tr>
</tbody>
</table>

*Jobs over 69,000 Volts:
- Lineman, Pole Sprayer: $9.31, H & W = .35, Pensions = 1%, Vacation = 1/26
- Cable Splicer: $9.60, H & W = .35, Pensions = 1%, Vacation = 1/26
- Line Equipment Operators: $8.53, H & W = .35, Pensions = 1%, Vacation = 1/26
- Powderman: $7.94, H & W = .35, Pensions = 1%, Vacation = 1/26
- Groundman: $7.36, H & W = .35, Pensions = 1%, Vacation = 1/26

*Jobs 69,000 Volts or less:
- Lineman: $8.65, H & W = .35, Pensions = 1%, Vacation = 1/26
- Cable Splicer: $9.56, H & W = .35, Pensions = 1%, Vacation = 1/26
- Line Equipment Operators: $8.47, H & W = .35, Pensions = 1%, Vacation = 1/26
- Groundman: $5.93, H & W = .35, Pensions = 1%, Vacation = 1/26
- Experienced Groundman (1000 hours) Truck Drivers: $6.68, H & W = .35, Pensions = 1%, Vacation = 1/26

**Notice**: For the Federal Register, Vol. 42, No. 131—Friday, July 8, 1977
<table>
<thead>
<tr>
<th>Position</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>Assistant Mate (Deckhand)</td>
<td>10.04</td>
<td>.40</td>
<td>1.05</td>
<td>.11</td>
<td></td>
</tr>
<tr>
<td>Fireman</td>
<td>10.14</td>
<td>.40</td>
<td>1.05</td>
<td>.11</td>
<td></td>
</tr>
<tr>
<td>Oilier</td>
<td>10.14</td>
<td>.40</td>
<td>1.05</td>
<td>.11</td>
<td></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>
<td></td>
</tr>
<tr>
<td>Mates and Boatman</td>
<td>10.48</td>
<td>.60</td>
<td>1.05</td>
<td>.11</td>
<td></td>
</tr>
<tr>
<td>Engineer Welder</td>
<td>10.53</td>
<td>.60</td>
<td>1.05</td>
<td>.11</td>
<td></td>
</tr>
<tr>
<td>Cranesman</td>
<td>10.53</td>
<td>.60</td>
<td>1.05</td>
<td>.11</td>
<td></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>
<td></td>
</tr>
<tr>
<td>Leverman, Dipper:</td>
<td></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>
<td></td>
</tr>
<tr>
<td>(b) Over 5 Yards</td>
<td>11.04</td>
<td>.60</td>
<td>1.05</td>
<td>.11</td>
<td></td>
</tr>
<tr>
<td>Leverman, Hydraulic</td>
<td>10.90</td>
<td>.60</td>
<td>1.05</td>
<td>.11</td>
<td></td>
</tr>
</tbody>
</table>

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>Laborers</th>
<th>Basic Hourly Rates</th>
<th>Health &amp; Welfare</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASBESTOS WORKERS</td>
<td>$11.92</td>
<td>.78</td>
<td>$1.57</td>
<td>$1.00</td>
<td>.06</td>
</tr>
<tr>
<td>BRICKLaying</td>
<td>11.37</td>
<td>.70</td>
<td>.60</td>
<td>.00</td>
<td>.00</td>
</tr>
<tr>
<td>BRICK Tenders</td>
<td>8.47</td>
<td>.51</td>
<td>1.25</td>
<td>1.00</td>
<td>.00</td>
</tr>
<tr>
<td>CARPENTERS</td>
<td>11.19</td>
<td>.65</td>
<td>.00</td>
<td>.00</td>
<td>.00</td>
</tr>
<tr>
<td>Floor Layers</td>
<td>11.215</td>
<td>.65</td>
<td>.90</td>
<td>.80</td>
<td>.03</td>
</tr>
<tr>
<td>MILL Wrights</td>
<td>11.69</td>
<td>.65</td>
<td>.90</td>
<td>.80</td>
<td>.03</td>
</tr>
<tr>
<td>CEMENT MASONs</td>
<td>8.25</td>
<td>1.00</td>
<td>.40</td>
<td>2.00</td>
<td>.08</td>
</tr>
<tr>
<td>Floor Finishing Machine</td>
<td>8.68</td>
<td>1.00</td>
<td>.40</td>
<td>2.00</td>
<td>.08</td>
</tr>
<tr>
<td>LABORERS</td>
<td>8.08</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 1</td>
<td>8.13</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 2</td>
<td>8.16</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 3</td>
<td>8.18</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 4</td>
<td>8.20</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 5</td>
<td>8.22</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 6</td>
<td>8.23</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 7</td>
<td>8.26</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 8</td>
<td>8.27</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 9</td>
<td>8.29</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 10</td>
<td>8.31</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 11</td>
<td>8.33</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 12</td>
<td>8.35</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 13</td>
<td>8.37</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 14</td>
<td>8.39</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 15</td>
<td>8.41</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 16</td>
<td>8.43</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 17</td>
<td>8.45</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
<tr>
<td>Group 18</td>
<td>8.47</td>
<td>.51</td>
<td>1.25</td>
<td>.125</td>
<td>.06</td>
</tr>
</tbody>
</table>
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; Rock Attendant (jobsite only); Gas and oil pipeline laborer

Group 2: Cutting torch operator (demolition); Tamman and Mortarman

Group 3: Guinea Chaser

Group 4: Pile 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: Underground laborer including shalloon bellows (except tunnels)

Group 7: Chuck tender (except tunnels); Scaler; Tank scaler and cleaner

Group 8: Cesspool 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 rollers; Asphalt faker, ironer, spreader; Hoggymobile man; Cement dumper (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 grinding machines; Roto-scraper; Tree climber, faller, chain saw operator; Pittsburgh chipper and similar type brush shredders
## POWER EQUIPMENT OPERATORS (except Piledriving and Steel Erection)

<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>W &amp; W</td>
</tr>
<tr>
<td>Group 1</td>
<td>9.98</td>
<td>.95</td>
</tr>
<tr>
<td>Group 2</td>
<td>10.22</td>
<td>.95</td>
</tr>
<tr>
<td>Group 3</td>
<td>10.46</td>
<td>.95</td>
</tr>
<tr>
<td>Group 4</td>
<td>10.57</td>
<td>.95</td>
</tr>
<tr>
<td>Group 5</td>
<td>10.76</td>
<td>.95</td>
</tr>
<tr>
<td>Group 6</td>
<td>10.88</td>
<td>.95</td>
</tr>
<tr>
<td>Group 7</td>
<td>9.76</td>
<td>.75</td>
</tr>
<tr>
<td>Group 7-A</td>
<td>9.47</td>
<td>.75</td>
</tr>
<tr>
<td>Group 7-B</td>
<td>9.36</td>
<td>.75</td>
</tr>
<tr>
<td>Group 7-C</td>
<td>9.12</td>
<td>.75</td>
</tr>
</tbody>
</table>

**Group 1:** Air Compressor, Pump or Generator; Engineer; Oiler; Heavy Duty Repairman's Helpers; Switchman or Brakeman.

**Group 2:** Concrete Mixer, Skip type; Conveyor and Beltman; Fireman; Generator; Pump or Compressor (2-5 units inclusive, over 5 units, $0.10 per hour for each additional unit up to 10 units, portable unit); Generator, Pump or Compressor Plant; Rotary Drill Helper (oilfield type); Skiploder, wheeltip; Ford, Ferguson, Jeep or similar type, 3/4 yard or less (w/o drag-type attachments); Temporary Heating Plant; Truck Crane Oiler; Hydrostatic Pump.

**Group 3:** A-Frame or Winch Trucks; Dinky Locomotive or Tunnel Motor; Elevator Hoist; Equipment Greaser; Ford, Ferguson or similar type (with drag-type attachments); Hydra-Hammer or similar type equipment; Power Concrete Curing Machine; Power Concrete Saw; Power-driven Pump; Quicksilver Machine; Stationary Pipe Wrapping and Cleaning Machine; Towblade Operator.

**Group 4:** Asphalt Plant Fireman; Box (concrete or asphalt plant); Derrickman (oilfield type); Drilling Machine (including water wells); Highline Cableway Signalman; Locomotive Engineer; Power Sweeper; Roller, compacting, Screw; Trenching Machine (up to 4 feet depth).

**Group 5:** Asphalt or Concrete Spreading, Mechanical Tamping or Finishing Machine - Roller (all types and sizes); Soil, Cement, Asphalt - Finishes Asphalt Plant Engineer; Deck Engine; Grade Checker; Heavy Duty Welder; Machine Tool; Pavement Breaker; Pneumatic Beadling Shield - Tunnel; Road Grader Mixing Machine; Forklift, under five tons; Rubber-tired, heavy duty equipment (Oshkosh, Gr, Eucld, LaPlant-Choate, or similar type equipment with any type attachments); Sliploader, wheeltip, over 3/4 yards, up to and including 1 yard; Slip Form Pump (power-driven hydraulic lifting device for concrete forms); Tractor Operator - drag-type Shovel, Bulldozer, Tamper, Scraper; and Push Tractor.
POWER EQUIPMENT OPERATORS (Cont'd)
(Except Piledriving and Steel Erection)

Group 6: Combination Heavy Duty Repairman and Welder; Concrete Mixer - paving; Concrete Mobile Mixer; Concrete Pump or Pumpcrete Gun; Crushing Plant Engineer; Elevating Grader; Heavy Duty Repairman; Highline Cableway; Hoist (Chicago Boom and Mole); Kolman Belt Loader and similar types; Lift Slab Machine; Loader Operator - Athey, Buclid, Hancock, Sierra or similar types; Motor Patrol (any type or sizes); Multiple-engine earth-moving machinery; Pneumatic Concrete placing machines -  Hackley-Presswell or similar types; Rotary Drill, excluding Classen types; Skiploader, wheeletype, over 1/4 yard; 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 feet depth); Universal equipment (Shovel, Backhoe, Dragline, Clamshell, Derrick, Derrick Barge, Crane, Pile-driver and Mucking Machine); Forklift, over 5 tons

Group 7: Driller Operator; Fishing tool engineer

Group 7-A: Derrickman

Group 7-B: Motorman

Group 7-C: Drill Helper

TRUCK DRIVERS:

<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
<th>Education and/or Approx. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>$ 9.37</td>
<td>.39</td>
<td>.70</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>$ 9.48</td>
<td>.39</td>
<td>.70</td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td>$ 9.63</td>
<td>.39</td>
<td>.70</td>
<td></td>
</tr>
<tr>
<td>Group 4</td>
<td>$ 9.69</td>
<td>.39</td>
<td>.70</td>
<td></td>
</tr>
<tr>
<td>Group 5</td>
<td>$ 9.77</td>
<td>.39</td>
<td>.70</td>
<td></td>
</tr>
</tbody>
</table>
Group 1: Light Duty Driver
Group 2: Bootman; Truck Geasser; Light Vehicle Dispatcher
Group 3: Fillman; Warehouse Clerk
Group 4: Heavy Duty Driver; Forklift Driver; Equipment Repairman
Group 5: Extra Heavy Duty Driver
### SUPERSEDES DECISION

**STATE:** New Jersey  
**COUNTIES:** Bergen, Essex, Hudson, Hunterdon, Middlesex, Morris, Passaic, Somerset, Sussex, Union and Warren

**DECISION NO.:** NJ77-3093  
**DATE:** Date of Publication

Supersedes Decision No. NJ77-3038 dated June 3, 1977 in 42 FR 28779

**DESCRIPTION OF WORK:** Building Construction, (does not include single family homes and garden type apartments up to and including 4 stories), Heavy and Highway Construction.

<table>
<thead>
<tr>
<th>Basic Hourly</th>
<th>Fringe Benefit 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>

**AIR CONDITIONING & REFRIGERATION MECHANIC:**
Installation of refrigeration equipment for any type of building where the combined compressor tonnage does not exceed 10 tons (includes the piping of component system and the erection of the water tower); installation of air-cooled air conditioning that does not exceed 15 tons

<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly</th>
<th>Fringe Benefit Payments</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 1</td>
<td>8.50</td>
<td>.965</td>
<td>.18</td>
</tr>
<tr>
<td>Zone 2</td>
<td>11.60</td>
<td>.90</td>
<td>1.03</td>
</tr>
<tr>
<td>Zone 3</td>
<td>10.25</td>
<td>.92</td>
<td>1.03</td>
</tr>
</tbody>
</table>

**ASBESTOS WORKERS:**

**ZONE 1** - Hunterdon (Alexander, Bethlehem, Bloomsbury, Clinton, Delran, East Armwell, Flemington, Franklin, Frenchtown, Flemington, Hampton, High Bridge, Holland, Kingwood, Lambertville, Lebanon, Milford, Harriton, Readington, Stockton, Union, and West Armwell Townships); Middlesex (Cranbury, East Brunswick, Helmetta, Jamesburg, Milltown, Monroe, North Brunswick, Plainboro, South Brunswick, and Spotswood Townships); Somerset (Branchburg, Franklin Hillsborough, Manville, Millstone, Montgomery and Rocky Hill Townships) and Warren (Franklin, Greenwich, Hopatcong, Oxford, Phillipsburg, Pompton, Washington and White Township) Counties.

**ZONE 2** - Bergen (North Arlington, Lyndhurst, and west to Rutherford Avenue and Eide Bridge); Essex (except Millburn Township); Hudson (remainder of county) County.

**ZONE 3** - Hunterdon (Califon, Oldwick, Annadale, Lebanon, White House Station, Readington, Stanion and Three Bridges Townships) and Warren (remainder of county) Counties.

**ZONE 4** - Morris (remainder of county) County.

---

**FRIDAY, JULY 8, 1977**

---

**NOTICES**
### DECISION NO. NJ77-3093

#### Basic Hourly Rates

<table>
<thead>
<tr>
<th>Zone</th>
<th>Carpenters &amp; Insulators</th>
<th>Millwrights</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 1</td>
<td>10.36 $84.50 1.50 .02 1/5 of 1%</td>
<td>11.26 $84.50 1.50 .02 1/5 of 1%</td>
</tr>
<tr>
<td>Zone 2</td>
<td>10.95 $84.50 1.50 .02 1/5 of 1%</td>
<td>11.31 $84.50 1.50 .02 1/5 of 1%</td>
</tr>
<tr>
<td>Zone 3</td>
<td>10.36 $84.50 1.50 .02 1/5 of 1%</td>
<td>11.26 $84.50 1.50 .02 1/5 of 1%</td>
</tr>
<tr>
<td>Zone 4</td>
<td>10.36 $84.50 1.50 .02 1/5 of 1%</td>
<td>11.26 $84.50 1.50 .02 1/5 of 1%</td>
</tr>
<tr>
<td>Zone 5</td>
<td>10.36 $84.50 1.50 .02 1/5 of 1%</td>
<td>11.26 $84.50 1.50 .02 1/5 of 1%</td>
</tr>
</tbody>
</table>

**AREA COVERED BY CARPENTERS, ETC. ZONES**

- **Zone 1** - Bergen (east of the Hackensack River including but not limited to Cliffside, Fort Lee, Grantwood, Palisades Park, Ridgefield, Edgewater, Fairview, Leonia and Cuyetesville) and Hudson Counties.
- **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 Baptistown to Croton on 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 County; all territory south of a line beginning at Averill on the County Line to Fairview to Dutchtown to Plainville to Belle Mead to Griggstown to the Delaware and Raritan Canal Counties).
- **Zone 3** - Hunterdon (remainder of county), Middlesex, Morris, Passaic, Somerset (remainder of county), Sussex, Union and Warren Counties.
- **Zone 4** - Essex County
- **Zone 5** - Bergen (remainder of county)

### DECISION NO. NJ77-3093

#### Basic Hourly Rates

<table>
<thead>
<tr>
<th>Zone</th>
<th>Dock Builders &amp; Pile Drivers</th>
<th>Drywall Paper &amp; Finishers</th>
<th>Electricians &amp; Cable Splicers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 1</td>
<td>11.45 $1.40 1.78 .76 .02</td>
<td>11.40 $1.40 1.78 .76 .02</td>
<td>11.45 $1.40 1.78 .76 .02</td>
</tr>
<tr>
<td>Zone 2</td>
<td>11.60 $1.40 1.78 .76 .02</td>
<td>11.60 $1.40 1.78 .76 .02</td>
<td>11.60 $1.40 1.78 .76 .02</td>
</tr>
<tr>
<td>Zone 3</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
</tr>
<tr>
<td>Zone 4</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
</tr>
<tr>
<td>Zone 5</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
</tr>
<tr>
<td>Zone 6</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
</tr>
<tr>
<td>Zone 7</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
</tr>
<tr>
<td>Zone 8</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
</tr>
<tr>
<td>Zone 9</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
</tr>
<tr>
<td>Zone 10</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
</tr>
<tr>
<td>Zone 11</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
</tr>
<tr>
<td>Zone 12</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
</tr>
<tr>
<td>Zone 13</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
</tr>
<tr>
<td>Zone 14</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
</tr>
<tr>
<td>Zone 15</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
<td>11.68 $1.40 1.78 .76 .02</td>
</tr>
</tbody>
</table>

**AREA COVERED BY ELECTRICIANS & CABLE SPICLERS ZONES**

- **Zone 1** - Essex County
- **Zone 2** - Union (that portion east and north of a line running in a southerly direction from Morris Avenue along Baltusrol Way, across Baltusrol Country Club to Baltusrol Rd., along Baltusrol Rd. and Summit Lane 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 Martine Ave., to and northeast along the Harriton Rd., to and easterly along the Westfield-Scotch Plains Line, to the Lehigh Valley Railroad and southwest on the railroad to the County Line) County.
- **Zone 3** - 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 Martine Ave., to and northeast along the Harriton Rd., to and easterly along the Westfield-Scotch Plains Line to the Lehigh Valley Railroad and southwest on the railroad to Middlesex County Line) County.
- **Zone 4** - Union (remainder of county) County.
- **Zone 5** - Bergen (remainder of county) County.
ZONE 6 - Passaic County.
ZONE 7 - Morris and Sussex Counties.
ZONE 8 - Hunterdon (except Tewksbury Township and Califon Borough) 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., southwest on Mount Prospect Rd., west on Martinsville-Pluckemin Rd., west on Ewing Mill Rd., north on John Kane 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 west and south of a line following U.S. Highway #206 north from Mercer County Line, west along this road and continuing on the Washington Road and Maplewood Avenue in Cranbury to Scott Avenue, north on Scott Avenue to Main Street, on Main Street and the Turnpike to the Millstone River County.)
ZONE 9 - Hunterdon (Tewksbury Township and Califon Borough) 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., southwest on Mount Prospect Rd., west on Martinsville-Pluckemin Rd., west on Ewing Mill Rd., north on John Kane Rd., west on Whitney Rd., west on Stillwell Rd., and west on Hall's Bridge Rd. to Hunterdon County Line) Counties.
ZONE 10 - Somerset (remainder of county) County.
ZONE 11 - Middlesex (that portion north and west of a line following the Philadelphia and Reading Railroad east from the Harriton River to Delsea Rd., northeast on Delsea 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 (that portion north and west of a line following the Philadelphia and Reading Railroad east from the Harriton River to Delsea Rd., northeast on Delsea 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 13 - Middlesex (remainder of county) County.
ZONE 14 - Warren (from Pahaquarry, Blairstown, Knowlton, Hope, Liberty, White, Oxford, Washington, Hampton, Franklin, Logan Township, Greenfield, Pohatcong Townships, and that portion of Mansfield Township west of line following the Point Mt. - Port Murray Rd. to Independence Township) County.
ZONE 15 - Warren (remainder of county) County.
### Basic Hourly Rates and Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Zone</th>
<th>Laborers, Building Construction</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pension</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZONE 1</td>
<td>Laborers, Air Tool Ops. (jackhammers, vibrators), Mason Tenders, Mortar Mixers, PileLAYERS (concrete &amp; clay) &amp; Plasterer Tenders</td>
<td>7.50</td>
<td>.75</td>
<td>.85</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>ZONE 2</td>
<td>Laborers, Air Tool Ops. (jackhammers, vibrators), Mason Tenders, Mortar Mixers, PileLAYERS (concrete &amp; clay) &amp; Plasterer Tenders</td>
<td>8.50</td>
<td>.75</td>
<td>.85</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>ZONE 3</td>
<td>Laborers, Air Tool Ops. (jackhammers, vibrators), Mason Tenders, Mortar Mixers, PileLAYERS (concrete &amp; clay) &amp; Plasterer Tenders</td>
<td>7.00</td>
<td>.75</td>
<td>.85</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>ZONE 4</td>
<td>Laborers, Air Tool Ops. (jackhammers, vibrators), Mason Tenders, Mortar Mixers, PileLAYERS (concrete &amp; clay) &amp; Plasterer Tenders</td>
<td>8.00</td>
<td>.75</td>
<td>.85</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>ZONE 5</td>
<td>Laborers, Air Tool Ops. (jackhammers, vibrators), Mason Tenders, Mortar Mixers, PileLAYERS (concrete &amp; clay) &amp; Plasterer Tenders</td>
<td>8.50</td>
<td>.75</td>
<td>.85</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>ZONE 6</td>
<td>Laborers, Air Tool Ops. (jackhammers, vibrators), Mason Tenders, Mortar Mixers, PileLAYERS (concrete &amp; clay) &amp; Plasterer Tenders</td>
<td>8.00</td>
<td>.75</td>
<td>.85</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>ZONE 7</td>
<td>Laborers, Air Tool Ops. (jackhammers, vibrators), Mason Tenders, Mortar Mixers, PileLAYERS (concrete &amp; clay) &amp; Plasterer Tenders</td>
<td>7.00</td>
<td>.75</td>
<td>.85</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>ZONE 8</td>
<td>Laborers, Air Tool Ops. (jackhammers, vibrators), Mason Tenders, Mortar Mixers, PileLAYERS (concrete &amp; clay) &amp; Plasterer Tenders</td>
<td>8.50</td>
<td>.75</td>
<td>.85</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>ZONE 9</td>
<td>Laborers, Air Tool Ops. (jackhammers, vibrators), Mason Tenders, Mortar Mixers, PileLAYERS (concrete &amp; clay) &amp; Plasterer Tenders</td>
<td>8.00</td>
<td>.75</td>
<td>.85</td>
<td>.02</td>
<td></td>
</tr>
</tbody>
</table>

### Zone Descriptions
- **ZONE 1**: Warren County, Bergen, Essex, Hudson, Hunterdon, Middlesex, Morris, Passaic, Somerset, Sussex & Union Counties.
- **ZONE 2**: Bergen County.
- **ZONE 3**: Essex County.
- **ZONE 4**: Morris County.
- **ZONE 5**: Passaic County.
- **ZONE 6**: Sussex County.
- **ZONE 7**: Union County.
- **ZONE 8**: Bergen County.
- **ZONE 9**: Essex County.
- **ZONE 10**: Morris County.
- **ZONE 11**: Passaic County.
- **ZONE 12**: Sussex County.
- **ZONE 13**: Warren County.
- **ZONE 14**: Berkeley County.
- **ZONE 15**: Atlantic County.
- **ZONE 16**: Hudson County.
- **ZONE 17**: Cumberland County.

### Relevant Sections
- **LABORERS, BUILDING CONSTRUCTION**
- **ZONE 10**: Laborers, Wrecking, Demolition, Concrete Mixers, H/O Hoppers, Drill Runners, Jackhammers, Mason Tenders, Mortar Mixers, Excavation & Foundations, Scaffold Builders, Carpenter Tenders & Grading for Concrete.
- **ZONE 11**: Laborers, Air Tool Ops. (Jackhammer, Vibrator), Mason Tenders, Mortar Mixers, Plasterer Tenders, PileLAYERS, Wreckers & Excavation.
- **ZONE 12**: Laborers, Tenders, Scaffolds, Excavation, Bituminous Concrete & Aggregates, PileLAYERS, Underpinning, Lagging, Bracing & Wrecking.
- **ZONE 13**: Laborers, Tenders, Scaffolds, Excavating & Site Preparation & Clearance, Bituminous Concrete & Aggregates, Trenches, Manholes, Handling & Distribution of Pipes, Underpinning, Lagging, Propping & Shoring.
- **ZONE 14**: Laborers, Hod Carriers, Power Tool Ops. & Plasterer Tenders.
### AREA COVERED BY LABORERS, BUILDING CONSTRUCTION ZONES

ZONE 1 - Bergen (Garfield, Passaic and Wallington Townships, Lodi, Lodi Boro. and East Patterson) and Passaic Counties.

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, Fanwood, Mountain Lakes, Pequannock, Pompton Plains and Riverdale Boro.) County.

ZONE 11 - Morris (Jefferson, Rockaway, Mt. Arlington, Rockaway Boro., Wharton, Mine Hill, Dover, WestEnd, Nanbary, Mt. Olive and Randolph Townships) and Sussex Counties.

ZONE 12 - Morris (Bedminster Township, Morris Township, Morris Plains, Hanover, Boonton, Chester, Brookside, Flanders, Ironia, Mt. Freedom, Mt. Tabor, Parsippany, Troy Hills, Pine Brook, Cel Knolls, Whippany, Hanover Township and Long Valley) County.

ZONE 13 - Morris (remainder of County) County.

ZONE 14 - Somerset (Townships of Bernardsville, Peapack, Gladstone, Far Hills, Bernards and Bedminster) County.

### AREA COVERED BY LABORERS, BUILDING CONSTRUCTION ZONES (Cont'd)

ZONE 15 - Somerset (Townships of Bridgewater, Branchburg, Raritan, Bound Brook, Somerville, Hanover, Milltown, Millstone, Montgomery and Rocky Hill) County.

ZONE 16 - Somerset (remainder of County) and Union (remainder of County) Counties.

ZONE 17 - Hunterdon and Warren Counties.

### LABORERS, HEAVY & HIGHWAY CONSTRUCTION:

<table>
<thead>
<tr>
<th>GROUP</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>GROUP 1</td>
<td>$9.10</td>
<td>.70</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
</tr>
<tr>
<td>GROUP 2</td>
<td>8.95</td>
<td>.70</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
</tr>
<tr>
<td>GROUP 3</td>
<td>8.70</td>
<td>.70</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
</tr>
<tr>
<td>GROUP 4</td>
<td>8.65</td>
<td>.70</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
</tr>
<tr>
<td>GROUP 5</td>
<td>8.55</td>
<td>.70</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
</tr>
<tr>
<td>GROUP 6</td>
<td>8.45</td>
<td>.70</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
</tr>
<tr>
<td>GROUP 7</td>
<td>8.30</td>
<td>.70</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
</tr>
<tr>
<td>GROUP 8</td>
<td>8.05</td>
<td>.70</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
</tr>
<tr>
<td>GROUP 9</td>
<td>8.00</td>
<td>.70</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
</tr>
</tbody>
</table>
**CLASSIFICATION DEFINITIONS**

**LABORERS, HEAVY AND HIGHWAY CONSTRUCTION**

<table>
<thead>
<tr>
<th>GROUP</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP 1</td>
<td>Blasters</td>
</tr>
<tr>
<td>GROUP 2</td>
<td>Finishers, Rammers, Pavers, Gunite Nozzle Men and Stonecutters.</td>
</tr>
<tr>
<td>GROUP 3</td>
<td>Rimbermen</td>
</tr>
<tr>
<td>GROUP 4</td>
<td>Formsetters</td>
</tr>
</tbody>
</table>

| GROUP 5 | Migrant Drill Operators, Drill Masters, Jackhammers, Chipping Rammers,      |
|         | Pavement Breakers, Power Buggies, Concrete Cutters, Asphalt Cutters, Sheet  |
|         | Hammer and Tree 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 | Migrant 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, Pilemen and Dumpermen, Waterproofing, Raters and         |
|         | Tamperers on cold patch work.                                              |

**LABORERS, FREE AIR TUNNEL JOBS**

<table>
<thead>
<tr>
<th>GROUP 1</th>
<th>Hourly Rate</th>
<th>Fringe Benefit Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pensions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vacation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Education and/or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Apprenticeship</td>
</tr>
<tr>
<td>GROUP 1</td>
<td>9.47</td>
<td>.70</td>
</tr>
<tr>
<td>GROUP 2</td>
<td>9.07</td>
<td>.70</td>
</tr>
<tr>
<td>GROUP 3</td>
<td>8.91</td>
<td>.70</td>
</tr>
<tr>
<td>GROUP 4</td>
<td>8.40</td>
<td>.70</td>
</tr>
</tbody>
</table>

**CLASSIFICATION DEFINITIONS**

**LABORERS, ASPHALT CONSTRUCTION:**

**ZONE 1 - STREETS**

<table>
<thead>
<tr>
<th>Position</th>
<th>Hourly Rate</th>
<th>Fringe Benefit Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head Raker</td>
<td>8.30</td>
<td>.71</td>
</tr>
<tr>
<td>Bakers &amp; Screen Men</td>
<td>8.05</td>
<td>.71</td>
</tr>
<tr>
<td>Tamperers, Smoothers, Reballers, Painters, Top Shovelers &amp; Roller Boys</td>
<td>7.80</td>
<td>.71</td>
</tr>
</tbody>
</table>

**ZONE 1 - PLANT**

<table>
<thead>
<tr>
<th>Scale Mixer &amp; Burner Men</th>
<th>Hourly Rate</th>
<th>Fringe Benefit Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8.95</td>
<td>.71</td>
</tr>
<tr>
<td>Scale Feeders &amp; Dust Men</td>
<td>7.80</td>
<td>.71</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.

### LABORERS, ASPHALT CONSTRUCTION:

<table>
<thead>
<tr>
<th>Zone</th>
<th>CASTING</th>
<th>STREET</th>
<th>HEAD RAKERS</th>
<th>RAKERS AND SCREED MEN</th>
<th>TAMERS, SMOOTHERS, SETTLEMASTERS</th>
<th>PAINTERS, SHOELEARS AND ROLLER BOYS</th>
<th>PLANT</th>
<th>SCALE MIXER AND BURNER MEN</th>
<th>FEEDERS AND DUST MEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
<td>Head Rakers</td>
<td>7.90</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rakers and Screed Men</td>
<td>7.75</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tamers, Smoothers, Settlemaстers</td>
<td>7.50</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Painters, Shoeleurs and Roller Boys</td>
<td>7.75</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Scale Mixer and Burner Men</td>
<td>7.75</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feeders and Dust Men</td>
<td>7.50</td>
<td>1.00</td>
<td>e</td>
<td>.10</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### BASIC HOURLY RATES

<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>2</td>
<td>10.00</td>
<td></td>
<td>0.25</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10.75</td>
<td></td>
<td>0.25</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td></td>
<td>13.24</td>
<td>7%</td>
<td>10%</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11.33</td>
<td>6%</td>
<td>8%</td>
<td>0.4 of 1%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>14.64</td>
<td>6%</td>
<td>8%</td>
<td>0.4 of 1%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9.33</td>
<td>6%</td>
<td>8%</td>
<td>0.4 of 1%</td>
<td></td>
</tr>
</tbody>
</table>

### FRINGE BENEFITS PAYMENTS

<table>
<thead>
<tr>
<th>Zone</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>12.68</td>
<td>6%</td>
<td>0%</td>
<td>3/4 of 1%</td>
</tr>
<tr>
<td></td>
<td>12.95</td>
<td>6%</td>
<td>0%</td>
<td>3/4 of 1%</td>
</tr>
<tr>
<td></td>
<td>12.95</td>
<td>4%</td>
<td>0%</td>
<td>3/4 of 1%</td>
</tr>
<tr>
<td></td>
<td>12.95</td>
<td>4%</td>
<td>0%</td>
<td>3/4 of 1%</td>
</tr>
<tr>
<td></td>
<td>12.95</td>
<td>4%</td>
<td>0%</td>
<td>3/4 of 1%</td>
</tr>
<tr>
<td></td>
<td>11.55</td>
<td>6%</td>
<td>0%</td>
<td>3/4 of 1%</td>
</tr>
<tr>
<td></td>
<td>11.55</td>
<td>6%</td>
<td>0%</td>
<td>3/4 of 1%</td>
</tr>
<tr>
<td></td>
<td>10.09</td>
<td>6%</td>
<td>0%</td>
<td>3/4 of 1%</td>
</tr>
<tr>
<td></td>
<td>10.09</td>
<td>6%</td>
<td>0%</td>
<td>3/4 of 1%</td>
</tr>
<tr>
<td></td>
<td>12.00</td>
<td>6%</td>
<td>0%</td>
<td>3/4 of 1%</td>
</tr>
<tr>
<td></td>
<td>12.00</td>
<td>6%</td>
<td>0%</td>
<td>3/4 of 1%</td>
</tr>
</tbody>
</table>

### LINE CONSTRUCTION:

<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>1</td>
<td>10.00</td>
<td></td>
<td>0.25</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10.75</td>
<td></td>
<td>0.25</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td></td>
<td>13.24</td>
<td>7%</td>
<td>10%</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11.33</td>
<td>6%</td>
<td>8%</td>
<td>0.4 of 1%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>14.64</td>
<td>6%</td>
<td>8%</td>
<td>0.4 of 1%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9.33</td>
<td>6%</td>
<td>8%</td>
<td>0.4 of 1%</td>
<td></td>
</tr>
</tbody>
</table>
## AREA COVERED BY LINE CONSTRUCTION ZONES

<table>
<thead>
<tr>
<th>Zone</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Essex County</td>
</tr>
<tr>
<td>2</td>
<td>Passaic County</td>
</tr>
<tr>
<td>3</td>
<td>Bergen and Hudson Counties</td>
</tr>
<tr>
<td>4</td>
<td>Union (that portion east and north of a line running in a southerly direction from Morris Ave., along Baltusrol Way, across Baltusrol Country Club to Baltusrol Rd., along Baltusrol Rd. and Summit Lane 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 Martine Ave., to and northeast along the Raritan Rd., to and east along the Westfield-Scotch Plains Line to the Lehigh Valley Railroad and southwest on the railroad to the County Line) County.</td>
</tr>
<tr>
<td>5</td>
<td>Union (that portion north and west of a line following the Philadelphia and Reading Railroad east from the Raritan 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.</td>
</tr>
<tr>
<td>6</td>
<td>Union (remainder of County) County.</td>
</tr>
<tr>
<td>7</td>
<td>Warren (from Pahaquarry, Blairstown, Knowlton, Hope, Liberty, White, Oxford, Washington, Harmony, Franklin, Hopatcong, Greenwich, Pohatcong Twp., and that portion of Mansfield Twp. west of line following the Point Mt. - Port Murray Rd. to Independence Twp.) County.</td>
</tr>
<tr>
<td>8</td>
<td>Warren (remainder of County) County.</td>
</tr>
</tbody>
</table>

### Basic Hourly Rates and Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Zone</th>
<th>Linemen and Equipment Operators</th>
<th>Groundmen and Winch Operators</th>
<th>Linemen, Line Truck Operators, Equipment Operators and Cable Splicers</th>
<th>Groundmen</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>12.90 12% 7% 1/4 of 17</td>
<td>12.00 12% 7% 1/4 of 17</td>
<td>11.20 6% 3% + .50 1/4 of 17</td>
<td>6.67 6% 3% + .50 1/4 of 17</td>
</tr>
<tr>
<td>13</td>
<td>11.20 6% 3% + .50 1/4 of 17</td>
<td>6.67 6% 3% + .50 1/4 of 17</td>
<td>6.67 6% 3% + .50 1/4 of 17</td>
<td>6.67 6% 3% + .50 1/4 of 17</td>
</tr>
</tbody>
</table>

### Education and/or Appr. Training

- 1/4 of 17
- 1/4 of 17
- 1/4 of 17
- 1/4 of 17
### Basic Hourly Rates

<table>
<thead>
<tr>
<th></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>
</tbody>
</table>

### MARBLESETTERS, TERRAZZO WORKERS & TILESETTERS

#### ZONE 1

- **Marble Setters:**
  - H & W: 11.19
  - Pensions: 0.70
  - Vacation: 0.75
  - Education and/or Appr. Tr.: 0.82

- **Terraico Workers:**
  - H & W: 10.00
  - Pensions: 1.13
  - Vacation: 1.19
  - Education and/or Appr. Tr.: 0.95

- **Tile Setters:**
  - H & W: 9.13
  - Pensions: 0.80
  - Vacation: 1.10
  - Education and/or Appr. Tr.: 0.75

#### ZONE 2

- **Marble Setters:**
  - H & W: 10.00
  - Pensions: 1.13
  - Vacation: 1.19
  - Education and/or Appr. Tr.: 0.95

- **Terraico Workers:**
  - H & W: 10.75
  - Pensions: 1.21
  - Vacation: 1.56
  - Education and/or Appr. Tr.: 0.82

- **Tile Setters:**
  - H & W: 9.13
  - Pensions: 0.80
  - Vacation: 1.10
  - Education and/or Appr. Tr.: 0.75

#### AREA COVERED BY MARBLESETTERS, TERRAZZO WORKERS & TILESETTERS ZONES

- **ZONE 1** - Hunterdon (remainder of county), Morris (Stepheensburg, Pleasant Grove, Middle Valley and Parker Tpks.), Sussex (Branchville, Flat Brookville, Swartswood, Halsey, Newton and Stillwater Tpks.) and Warren County.

- **ZONE 2** - Bergen, Essex, Hunterdon (Wertsville, Reaville, Flemington, Hampton, Clinton, Penwell and cities east thereof to the County Line), Middlesex, Morris (remainder of county), Passaic, Somerset, Sussex (remainder of county) and Union Counties.

### MARBLESETTERS, TERRAZZO WORKERS & TILESETTERS FINISHERS

#### ZONE 1

- **Marble Setters Finishers:**
  - H & W: 8.28
  - Pensions: 1.09
  - Vacation: 1.19
  - Education and/or Appr. Tr.: 0.95

#### ZONE 2

- **Terraico Workers Finishers:**
  - H & W: 9.14
  - Pensions: 0.76
  - Vacation: 1.19

#### ZONE 3

- **Tile Setters Finishers:**
  - H & W: 9.00
  - Pensions: 0.84
  - Vacation: 0.91

### AREA COVERED BY MARBLESETTERS FINISHERS, ETC. ZONES

- **ZONE 1** - Bergen, Essex, Hudson, Hunterdon (Wertsville, Reaville, Flemington, Hamden, Clinton, Penwell and cities east thereof to the County Line), Middlesex, Morris (remainder of county), Passaic, Somerset, Sussex (remainder of county) and Union Counties.

- **ZONE 2** - Bergen, Essex, Hunterdon, Middlesex, Morris, Passaic, Somerset, Sussex (Calleville, Beemerville, Mt. Pisah, Swartswood, Huntsburg and all cities inclusive to the Morris and Passaic County Line) and Union Counties.

### PAINTERS

#### ZONE 1

- **Painters and Tapers:**
  - Steel outside:
    - H & W: 10.00
    - Pensions: 0.95
    - Vacation: 1.60
    - Education and/or Appr. Tr.: 0.30

- **Spray and Sandblasting:**
  - H & W: 11.00
  - Pensions: 0.95
  - Vacation: 1.60
  - Education and/or Appr. Tr.: 0.06

- **Rollers on vitreous coatings, exotic coatings, insul-rock ceilings, stacks and storage tanks:**
  - H & W: 11.55
  - Pensions: 0.95
  - Vacation: 1.60
  - Education and/or Appr. Tr.: 0.06

#### ZONE 2

- **Brush and Roller:**
  - H & W: 9.40
  - Pensions: 0.85
  - Vacation: 0.00

- **Spray:**
  - H & W: 10.30
  - Pensions: 0.85
  - Vacation: 0.00

- **Repaint work:**
  - H & W: 9.00
  - Pensions: 0.85
  - Vacation: 0.00

#### ZONE 3

- **Painters on new construction and major alterations:**
  - H & W: 9.40
  - Pensions: 0.55
  - Vacation: 0.50
  - Education and/or Appr. Tr.: 0.30

- **Painters on repaint work:**
  - H & W: 8.90
  - Pensions: 0.55
  - Vacation: 0.50
  - Education and/or Appr. Tr.: 0.30

- **Spraying or application of hazardous or dangerous materials on repaint work:**
  - H & W: 9.50
  - Pensions: 0.55
  - Vacation: 0.50
  - Education and/or Appr. Tr.: 0.30

- **Exterior work exceeding 3 stories in height for painting of open structural steel and tanks under 3 stories in height except flat tanks on the ground and on interior work which requires painting higher than 20' above the ground or floor (this shall not be applicable to machinery or equipment located therein):**
  - H & W: 9.35
  - Pensions: 0.55
  - Vacation: 0.50
  - Education and/or Appr. Tr.: 0.30

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

NOTICES 35575
## DECISION NO. NJ77-3093

<table>
<thead>
<tr>
<th>Fringe Benefits Payments</th>
<th>Basic Hourly Rates</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W Pensions</td>
<td>Vacation</td>
</tr>
</tbody>
</table>

**Hypolite work as described above**

- **On bridges, television and radio towers, structural steel and tanks above 3 stories in height (28' or over), smoke stacks, water towers, sandblasting, steam-cleaning, spraying or application of hazardous materials:**
  - **Rates:** 9.05 - 0.55 - 0.50 - 0.30 - 0.05

**ZONE 4**

- **Commercial & Industrial Sprayers, Tapers, Coverers, & Spacklers:**
  - **Rates:** 9.57 - 0.90 - 1.75 - 0.50

- **Paperhangers:**
  - **Rates:** 10.00 - 0.90 - 1.75 - 0.50

- **All extension ladder work, 35' high or over, scaffold work, structural steel, tanks, bridges, towers, smoke stacks, radio towers, television towers, flag poles (steel or wood), fire escapes from top to bottom, cable work & hazardous work:**
  - **Rates:** 10.16 - 0.90 - 1.75 - 0.50

- **Sandblasting & Spraying:**
  - **Rates:** 10.50 - 0.90 - 1.75 - 0.50

**AREA COVERED BY PAINTER S ZONES**

**ZONE 1** - Bergen, Passaic and Sussex Counties.

**ZONE 2** - Middlesex (Edison Twp., South of Metuchen, Highland Park, New Brunswick, North Brunswick, East Brunswick and South Brunswick Tpws, and Monroe Twp.) and Somerset (Franklin Twp.) Counties.

**ZONE 3** - 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).
### PLUMBERS & GASFITIERS:

**Essex (except all of the Oranges, Livingston & Maplewood) & Hudson (Elizabeth, West Newark & Kearny) Counties**

<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 1</td>
<td>12.43</td>
<td>.65</td>
<td>1.00</td>
</tr>
</tbody>
</table>

### PLUMBERS & PIPEFITIERS:

<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 1</td>
<td>10.51</td>
<td>.65</td>
<td>1.00</td>
</tr>
<tr>
<td>Zone 2</td>
<td>12.10</td>
<td>.65</td>
<td>1.00</td>
</tr>
<tr>
<td>Zone 3</td>
<td>10.63</td>
<td>.65</td>
<td>1.00</td>
</tr>
</tbody>
</table>

**AREA COVERED BY PLUMBERS AND PIPEFITIERS ZONES**

- **ZONE 1**: Essex (Orange, West Orange, East Orange, South Orange, Maplewood and Livingston) County.
- **ZONE 2**: Middlesex (Placentia to Old Bridge to the County Line and North thereof) County.
- **ZONE 3**: Middlesex (Adams, Borden's Corners, Daytton, Deans, Helmetta, Highland Park, Kingston, Livingston Park, Jamesburg, Milltown, Monroe Township, New Brunswick, New Dorham, North Brunswick Township, Northfield, Old Bridge, Placentia, Harriton Township, South Brunswick Township, South River, Spotswood and Steelmanville) and Somerset (Clyde, Millburn, South Bound Brook, South Branch, Voorhees, Warren Township, and West New Brunswick) Counties.
- **ZONE 5**: Morris (Beginning at Dover to Rockaway, Mount Olive, Mount Olive Township, Florham Park, and Mount Olive Township) County.
- **ZONE 6**: Morris (remainder of county) County.
- **ZONE 7**: Morris (remainder of county) County.
- **ZONE 8**: Essex (except Millburn and Short Hills), Middlesex (Middlesex Borough, North Plainfield, and Greenbrook), and Union (except Springfield and a portion of Dunellen) Counties.

### STEAMFITIERS:

<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 1</td>
<td>11.50</td>
<td>.65</td>
<td>1.00</td>
</tr>
<tr>
<td>Zone 2</td>
<td>10.90</td>
<td>.65</td>
<td>1.00</td>
</tr>
</tbody>
</table>

**AREA COVERED BY PLUMBERS AND STEAMFITIERS ZONES**

- **ZONE 1**: Bergen (Lodi, Garfield, and Wallington) County.
- **ZONE 2**: Essex (Short Hills and Millburn) and Union (Ashbrook, Berkeley Heights, Great Island, Murray Hill, Springfield, Chatham Township, Millburn, Unionville, Vauxhall, Warren, Summit, Summit Township, New Providence, and New Providence Township) Counties.
- **ZONE 3**: Hunterdon (Huntington, Raritan, Roundtown, Plainsboro, Plainsboro Township, Prospect Plains, and Somerville) and Somerset (Stapleton, Millington, Ringwood, and Stockton) Counties.
- **ZONE 4**: Hunterdon (remainder of county), Middlesex (Cranbury, Cranbury Township, and Prospect Plains) Counties.
- **ZONE 5**: Somerset (remainder of county) and Warren (area encompassed by the Delaware River, Hunterdon and Morris County Lines including Belvidere and South thereof) Counties.
- **ZONE 6**: Morris (beginning at Dover to Rockaway, Mountain Lakes, Denville, Succasenna, Budd Lake, Hackettstown, Columbus, Flatbrookville, Montague, Montville, Port Jervis, and Glenwood, and returning to Dover) Counties.
- **ZONE 7**: Morris (remainder of county) County.
- **ZONE 8**: Essex (except Millburn and Short Hills), Middlesex (Middlesex Borough, North Plainfield, New Market, Dunellen, New Market, a portion of Parsippany Township, and a portion of Edison Township), and Union (except Springfield and a portion of Somerville and Union Township) Counties.
### DECISION NO. M177-___

**Classification Definitions - Power Equipment Operators**

<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>H &amp; V Pen./Vac.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>15.31</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>13.49</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td>12.61</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
<tr>
<td>Group 4</td>
<td>11.70</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
<tr>
<td>Group 5</td>
<td>10.86</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
<tr>
<td>Group 6</td>
<td>10.06</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
<tr>
<td>Group 7</td>
<td>9.95</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
<tr>
<td>Group 8</td>
<td>9.82</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
<tr>
<td>Group 9</td>
<td>9.53</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
<tr>
<td>Group 10</td>
<td>9.20</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
<tr>
<td>Group 11</td>
<td>9.00</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
<tr>
<td>Group 12</td>
<td>8.95</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
<tr>
<td>Group 13</td>
<td>8.75</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
<tr>
<td>Group 14</td>
<td>8.50</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
<tr>
<td>Group 15</td>
<td>8.10</td>
<td>76 154 - h 3%</td>
<td></td>
</tr>
</tbody>
</table>

**Rates**

- **$5.00 per hour on machines where "Cat Head" or "Sheave Point" is at least 100 feet above ground level and less than 140 feet; $7.50 per hour on machines where "Cat Head" or "Sheave Point" is 140 feet, or over above ground level.**

---

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

GROUP 7 - Asphalt curbing machines; asphalt plant engineers; autograde tube finishers; texturing machines (CMI & similar types); autograde concrete machines (CMI & similar types); autograde curb trimmers & sidewalk shoulder, slipform (CMI & similar types); backhoe machines (power); batchers, batcher plant & crasher on site; bet convey or system; boilers and steam jennies (building & heavy construction rate only); boom type skimmer machines (building & heavy construction rate only); car dumpers (railroad); compressor and blower type units; concrete breaking machines; concrete finishing machines; concrete saws & cutters (ride on type); concrete spreaders-hetzel, recomatic & similar types; concrete vibrators (highway, road, street & sewer construction rate only); conveyors, under 125 ft.; crushing machines; ditching machine, small (ditch winch or similar); drill doctor (duties include dust collector); dozer pots (mechanical with or without pump); dumpers; fine grade machine (large type); front end loaders (1 yd. & over but less than 2 yd.); high, road, street & sewer construction rate only; front end loaders (under 2 yd.); building and heavy construction rates only; front end loaders (under 2 yd.); building and heavy construction rates only; front end loaders (1 yd. & over but less than 2 yd.); high, road, street & sewer construction rate only; front end loaders (under 2 yd.); building and heavy construction rates only; front end loaders (under 2 yd.); building and heavy construction rates only; generators; giraffe graders; graders and motor patrol's; ginane machines (excluding nozzle); hammer vibratory (in conjunction with generator); hoppers; hopper doors (power operated); ladder (motorized); building & heavy construction rate only; ladder; light jacks; portable generating light plants; locomotive (dinky type); mechanic; mixers (excluding paving mixers); motor patrol's; pumps (4 inch suction & over including submersible pumps); pumps (2 of less than 4 inch suction including submersible pumps); pumps, diesel engine & hydraulic (immaterial of power); highway, road, street & sewer construction rate only; temporary heating plant (Nelson or other type, including propane, natural gas or flow type units); welding machines, gas or electric converters of any type - single (building & heavy construction rate only); wellpoint systems (including installation and maintenance).

GROUP 8 - Compressors (2 or 3 within a total distance of 100' constitutes a battery) - building & heavy construction rate only; welding machines, gas or electric converters of any type (2 or 3 in battery) - highway, road, street & sewer construction rate only; welder and repair mechanic.

GROUP 9 - Broom & sweepers; bulldozers, D5 and over; fireman; sprinkler and water pump trucks (used on job site or in conjunction with job site); stone spreaders; sweepers & brooms; tractors, D8 & over; water and sprinkler trucks (used on job site or in conjunction with job site).

GROUP 10 - Compressors (2 or 3 within a total distance of 100' constitutes a battery) - highway, road, street and sewer construction rate only.

GROUP 11 - Front end loader (under 1 yd.) - highway, road, street & sewer construction rate only.

GROUP 12 - Compressors (single); heaters (Nelson or other type including propane, natural gas or flow type units); pumps (4 inch suction & over including submersible pumps); pumps (2 of less than 4 inch suction including submersible pumps); pumps, diesel engine & hydraulic (immaterial of power); highway, road, street & sewer construction rate only; temporary heating plant (Nelson or other type, including propane, natural gas or flow type units); welding machines, gas or electric converters of any type - single (building & heavy construction rate only); wellpoint systems (including installation and maintenance).

GROUP 13 - Concrete spreaders, (small type) convey or loaders (not including elevator graders) - highway, road, street & sewer construction rate only; farm tractors (highway, road, street & sewer construction rate only); fertilizing equipment; fine grade machine (small type) - highway, road, street and sewer construction rate only; form line graders (small type) - highway, road, street and sewer construction rate only; grease, gas, fuel and oil supply trucks; mixers, concrete small (highway, road, street and sewer construction rate only); mowing equipment; road finishing machines (small type) - highway, road, street and sewer construction rate only; seeding equipment; tamping machines, vibrating self-propelled; welding machines, gas or electric converters of any type - single (highway, road, street and sewer construction rate only).

GROUP 14 - Assistant engineer/oiler; mechanics helper; tire repair and maintenance.
<table>
<thead>
<tr>
<th>POWER EQUIPMENT OPERATORS:</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP 1</td>
<td>17.12</td>
<td>7% 15% 6%</td>
<td>b  3%</td>
</tr>
<tr>
<td>GROUP 2</td>
<td>15.31</td>
<td>7% 15% 6%</td>
<td>b  3%</td>
</tr>
<tr>
<td>GROUP 3</td>
<td>13.60</td>
<td>7% 15% 6%</td>
<td>b  3%</td>
</tr>
<tr>
<td>GROUP 4</td>
<td>11.66</td>
<td>7% 15% 6%</td>
<td>b  3%</td>
</tr>
<tr>
<td>GROUP 5</td>
<td>11.28</td>
<td>7% 15% 6%</td>
<td>b  3%</td>
</tr>
<tr>
<td>GROUP 6</td>
<td>11.24</td>
<td>7% 15% 6%</td>
<td>b  3%</td>
</tr>
<tr>
<td>GROUP 7</td>
<td>10.97</td>
<td>7% 15% 6%</td>
<td>b  3%</td>
</tr>
<tr>
<td>GROUP 8</td>
<td>10.81</td>
<td>7% 15% 6%</td>
<td>b  3%</td>
</tr>
</tbody>
</table>

CLASSIFICATIONS DEFINITIONS
POWER EQUIPMENT OPERATORS (CONT'D)

GROUP 1 - Helicopters pilot/engineer.

GROUP 2 - Cranes (all cranes - land or floating with booms - including jib, 140 feet and over above the ground); derricks (land or floating with booms including jib, 140 feet and over above the ground); helicopters co-pilot and communications engineer.

GROUP 3 - Cranes (all cranes - land or floating with booms - including jib, less than 140 feet above the ground); derricks (land or floating, with booms including jib, less than 140 feet above the ground).

GROUP 4 - Aerial platforms used as hoists; A-frame; cherry pickers - 6 tons and under (over 6 tons - crane rate applies); jack 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 1 or 2 in battery multiple welders); welding system multiple (rectifier transformer type).

GROUP 6 - Maintenance engineer.

GROUP 7 - Firemen

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.

---

<table>
<thead>
<tr>
<th>ROOFERS:</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZONE 1</td>
<td>10.35</td>
<td>1.00 1.00</td>
<td></td>
</tr>
<tr>
<td>ZONE 2</td>
<td>10.15</td>
<td>1.00 1.00</td>
<td></td>
</tr>
<tr>
<td>ZONE 3</td>
<td>10.00</td>
<td>1.00 1.00</td>
<td></td>
</tr>
<tr>
<td>ZONE 4</td>
<td>9.85</td>
<td>1.00 1.00</td>
<td></td>
</tr>
</tbody>
</table>

AREA COVERED BY ROOFERS ZONES

ZONE 1 - Bergen and Passaic Counties.


ZONE 3 - Essex, Hudson (west of the Hackensack River), Morris, Somerset (Pottersville, Peapack, Gladstone, Bernardsville, Basking Ridge, Bedminster, Far Hills, Mine Brook, Lyons, Liberty Corner, Plucksm, Mt. Bethel and Watchung), Sussex, Union (remainder of county) and Warren Counties.

ZONE 4 - Bergen, Passaic and Sussex Counties.

ZONE 5 - Sussex Hudson, Morris, Somerset (Pottersville, Peapack, Gladstone, Bernardsville, Basking Ridge, Bedminster, Far Hills, Mine Brook, Lyons, Liberty Corner, Plucksm, Mt. 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 Raraway) Counties.

ZONE 7 - Hudson (remainder of county) County.
DECISION NO. 4732-PRO.

CLASSIFICATION DEFINITIONS

TRUCK DRIVERS - GROUP 1 AND 2

GROUP 1 - Mechanic Helper:

GROUP 2 - Drivers on the following type vehicles: Straight Dumps, Floats, Floats, Pickups, Container Haulers, Fuel, Water Sprinkler, Road Oil, Stringer, Mud, Bus, Dump, Bulk, Transit Mixers, Agitator Mixer, Raff Truck, Winch Truck, Side-Matic, Dumper, Dumper, X-Ray, Rolling, Lift, Dump, Carrier, Station Wagon, Stringer, A-Frame, All Dual Purpose Trucks, trucks with mechanical tail gate, Asphalt Distributor, Batch Trucks, Seeding, Mulching, Fertilizer, Air Compressor Trucks, (intransit), Flatbed, excavator, Scissors, Lift, Telehandler, Concrete Breaker, Gin Pole, Convey, Sand, Asphalt Distributor and Spreader, Ripper, Fuel Trucks (drivers on Fuel Trucks including handling of hose and nozzle-entire unit), Team Drivers, Vacuum or Vac-all Trucks (entire unit), Oil Truck (entire container - entire unit), Concrete Mobile Trucks (entire unit), Equipped (parts changer), Belt, Truck, Pump, Concrete Trucks, Line Truck, Fuel, Truck, Reckers, Utility Trucks, Truck Tractors, Warehousemen, Warehouse Parts-Men, Yardmen, Lift Truck in Warehouse, Helper when required on Lift Truck in Warehouse, Warehouse Clerk, Parts Man, Material Checker, Receivers, Shippers, Smaller (Materials), Carder Man, Helper when required on Broyhill Coal Tar, Epoxy Truck and Asphalt and Bituminous Distributor Truck, Drivers on the following type vehicles: Broyhill Coal Tar Epoxy Trucks, Little Ford Bituminous Distributor, Slurry Seal Truck or Vehicle, Trololo Truck, Mover Truck, Pickup (Chop Cat Pickup), Bucket Loader Dump Truck and any rubber tired Tractor 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 Materials: Trucks and Floats.

GROUP 4 - Drivers on all Road Type Vehicles: Roadside, International Harvester, Mack, Caterpillar, Boom Truck, Transports and Wagon, Dump Trucks, Straight, Bottom, Rear and Side Dumps, Carryalls and Scrappers (not self loaders-loading over the top), Water Sprinkler Trailers, Water Pulls and similar types of Vehicles: Drivers on Tractors and Trailer type vehicles: Flat, Floats, I-Beams, Low Beds, Water Sprinkler, Bituminous Transit Mix, Road Oil, Fuel, Bottom Dumper, Hooper, Rear Dump, Office, Shanty, Epoxy, Asphalt, Agitator Mixer, Mulching, Stringer, Seeding, Fertilizing Pole, Spread, Bituminous Distributor, Water Pulls (entire unit) (Tractor Trailer), Reel Trailer, and similar types of vehicles.

GROUP 5 - Winch Trailers Drivers

AREA COVERED BY SPRINKLER FITTERS ZONES

ZONE 1 - Bergen, Essex, Hudson, Middlesex (New Brunswick, Milltown, Old Bridge, New Brunswick, Milltown, and North thereof), Morris, Passaic, Somerset (Bernardsville, Basking Hills, Mine Brook, Hard Hills, Lyons, Martinville, East Hanover, Watchung, North Plainfield, Martinsville and Bernardsville) and Union Counties.

ZONE 2 - Hunterdon, Middlesex (remainder of county), Somerset (remainder of county), Sussex and Warren Counties.

SOFT FLOOR LAYERS:

AREA COVERED BY SPRINKLER FITTERS ZONES

ZONE 1 - Bergen, Essex, Hudson, Middlesex (New Brunswick, Milltown, Old Bridge, Browntown and North thereof), Morris, Passaic, Somerset (Bernardsville, Basking Ridge, Mine Brook, Hard Hills, Lyons, Mine Brook, East Hanover, Watchung, North Plainfield, Martinsville and Bernardsville) and Union Counties.

ZONE 2 - Hunterdon, Middlesex (remainder of county), Somerset (remainder of county), Sussex and Warren Counties.
AREA COVERED BY TRUCK DRIVERS ZONES

ZONE 1 - Bergen, Hudson, Hunterdon, Middlesex, Passaic, Somerset, 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; E-Christmas Day.

FOOTNOTES:

a. Employer contributes $8.00 per day per employee to an Annuity Fund.


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.

e. Holidays: A through F; plus Washington’s Birthday, Veterans’ Day and Presidential Election 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.

f. Employer contribution of 3% based on the basic hourly rate plus Health and Welfare plus Pension and Vacation Fringes.

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 F; plus Lincoln’s Birthday, Washington’s Birthday, Good Friday, Columbus Day and Veterans’ Day, providing the employee works any day of the President’s birth.

k. Employee has been on the employer during 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.

l. Employer contribution of $116.00 per month per employee to Health and Welfare Funds.

m. Holidays: A through F; plus Armistice Day and Washington’s Birthday.
### Basic Hourly Rates and Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Description of Work</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASBESTOS WORKERS</strong></td>
<td>$11.31</td>
<td>1.02</td>
<td>.55</td>
<td>.04</td>
</tr>
<tr>
<td><strong>BOILERMAKERS</strong></td>
<td>10.60</td>
<td>.70</td>
<td>1.00</td>
<td>.02</td>
</tr>
<tr>
<td><strong>BRICKLAYERS &amp; STONE MASONES</strong></td>
<td>12.39</td>
<td>.55</td>
<td>1.40</td>
<td></td>
</tr>
<tr>
<td><strong>TERRAZZO WORKERS &amp; TILE SETTERS</strong></td>
<td>12.10</td>
<td>.55</td>
<td>1.40</td>
<td></td>
</tr>
<tr>
<td><strong>MASON MASONES</strong></td>
<td>12.01</td>
<td>.55</td>
<td>1.40</td>
<td></td>
</tr>
<tr>
<td><strong>CARPENTERS, BUILDING:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grand Island north of White Haven Road</td>
<td>12.69</td>
<td>.55</td>
<td>1.10</td>
<td>.02</td>
</tr>
<tr>
<td><strong>MILLWRIGHTS</strong></td>
<td>12.80</td>
<td>.55</td>
<td>1.10</td>
<td>.02</td>
</tr>
<tr>
<td><strong>REMAINDER OF COUNTY, BUILDING, HEAVY &amp; HIGHWAY:</strong></td>
<td>11.33</td>
<td>.86</td>
<td>1.55</td>
<td></td>
</tr>
<tr>
<td><strong>DIVERS</strong></td>
<td>18.62</td>
<td>.65</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CEMENT MASONS</strong></td>
<td>12.68</td>
<td>.25</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ELECTRICIANS</strong></td>
<td>12.49</td>
<td>.65</td>
<td>3%+</td>
<td>.05</td>
</tr>
<tr>
<td><strong>ELEVATOR CONSTRUCTORS</strong></td>
<td>12.51</td>
<td>.74</td>
<td>.35</td>
<td>.02</td>
</tr>
<tr>
<td><strong>ELEVATOR CONSTRUCTORS HELPERS</strong></td>
<td>8.76</td>
<td>.74</td>
<td>.35</td>
<td>.02</td>
</tr>
<tr>
<td><strong>ELEVATOR CONSTRUCTORS HELPERS (PROB.)</strong></td>
<td>6.25</td>
<td>.74</td>
<td>.35</td>
<td></td>
</tr>
<tr>
<td><strong>GLAZIERS</strong></td>
<td>10.34</td>
<td>1.60</td>
<td>.70</td>
<td>.15</td>
</tr>
<tr>
<td><strong>IRONWORKERS, STRUCTURAL, ORNAMENTAL &amp; REINFORCING:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grand Island to White Haven Road</td>
<td>10.82</td>
<td>.86</td>
<td>.82</td>
<td></td>
</tr>
<tr>
<td><strong>REMAINDER OF COUNTY</strong></td>
<td>11.52</td>
<td>.86</td>
<td>.82</td>
<td></td>
</tr>
<tr>
<td><strong>LATHERS</strong></td>
<td>11.92</td>
<td>1.01</td>
<td>.01</td>
<td></td>
</tr>
<tr>
<td><strong>LEAD BURNERS</strong></td>
<td>10.75</td>
<td>.40</td>
<td>.25</td>
<td>.01</td>
</tr>
<tr>
<td><strong>LINEMEN</strong></td>
<td>11.10</td>
<td>.65</td>
<td>.60</td>
<td></td>
</tr>
<tr>
<td><strong>CABLE SPLICER</strong></td>
<td>12.21</td>
<td>.65</td>
<td>.60</td>
<td></td>
</tr>
<tr>
<td>**GROUNDMEN» DIGGING MACHINE OPERATOR»</td>
<td>9.99</td>
<td>.50</td>
<td>.55</td>
<td></td>
</tr>
<tr>
<td>**GROUNDMEN TRUCK DRIVER AND MECHANIC»</td>
<td>8.88</td>
<td>.50</td>
<td>.55</td>
<td></td>
</tr>
<tr>
<td>**GROUNDMEN DYNAMITE MAN»</td>
<td>8.88</td>
<td>.50</td>
<td>.55</td>
<td></td>
</tr>
<tr>
<td><strong>FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DECISION NO. NY77-3087

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 2% basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.
c. Holidays: A through F; Washington's Birthday, Good Friday and Christmas Eve, providing employee has worked 36 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 vacations are 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>LABORERS</td>
<td></td>
</tr>
<tr>
<td>BUILDING</td>
<td></td>
</tr>
<tr>
<td>Bottom man, blaster; plumbing laborer, wagon drill operator; swing scaffold</td>
<td>8.555</td>
</tr>
<tr>
<td>Pneumatic-gas-electric tool operator</td>
<td>8.405</td>
</tr>
<tr>
<td>Tool operator (over 8 feet deep)</td>
<td>8.505</td>
</tr>
<tr>
<td>Mortar mixer</td>
<td>8.455</td>
</tr>
<tr>
<td>Foundation laborer (over 8 feet deep)</td>
<td>8.405</td>
</tr>
<tr>
<td>Rod carriers; plasterer tender; plasterer scaffold builder; pneumatic gas-electric tool operator</td>
<td>8.305</td>
</tr>
<tr>
<td>WRECKING</td>
<td></td>
</tr>
<tr>
<td>Wagon drill operator</td>
<td>8.555</td>
</tr>
<tr>
<td>Pneumatic-gas-electric tool operator</td>
<td>8.405</td>
</tr>
<tr>
<td>Wrecking &amp; topman</td>
<td>8.305</td>
</tr>
<tr>
<td>OPEN CUT HOES</td>
<td></td>
</tr>
<tr>
<td>Blaster: Wagon drill op.</td>
<td>8.555</td>
</tr>
<tr>
<td>Pneumatic-gas-electric tool op.</td>
<td>8.405</td>
</tr>
<tr>
<td>Laborers: Top men</td>
<td>8.305</td>
</tr>
<tr>
<td>CAISSON-SHAFT-COFFERDAMS (OPEN CUT)</td>
<td></td>
</tr>
<tr>
<td>Blaster: Bottom men; wagon drill op.</td>
<td>8.555</td>
</tr>
<tr>
<td>Pneumatic-gas-electric tool op.</td>
<td>8.405</td>
</tr>
<tr>
<td>Top men</td>
<td>8.305</td>
</tr>
<tr>
<td>SOFT GROUND TUNNEL OR JACKING</td>
<td></td>
</tr>
<tr>
<td>Rodman (reinforcement); welder</td>
<td>8.905</td>
</tr>
<tr>
<td>Lead miner</td>
<td>8.795</td>
</tr>
<tr>
<td>Concrete form mover; Monkey 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 mucker; 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>
<tr>
<td>CLASS</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>A</td>
<td>Basic Hourly Wages:</td>
</tr>
<tr>
<td></td>
<td>Rock Tunnel:</td>
</tr>
<tr>
<td></td>
<td>Rodmen (reinforce); welder</td>
</tr>
<tr>
<td></td>
<td>Lead heading rock drillers</td>
</tr>
<tr>
<td></td>
<td>Concrete form miers:</td>
</tr>
<tr>
<td></td>
<td>Plug hole and roof bolt drillers; Mucking machine tender; tunnel &amp; shaft muckers; shaft sinking drillers</td>
</tr>
<tr>
<td></td>
<td>Bottom shaft man</td>
</tr>
<tr>
<td></td>
<td>Concrete form miers:</td>
</tr>
<tr>
<td></td>
<td>Stone, wood &amp; brick pavers</td>
</tr>
<tr>
<td></td>
<td>Shovelers</td>
</tr>
<tr>
<td></td>
<td>Curb setter helper</td>
</tr>
<tr>
<td></td>
<td>Curb setter &amp; flag layers</td>
</tr>
<tr>
<td>B</td>
<td>Basic Hourly Wages:</td>
</tr>
<tr>
<td></td>
<td>Asphalt work:</td>
</tr>
<tr>
<td></td>
<td>Rock or drilling machine operators (except quarry master and similar type),</td>
</tr>
<tr>
<td></td>
<td>acetylene torch op., asphalt raker, powderman</td>
</tr>
<tr>
<td>C</td>
<td>Basic Hourly Wages:</td>
</tr>
<tr>
<td></td>
<td>Asphalt workers and curb setting:</td>
</tr>
<tr>
<td></td>
<td>asphalt plant men, blacksmith, dumpers, gutterman, painters, smoothers</td>
</tr>
<tr>
<td></td>
<td>Rakers, screed man</td>
</tr>
<tr>
<td></td>
<td>Stone brick pavers</td>
</tr>
<tr>
<td>D</td>
<td>Basic Hourly Wages:</td>
</tr>
<tr>
<td></td>
<td>Laborers:</td>
</tr>
<tr>
<td></td>
<td>Laborers, drill helper, flagmen, outboard and hand boats</td>
</tr>
<tr>
<td></td>
<td>Bull float, chain saw, concrete aggregate, bin, concrete hopper, gin buggy,</td>
</tr>
<tr>
<td></td>
<td>hand or machine vibrator, jackhammer, masonry tender, mortar mixer, pavement</td>
</tr>
<tr>
<td></td>
<td>breaker, handlers of all steel mesh, small generators for laborer's tools,</td>
</tr>
<tr>
<td></td>
<td>installation of bridge drainage pipe, pipe layers, vibrator type rollers,</td>
</tr>
<tr>
<td></td>
<td>tamper, drill doctor, ball or screw op. on asphalt paver, water pump op.</td>
</tr>
<tr>
<td></td>
<td>(1/4 &amp; single diaphragm), nozzle (asphalt, gunite, seeding and sand blasting),</td>
</tr>
<tr>
<td></td>
<td>laborers on chain link fence erection, rock splitter and power unit,</td>
</tr>
<tr>
<td></td>
<td>pusher type concrete saw and all other gas, electric, oil and air tool</td>
</tr>
<tr>
<td></td>
<td>operators, wrecking laborer</td>
</tr>
<tr>
<td></td>
<td>Blasters; form setters, stone or granite curb setters</td>
</tr>
</tbody>
</table>

**Paid Holidays:**
- A-New Year's Day
- B-Memorial Day
- C-Independence Day
- D-Labor Day
- E-Thanksgiving Day
- E-Christmas Day.

**Footnote:**
- Paid Holidays A through F, provided the employee has worked the day before and after the holiday.
### POWER EQUIPMENT OPERATORS

<table>
<thead>
<tr>
<th>Group</th>
<th>Hours Rate</th>
<th>H &amp; W %</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Ed. &amp; Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP I</td>
<td>12.32</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP II</td>
<td>12.235</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP III</td>
<td>12.08</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP IV</td>
<td>12.04</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP V</td>
<td>11.955</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP VI</td>
<td>9.15</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP VII</td>
<td>12.04</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP VIII</td>
<td>8.835</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP IX</td>
<td>8.68</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP X</td>
<td>11.185</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP XI</td>
<td>11.80</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP XII</td>
<td>9.305</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP XIII</td>
<td>12.645</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP XIV</td>
<td>8.535</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP XV</td>
<td>12.735</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP XVI</td>
<td>13.235</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP XVII</td>
<td>13.735</td>
<td>1.00</td>
<td>.75</td>
<td>a</td>
<td>.15</td>
</tr>
</tbody>
</table>

### BUILDING - POWER EQUIPMENT OPERATORS

**GROUP I: Master Mechanic**

- All boom type equipment (100 ft or less), all pum and carry-all operators, anchor hoist, tank and full hoist operator, blast or rotary drill, track or cat mounted, hoist (when used for power), boom trucks, subways, operator, concrete paver machine, crane operator, derrick operator, augerine operator, elevating grader (self-propelled), head tower operator, hoist roller (finishing courses), hydraulic boom, hoist crane, maintenance engineer, mounting machine operator, multiple drum hoist, more than 1 drum in use, Feins crane, pile driving machine operator, power grader machine operator, scoopmobile, shovel operator, skimmer operator, tractor shovel operator, vertical caisson auger drill, well drilling machine

**GROUP III: Back filling machine operator, kolman loader, roller machine operator, switch and pusher cats, stone crusher, towed or self-propelled rollers, trenching machine operator

**GROUP IV: Air hoist operator, cage hoist operator, conveyor operator, conveyor system, (belt-crete or similar), hoisting engine op., boards elevator, (when used for hoisting), industrial tractor, Locomotive op., (irrespective of power), push button hoist op., Strato tower, tractors (when using winch power)

**GROUP VI: Concrete mixer op., % c.y. or over), gasoline driven boring machine, hydraulic system pumps, hydro hammer, finishing machine op., (asphalt spreader), finishing machine op.

**GROUP VII: Air compressor operator, (under 160 CFM), air compressor op., (over 160 CFM), generator mechanical heater, (when 3 are in a battery), power plant (in excess of 100KW), welding machine operator, (to and including 3 machines)

**GROUP VIII: Firemen

**GROUP IX: Truck crane drivers
## Building - Power Equipment Operators

### Group X
- Aggregate bin op., cement bin op., concrete mixer op., (under ½ c.y.), tractor machines

### Group XI
- Grout machine operator, heating boiler operator (used for temporary heat), lubrication unit on truck, pneumatic mixer operator

### Group XII
- Pump operator (4" or over); pump operator 2-3 in. sq. battery

### Group XIII
- Bulldozer & tractor (50 H.P. drawbar and under), jeep trench, mulchcrs, power brooms 7 rakes, seeders

### Group XIV
- Apprentice engineer or oiler, mechanical heaters (when 1 or 2 are used), pump operators (one inch), pump operators (2 inches), pump operators (3 inches)

### Group XV
- Crane with boom over 100 feet

### Group XVI
- Crane with boom over 200 feet

### Group XVII
- Crane with boom over 300 feet

### Holidays
- A - New Year's Day; B - Memorial Day; C - Independence Day; D - Labor Day; E - Thanksgiving Day; F - Christmas Day.

### Footnote

a. Holidays: A through F; Election Day.

---

<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>POWER EQUIPMENT OPERATOR</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HEAVY AND HIGHWAY CONSTRUCTION</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLASS 1</td>
<td>11.29</td>
<td>1.00</td>
<td>1.15</td>
<td>a</td>
</tr>
<tr>
<td>CLASS 2</td>
<td>11.23</td>
<td>1.00</td>
<td>1.15</td>
<td>a</td>
</tr>
<tr>
<td>CLASS 3</td>
<td>8.09</td>
<td>1.00</td>
<td>1.15</td>
<td>a</td>
</tr>
<tr>
<td>CLASS 4</td>
<td>10.79</td>
<td>1.00</td>
<td>1.15</td>
<td>a</td>
</tr>
<tr>
<td>CLASS 5-A</td>
<td>10.34</td>
<td>1.00</td>
<td>1.15</td>
<td>a</td>
</tr>
<tr>
<td>CLASS 5-B</td>
<td>8.84</td>
<td>1.00</td>
<td>1.15</td>
<td>a</td>
</tr>
<tr>
<td>CLASS 5-C</td>
<td>8.39</td>
<td>1.00</td>
<td>1.15</td>
<td>a</td>
</tr>
<tr>
<td>CLASS 6</td>
<td>10.25</td>
<td>1.00</td>
<td>1.15</td>
<td>a</td>
</tr>
<tr>
<td>CLASS 7</td>
<td>7.59</td>
<td>1.00</td>
<td>1.15</td>
<td>a</td>
</tr>
<tr>
<td>CLASS 8</td>
<td>12.46</td>
<td>1.00</td>
<td>1.15</td>
<td>a</td>
</tr>
<tr>
<td>CLASS 9</td>
<td>11.75</td>
<td>1.00</td>
<td>1.15</td>
<td>a</td>
</tr>
<tr>
<td>CLASS 10</td>
<td>12.12</td>
<td>1.00</td>
<td>1.15</td>
<td>a</td>
</tr>
<tr>
<td>CLASS 11</td>
<td>12.37</td>
<td>1.00</td>
<td>1.15</td>
<td>a</td>
</tr>
<tr>
<td>CLASS 12</td>
<td>12.87</td>
<td>1.00</td>
<td>1.15</td>
<td>a</td>
</tr>
</tbody>
</table>

**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.M.I. and similar type), backfilling machine operator, back and pull hoe operator, belt plant, blast or rotary drill, track or earth moving, boiler (when used for power), boom trucks, boring machine operator, bulldozer (all sizes), cableway operator, caisson auger, cableway operator, caisson 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, grader, head tower operator, hydro crane, hydraulic booms, lubrication unit on truck, maintenance engineer, mucking machine operator, multiple drum hoist (more than 1 drum in use), overhead crane, plate crane or similar type, pile driving machine operator, pump crane, push or snatch cats, quarry master or equivalent, ready mix concrete plants, road winders, rock bit sharpener (all types), scorpiboride, shovel, side boom, skimmer operator, slip form paver (C.M.I. and similar type), tire truck and repair, tractor drawn belt type graders, trenching machine, tractor shovel operator, truck crane, tunnel scoop mobile, well drilling machine winch, winch truck with A Frame.
POWER EQUIPMENT OPERATORS: HEAVY AND HIGHWAY CONT'D

CLASS 2
Airhoist operator, automatic fine grade machine (C.M.I. and similar type), belt placer (C.M.I. and similar type), bender machine (pipe), boring machine operator, continuous spreader and mixer, concrete hoist operator, concrete finishing machine, concrete mixer operator 1 cu. yd. or more, concrete saw - self-propelled, concrete spreader, conveyer operator, conveyer systems (belt or crate or similar), hoisting engine operator, house elevator (when used for hoisting), hydraulic jackmachine or similar type machine, industrial tractor, Kolman loader or similar type machine, locomotive operator, mixer for stabilized base self-propelled, mobile, plant engineer, push button hoist operator, roller machine operator, slip form paving (C.M.I. and similar type), snorkel, stone crushers, strato-tower, towel 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 heater (when 3 are in a battery), generator, pump operator (2 or 3 in battery)

CLASS 4
Firemen, jeep trencher, motorized hydraulic seeders, mulching machine power broom and rakes

CLASS 5-A
Aggregate bid operator, apprentice engineer or oiler, C.M.I. and similar type, concrete spreader, cement bid operators, concrete mixer operator (under 1 cu. mechanical heaters (when one or two are used), pump operator (one inch), pump operator (two inch), pump operator (three inch), revinius 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.
**SUPERSEDAS DECISION**

**STATE:** Ohio  
**COUNTIES:** Statewide  
**DECISION NO.:** OH77-2108  
**DATE:** Date of Publication  
**Supersedes Decision No. OH77-2063., dated April 15, 1977.**

**DESCRIPTION OF WORK:** Heavy and Highway Construction

---

<table>
<thead>
<tr>
<th>BRICKLAYERS &amp; STONE MASONS:</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appro Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bricklay * &amp; Stonemasons</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adams &amp; Scioto Cos.</td>
<td>$ 9.70</td>
<td>.20</td>
<td></td>
</tr>
<tr>
<td>Allen, Audairs, Mercer &amp; Van Kent Cos.</td>
<td>11.06</td>
<td></td>
<td>.20</td>
</tr>
<tr>
<td>Ashtabula, Crawford, Harbon, Holmes, Marion, Monron, Richland, &amp; Wayne Cos. &amp; York Co. (except Townships of Crawford, Richland, Kide &amp; Tymochtee)</td>
<td>10.63</td>
<td>.60</td>
<td>.60</td>
</tr>
<tr>
<td>ASHTRALA County Bricklayers</td>
<td>10.63</td>
<td>.60</td>
<td>.60</td>
</tr>
<tr>
<td>Ashville Bricklayers</td>
<td>10.63</td>
<td>.60</td>
<td>.60</td>
</tr>
<tr>
<td>Astraea County Bricklayers</td>
<td>10.25</td>
<td>.60</td>
<td>.60</td>
</tr>
<tr>
<td>Belmont &amp; Monroe Counties &amp; Jefferson County (Townships of Mt. Pleasant &amp; Warren &amp; City of Billionvales)</td>
<td>9.60</td>
<td>.60</td>
<td>.25</td>
</tr>
<tr>
<td>Brown, Clement &amp; Hamilton Cos. Bricklayers &amp; Stonemasons</td>
<td>11.24</td>
<td>.60</td>
<td>.60</td>
</tr>
<tr>
<td>Butler &amp; Warren Cos. &amp; Preble Co. (Townships of Dixon, Gratiot, Jerell, Lenier, &amp; Somers)</td>
<td>10.45</td>
<td>.45</td>
<td>.45</td>
</tr>
<tr>
<td>Carroll, Star &amp; Tuscarawas Cos. &amp; Magnifying Co. (Township of Smith)</td>
<td>10.79</td>
<td>.60</td>
<td>.60</td>
</tr>
<tr>
<td>Censasan, Clark &amp; Logan Cos.</td>
<td>10.66</td>
<td>.60</td>
<td>.60</td>
</tr>
<tr>
<td>Clinton &amp; Highland Cos.</td>
<td>8.50</td>
<td>.60</td>
<td>.60</td>
</tr>
<tr>
<td>Columbiana Co., Townships of Center, Elk Run, Fairfields, Middletown, New Waterford, Perry, Salem &amp; Unity, Mansfield Co. (except Smith Town)</td>
<td>11.36</td>
<td>.60</td>
<td>.60</td>
</tr>
</tbody>
</table>

---

**NOTICES**
<table>
<thead>
<tr>
<th>Fringe Benefits Payments</th>
<th>Education</th>
<th>Average</th>
<th>Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>H &amp; W</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic</td>
<td>Fringe</td>
<td>Vacation</td>
<td></td>
</tr>
<tr>
<td>Noble Co. (Twps. of Beaver, Buffalo, Marion, Seneca &amp; Wayne)</td>
<td>10.66</td>
<td>.70</td>
<td>1.00</td>
</tr>
<tr>
<td>Harrison Co. &amp; the remainder of Jefferson Co.</td>
<td>10.53</td>
<td>.50</td>
<td>.02</td>
</tr>
<tr>
<td>Jackson &amp; Vinton Cos.</td>
<td>10.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lawrence County</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lorain Co. &amp; the remainder of Lucas Co., the remainder of Fulton Co. &amp; Wood Co. (Twps. of Lake, Perrysburg &amp; Ross)</td>
<td>11.65</td>
<td>.73</td>
<td>.80</td>
</tr>
<tr>
<td>Portage &amp; Summit Cos.</td>
<td>10.97</td>
<td>.57</td>
<td>.50</td>
</tr>
<tr>
<td>Trumbull County</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Washington Co. &amp; the remainder of Noble Co.</td>
<td>10.46</td>
<td>.50</td>
<td>.70</td>
</tr>
<tr>
<td>The remainder of Wood Co. &amp; Huron. Co.</td>
<td>10.52</td>
<td>.50</td>
<td>.50</td>
</tr>
<tr>
<td>Ashland, Crawford, Huron, Lorain and Richland Counties</td>
<td>10.66</td>
<td>.70</td>
<td>1.00</td>
</tr>
<tr>
<td>Erie (East of B &amp; O Railroad Tracks)</td>
<td>10.66</td>
<td>.70</td>
<td>1.00</td>
</tr>
<tr>
<td>Erie (West of B &amp; O Railroad Tracks), Ottawa, Sandusky and Seneca Counties and City of Fostoria in Wood and Hancock Counties</td>
<td>11.97</td>
<td>.73</td>
<td>.50</td>
</tr>
<tr>
<td>Ashtabula, Cuyahoga, Geauga and Lake Counties</td>
<td>12.10</td>
<td>.77</td>
<td>1.25</td>
</tr>
<tr>
<td>Athens, Hocking, Vinton and Washington Counties</td>
<td>9.80</td>
<td>.50</td>
<td>.70</td>
</tr>
<tr>
<td>Belmont and Monroe Counties</td>
<td>10.52</td>
<td>.50</td>
<td>.50</td>
</tr>
<tr>
<td>Brown, Butler, Clermont, Clinton, Hamilton and Warren Counties</td>
<td>11.40</td>
<td>.60</td>
<td>.65</td>
</tr>
<tr>
<td>Carroll, Stark, Tuscarawas and Wayne Counties</td>
<td>10.28</td>
<td>.50</td>
<td>.50</td>
</tr>
<tr>
<td>Columbiana, Harrison and Jefferson Counties</td>
<td>10.40</td>
<td>.50</td>
<td>.50</td>
</tr>
<tr>
<td>Dearborn, Greene, Highland, Jefferson, Lawrence, Meigs, Pike, Ross, Scioto, Adams, Fayette, Gallia, Highland, Jackson, Lawrence, Meigs, Pike, Ross, &amp; Scioto Cos.</td>
<td>10.41</td>
<td>.40</td>
<td>.50</td>
</tr>
<tr>
<td>Allen, Auglaize, Champaign, Clark, Coshocton, Delaware, Fairfield, Franklin, Guernsey, Hardin, Holmes, Knox, Licking, Logan, Madison, Marion, Mercer, Morgan, Morrow, Muskingum, Noble, Perry, Pickaway, Putnam, Union, Van Wert, &amp; Wyandot Cos.</td>
<td>10.41</td>
<td>.40</td>
<td>.50</td>
</tr>
</tbody>
</table>
### Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Location</th>
<th>Hourly Rates</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Carpenters &amp; Piledriversmen</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Darke, Greene, Miami, Montgomery, Preble and Shelby Counties</td>
<td>$10.35</td>
<td>.65</td>
<td>1.00</td>
<td>.05</td>
</tr>
<tr>
<td>Darke, Greene, Miami, Montgomery, Preble and Shelby Counties</td>
<td>10.35</td>
<td>.65</td>
<td>1.00</td>
<td>.05</td>
</tr>
<tr>
<td>Darke, Greene, Miami, Montgomery, Preble and Shelby Counties</td>
<td>11.29</td>
<td>.73</td>
<td>.40</td>
<td></td>
</tr>
<tr>
<td>Darke, Greene, Miami, Montgomery, Preble and Shelby Counties</td>
<td>11.97</td>
<td>.73</td>
<td>.50</td>
<td>.05</td>
</tr>
<tr>
<td>Defiance,Henry,Paulding</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Defiance, Henry, Paulding</td>
<td>11.97</td>
<td>.73</td>
<td>.50</td>
<td>.05</td>
</tr>
<tr>
<td>Defiance, Henry, Paulding</td>
<td>11.97</td>
<td>.73</td>
<td>.50</td>
<td>.05</td>
</tr>
<tr>
<td>Fulton, Hancock, Lucas and Wood Counties, excluding the City of Youngstown in Hancock and Wood Counties</td>
<td>11.97</td>
<td>.73</td>
<td>.50</td>
<td>.05</td>
</tr>
<tr>
<td>Fulton, Hancock, Lucas and Wood Counties, excluding the City of Youngstown in Hancock and Wood Counties</td>
<td>11.97</td>
<td>.73</td>
<td>.50</td>
<td>.05</td>
</tr>
<tr>
<td>Macon and Trumbull Counties</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Macon and Trumbull Counties</td>
<td>9.45</td>
<td>.87</td>
<td>.65</td>
<td>.02</td>
</tr>
<tr>
<td>Macon and Trumbull Counties</td>
<td>10.60</td>
<td>1.07</td>
<td>.80</td>
<td>.02</td>
</tr>
<tr>
<td>Medina, Portage and Summit Counties</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medina, Portage and Summit Counties</td>
<td>11.55</td>
<td>.50</td>
<td>.70</td>
<td>.02</td>
</tr>
<tr>
<td>Medina, Portage and Summit Counties</td>
<td>12.10</td>
<td>.77</td>
<td>1.25</td>
<td>.03</td>
</tr>
<tr>
<td>cement Masons</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cuyahoga, Fulton, Geauga, Hancock, Henry, Licking, Lorain, Lucas, Putnam, and Wood Counties</td>
<td>11.33</td>
<td>.60</td>
<td>.15</td>
<td>.02</td>
</tr>
<tr>
<td>Ashtabula, Brown, Butler, Columbiana, Defiance, Erie, Hamilton, Highland, Huron, Mahoning, Medina, Ottawa, Paulding, Portage, Sandusky, Seneca, Stark, Summit, Trumbull, Warren, and Williams Counties</td>
<td>10.48</td>
<td>.60</td>
<td>.15</td>
<td>.02</td>
</tr>
<tr>
<td>Remaining Counties</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remaining Counties</td>
<td>9.88</td>
<td>.60</td>
<td>.15</td>
<td>.02</td>
</tr>
<tr>
<td>Footnote: 1 Paid Holiday: Memorial Day and Independence Day.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Location</th>
<th>Hourly Rates</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allen, Ashtabula, Harris, Logan, Mercer, Shelby, &amp; Van Wert Counties, &amp; Wyandot Co. (West of Crane, Pits, &amp; Tymochtee Twp.)</td>
<td>10.94</td>
<td>.31</td>
<td>1.02</td>
<td>.04</td>
</tr>
<tr>
<td>Ashtabula, Crawford, Marion, Morrow &amp; Richland Co., Wyandot Co. (Remainder of County), Richland Co. (North &amp; including Clinton, Howard, Liberty, Monroe &amp; Union Twp.), &amp; Marion Co. (Twp. of Greenwich, New Haven, Richmond &amp; Ripley)</td>
<td>11.35</td>
<td>.45</td>
<td>1.06</td>
<td>.18</td>
</tr>
<tr>
<td>Athens, Kidder, Monroe, Noble &amp; Washington Co., &amp; Vinton Co. (East of Clinton, Elk &amp; Swan Twp.)</td>
<td>12.00</td>
<td>.90</td>
<td>1.02</td>
<td>.28</td>
</tr>
<tr>
<td>Belmont Co.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brown, Clermont &amp; Hamilton Counties</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 18 Mi. of Hamilton County Court House</td>
<td>11.30</td>
<td>.70</td>
<td>1.02</td>
<td>.04</td>
</tr>
<tr>
<td>From 18 to 21 Miles</td>
<td>11.60</td>
<td>.70</td>
<td>.95</td>
<td>.03</td>
</tr>
<tr>
<td>From 21 to 25 Miles</td>
<td>11.70</td>
<td>.70</td>
<td>.95</td>
<td>.03</td>
</tr>
<tr>
<td>Over 25 Miles</td>
<td>11.85</td>
<td>.70</td>
<td>.95</td>
<td>.03</td>
</tr>
<tr>
<td>Butler County &amp; Warren Co.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excluding Clear Creek, Franklin &amp; Wayne Twp. Within City Limits of Butler or Hamilton Counties, Outside City Limits West of Interstate 75</td>
<td>11.40</td>
<td>.60</td>
<td>1.02</td>
<td>.04</td>
</tr>
<tr>
<td>Outside City Limits East of Interstate 75</td>
<td>11.75</td>
<td>.60</td>
<td>1.02</td>
<td>.04</td>
</tr>
<tr>
<td>Champaign &amp; Clark Co. &amp; Morgan Co. (Twp. of Paint, Pike, Somerford, Stokes &amp; Union)</td>
<td>10.45</td>
<td>.45</td>
<td>1.02</td>
<td>.04</td>
</tr>
</tbody>
</table>

---

Federal Register, Vol. 42, No. 131—Friday, July 8, 1977
### Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Electricians (Cont'd)</th>
<th>Basic Hours Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
</table>
| Clinton, Darke, Greene, Miami, Montgomery & Preble Co.s, & Warren Co. (Rem. of Co.) Within 11 Mi. radius of 3rd & Main Streets, Dayton Beyond 11 Mi. radius Columbiana Co. (except Twp. of Butler, Fairfield, Knox, Perry, Salem, & Unity) Coshocton Co., Knox (Jackson, Clay, Morgan, Miller, Milford, Hilliard, Butler, Harrison, Pleasant, & College Twp.s), Hocking Co., (incl. Twp. of Auburn, Clay, Rush, York, Salem, Jefferson, Oxford, Washington, Perry, & Bucks) Guernsey, Muskingum and Perry Cos. Harrison and Jefferson Counties and Carroll County (south of Fox, Harrison, Rose and Washington Twp.s) Holmes and Stark Counties, the remainder of Carroll and Tuscarawas Counties, Columbiana County (Kees Twp.), Mahoning County (Smith Twp.), and Wayne County (South of Springfield, Chester, Green and Wayne Twp.s) Lake County and Geauga County (all but Auburn, Bainbridge, Chester, Middlefield, Parkman, Russell, and Troy Twp.s) Lawrence County Lorain County (remainder of Co.) and Medina County (Twp. of Smithsonian and Smith Twp.s), Trumbull Co. (Twp. of Hubbard and Liberty) and Columbiana County (Twp. of Butler, Fairfield, Perry, Salem and Unity) Summit County, the remainder of Medina and Wayne Counties and Portage County (excluding Twp. of Charleston, Edinburg, Freedom, Hiram, Palmyra, Paris and Windham) Morgan County Ashtabula (remainder of Co.), Rem. of Portage and Trumbull Counties, Geauga County (Twp. of Auburn, Middlefield, Parkman and Troy), and Mahoning County (Twp. of Milton) Cuyahoga, Lorain Co. (Twps. of Columbia), & Geauga Co. (Twps. of Bainbridge, Chester & Russell) Delaware, Fairfield, Franklin, & Union Co.s, Madison (Rem. of Co.), & Pickaway Co. (Excl. Deer Creek, Perry, Pickaway, Salt Creek & Wayne Twp.s) Erie Co., Huron Co. (Rem. of Co.) Fayette, Highland, Hocking, & Ross Co.s, & Jackson Co. (Rem. of Co.), Pickaway, Pike & Vinton Co.s Gallia Co. 

---

Footnote: a. 9 paid holidays: New Year’s Day; Memorial Day; Independence Day; Labor Days; Thanksgiving Day; Christmas Day; Good Friday; Day after Thanksgiving Day and Day before Christmas
<table>
<thead>
<tr>
<th>DECISION NO. OH77-2108</th>
<th>DECISION NO. OH77-2108</th>
</tr>
</thead>
</table>

### Ironworkers

**Ironworkers:**
ADCMS (Part), BROWN, CLEMONT and HAMILTON Counties and the South half of BUTLER and WARREN Cos. Structural and Ornamental Reinforcing

**Ironworkers:**
ADAMS, ALVALE, CLINTON, DARKE, GREENE, MERCER, MIAMI, MONTGOMERY, PENDLE & SMELBY Cos., the North 1/4 of BUTLER & WARREN Cos., the West 2/5 of CLARK & LOGAN Cos., the West 3/5 of CLARK Co., & the West 4/5 of RICHLAND Co., Dayton Metropolitan Area
Outside Dayton Metro Area
ASHLAND, CRAWFORD, MARION, RICHLAND, STARK, TUSCARA
NAS, & WAYNE Cos.
CUMBERLAND, ENTRANCE, HEBRON, LAKE, LOBAIN, MEDINA & SUMMIT, Cos., & ASHTABULA Co. (except the Ravenna Ordinance Dept.)
ASHTABULA (Remainder of Co.)
ATHENS, MEIGS, MORGAN, NOBLE, & SCOTT COS.
BELMONT, GIBSON, HARRIS, JEFFERSON & NEMOURS COS.
COLUMBIA, MARSHING & TROYNELL, COS. & The Ravenna Ordinance Dept in PORTAGE CO.
CRANDALL, PAULY, RAYMOND, NOCKING, JACKSON (9 1/2 of Co.), KNOX, MARION, MERCER, MUSKINGUM, PERRY, PIKE (P.), ROSS, VINTON, WARREN, & the rem. of CLARK, CLARK, RICHLAND & LOGAN Cos.
DELAWARE, FAIRFIELD, LICKING, MASON, PICKAWAY & UNION COS.
FRANKLIN Co.
FRANKTOWN, MARSHING, PUTNAM, HANCOCK, RICHLAND, & WASHINGTON CO.
FULTON, HACOCK, HENRY, LUCAS, MCDONALD, GALCIA, SCIOTO, ADAMS (P.), JACKSON (8 1/2 of Co.), & PIKE (P.) COs.
GALLIA, LAWRENCE, SCOTT, ADAMS (P), JACKSON (8 1/2 of Co.), & PIKE (P.) COs.

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
</tr>
<tr>
<td>11.48</td>
<td>0.90</td>
<td>1.05</td>
</tr>
<tr>
<td>11.06</td>
<td>0.90</td>
<td>1.05</td>
</tr>
<tr>
<td>10.06</td>
<td>0.90</td>
<td>1.25</td>
</tr>
<tr>
<td>11.11</td>
<td>0.90</td>
<td>1.25</td>
</tr>
<tr>
<td>11.11</td>
<td>0.70</td>
<td>0.75</td>
</tr>
<tr>
<td>11.22</td>
<td>0.80</td>
<td>1.10</td>
</tr>
<tr>
<td>10.92</td>
<td>0.75</td>
<td>0.85</td>
</tr>
<tr>
<td>9.30</td>
<td>0.60</td>
<td>0.50</td>
</tr>
<tr>
<td>11.76</td>
<td>0.40</td>
<td>1.15</td>
</tr>
<tr>
<td>11.76</td>
<td>0.75</td>
<td>1.35</td>
</tr>
<tr>
<td>11.20</td>
<td>0.40</td>
<td>1.20</td>
</tr>
<tr>
<td>11.35</td>
<td>0.75</td>
<td>1.35</td>
</tr>
<tr>
<td>11.20</td>
<td>0.75</td>
<td>1.35</td>
</tr>
<tr>
<td>11.20</td>
<td>0.90</td>
<td>1.20</td>
</tr>
<tr>
<td>11.75</td>
<td>0.73</td>
<td>1.06</td>
</tr>
</tbody>
</table>

**Linden**

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
</tr>
<tr>
<td>11.04</td>
<td>0.45</td>
<td>34.50</td>
</tr>
<tr>
<td>11.38</td>
<td>0.45</td>
<td>34.50</td>
</tr>
<tr>
<td>12.00</td>
<td>0.90</td>
<td>34.65</td>
</tr>
<tr>
<td>10.50</td>
<td>0.50</td>
<td>34.32</td>
</tr>
<tr>
<td>12.00</td>
<td>0.90</td>
<td>34.65</td>
</tr>
<tr>
<td>11.00</td>
<td>1.20</td>
<td>34.40</td>
</tr>
<tr>
<td>11.30</td>
<td>0.70</td>
<td>34.40</td>
</tr>
<tr>
<td>11.50</td>
<td>0.70</td>
<td>34.40</td>
</tr>
<tr>
<td>11.70</td>
<td>0.70</td>
<td>34.40</td>
</tr>
<tr>
<td>11.95</td>
<td>0.70</td>
<td>34.40</td>
</tr>
<tr>
<td>11.20</td>
<td>0.90</td>
<td>34.45</td>
</tr>
<tr>
<td>11.74</td>
<td>0.40</td>
<td>34.45</td>
</tr>
<tr>
<td>11.99</td>
<td>0.40</td>
<td>34.45</td>
</tr>
</tbody>
</table>

**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
### Fringe Benefits Payments

<table>
<thead>
<tr>
<th>County, City, Township</th>
<th>FR &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education &amp; Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CHAMPAIGN, CLARK COS.</strong></td>
<td>9.143</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>CLINTON, DARKE, GREENE, MIAMI, MONTGOMERY, &amp; PREBLE Cos. &amp; WARREN CO. (Rem. of Co.)</strong></td>
<td>9.113</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>COLUMBIANA Co. except the Twps. of Butler, Fairfield, Perry, Salem &amp; Unity</strong></td>
<td>10.876</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>COSHOCTON &amp; TUSCARAWAS Cos.</strong></td>
<td>10.628</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>CUYAHOGA Co., GEAUGA Co. (Twps. of Bainbridge, Chester, &amp; Russell), LORAIN Co. (Columbia Twp.) &amp; MEDINA Co. (Twps. of Litchfield &amp; Liverpool)</strong></td>
<td>11.433</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>DEFIANCE, FULTON, HANCOCK, HENRY, LUCAS, OTTAWA, PAULDING, PUTNAM, SENECA, WILLIAMS &amp; WOOL Cos.</strong></td>
<td>11.433</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>DELAWARE, MADISON, PICKAWAY &amp; UNION Cos.</strong></td>
<td>11.433</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>ERIE Co., HURON Co. (Remainder of Co.)</strong></td>
<td>11.433</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>FAIRFIELD &amp; LICKING Cos. &amp; KNOX Co. (Remainder of Co.)</strong></td>
<td>10.876</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>FAYETTE, HIGHLAND, HOCKING &amp; ROSS Cos. &amp; the remainder of JACKSON, PIKE &amp; VINTON Cos.</strong></td>
<td>10.876</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>FRANKLIN Co.</strong></td>
<td>10.876</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>GUERNSEY Co.</strong></td>
<td>9.143</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>HARRISON, JEFFERSON Cos. &amp; CARROLL Co. (South of Fox, Harrison, Rose &amp; Washington Twps.)</strong></td>
<td>10.876</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>HOLMES, &amp; STARK Cos., CARROLL (Remainder of Co.), COLUMBIANA Co. (Knox Twp.), &amp; WAYNE Co. (South of Baughman, Chester, Green &amp; Wayne Twps.)</strong></td>
<td>11.433</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>LAKE CO. &amp; GEAUGA Co. except the Twps. of Auburn, Bainbridge, Chester, Middlefield, Parkman, Russell &amp; Troy</strong></td>
<td>11.433</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>LORAIN Co. (except Columbia Twp.) &amp; MEDINA Co. (Twps. of Litchfield &amp; Liverpool)</strong></td>
<td>11.433</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>MAHONING &amp; TRUMBULL Cos., ASHTABULA Co. (Remainder of Co.)</strong></td>
<td>11.433</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>COLUMBIANA Co. (Twps. of Butler, Fairfield, Perry, Salem &amp; Unity)</strong></td>
<td>11.433</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>GEAUGA Co. (Townships of Auburn, Middlefield, Parkman, &amp; Troy)</strong> &amp; PORTAGE Co. (Twps of Charlestown, Edinburg, Freedom, Hiram, Nelson, Palmyra, Paris &amp; Windham)**</td>
<td>11.433</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>MONROE, NOBLE &amp; WASHINGTON Cos.</strong></td>
<td>11.433</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>MUSKINGUM &amp; PERRY COS.</strong></td>
<td>11.433</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
<tr>
<td><strong>SUMMIT Co. &amp; the remainder of MEDINA, PORTAGE &amp; WAYNE Cos.</strong></td>
<td>11.433</td>
<td>-30 781.00</td>
<td>-40 320.00</td>
<td>86</td>
</tr>
</tbody>
</table>

**FOOTNOTES**

- a. 9 paid holidays: New Year's Day; Thanksgiving Day; Christmas Day; Thanksgiving Day; Christmas Eve; New Year's Eve & Day after New Year's Day.

### Painters

#### Basic Hourly Rates

<table>
<thead>
<tr>
<th>County, City, Township</th>
<th>Basic Hourly Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCIOTO COS.</td>
<td>11.433</td>
</tr>
</tbody>
</table>

#### Sprays

<table>
<thead>
<tr>
<th>County, City, Township</th>
<th>Sprays Hourly Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCIOTO COS.</td>
<td>11.433</td>
</tr>
</tbody>
</table>
### DECISION NO. OH77—21Q8

#### PAINTERS: (CONT'D)

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allen, AuSable, Defiance, Hardin, Mercer, Paulding, Putnam, Shelby, Van Wert and Williams Counties</td>
<td>$8.90</td>
<td>.73</td>
<td>.50</td>
<td>.03</td>
<td>.69</td>
</tr>
<tr>
<td>Ashland, Crawford, Marion, Monroe, and Richland Counties</td>
<td>Brush 8.95</td>
<td>.50</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Structural Steel 8.55</td>
<td>.50</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spray 8.80</td>
<td>.50</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Athens and Hocking Counties</td>
<td>Brush 11.08</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spray 12.08</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belmont County</td>
<td>Brush 7.50</td>
<td>.30</td>
<td>.25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brown, Clermont and Hamilton Cos.</td>
<td>Brush 10.80</td>
<td>.25</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spray 11.20</td>
<td>.25</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Butler and Warren Counties</td>
<td>Brush 10.23</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spray 10.73</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carroll, Holmes, Stark, Tuscarawas and Wayne Counties</td>
<td>Brush 9.47</td>
<td>.55</td>
<td>.50</td>
<td>.02</td>
<td>.62</td>
</tr>
<tr>
<td></td>
<td>Spray 9.97</td>
<td>.55</td>
<td>.50</td>
<td>.02</td>
<td>.62</td>
</tr>
<tr>
<td></td>
<td>Structural Steel 10.19</td>
<td>.55</td>
<td>.50</td>
<td>.02</td>
<td>.62</td>
</tr>
<tr>
<td>Clay, Clark and Logan Cos.</td>
<td>Brush 7.60</td>
<td>.10</td>
<td>.25</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Structural Steel 8.35</td>
<td>.10</td>
<td>.25</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spray 8.50</td>
<td>.10</td>
<td>.25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinton, Darke, Greene, Miami, Montgomery and Preble Counties</td>
<td>Brush 11.55</td>
<td>.40</td>
<td>.40</td>
<td>.02</td>
<td>.62</td>
</tr>
<tr>
<td></td>
<td>Structural Steel 11.45</td>
<td>.40</td>
<td>.40</td>
<td>.02</td>
<td>.62</td>
</tr>
<tr>
<td></td>
<td>Spray 21.55</td>
<td>.40</td>
<td>.40</td>
<td>.02</td>
<td>.62</td>
</tr>
</tbody>
</table>

**PORTAGE and SUMMIT Counties**

- **North of the Ohio Turnpike**
  - Brush $11.66 | .63 | .74 | .05 |
  - Closed steel below 55'; Spray 12.06 | .63 | .74 | .05 |
- **Bridge and open steel; closed steel over 55'; Spray 12.06 | .63 | .74 | .05 |

**DELAWARE, FAIRFIELD, FAYETTE, FRANKLIN, MADISON, PICKAWAY and UNION Counties**

- **Brush 9.45 | .55 | .55 | .05 |
- **Structural Steel 9.75 | .55 | .55 | .05 |
- **Spray 9.95 | .55 | .55 | .05 |

**BELMONT County**

- **Brush 7.50 | .30 | .25 | | |

**ERIE, HANCOCK, HURON, SANDUSKY, SENECA and WYANDOT Counties**

- **Brush 8.95 | .50 | .50 | | |
- **Structural Steel and Bridges 9.65 | .50 | .50 | | |

**FULTON, HENRY, LUCAS, OTOE, and WOOD Counties**

- **Brush 8.95 | .50 | .50 | | |
- **Spray 9.55 | .50 | .50 | | |

**GALLIA, LAWRENCE, MEIGS, and VINTON Counties**

- **Brush 9.45 | .48 | .48 | .02 |
- **Spray 9.75 | .48 | .48 | .02 |

**GUERNSEY County**

- **Brush 7.00 | .30 | .25 | | |
- **Structural Steel 7.50 | .30 | .25 | | |
- **Spray and Bridges 8.75 | .30 | .25 | | |

**HARRISON and JEFFERSON Counties**

- **Brush 7.70 | .30 | .25 | | |
- **Spray and Sandblaster 8.30 | .30 | .25 | | |
- **Hot Stacks 9.30 | .30 | .25 | | |
- **BRIDGE 8.00 | .30 | .25 | | |

**LORAIN County (Remainder of Cty.)**

- **Brush 9.05 | .48 | .48 | .02 |
- **Spray 9.55 | .48 | .48 | .02 |
- **Structural Steel and Bridge 10.35 | .48 | .48 | .02 |
<table>
<thead>
<tr>
<th>DECISION NO. OH77-2108</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAINTERS (CONT'D)</td>
<td></td>
<td></td>
<td>Attr. Tr.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
<tr>
<td>COLUMBIANA, MAHONING &amp; TRUMBULL Cos. &amp; the Ravenna Ordnance Depot in PORTAGE County</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brush</td>
<td>Spray</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDINA Co. &amp; PORTAGE &amp; SUMMIT Co. South of Ohio Turnpike excluding the Ravenna Ordnance Depot in PORTAGE Co.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brush</td>
<td>Spray</td>
<td>Structural Steel</td>
<td></td>
</tr>
<tr>
<td>MINERVA, MORGAN,ホール &amp; WASHINGTON Co.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brush</td>
<td>Spray</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PLUMBERS &amp; STEAMFITTERS:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADAMS, ATHENS, CALLA, HIGHLAND, JACKSON, LAWRENCE, PIES, SCIO, &amp; VINTON Co.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALLEN, AUGLAIZE, HARDIN, MERCE, &amp; WARNEI Co.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASHLAND, CRICKET, ROY, HERON, KNOX, DORIS, MORRIS, RICHARD &amp; WABASH Co.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASHTABULA, CUYAHOGA, GEAUGA &amp; LAKE Co. &amp; MEDINA Co. N. of Rt. 18 &amp; Smith Rd. &amp; SUMMIT Co. N. of Rt. 18 - Plumbers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ELBERT Co. &amp; HUNDR Co. South of Rt. 78</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BRUN, CLEMON, HAMILTON &amp; MARSH Co.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plumbers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STEAMFITTERS:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BUTLER Co. North half</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BUTLER Co. South half</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COLUMBUS Co. (except Twp. of Hoon, Monroe, Union, Lee, Orange, Perry &amp; London), STARK &amp; WAYNE Co.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COLUMBUS (Twp. of Ross, Monroe, Union, Lee, Orange, Perry &amp; London) CORBICHTON, GUARDIAN, KELLY, MORGAN (South of State Route 178 &amp; from McConnellsville West on State Route 41 to the Perry Co. line), MUSKINGUM, NOBLE, &amp; TUSCARAWAS Co.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHAMPAIGN, CLARK &amp; LOGAN Co., GREENE Co. (Twp. of Cedarville, Cereal Creek, New Jersey, Jefferson, &amp; Ross), MADISON Co. (West of Rt. 38 including the City of London)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLINTON, DRUMS, FAYETTE, FAYETTE, KENTUCKY, FIBER &amp; SHERIDAN Co. &amp; GREENE Co. (Remainder of Co.)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COLUMBIANA &amp; MARION Co. &amp; TRUMBULL Co. (Hubbard Liberty Twp, Elyton Town Municipal Airport &amp; the Filtration Plant of the Mahoning Valley Sanitary District)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
<th>Basic Hourly Rates</th>
<th>Basic Hourly Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 1</td>
<td>$9.53</td>
<td>$9.70</td>
<td>$9.27</td>
</tr>
<tr>
<td>Zone 3</td>
<td>$9.73</td>
<td>$9.99</td>
<td>$8.67</td>
</tr>
<tr>
<td>Zone 4</td>
<td>$9.88</td>
<td>$9.05</td>
<td>$8.62</td>
</tr>
<tr>
<td>Zone 5</td>
<td>$10.18</td>
<td>$9.35</td>
<td>$9.92</td>
</tr>
</tbody>
</table>

**GROUP I - Laborers (construction):**
- Plant laborers or yardmen; right-of-way laborers; landscape laborers; utility man or handyman; joint setters; flagmen; carpenter helper; waterproofing laborers; slump seal; seal coating surface treatment or road mix laborers; Asphalt laborer; Dump man (batch trucks); Sign Installer; Gardeil & fence installers; mesh handlers & placers; concrete pumper applicator; scaffold erector; HDPE laborers & grinders; Grade checker
- Asphalt raker; concrete puddler; kettle man (pipelines); machine driven tools; mason tender; mortar mixer; sheeting & aboring; surface grider; power buggy or power wheelbarrow
- Blaster; Powder man; muckers; wrencher (mechanical joints & utility pipeline); yarner; top lander
- Curb setter & cutter; miner without air; concrete crew in tunnels; utility pipeline tapper; gunnite nozzle man; waterline caulker

**ZONE DEFINITIONS**
- Zone 1 - Cuyahoga, Geauga & Lake Cos.
- Zone 3 - Remainder of Counties
**POWER EQUIPMENT OPERATORS**

**ZONE 1 - Columbiana, Mahoning & Trumbull Counties**

<table>
<thead>
<tr>
<th>CLASS</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>CLASS I</td>
<td>12.01</td>
<td>.65</td>
</tr>
<tr>
<td>CLASS II</td>
<td>11.32</td>
<td>.65</td>
</tr>
<tr>
<td>CLASS III</td>
<td>10.68</td>
<td>.65</td>
</tr>
<tr>
<td>CLASS IV</td>
<td>10.27</td>
<td>.65</td>
</tr>
<tr>
<td>CLASS V</td>
<td>10.17</td>
<td>.65</td>
</tr>
<tr>
<td>CLASS VI</td>
<td>12.28</td>
<td>.65</td>
</tr>
</tbody>
</table>

**CLASS I - Asphalt planer heater; Austin western & similar type; Backhoe; Batch plant-central mix; Batch plant-portable concrete; Berm builder-automatic; Backfiller w/drag attachment; Boat derrick; Boat-tug; Boring mach. attached to tractor; Halliclaim; Bulldozer; C.M.I. road builder & similar types; Cable plater & layer; Carrier-straddle; Carryall - scraper or scogy; Chicago boom; Compactor w/blade attached; Concrete spreader-finisher comb.; Crane; Crane-stationary or climbing; Crane-electric overhead; Crane-side boom; Crane truck; Crane-tower; Derrick-boom; Derrick-car; Digger-wheel (not trencher or road widener); Double nine; Drag line; Dredge; drill-Kenny or similar type; Electromatics; Fork lift; Frankie pile; Grader; Grader-power; Gurry; Gurry-self-propelled; High lift; Holst-monorail; Hoist-mobile tractor; Hoist-2 or 3; Jackall; Jumbo; Kocal or Kuhlman; Land-seeding vehicle; Loader - Elevating; Loader-front ends; Locomotive; Mechanical as welder; Metro clip Harvester w/boom; Mowing mach.; Paver-aspalt finishing mach.; Paver-road concrete; Paver-slip form; Placecrete mach.; Post driver; Power driven hydraulic pumps & jacks; Pump crete machine; Regulator-ballast; Recharge-drilling; Shovels; Spikehammer; Stonecrusher; Tie puller & loaders; Tie tamper; Tractor-double boom; Tractor w/attachments; Trucks-boom; Truck-tire-assigned to job; Trench mach.; Tunnel machine; (Mark 21; Java or similar); Wally; **

**CLASS II - Asphalt plant; Bending machine; Boring mach.; Chip harvester w/o boom; Cleaning mach.-pipeline type; Coating Mach-pipeline type; Concrete belt planer; Concrete finisher; Concrete planer or asphalt; Concrete spreader; Elevator; Fork lift; walk behind; form line mach.; Grease truck op.; Grout pumps; Gunite mach.; Hauling bolting Mach.; Hydraulic scaffold; Paving breaker; Pipe dream; Pot fires; Power broom; Refrigeration plants; Sander derrick; Seeding Mach.; Self-propelled mobile vibratory compactor or roller; Soil-stabilizer (pump type); Spray cures Mach.-self-propelled; Straw blower mach.; Sub-grader; Tube Finisher or broom C.M.I. or similar type; Tugger Boist **

**CLASS III - Batch plant-job related; Boiler op.; Compressor (125 CFM or over); Curb builder (self-propelled); Generator-steam; Jack-hydraulic driven; Mixer-concrete; Mulching Mach.; Fin puller; Pulverizer; Pump; Road finishing mach. (pulite type); roller; Saw-concrete-self propelled; signal; man; spray cures mach.-motor powered; Spreader (side driver shoulder attachment); Crane; Trencher-form; Water Blaster**

**CLASS IV - Brake man; Compressor under 125 CFM; Conveyor; Conveyor 12 feet or under; other than servicing bricklayers; Deck hand; Drill wagon; furnace; Generator sets; Heaters-portable power (2 to 5); Helper-mechanic; Jacks; Hydraulic (railroad); Ladderbot; Mover (walk behind 1 ton or over); Steam jenny; Hyphons; Vibrator-gasoline; Welding machines (2) (fuel burning)**

**CLASS V - Oiler**

**CLASS VI - Rigs-pile driving or caisson type**
<table>
<thead>
<tr>
<th>CLASS</th>
<th>BASE HOURS RATE</th>
<th>H &amp; W</th>
<th>PENSION</th>
<th>VACATION</th>
<th>EDUCATION</th>
<th>APPR. TR.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>$12.03</td>
<td>.56</td>
<td>1.00</td>
<td>.15</td>
<td>.15</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>11.93</td>
<td>.56</td>
<td>1.00</td>
<td>.15</td>
<td>.15</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>11.89</td>
<td>.56</td>
<td>1.00</td>
<td>.15</td>
<td>.15</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>10.42</td>
<td>.56</td>
<td>1.00</td>
<td>.15</td>
<td>.15</td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>8.73</td>
<td>.56</td>
<td>1.00</td>
<td>.15</td>
<td>.15</td>
<td></td>
</tr>
</tbody>
</table>

**ZONE DEFINITIONS**

**ZONE 2** - Ashtabula, Cuyahoga, Erie, Geauga, Lake, Lorain, Medina, Portage & Summit Counties

**ZONE 3** - Remainder of counties
<table>
<thead>
<tr>
<th>CLASS</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>H &amp; W Pensions</td>
<td>Vacation</td>
<td></td>
</tr>
<tr>
<td>CLASS I</td>
<td>$7.70</td>
<td>26.00a</td>
<td>b&amp;C</td>
</tr>
<tr>
<td>CLASS II</td>
<td>$7.85</td>
<td>26.00a</td>
<td>b&amp;C</td>
</tr>
<tr>
<td>CLASS III</td>
<td>$8.20</td>
<td>26.00a</td>
<td>b&amp;C</td>
</tr>
<tr>
<td>CLASS IV</td>
<td>$8.20</td>
<td>26.00a</td>
<td>b&amp;C</td>
</tr>
</tbody>
</table>

CLASS I - Straight & dumps (including asphalt); Warehousemen; Straight fuel.
CLASS II - Semi fuel; semi pole drivers (hauling steel pipe); & semi tractor drivers.
CLASS III - Ready-mix; agitator or bulk concrete drivers; dry batch truck.
CLASS IV - Euclids; darts; tank asphalt spreaders; low boys; carry-all drivers; toucher drivers; hi-lifts; forklifts; extra long trailers; semi pole trailers except when hauling steel pipe; double hook-up tractors; trailers including team track & railroad siding; semi tractor & tri-axle trailer; tandem tractor; tandem trailer & tri-axle trailer; tag 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. Per 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>CLASS</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>H &amp; W Pensions</td>
<td>Vacation</td>
<td></td>
</tr>
<tr>
<td>CLASS I</td>
<td>$8.52</td>
<td>23.00a</td>
<td>.05</td>
</tr>
<tr>
<td>CLASS II</td>
<td>$8.57</td>
<td>23.00a</td>
<td>.05</td>
</tr>
<tr>
<td>CLASS III</td>
<td>$8.72</td>
<td>23.00a</td>
<td>.05</td>
</tr>
<tr>
<td>CLASS IV</td>
<td>$9.15</td>
<td>23.00a</td>
<td>.05</td>
</tr>
<tr>
<td>CLASS V</td>
<td>$9.99</td>
<td>23.00a</td>
<td>.05</td>
</tr>
</tbody>
</table>

CLASS I - 4 wheel service trucks; 4 wheel dump trucks; batch trucks; oil distributors; asphalt distributors.
CLASS II - Tandem.
CLASS III - Semi tractor trucks; pole trailers; fuel trucks.
CLASS IV - All trucks five axle & over.
CLASS V - Asphalt oiler spraybar man when operated from cab.
CLASS VI - Euclid wagons; Euclid end dumps; load boys; heavy duty equipment over 12 cu. yds. capacity when used exclusively for transportation; truck mechanics.

FOOTNOTE:
a. Per week per employee.
**SUPERSEDES DECISION**

**STATE: PUERTO RICO**  
**COUNTY: ISLAND WIDE**  
**DECISION NO.: PR77-3696**  
**DATE: DATE OF PUBLICATION**

Supersedes Decision No. PR75-3091 dated August 8, 1975 in FR 33613.

**DESCRIPTION OF WORK:** Residential Construction consisting of single family homes and garden type apartments up to and including 4 stories.

---

**SUPERSEDES DECISION**

**STATE: PUERTO RICO**  
**COUNTY: ISLAND WIDE**  
**DECISION NO.: PR77-3090**  
**DATE: DATE OF PUBLICATION**

Supersedes Decision No. PR75-3091 dated August 8, 1975 in FR 33613.

**DESCRIPTION OF WORK:** Building Construction, (does not include single family homes and garden type apartments up to and including 4 stories).

---

### Basic Hourly Rates

<table>
<thead>
<tr>
<th>Trade</th>
<th>Basic Hourly Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bricklayers</td>
<td>$2.50</td>
</tr>
<tr>
<td>Carpenters</td>
<td>$2.25</td>
</tr>
<tr>
<td>Cement Masons</td>
<td>$2.50</td>
</tr>
<tr>
<td>Electricians</td>
<td>$2.50</td>
</tr>
<tr>
<td>Ironworkers, Reinforcing</td>
<td>$2.25</td>
</tr>
<tr>
<td>Ladders</td>
<td>$2.25</td>
</tr>
<tr>
<td>Painters</td>
<td>$2.25</td>
</tr>
<tr>
<td>Plumbers</td>
<td>$2.25</td>
</tr>
<tr>
<td>Roofers</td>
<td>$2.25</td>
</tr>
<tr>
<td>Truck Drivers:</td>
<td>$2.25</td>
</tr>
<tr>
<td>Power Equipment Operators:</td>
<td></td>
</tr>
<tr>
<td>Bulldozer</td>
<td>$1.45</td>
</tr>
<tr>
<td>Crane</td>
<td>$1.50</td>
</tr>
<tr>
<td>Digger and Transcavator</td>
<td>$2.65</td>
</tr>
</tbody>
</table>

### Fringe Benefits Payments

<table>
<thead>
<tr>
<th></th>
<th>H &amp; W</th>
<th>Pension</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bricklayers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carpenters</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cement Masons</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ironworkers, Reinforcing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ladders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Painters</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plumbers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roofers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Truck Drivers:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulldozer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crane</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Digger and Transcavator</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
SUPERSEDES DECISION
STATE: PUERTO RICO  COUNTY: ISLAND WIDE
DECISION NO.: PR77-3089  DATE: DATE OF PUBLICATION
Supersedes Decision No. PR75-3089 dated August 8, 1975 in FR33613
DESCRIPTION OF WORK: Heavy and Highway Construction.

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
<tr>
<td>Carpenters</td>
<td>$2.69</td>
</tr>
<tr>
<td>Cement Masons</td>
<td>$2.19</td>
</tr>
<tr>
<td>Electricians</td>
<td>$2.85</td>
</tr>
<tr>
<td>Ironworkers</td>
<td>$2.25</td>
</tr>
<tr>
<td>Laborers:</td>
<td></td>
</tr>
<tr>
<td>Laborers</td>
<td>$2.25</td>
</tr>
<tr>
<td>Air tool operator (jackhammer, vibrator)</td>
<td>$2.85</td>
</tr>
<tr>
<td>Asphalt raker</td>
<td>$2.22</td>
</tr>
<tr>
<td>Pile drivers</td>
<td>$2.15</td>
</tr>
<tr>
<td>Plumbers and Pipefitters</td>
<td>$2.70</td>
</tr>
<tr>
<td>Truck Drivers:</td>
<td></td>
</tr>
<tr>
<td>1/4 ton to 3 ton</td>
<td>$2.50</td>
</tr>
<tr>
<td>3/4 ton to 5 ton</td>
<td>$2.90</td>
</tr>
<tr>
<td>Heavy, over 5 ton</td>
<td>$3.90</td>
</tr>
<tr>
<td>Bulldozer</td>
<td>$3.80</td>
</tr>
<tr>
<td>Velders</td>
<td>$3.05</td>
</tr>
<tr>
<td>Power Equipment Operators:</td>
<td></td>
</tr>
<tr>
<td>Hauler</td>
<td>$3.73</td>
</tr>
<tr>
<td>Crane, Derrick</td>
<td>$3.92</td>
</tr>
<tr>
<td>Digger</td>
<td>$3.50</td>
</tr>
<tr>
<td>Front End Loader</td>
<td>$3.32</td>
</tr>
<tr>
<td>Graveler</td>
<td>$3.40</td>
</tr>
<tr>
<td>Grader</td>
<td>$3.75</td>
</tr>
<tr>
<td>Mechanic</td>
<td>$3.90</td>
</tr>
<tr>
<td>Giler, Greaser</td>
<td>$9.50</td>
</tr>
<tr>
<td>Paver</td>
<td>$9.96</td>
</tr>
<tr>
<td>Rigger</td>
<td>$7.70</td>
</tr>
<tr>
<td>Roller</td>
<td>$2.41</td>
</tr>
<tr>
<td>Snowplow</td>
<td>$3.45</td>
</tr>
<tr>
<td>Transit Operators</td>
<td>$3.78</td>
</tr>
</tbody>
</table>
**SUPERSEDED DECISION**

**TENNESSEE COUNTIES:** *See below*

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>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>
<tr>
<td>Asbestos workers</td>
<td>10.00</td>
<td>.45</td>
</tr>
<tr>
<td>Holders and renters</td>
<td>9.50</td>
<td>.50</td>
</tr>
<tr>
<td>Bricklayers</td>
<td>8.82</td>
<td>.40</td>
</tr>
<tr>
<td>Carpenters</td>
<td>8.42</td>
<td>.40</td>
</tr>
<tr>
<td>Connecticut</td>
<td>7.74</td>
<td>.02</td>
</tr>
<tr>
<td>Electricians</td>
<td>9.02</td>
<td>.40</td>
</tr>
<tr>
<td>Asbestos workers</td>
<td>10.00</td>
<td>.45</td>
</tr>
<tr>
<td>Holders and renters</td>
<td>9.50</td>
<td>.50</td>
</tr>
<tr>
<td>Bricklayers</td>
<td>8.82</td>
<td>.40</td>
</tr>
<tr>
<td>Carpenters</td>
<td>8.42</td>
<td>.40</td>
</tr>
<tr>
<td>Connecticut</td>
<td>7.74</td>
<td>.02</td>
</tr>
<tr>
<td>Electricians</td>
<td>9.02</td>
<td>.40</td>
</tr>
<tr>
<td>Asbestos workers</td>
<td>10.00</td>
<td>.45</td>
</tr>
<tr>
<td>Holders and renters</td>
<td>9.50</td>
<td>.50</td>
</tr>
<tr>
<td>Bricklayers</td>
<td>8.82</td>
<td>.40</td>
</tr>
<tr>
<td>Carpenters</td>
<td>8.42</td>
<td>.40</td>
</tr>
<tr>
<td>Connecticut</td>
<td>7.74</td>
<td>.02</td>
</tr>
<tr>
<td>Electricians</td>
<td>9.02</td>
<td>.40</td>
</tr>
</tbody>
</table>

---

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

---

**NOTICES**

---

**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.
### LABORERS

<table>
<thead>
<tr>
<th>GROUP</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP A</td>
<td>5.14</td>
<td>.15</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP B</td>
<td>5.29</td>
<td>.15</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP C</td>
<td>5.32</td>
<td>.15</td>
<td>.15</td>
</tr>
<tr>
<td>GROUP D</td>
<td>5.44</td>
<td>.15</td>
<td>.15</td>
</tr>
</tbody>
</table>

**GROUP A:** Construction laborers

**GROUP B:** Mortar mixer, plasterer tender

**GROUP C:** Hod carriers, power buggies, yarnec, potman, grademan, snake man, form settee & strippers, pipelayers, asphalt taker, jackhammer op., air tool operator, vibrator operator, chain saw operator, barco tamper operator all power driven tool operator

**GROUP D:** Acetylene burner

**GROUP E:** Wagon drill operator

### POWER EQUIPMENT OPERATORS

<table>
<thead>
<tr>
<th>GROUP</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP A</td>
<td>8.19</td>
<td>.30</td>
<td>.30</td>
</tr>
<tr>
<td>GROUP B</td>
<td>7.61</td>
<td>.30</td>
<td>.30</td>
</tr>
<tr>
<td>GROUP C</td>
<td>6.36</td>
<td>.30</td>
<td>.30</td>
</tr>
<tr>
<td>GROUP D</td>
<td>5.84</td>
<td>.30</td>
<td>.30</td>
</tr>
</tbody>
</table>

**GROUP A:** Backhoes; cable ways; ross carrier; elasmahel; cranes; derricks; drill rings; tower pulls; pans; scrapers; scoops, etc.; head tower machines; locomotives (over 20 tons); shovels; mechanics & welders; winch trucks with A-frame; shovels; scoop; scraper; massive crane; over-head crane; pile drivers; skid rings; side boom tractors; Euclid loaders; hoists (any size handling steel or stone); derrick boats; derrick boats; engines used in connection with hoist material with an attached device on tower or engine; mecking machines; hi-lifts or end loaders; finish graders; cherry-pickers; tower crane; sky lift & gradall; dozers; earth augers and pole machine operators; stone drill & foundation drills

**GROUP B:** Tractors, farm type tractors with attachments; central compressor plants; elevators, used for hoisting building material, central mixing plants; hoist; pump crece machines; concrete pumps; trenching machines; backfillers (other than cranes); crushing plant operators; elevating graders; paving machines (black top); fork lift; paving machines, concrete; boat operator or engineer (20 tons or over); tranmills; maintainers; blacktop rollers; switchbacks; locomotive under 20 tons

**GROUP C:** Asphalt plant operators; harber green type loaders; engine tender other than steam; mixers, over 2 bags not include central plants; pumps; 1 not more than 3; scarifiers; spreader box (bituminous); asphalt mixers; portable compressors, 2 not more than 3; rollers; sub-grader machine; tractors, farm type without attachments; cable head tower enginemen; dredge; booster pump operators; boat operator or engineer, under 30 tons; pick-up; engine, (20 tons); finishing machine, fireman & oiler (combination); motor crane oiler & driver; welding machine, 2 not more than 3; beaters, stationery or portable (to 5); compressors, portable 2 not more than 3; greaser or fuel trucks

**GROUP D:** Air compressor (1 portable); firemen; portable crushers; welding machine (1); conveyors; pumps (1); oiler; boiler (1)
SUPERSEDES DECISION

STATE: Texas
COUNTRIES: Bell, Bosque, Coryell, Falls, Hill & McLennan
DECISION NO.: TX77-4151 DATE: Date of Publication
Supersedes Decision No. TX77-4053, dated March 4, 1977, in 42 FR 12668.

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 in Bosque, Falls, Hill & McLennan Counties).

<table>
<thead>
<tr>
<th>ASBESTOS WORKERS:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ZONE 1 - Bell, Coryell &amp; Falls Counties</td>
<td></td>
</tr>
<tr>
<td>CARPENTERS</td>
<td>8.20</td>
</tr>
<tr>
<td>MILLwrights</td>
<td>8.45</td>
</tr>
<tr>
<td>ZONE 2 - Bosque, Falls, Hill &amp; McLennan Counties:</td>
<td></td>
</tr>
<tr>
<td>CARPENTERS</td>
<td>8.45</td>
</tr>
<tr>
<td>MILLwrights</td>
<td>8.85</td>
</tr>
<tr>
<td>UNION MASONRY</td>
<td>8.69</td>
</tr>
<tr>
<td>9.55</td>
<td>1.00</td>
</tr>
<tr>
<td>10.60</td>
<td>1.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GLAZIERS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6.90</td>
<td>.42</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IRONWORKERS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>9.45</td>
<td>.55</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LABORERS:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Unskilled</td>
<td>2.97</td>
</tr>
<tr>
<td>Mason tenders</td>
<td>3.55</td>
</tr>
<tr>
<td>Yoder mixers</td>
<td>3.55</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LINE CONSTRUCTION:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Linemen; Linemen operators</td>
<td>11.26</td>
</tr>
<tr>
<td>Line tenders</td>
<td>12.29</td>
</tr>
<tr>
<td>Groundmen, 1st 6 months</td>
<td>6.76</td>
</tr>
<tr>
<td>Groundmen, 2nd 6 months</td>
<td>7.32</td>
</tr>
<tr>
<td>Groundmen, 1 year &amp; over</td>
<td>7.88</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PAINTERS:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 - Brush</td>
<td>7.15</td>
</tr>
<tr>
<td>Group 2 - Boiler &amp; steel, structural steel, window frames, roof, stage work, smoke stack, water towers, boat, valve chair</td>
<td>7.65</td>
</tr>
<tr>
<td>Group 3 - Ammonium for dry walls</td>
<td>7.75</td>
</tr>
<tr>
<td>Group 4 - Spray work &amp; self feeding rollers</td>
<td>7.90</td>
</tr>
<tr>
<td>Group 5 - ASI cleaning, sand blasting &amp; hazardous work</td>
<td>8.25</td>
</tr>
<tr>
<td>PLUMBERS &amp; PIPEFITTERS:</td>
<td></td>
</tr>
<tr>
<td>Group 1 - Area within 35 mile radius of Waco, including Temple, Belton, College &amp; Hillsboro</td>
<td>8.70</td>
</tr>
<tr>
<td>Group 2 - All other areas</td>
<td>9.10</td>
</tr>
</tbody>
</table>

| PLASTERERS | 9.54 | .35 | .20 |

<table>
<thead>
<tr>
<th>PLUMBERS &amp; PIPEFITTERS:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 - Area within a 35 mile radius of Waco, including Temple, Belton, College &amp; Hillsboro</td>
<td>8.70</td>
</tr>
<tr>
<td>Group 2 - All other areas</td>
<td>9.10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PLUMBERS &amp; PIPEFITTERS:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ZONE 1 - Area within a 35 mile radius of Waco, including Temple, Belton, College &amp; Hillsboro</td>
<td>8.70</td>
</tr>
<tr>
<td>ZONE 2 - All other areas</td>
<td>9.10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ELEVATOR CONSTRUCTORS:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanics</td>
<td>9.33</td>
</tr>
<tr>
<td>Helpers</td>
<td>70.38</td>
</tr>
<tr>
<td>Helpers (Probationary)</td>
<td>50.38</td>
</tr>
</tbody>
</table>
## BUILDING CONSTRUCTION

### SHEET METAL WORKERS:

**ZONE 1** - Within a radius of 20 miles from the McLennan County Court House, Waco

**ZONE 2** - Over 20 miles but less than 45 miles including the towns of Hillsboro, Temple, Merlot, Gatesville & Glinton

**ZONE 3** - Over 45 miles

### SPRINKLER FITTERS

WELDERS - receive 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

- New Years Day
- Memorial Day
- Independence Day
- Labor Day
- Thanksgiving Day
- Christmas Day

---

<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>$9.26</td>
<td>976</td>
<td>.39</td>
</tr>
<tr>
<td>9.76</td>
<td>10.26</td>
<td>.39</td>
</tr>
<tr>
<td>10.26</td>
<td>11.15</td>
<td>.39</td>
</tr>
</tbody>
</table>

### POWER EQUIPMENT OPERATORS

**GROUP 1**

- Heavy Duty Mechanic; Blade Grader - Self-propelled; Bull Claw; Back Filler; Berreloads, power operated (all types); Bulldozing; Push Cat Operator; Bulldozer Operator; Bull Dozer and all types of Graders; Cable-Dray; Back Shop; Crane, Power Operated (all types); Elevating Grader, self-propelled; Hoist, Motor Driver, two drums or more; Mix Mobile; High-Lifts & Loaders, over 1/3 cu. yd; capacity; Winch Trucks; Locomotive; Mixer, 14 cu. ft. or over; Paving Mixer (all sizes); Straper; Trenching Machine (all sizes); Gradally; Foundation Boring Machine; Scoopmobile; Shovel; power operated; Pumps; Heavy Equipment Operators; Rock Crusher Operated on Job; Welding Machine, 6 to 12; Two 125 cu. ft. Compressors; Well points, including installations

**GROUP 2**

- Blade Grader, Towed; Flex Planer; Form Grader; Mixer, less than 14 cu. ft.; Pulsometer; Truck Crane Driver & Oiler, Combination man; Concrete or Diesel Driven Welding Machine, 3 to 6; Hoist, Single Drum, Pump, 25 ft. or larger; Promatic Roller; High-Lifts & Loaders, 1/3 cu. yd. or less; Forklift, 1500 lbs. capacity or less; Air Compressors, anytime there are two or more attachments operating on a 125 cu. ft. compressor, less 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

**GROUP 3**

- Fireman

**GROUP 4**

- Oiler
### INCIDENTAL PAVING & UTILITIES
(BELL & CORYELL COUNTIES)

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacations</th>
<th>Education and/or Appro. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air Tool Man</td>
<td>$3.25</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asphalt Heatman</td>
<td>3.40</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asphalt Raker</td>
<td>4.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Batching Plant Scaleman</td>
<td>4.40</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carpenter</td>
<td>4.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carpenter Helper</td>
<td>3.60</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concrete Finisher (Paving)</td>
<td>4.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concrete Finisher Helper (Paving)</td>
<td>4.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concrete Finisher (Structures)</td>
<td>4.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concrete Finisher Helper (Structures)</td>
<td>4.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concrete Rubber</td>
<td>3.35</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrician</td>
<td>6.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrician Helper</td>
<td>4.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Form Builder ( Structures)</td>
<td>4.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Form Builder Helper (Structures)</td>
<td>4.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Form Setter (Paving and Ordb)</td>
<td>4.20</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Form Setter (Structures)</td>
<td>4.30</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Form Setter Helper (Structures)</td>
<td>4.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laborer, Common</td>
<td>2.80</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laborer, Utility Man</td>
<td>3.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanic</td>
<td>4.25</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanic Helper</td>
<td>4.10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oiler</td>
<td>3.25</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serviceman</td>
<td>3.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pile Driver</td>
<td>4.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pipelayer (Concrete &amp; Clay)</td>
<td>3.85</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pipelayer Helper (Concrete &amp; Clay)</td>
<td>3.85</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plumbers:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 1 - 35 miles from Waco, Texas including town of Temple</td>
<td>8.70</td>
<td>.30</td>
<td>.33</td>
<td>.03</td>
<td></td>
</tr>
<tr>
<td>Zone 2 - all area not included in Zone 1</td>
<td>9.10</td>
<td>.30</td>
<td>.33</td>
<td>.03</td>
<td></td>
</tr>
<tr>
<td>Ponderman</td>
<td>4.60</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ponderman</td>
<td>4.60</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reinforcing Steel Setter (Structures)</td>
<td>4.20</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reinforcing Steel Setter Helper</td>
<td>3.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sign Erector</td>
<td>3.75</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sign Erector Helper</td>
<td>3.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spreader Box Man</td>
<td>4.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swapper</td>
<td>3.30</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### INCIDENTAL PAVING & UTILITIES
(BELL & CORYELL COUNTIES)

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacations</th>
<th>Education and/or Appro. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Equipment Operators:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asphalt Distributor</td>
<td>3.85</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asphalt Paving Machine</td>
<td>3.85</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Broom or Sweeper Operator</td>
<td>3.85</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulldozer, 150 HP and Less</td>
<td>4.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulldozer, over 150 HP</td>
<td>4.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concrete Paving Saw Machine</td>
<td>4.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concrete Paving Saw</td>
<td>4.75</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (less than 1% CT)</td>
<td>4.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (1% CT and Over)</td>
<td>4.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crusher or Screening Plant Operator</td>
<td>4.15</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foundation Drill Operator (Truck Mounted)</td>
<td>5.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foundation Drill Operator Helper</td>
<td>3.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Front End Loader (2% CY &amp; Less)</td>
<td>4.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Front End Loader (Over 2% CY)</td>
<td>4.15</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Motor Grader Operator, Fine Grade</td>
<td>5.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Motor Grader Operator</td>
<td>6.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roller, Steel Wheel (Plant-Mix Pavements)</td>
<td>3.15</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roller, Steel Wheel (Other-Flat Wheel or Tamping)</td>
<td>3.55</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roller, Pneumatic (Self-Propelled)</td>
<td>3.40</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scrapers (17 CY and Less)</td>
<td>3.75</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scrapers (Over 17 CY)</td>
<td>4.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tractor (Crawler Type) 150 HP and Less</td>
<td>3.25</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tractor (Crawler Type) over 150 HP</td>
<td>3.75</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tractor (Pneumatic) 80 HP &amp; Less</td>
<td>3.25</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tractor (Pneumatic) over 80 HP</td>
<td>3.75</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Traveling Mixer</td>
<td>3.60</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trenching Machine, Light</td>
<td>3.75</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trenching Machine, Heavy</td>
<td>4.05</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic Hourly Rate</td>
<td>H &amp; W Fees</td>
<td>Vacation</td>
<td>Education &amp;/or Apprenticeship</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>------------</td>
<td>----------</td>
<td>-----------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power Equipment Operators (Crew-Member)</td>
<td>$3.90</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Truck Drivers: Single Axle, Light</td>
<td>$3.40</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tandem Axle or Semitrailer</td>
<td>$3.45</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lowboy-Float</td>
<td>$3.95</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Welder</td>
<td>$4.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Welder Helper</td>
<td>$3.25</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**DECISION NO. TX77-4151**

**INCIDENTAL PAVING & UTILITIES**

(BELL & CORYELL COUNTIES)

Power Equipment Operators (Crew-Member)

Truck Drivers: Single Axle, Light/Tandem Axle or Semitrailer

Lowboy-Float

Welder

Welder Helper

---
SUPERSEDANT DECISION

STATE: Texas


DECISION NO.: TX77-4152

DATE: Date of Publication

Supersedes Decision No. TX77-4044, dated February 25, 1977, in 42 FR 11226.

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).

Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASBESTOS WORKERS</td>
<td>8.95</td>
<td>.55</td>
<td>.45</td>
<td>.07</td>
</tr>
<tr>
<td>ROOFERS</td>
<td>10.30</td>
<td>.60</td>
<td>.40</td>
<td>.02</td>
</tr>
<tr>
<td>ELECTRICIANS</td>
<td>9.39</td>
<td>.40</td>
<td>.40</td>
<td>.02</td>
</tr>
<tr>
<td>MILLWrights</td>
<td>9.74</td>
<td>.20</td>
<td>.20</td>
<td>.02</td>
</tr>
<tr>
<td>CARPENTER</td>
<td>9.39</td>
<td>.20</td>
<td>.20</td>
<td>.02</td>
</tr>
<tr>
<td>MILLWrights</td>
<td>9.74</td>
<td>.20</td>
<td>.20</td>
<td>.02</td>
</tr>
<tr>
<td>CONCRETE MASON</td>
<td>9.30</td>
<td>.60</td>
<td>.60</td>
<td>.02</td>
</tr>
<tr>
<td>MASON MAINT.</td>
<td>8.30</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MACHINE OPERATORS</td>
<td>8.55</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ELECTRICIANS</td>
<td>10.40</td>
<td>.50</td>
<td>.35</td>
<td>1/2Y</td>
</tr>
<tr>
<td>CABLE INSTALLERS</td>
<td>11.50</td>
<td>.50</td>
<td>.35</td>
<td>1/2Y</td>
</tr>
<tr>
<td>SPAWING MASON</td>
<td>10.35</td>
<td>.60</td>
<td>.45</td>
<td>1/2Y</td>
</tr>
<tr>
<td>CABLE INSTALLERS</td>
<td>12.30</td>
<td>.60</td>
<td>.45</td>
<td>1/2Y</td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### DECISION NO. TX77-A152

#### Basic Hourly Rates vs. Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
</tbody>
</table>

#### LINE CONSTRUCTION (CONT'd):

**ZONE 2 - Childress County:**
- Lineman; Operator: $11.26
- Cable splicer: $11.20
- Groundman, 1st 6 months: $8.28
- Groundman, 2nd 6 months: $7.32
- Groundman, 1 year & over: $7.08

#### MARBLE MASON (EXTENSION):
- Hallway: $9.70

#### PAINTERS:

**GROUP 1 - Brush & roller, paper-hangers, perforators:** $8.30

**GROUP 2 - Structural steel painters, swinging stage or chair below 50 ft.:** $8.32

**GROUP 3 - Spray painters & sandblasters:** $8.95

**GROUP 4 - Perforator machine operators:** $8.65

#### PLASTERERS:
- Hallway: $9.55

#### PLUMBERS & PIPE FITTERS:

**ZONE 1 - shall extend a distance of 25 road miles from the police station in either Amarillo or Borger:** $9.21

**ZONE 2 - shall extend a distance of 25 to 50 road miles from either Amarillo or Borger:** $9.46

**ZONE 3 - shall extend a distance of 50 road miles & over from either Amarillo or Borger:** $9.71

#### ROOFERS:
- Hallway: $4.50

#### SHEET METAL WORKERS:
- Hallway: $9.60

#### SPRINKLER FITTERS:
- Hallway: $11.15

#### TRUCK DRIVERS:

- 1/2 ton to 3 tons: $2.08
- 3 to 5 tons: $3.13
- 5 tons and over: $3.28

#### WELDERS:
- Receive rate prescribed for craft performing operation to which welding is incidental,

---

**FOOTNOTE:**
- a - Paid holidays A thru F

**PAID HOLIDAYS:**
- A-New Years' Day; B-Memorial Day;
- C-Independence Day; D-Labor Day;
- E-Thanksgiving Day; F-Christmas Day

---

**FOOTNOTE:**
- a - Paid holidays A thru F

---

**PAID HOLIDAYS:**
- A-New Years' Day; B-Memorial Day;
- C-Independence Day; D-Labor Day;
- E-Thanksgiving Day; F-Christmas Day
### Declination No. TX77-4152

**Basic Hourly Rates**

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>$8.75</td>
<td>$8.25</td>
<td>$6.30</td>
</tr>
</tbody>
</table>

**Fringe Benefits Payments**

<table>
<thead>
<tr>
<th></th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>.40</td>
<td>.50</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>.40</td>
<td>.50</td>
<td>.10</td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td>.40</td>
<td>.50</td>
<td>.10</td>
<td></td>
</tr>
</tbody>
</table>

**Power Equipment Operators Classification Definitions**

**Group 1** - Blade Grader, self-propelled; Clam Shells; Cable Ways; Cranes, power operated (all types); Air Compressors, Pumps, Welding Machines & Light Plants (7 to 12 machines); Derricks, power operated (all types); Derrick; Elevating Cranes, self-propelled; Hoist, 2 drum or more; Locomotives; Motor Vehicles; Paving Machines, all types; Tile Drivers; Scraper; Bulldozer; Gland Room; Cherry Pickers - 12% tons & over; Shovels; Heavy Duty Mechanics; All Loaders; All tractors with power attachments; Ditching Machines - crawler type; Farm type Tractor (Loaders, 1 yd., 6 over) with Backhoes; 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 (3 to 6 machines); Cherry Pickers - under 12% tons; Ditch Witch - J 50 and under; Farm type Tractor (Loader under 1 yd.) with Backhoes; Go-Devil; Excav, 14 cu. ft. or over; Rollers over 10 tons; Air Compressor and one Tugger; Rollers, 2 or more; Bunch Trucks; Front End Scoopmobile; Loader and Payloader; Blade Grader, towed; Graders, building; Fork Lift; Hoist, single drum or 1 line hoisting (1 tugger); Mixers less than 15 cu. ft.; Rollers; Screening Plants; Crushing Plants; Tractors - Track type except when hauling material; All other equipment of similar nature coming within the Heavy Equipment Classification, when power operated.

**Group 3** - Oiler-Fireman-Greaser

---

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

STATE: Texas
COUNTY: Brazos

SUPERSEDES DECISION NO. TX77-4153 DATED MARCH 4, 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).

<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>ASBESTOS WORKERS</td>
<td>$10.00</td>
</tr>
<tr>
<td>ROOFERS</td>
<td>$10.00</td>
</tr>
<tr>
<td>BRICKLAYERs</td>
<td>10.53</td>
</tr>
<tr>
<td>CARPENTERS</td>
<td>9.25</td>
</tr>
<tr>
<td>CEMENT MASONs</td>
<td>11.05</td>
</tr>
</tbody>
</table>

LABORERS CLASSIFICATION DEFINITIONS

GROUP 1 - Construction labor, including excavation, concrete work, reinforcing, mason handler and wheeler (stock pile), asphalt trowel and rake, water proofing tender, pipe layer (non-metallic), pump crete pipe (handling and laying) and all building construction labor excepting that hereafter classified; window washer, carpenters tender, cement mason tender, vibrator operator, other mechanic tender (except as otherwise classified); Dumper & Spotter.

GROUP 2 - Air tool operator

GROUP 3 - Well driller

GROUP 4 - Cutting torch man; mason tender; mason handler & wheelers handling material from first stock pile; concrete pipe (handling and laying); Sand blaster; Power hoist operator; plasterer tender & hod carrier; plaster tender; well driller tender.

GROUP 5 - Tool room tender; water main (tee and otherwise); Blaster, powder man; gunite worker

GROUP 6 - Gunite mason

LINE CONSTRUCTION:

- Lineman & cable puller
- Groundman (1st 6 months)
- Groundman (2nd 6 months)
- Groundman

PAINTERS:

GROUP 1 - All brush painting, hand roller, steam cleaning, all pneumatic tools

GROUP 2 - All spray painting, sandblasting, waterblasting

GROUP 3 - Tape, float & drywall

GROUP 4 - Steeple jack work, hot materials

GROUP 5 - Pipeliners

GROUP 6 - Ironworkers

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 Years' Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### Power Equipment Operators: Classification Definitions

**GROUP 1** - Heavy Duty Mechanic; Blade Grader, Self-propelled; Bull Claw; Back Filler; Derrick-power operated (all types); Clam Shell; Draglines; Push Cat Operator; Bull Dozer & all types Cat Tractors; Cable-Way; Machine; Shovel; power operated; Crown; power operated (all types); Elevating Grader, Self-propelled; Loader, Motor-Driven; Drum or more; Mix Plant; Water Well Drilling Machines, used on construction; Building Elevator, used on construction; Tip-Off Operator, assigned to construction; Winch Truck; Locomotive Crane; Concrete Mixer, 16 cubic feet or more; Boring Mixer (all types); Pile Driver; Scraper, heavy type, over 3 cubic yards; Tunneling Machine (all sizes); Gravel; High-Lift; Foundation Boring Machine; Gasoline or Diesel-Driven Welding Machines, 7 or more; Pneumatic Machine Operator; Turnapull; D-13 Caterpillar, S-18 Euclid and similar tractors; Asphalt Plant Mixer Operator on job; Crusher Operator on job; Scoopmobiles; Forklift used on construction (not exclusion warehouses); Well Point Pump; Concrete Batch Plant Operator; Pneumatic Slicks, self-propelled; All other equipment of similar nature coming under the Heavy Equipment Class, when power operated.

**GROUP 2** - Air Compressors; Blade Grader, Towed; Flex Plane; Form Grades; Concrete Mixer, less than 14 cubic feet; Pumps; Pulsometer; Truck Crane Driver; Gasoline or Diesel-driven welding machines (on 3 or more, up to 6 machines); Bids; Single Drum; Scraper, 3 cubic yards or less; Mogul Drill Operator; Conveyor; Generator, gasoline or diesel-driven, over 1500 watts; Rubber Tired Pile Driver with attachments; A light equipment operator may run 1 or 2 150 cfm compressors; All other equipment of similar nature coming under the Light Equipment Class, when power operated.

**GROUP 3** - Fireman

**GROUP 4** - Oiler

---

### Basic Hourly Rates

<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pension</th>
<th>Vacation</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP 1</td>
<td>$9.87</td>
<td>.35</td>
<td>.65</td>
<td>.06</td>
<td></td>
</tr>
<tr>
<td>GROUP 2</td>
<td>8.38</td>
<td>.35</td>
<td>.65</td>
<td>.06</td>
<td></td>
</tr>
<tr>
<td>GROUP 3</td>
<td>7.84</td>
<td>.35</td>
<td>.65</td>
<td>.06</td>
<td></td>
</tr>
<tr>
<td>GROUP 4</td>
<td>7.66</td>
<td>.35</td>
<td>.65</td>
<td>.06</td>
<td></td>
</tr>
</tbody>
</table>
### SUPERSEDED DECISION

**STATE:** Texas  
**COUNTY:** Gregg

**DECISION NO.:** TX77-4154  
**DATE:** Date of Publication

Supersedes Decision No. TX77-4055, dated March 4, 1977, in 42 FR 12673.

**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>Craft</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASBESTOS WORKERS</strong></td>
<td>$10.03</td>
<td>.40</td>
<td>.76</td>
</tr>
<tr>
<td><strong>MACHINISTS</strong></td>
<td>10.00</td>
<td>.60</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>ELECTRICIANS</strong></td>
<td>8.50</td>
<td>.35</td>
<td>.35</td>
</tr>
<tr>
<td><strong>ASBESTOS WORKERS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BOILERMAKERS</strong></td>
<td>10.00</td>
<td>.50</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>BLACKSMITHS</strong></td>
<td>8.85</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td><strong>PLUMBERS</strong></td>
<td>8.25</td>
<td>.35</td>
<td>.05</td>
</tr>
<tr>
<td><strong>CEMENT MASON</strong></td>
<td>6.50</td>
<td>.20</td>
<td>.10</td>
</tr>
<tr>
<td><strong>ELECTRICIANS</strong></td>
<td>6.50</td>
<td>.30</td>
<td>.05</td>
</tr>
<tr>
<td><strong>GLAZIERS</strong></td>
<td>5.80</td>
<td>.20</td>
<td>.10</td>
</tr>
<tr>
<td><strong>IRONWORKERS</strong></td>
<td>8.75</td>
<td>.43</td>
<td>.35</td>
</tr>
<tr>
<td><strong>LABORERS</strong></td>
<td>3.40</td>
<td>.50</td>
<td>.10</td>
</tr>
<tr>
<td><strong>MASON TENDERS</strong></td>
<td>3.70</td>
<td>.35</td>
<td>.10</td>
</tr>
<tr>
<td><strong>PLASTERERS</strong></td>
<td>6.87</td>
<td>.25</td>
<td>.10</td>
</tr>
<tr>
<td><strong>PLUMBERS &amp; PIPEFITTERS</strong></td>
<td>7.25</td>
<td>.40</td>
<td>.10</td>
</tr>
<tr>
<td><strong>MACHINISTS</strong></td>
<td>6.45</td>
<td>.25</td>
<td>.10</td>
</tr>
<tr>
<td><strong>ELECTRICIANS</strong></td>
<td>8.95</td>
<td>.35</td>
<td>.35</td>
</tr>
<tr>
<td><strong>PLUMBERS &amp; PIPEFITTERS</strong></td>
<td>7.79</td>
<td>.30</td>
<td>.10</td>
</tr>
<tr>
<td><strong>TRUCK, DRIVERS</strong></td>
<td>6.40</td>
<td>.50</td>
<td>.05</td>
</tr>
<tr>
<td><strong>POWER EQUIPMENT OPERATORS:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BACKHOES</strong></td>
<td>4.50</td>
<td>.30</td>
<td>.10</td>
</tr>
<tr>
<td><strong>.Blade graders</strong></td>
<td>4.50</td>
<td>.30</td>
<td>.10</td>
</tr>
<tr>
<td><strong>Backhoes</strong></td>
<td>4.50</td>
<td>.30</td>
<td>.10</td>
</tr>
<tr>
<td><strong>BULLDOZERS</strong></td>
<td>4.75</td>
<td>.30</td>
<td>.10</td>
</tr>
<tr>
<td><strong>Cable splicers</strong></td>
<td>9.00</td>
<td>.10</td>
<td>.05</td>
</tr>
<tr>
<td><strong>CABLE SPICLERS</strong></td>
<td>8.60</td>
<td>.30</td>
<td>.10</td>
</tr>
<tr>
<td><strong>ELECTRICIANS</strong></td>
<td>8.75</td>
<td>.30</td>
<td>.10</td>
</tr>
<tr>
<td><strong>GLAZIERS</strong></td>
<td>5.80</td>
<td>.20</td>
<td>.10</td>
</tr>
<tr>
<td><strong>MACHINISTS</strong></td>
<td>8.50</td>
<td>.35</td>
<td>.10</td>
</tr>
<tr>
<td><strong>PLUMBERS &amp; PIPEFITTERS</strong></td>
<td>7.25</td>
<td>.43</td>
<td>.35</td>
</tr>
<tr>
<td><strong>MACHINISTS</strong></td>
<td>6.45</td>
<td>.25</td>
<td>.10</td>
</tr>
<tr>
<td><strong>PLUMBERS &amp; PIPEFITTERS</strong></td>
<td>7.79</td>
<td>.30</td>
<td>.10</td>
</tr>
<tr>
<td><strong>TRUCK, DRIVERS</strong></td>
<td>6.40</td>
<td>.50</td>
<td>.05</td>
</tr>
</tbody>
</table>

WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.
STATE: Texas  
COUNTY: Lubbock  

DECISION NO.: TX77-4155  
DATE: Date of Publication  

Supersedes Decision No. TX76-4197, dated December 26, 1976, in 41 FR 56602.  

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>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**  
- 3 9.85  
- 10.50  
- 8.67  
- 7.20  
- 9.55  
- 9.20  

**Boilermakers**  
- 10.50  
- 9.20  

**Bricklayers & Stonemasons**  
- 8.67  

**Carpenters**  
- 7.20  

**Central Pumps**  
- Electricians - 9.55  
- Cable splicers - 9.80  

**CIPERS**  
- Structural; Ornamental; Reinforcing - 6.23  
- All ironworkers on jobs 30 miles or more from the city of Lubbock - 8.355  

**Laborers**  
- Group 1 - Construction laborers, including excavation, pouring concrete, carpenter tenders, reinforcing, shoring, scaffolding, leading & unloading materials, wrecking buildings & all structures & all construction laborers except those named below - 4.925  
- Group 2 - Air tool operator (jackhammer, vibrator, tamper, brush hammer, chipper hammer, air or electric), power hoist, crane, cement, mason, plasterer tenders - 5.29  
- Group 3 - Mortar mixers, mason tenders, plasterer tenders, cement, bricklayer tenders, lather tenders - 5.125  
- Group 4 - Mason drill - 5.275  
- Group 5 - Blasters & powder make-up men - 5.525  

**Lathers**  
- 5.20  

**Line Construction**  
- Linemen - 9.35  
- Operators - 8.00  
- Groundmen (more than 1 year experience) - 5.00  
- Groundmen (less than 1 year experience) - 4.00  
- Enclosed truck operator - 5.00  

**Painters**  
- Brush - 6.55  
- Spray - 7.75  

**Pipefitters & Steamfitters**  
- 9.25  

**Pumpers**  
- 3.50  

**Sheet Metal Workers**  
- 9.60  

**Sprinkler Fitters**  
- 11.15  

**Truck Drivers**  
- 3.00  

Welders - receive rate prescribed for craft performing operation to which welding is incidental.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### Basic Hourly Rates

<table>
<thead>
<tr>
<th>Group</th>
<th>Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacations</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>7.20</td>
<td>0.30</td>
<td>0.50</td>
<td>0.10</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>8.10</td>
<td>0.30</td>
<td>0.50</td>
<td>0.10</td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td>8.50</td>
<td>0.30</td>
<td>0.50</td>
<td>0.10</td>
<td></td>
</tr>
</tbody>
</table>

### Power Equipment Operators Classification Definitions

**Group 1 - Oilers - Firemen**
- Air Compressors, Pumps, Welding Machines, Throttle Valves, Light Plants (3 to 6 machines); Conveyor; Wagon Drill; Elevators Building; Power Graders; Hoist, Single Drum; Fork Truck including blade and mower on rear; Mixers less than 24 cubic feet; Screening Plants; Crushing Plants; Fork Lifts (short, under 24 feet); Concrete Pumps (all types); Bobcat type equipment; Fork Tractor with any attachments (except blade and mower on rear); All other equipment of similar nature coming under the Light Equipment Class, when power operated.

**Group 2 - Backhoe; Drilling Machines (all types); Scoopmobiles; Hoist, two drums or more; Fork Lifts (over 25 feet); Binich Truck; Six Wheel Truck, when used continuously for 5 days; Mixermobile; Locomotives; Mixers, 24 cubic feet or over; Blade Graders, self-propelled; Cableways; Cranes—power operated (to 190 feet of boom); Derricks, power operated (all types); Graders; By-Ro; Hoist; baiting Mixers (all types); Hi-Lift Drivers; Mobile Concrete Mixers over 24 cubic feet; Bulldozers, Loaders, Tractor Loaders, Scrapers and Pulls; Welders; Trenching Machines; Rollers, ten tons or over; Air Compressors, Pumps, Welding Machines and Light Plants (7 to 12 machines); Air Compressor & Air Tugger; Boilers, 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.
**SUPERSEDES DECISION**

**STATE:** Texas  
**COUNTY:** Smith  
**DECISION NO.:** TX77-4156  
**DATE:** Date of Publication  
Supersedes Decision No. TX77-4057, dated March 4, 1977, in 42 FR 12673.

**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).

---

**Fringe Benefits Payments**

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apps. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AIR CONDITIONING MECHANICS</strong></td>
<td>8.46</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>BRICKLAYERS</strong></td>
<td>7.75</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Carpenters</strong></td>
<td>7.90</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Cement Masons</strong></td>
<td>5.82</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Electricians</strong></td>
<td>6.86</td>
<td>0.25</td>
<td>0.25</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>Cable Splicers</strong></td>
<td>11.35</td>
<td>0.25</td>
<td>0.25</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>GLAZERS</strong></td>
<td>9.00</td>
<td>0.25</td>
<td>0.25</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>INTERIOR WORKERS</strong></td>
<td>9.00</td>
<td>0.25</td>
<td>0.25</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>LABORERS</strong></td>
<td>3.00</td>
<td>0.25</td>
<td>0.25</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>PLUMBERS</strong></td>
<td>6.00</td>
<td>0.25</td>
<td>0.25</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>PLUMBERS &amp; PIPETEERS</strong></td>
<td>7.78</td>
<td>0.25</td>
<td>0.25</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>POWER EQUIPMENT OPERATORS</strong></td>
<td>6.66</td>
<td>0.25</td>
<td>0.25</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>Sheet Metal Workers</strong></td>
<td>8.15</td>
<td>0.25</td>
<td>0.25</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>Sheet Metal Workers</strong></td>
<td>7.75</td>
<td>0.25</td>
<td>0.25</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>Sprinkler Fitters</strong></td>
<td>11.15</td>
<td>0.25</td>
<td>0.25</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>TRUCK DRIVERS</strong></td>
<td>3.00</td>
<td>0.25</td>
<td>0.25</td>
<td>0.05</td>
</tr>
</tbody>
</table>

**NOTICES**

---

**SUPERSEDES DECISION**

**STATE:** Texas  
**COUNTY:** Taylor  
**DECISION NO.:** TX77-4157  
**DATE:** Date of Publication  
Supersedes Decision No. TX77-4171, dated October 8, 1976, in 41 FR 44664.

**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).

---

**Fringe Benefits Payments**

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apps. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AIR CONDITIONING MECHANICS</strong></td>
<td>8.60</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>ASBESTOS WORKERS</strong></td>
<td>8.00</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>BRICKLAYERS</strong></td>
<td>6.00</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Carpenters</strong></td>
<td>7.00</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Cement Masons</strong></td>
<td>5.44</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Electricians</strong></td>
<td>8.66</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Cable Splicers</strong></td>
<td>8.60</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>GLAZERS</strong></td>
<td>6.60</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>INTERIOR WORKERS</strong></td>
<td>6.60</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>LABORERS</strong></td>
<td>3.00</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>LINE CONSTRUCTION</strong></td>
<td>3.80</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>PLUMBERS</strong></td>
<td>6.00</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>PLUMBERS &amp; PIPEFITTERS</strong></td>
<td>6.00</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>POWER EQUIPMENT OPERATORS</strong></td>
<td>6.00</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Sheet Metal Workers</strong></td>
<td>6.00</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Sheet Metal Workers</strong></td>
<td>6.00</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Sprinkler Fitters</strong></td>
<td>6.00</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>TRUCK DRIVERS</strong></td>
<td>6.00</td>
<td>0.20</td>
<td>0.20</td>
<td>0.04</td>
</tr>
</tbody>
</table>

**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
### 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>Job Title</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASBESTOS WORKERS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BOILERS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BRICKLAYERS &amp; STONE Masons</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CARPENTERS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MILLWORKERS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SHEET METAL WORKEs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ELEVATOR CONSTRUCTORS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanics</td>
<td>9.29</td>
<td>.55</td>
<td>.35</td>
<td>.45</td>
</tr>
<tr>
<td>Helpers</td>
<td>7.05</td>
<td>.55</td>
<td>.35</td>
<td>.45</td>
</tr>
<tr>
<td>Helpers (Probationary)</td>
<td>5.85</td>
<td>.55</td>
<td>.35</td>
<td>.45</td>
</tr>
<tr>
<td><strong>GLAZIERS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>LABORERS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GROUP 1</strong> General laborer and pier hole men</td>
<td>5.65</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GROUP 2</strong> Mason tender; Plasterer (concrete &amp; clay); Cement finisher tender; Scaffold builder; Gunnite &amp; cement work mixer &amp; power tool operator</td>
<td>5.80</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GROUP 3</strong> Plaster tender; Rod carrier; Morter mixers; Ladder tender; Water or damp proofers</td>
<td>5.98</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GROUP 4</strong> Gunnite over 1/8&quot; thick; Roseline; Machine operator; Powderman &amp; blaster</td>
<td>8.05</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>LINERS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>LINE CONSTRUCTION:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Linemen</td>
<td>10.20</td>
<td></td>
<td>.10</td>
<td>1/25</td>
</tr>
<tr>
<td>Groundmen 1st year</td>
<td>5.01</td>
<td></td>
<td>.10</td>
<td>1/25</td>
</tr>
<tr>
<td>Groundmen (1st year)</td>
<td>5.20</td>
<td></td>
<td>.10</td>
<td>1/25</td>
</tr>
<tr>
<td><strong>MARBLE SETTERS</strong></td>
<td>7.36</td>
<td></td>
<td></td>
<td>.04</td>
</tr>
<tr>
<td><strong>MARBLE SETTERS' FINISHERS</strong></td>
<td>5.37</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### PAINTERS:

- **GROUP 1** - Brush; Taping & floating
- **GROUP 2** - Paperhangers; Chipper, burner, torch; Skeleton steel-work cutters
- **GROUP 3** - Spray; Steam cleaning, sand blast & other powered equipment

### PLUMBERS & STEAMFITTERS

### ROOFERS:

- **Roofers**
- **Kettlemen**

### SHEET METAL WORKERS

### SOFT FLOOR LAYERS

### SPRINKLER FITTERS

### TERRAZZO WORKERS

### TERRAZZO WORKERS' FINISHERS:

### TILE SETTERS

### TILE SETTERS' FINISHERS

### WELDERS

- Receive rate prescribed for craft performing operations 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

- New Year's Day; Lincoln Memorial Day; Independence Day; Labor Day; Thanksgiving Day; Christmas Day
### Power Equipment Operators

<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rate</th>
<th>H &amp; W</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP 1</td>
<td>$8.63</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>GROUP 2</td>
<td>7.56</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>GROUP 3</td>
<td>6.34</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>GROUP 4</td>
<td>6.23</td>
<td>40</td>
<td></td>
</tr>
</tbody>
</table>

### Power Equipment Operators Classification Definitions

#### GROUP 1
- Heavy Duty Mechanic; Blade Grader - Self-propelled; Bull Clam; Backfiller; Derrick, power operated (all types); Dragline; Push Cat Operator; Scraper Operator; Bull Dozer and all types of Cat Tractors; Cable-Way; Back Hoop Crane, Power Operated (all types); Elevating Grader, self-propelled; Hoist, Motor Driven, two drums or more; Mix Mobile; High-Lifts & Loaders, over 1/3 cu. yd. capacity; Winch Truck; Locomotive; Mixer, 14 cu. ft. or over; Paving Mixer (all sizes); Scraper; Trenching Machine (all sizes); Gradall; Foundation Boring Machine; Scooper; Shovel, Power Operated; Pump Crate Machine; Crimp Shell Operator; Back Cruiser, Operated on Job; Welding Machine, 6 to 12; Two 125 cu. ft. Compressors; Well Point, including Installations

#### GROUP 2
- Blade Grader, Towed; Flex Plane; Form Grader; Mixer, less than 14 cu. ft.; Pulsometer; Truck Crane Driver & Oiler, Combination man; Gasoline or Diesel Driven Welding Machine, 3 to 6; Hoist, Single Drum; Pump, 1/2 in. or larger; Pneumatic Rollers; High-Lifts & Loaders, 1/3 cu. yd. or less; Forklift, 1500 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. air compressor and two welding machines or any two air compressors equivalent to a 125 cu. ft. air compressor requires a light equipment operator

#### GROUP 3
- Firemen

#### GROUP 4
- Oiler
### SUPERSEDES DECISION

**STATE:** Texas  
**COUNTY:** Wichita  
**DECISION NO.:** TX77-4159  
**DATE:** Date of Publication  
**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>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>Pension</td>
</tr>
</tbody>
</table>

#### ASBESTOS WORKERS
- **RATES:** $9.00  
- **FRINGE:** .40  
- **VACATION:** .76  
- **EDUCATION:** .02  
- **TOTAL:** .025

#### BOILERS
- **RATES:**  
- **FRINGE:** .30  
- **VACATION:** 1.00  
- **EDUCATION:** .05

#### CARPENTERS
- **RATES:**  
- **FRINGE:** .43  
- **VACATION:** .40  
- **EDUCATION:** .07

#### MILLWORKERS
- **RATES:**  
- **FRINGE:** .43  
- **VACATION:** .40  
- **EDUCATION:** .07

#### CURTAIN RAILERS
- **RATES:** .855

#### ELECTRICIANS:
- **ZONE 1** - Work performed within a road mile radius from the local union hall business office up to 30 miles:  
  - **RATES:**  
  - **FRINGE:** .40  
  - **VACATION:** .3%  
  - **EDUCATION:** 1.10  
- **ZONE 2** - All work performed beyond Zone 1:  
  - **RATES:**  
  - **FRINGE:** .40  
  - **VACATION:** .3%  
  - **EDUCATION:** 1.10

#### MECHANICS:
- **RATES:**  
- **FRINGE:** .545  
- **VACATION:** 1.00  
- **EDUCATION:** .02

#### HELPERS (PROBATIONARY):
- **RATES:** .545

#### GLAZIERS
- **RATES:**  
- **FRINGE:** .275  
- **VACATION:** 1.00  
- **EDUCATION:** .10

#### LATHERS
- **RATES:**  
- **FRINGE:** .55  
- **VACATION:** 1.00  
- **EDUCATION:** .10

#### LINE CONSTRUCTION:
- **ZONE 1** - Withing 25 miles of Wichita Falls City limits  
  - **RATES:**  
  - **FRINGE:** .01  
  - **VACATION:** 1.75  
  - **EDUCATION:** .01
- **ZONE 2** - Between 25 & 40 miles of Wichita Falls City limits  
  - **RATES:**  
  - **FRINGE:** .01  
  - **VACATION:** 1.75  
  - **EDUCATION:** .01
- **ZONE 3** - Between 40 & 70 miles of Wichita Falls City limits  
  - **RATES:**  
  - **FRINGE:** .01  
  - **VACATION:** 1.75  
  - **EDUCATION:** .01
- **ZONE 4** - Between 70 & 100 miles of Wichita Falls City limits  
  - **RATES:**  
  - **FRINGE:** .01  
  - **VACATION:** 1.75  
  - **EDUCATION:** .01
- **ZONE 5** - Over 100 miles of Wichita Falls City limits  
  - **RATES:**  
  - **FRINGE:** .01  
  - **VACATION:** 1.75  
  - **EDUCATION:** .01

#### MARBLE SETTERS
- **RATES:**  
- **FRINGE:**  
- **VACATION:**  
- **EDUCATION:**

#### PAINTERS:
- **RATES:**  
- **FRINGE:** .01  
- **VACATION:**  
- **EDUCATION:**

#### PLASTERERS
- **RATES:**  
- **FRINGE:**  
- **VACATION:**  
- **EDUCATION:**

#### PLUMBERS:
- **RATES:**  
- **FRINGE:**  
- **VACATION:**  
- **EDUCATION:**

#### PIPEFITTERS:
- **RATES:**  
- **FRINGE:**  
- **VACATION:**  
- **EDUCATION:**

#### SHEET METAL WORKERS
- **RATES:**  
- **FRINGE:** .03

#### SOFTLOOR LAYERS
- **RATES:**  
- **FRINGE:**  
- **VACATION:**  
- **EDUCATION:**

#### TERRAZZO WORKERS
- **RATES:**  
- **FRINGE:**  
- **VACATION:**  
- **EDUCATION:**

#### TILE SETTERS
- **RATES:**  
- **FRINGE:**  
- **VACATION:**  
- **EDUCATION:**

#### TRUCK DRIVERS
- **RATES:**  
- **FRINGE:**  
- **VACATION:**  
- **EDUCATION:**

#### WELDERS
- **RATES:**  
- **FRINGE:** .25  
- **VACATION:**  
- **EDUCATION:**

---

**FOOTNOTES:**
- **a** - 1st 6 mths: none; 6 mths to 5 yrs: 1/4 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

---

**NOTES**

**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 Adj.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>M &amp; W</td>
<td>Pensions</td>
</tr>
<tr>
<td>GROUP 1</td>
<td>7.20</td>
<td>.30</td>
<td>.50</td>
</tr>
<tr>
<td>GROUP 2</td>
<td>8.10</td>
<td>.30</td>
<td>.50</td>
</tr>
<tr>
<td>GROUP 3</td>
<td>8.50</td>
<td>.30</td>
<td>.50</td>
</tr>
</tbody>
</table>

**Power Equipment Operators Classification Definitions**

**GROUP 1 - Oiler-Fireman**
- Air Compressors, Pumps, Welding Machines, Throttle Valves, Light Plants, (3 to 6 machines); Conveyors; Wagon Drills, Elevators Building; Farm Graders; Monitor, Single Drum; Hard Tractor including blade and mower on rear; Mixers less than 14 cubic feet; Screening Plants; Crushing Plants; Fork Lifts (20 to 25 feet); Concrete Pumps; Bobcat type equipment; Hard tractor or like with any attachments (except blade and mower on rear); All other equipment of similar nature coming under the Light Equipment Class, when power operated.

**GROUP 2 - Backhoe, Drilling Machines (all types); Scoops, Shovels; Dredges, two draws or more; Fork Lifts (over 25 feet); Milk Trucks; Air Power Truck, when used continuously for 5 days; Shearers; Locomotives; Mixers, 14 cubic feet or over; Blade Graders; Self-propelled; Cableways; Grader-power operated (to 100 feet of boom); Derrick, power operated (all types); Gradall; Hy-Mac; hopper: Fans; Mixers (all types); Pile Drivers; Mobile Concrete Mixers over 14 cu. ft.; Ball Screwers; Laders, Tractors, Scraper and Pulls; Podtowers; 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 (used by one man); Heavy Duty Mechanic; All other equipment of similar nature coming under the Heavy Equipment Class, when power operated.
Public Papers of the Presidents of the United States

Annual volumes containing the public messages and statements, news conferences, and other selected papers released by the White House.

Volumes for the following years are now available:

**HERBERT HOOVER**

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1929</td>
<td>$13.30</td>
</tr>
<tr>
<td>1930</td>
<td>$16.00</td>
</tr>
</tbody>
</table>

**HARRY S. TRUMAN**

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1945</td>
<td>$11.75</td>
</tr>
<tr>
<td>1946</td>
<td>$10.80</td>
</tr>
<tr>
<td>1947</td>
<td>$11.15</td>
</tr>
<tr>
<td>1948</td>
<td>$15.95</td>
</tr>
<tr>
<td>1949</td>
<td>$11.80</td>
</tr>
<tr>
<td>1950</td>
<td>$13.65</td>
</tr>
<tr>
<td>1951</td>
<td>$12.65</td>
</tr>
<tr>
<td>1952-53</td>
<td>$18.45</td>
</tr>
</tbody>
</table>

**DWIGHT D. EISENHOWER**

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1953</td>
<td>$14.60</td>
</tr>
<tr>
<td>1954</td>
<td>$17.20</td>
</tr>
<tr>
<td>1955</td>
<td>$14.50</td>
</tr>
<tr>
<td>1956</td>
<td>$17.30</td>
</tr>
<tr>
<td>1957</td>
<td>$14.50</td>
</tr>
<tr>
<td>1958</td>
<td>$14.70</td>
</tr>
<tr>
<td>1959</td>
<td>$14.85</td>
</tr>
<tr>
<td>1960-61</td>
<td>$16.85</td>
</tr>
<tr>
<td>1961</td>
<td>$15.95</td>
</tr>
<tr>
<td>1962</td>
<td>$15.55</td>
</tr>
</tbody>
</table>

**JOHN F. KENNEDY**

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1961</td>
<td>$14.35</td>
</tr>
<tr>
<td>1962</td>
<td>$15.50</td>
</tr>
<tr>
<td>1963</td>
<td>$15.35</td>
</tr>
<tr>
<td>1964</td>
<td>$14.35</td>
</tr>
<tr>
<td>1965</td>
<td>$12.25</td>
</tr>
<tr>
<td>1966</td>
<td>$12.35</td>
</tr>
<tr>
<td>1967</td>
<td>$13.30</td>
</tr>
<tr>
<td>1968-69 (Book I)</td>
<td>$14.05</td>
</tr>
<tr>
<td>1969</td>
<td>$17.15</td>
</tr>
<tr>
<td>1970</td>
<td>$18.30</td>
</tr>
<tr>
<td>1971</td>
<td>$18.85</td>
</tr>
</tbody>
</table>

**LYNDON B. JOHNSON**

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1963-64 (Book I)</td>
<td>$15.00</td>
</tr>
<tr>
<td>1963-64 (Book II)</td>
<td>$15.25</td>
</tr>
<tr>
<td>1965 (Book I)</td>
<td>$12.25</td>
</tr>
<tr>
<td>1965 (Book II)</td>
<td>$12.35</td>
</tr>
<tr>
<td>1966 (Book I)</td>
<td>$13.30</td>
</tr>
<tr>
<td>1966-69 (Book I)</td>
<td>$14.05</td>
</tr>
<tr>
<td>1967 (Book II)</td>
<td>$12.85</td>
</tr>
<tr>
<td>1968-69 (Book II)</td>
<td>$12.80</td>
</tr>
<tr>
<td>1970-71</td>
<td>$14.05</td>
</tr>
<tr>
<td>1972</td>
<td>$12.85</td>
</tr>
<tr>
<td>1973</td>
<td>$16.50</td>
</tr>
<tr>
<td>1974</td>
<td>$16.85</td>
</tr>
</tbody>
</table>

**RICHARD NIXON**

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1969</td>
<td>$17.15</td>
</tr>
<tr>
<td>1970</td>
<td>$18.50</td>
</tr>
<tr>
<td>1971</td>
<td>$18.85</td>
</tr>
<tr>
<td>1972</td>
<td>$18.55</td>
</tr>
<tr>
<td>1973</td>
<td>$16.50</td>
</tr>
<tr>
<td>1974</td>
<td>$12.30</td>
</tr>
</tbody>
</table>

**GERALD R. FORD**

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1974</td>
<td>$16.00</td>
</tr>
</tbody>
</table>

Published by Office of the Federal Register, National Archives and Records Service, General Services Administration

Order from Superintendent of Documents, U.S. Government Printing Office
Washington, D.C. 20402