AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

1–5–82
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federal register

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

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The **Federal Register** will be furnished by mail to subscribers, free of postage, for $75.00 per year, or $45.00 for six months, payable in advance. The charge for individual copies is $1.00 for each issue, or $1.00 for each group of pages as actually bound. Remit check or money order, made payable to the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

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

DEPARTMENT OF AGRICULTURE

Federal Grain Inspection Service

7 CFR Part 68

Adjustment of Fees for Certain Federal Inspection Services

AGENCY: Federal Grain Inspection Service [1], USDA.

ACTION: Final rule.

SUMMARY: The Federal Grain Inspection Service (FGIS) is increasing the fees for hay, hop, miscellaneous processed commodities, pulse, and straw inspection services to equate the fees, as nearly as possible, with the cost of the services. These services are made available upon request of an applicant. FGIS is also changing the fee schedule by adding some new laboratory tests and corresponding fees, eliminating the cross-referencing of other tests, and specifying the conditions for contract services which previously appeared only in the contract.

EFFECTIVE DATE: February 4, 1981.

FOR FURTHER INFORMATION CONTACT: Lewis Lebakken, Jr., Regulations and Directives Management, Resources Management Division, USDA, Federal Grain Inspection Service, Room 1636 South Building, 1400 Independence Avenue, SW., Washington, D.C. 20250, 202/447-9172.

SUPPLEMENTARY INFORMATION: This final action has been reviewed under USDA procedures pursuant to Secretary's Memorandum 1512-1 and Executive Order 12291 and has been classified as nonmajor because it does not meet the criteria for a major regulatory action

Kenneth A. Gilles, Administrator, has determined that this final action will not have a significant economic impact on a substantial number of small entities because most users of these Federal inspection services do not meet the requirements for small entities as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Section 203(h) of the Agricultural Marketing Act of 1946 provides for the collection of fees for services rendered which are reasonable and as nearly as possible cover the cost of the service. The fees currently in effect (7 CFR 68.42a) do not cover FGIS' costs of providing the services.

A proposed rule to increase the fees and make some miscellaneous changes in hay, hop, miscellaneous processed commodities, pulse (beans, peas, and/or lentils), and straw inspection services was published in the August 26, 1981, **Federal Register** (46 FR 43056-43057) with a 30-day public written comment period ending September 25, 1981. Only one written comment from the Oregon Commodities Company, Portland, Oregon, was received during the comment period. The commentor contended that an increase in the fees would result in a reduction of the volume inspected. FGIS does not anticipate any signficiant reduction in the requests for service as a result of the fee increase.

FGIS indicated in the proposal that the fees for these services have not been changed since 1977. Since 1977, there have been increases in Federal salaries totaling approximately 32 percent of the 1977 base. These increases, coupled with substantial increases in costs charged to FGIS by contract licensees, through the bidding process, and cooperator licensees who perform inspection services for FGIS on an hourly basis, as well as increases in chemicals, laboratory equipment, rent, utilities, transportation and other costs, have resulted in revenue not covering costs. Further, there has been a continuous and accelerating decrease in the operating reserve maintained for contingencies when fees may not cover costs of providing the service.

On the basis of the comment received and all other available information, FGIS has concluded that, in order to continue to provide inspection services to applicants in FY 1982, an increase in inspection service fees (7 CFR 68.42a) is necessary to more closely equate the fees with the costs of rendering the services. FGIS will continue to monitor costs and revenue to maintain fees at the minimum level necessary to continue an effective inspection program.

Accordingly, the regulations published as a proposed rule at 46 FR 43056-43057, are hereby adopted without change as the final rule.

(Sec. 203(h), Pub. L. 79-733, 60 Stat. 1087 (7 U.S.C. 1622))

Dated: December 16, 1981.

Kenneth A. Gilles,

Administrator.

PART 68—REGULATIONS AND STANDARDS FOR INSPECTION AND CERTIFICATION OF CERTAIN AGRICULTURAL COMMODITIES AND PRODUCTS THEREOF

Accordingly, 7 CFR 68.42a is revised to read as follows:

§ 68.42a Fees for certain Federal inspection services.

The following fees apply to the Federal inspection services specified below:

INSPECTION SERVICE

	Fee
Appeal Inspection:	
(a) Basis original or file sample	[1][3]
(b) Basis new sample	[2][3]
Bean, lentil, and pea inspection:	
(a) Lot inspection—	
(1) Field run (quality and dockage analysis), per lot	$13.40
(2) Other than field run (grade, class, and quality) per lot	[4] 10.00
(In addition to the fee for analysis or grading in (1) and (2), a fee for sampling, checkweighing, and checkloading, if any, will be assessed at the prescribed rate.)	
(b) Sample inspection—	
(1) Field run (quality and dockage analysis), per lot	13.40
(2) Other than field run (grade, class, and quality), per sample	[4] 10.00
Checkloading, per man-hour [5]	20.80
Checkweighing, per man-hour [5]	20.80
Condition examination, per man-hour	20.80
Contract service, per man-hour: FGIS may enter into contracts with applicants to perform continuous inspection services or other types of services. Applicant agrees to pay for 8 hours of service per day, per person, for at least 5 consecutive days per week. All hours of service performed in excess of the contract shall be charged at the rate of $20.80 per man-hour	16.60
Demonstration gradings—per request [5]	245.00
Extra copies of certificates—per copy	1.80
Factor analysis for nongraded, nonprocessed commodities—per factor	4.00
Factor fee, per factor	4.00

[1] Authority to exercise the functions of the Secretary of Agriculture contained in the Agricultural Marketing Act of 1946 as amended (7 U.S.C. 1621-1627) concerning inspection and standardization activities related to grain and similar commodities and products thereof has been delegated to the Administrator, Federal Grain Inspection Service (7 U.S.C. 75a, 7 CFR 68.2(e)).

INSPECTION SERVICE—Continued

	Fee
Grade factor analysis as defined in the applicable offical U.S. Standards, per factor	4.00
Hay and straw inspection:	
(a) Lot inspection, sampling and grading, per man-hour	20.80
(b) Sample inspection—	
(1) Grade only, per sample	13.40
(2) Factor analyses, per man-hour	20.80
Hop inspection:	
(a) Lot inspection: Seed, leaf, and stem content—per lot	20.80
(In addition to the fee for analysis, a charge for sampling, if any, will be assessed at the prescribed rate.)	
(b) Sample inspection: Seed, leaf, and stem content—per sample	20.80
Laboratory report	1.80
Laboratory testing:	
(a) In addition to the fees, if any, for sampling or other requested service, a fee will be assessed for each laboratory test as follows:	
(1) Acidity—Greek	5.20
(2) Acid value—oil	5.20
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(4) Aflatoxin (TLC)	36.40
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(6) Arachidic acid	10.00
(7) Ash	6.25
(8) Bacteria count	6.50
(9) Baking test—bread	15.60
(10) Baking test—cake	21.90
(11) Baking test-cookies	19.50
(12) Baumé	5.20
(13) Bostwick (cooked)	10.40
(14) Bostwick (uncooked)	5.20
(15) Calcium (AOAC)	6.50
(16) Calcium enrichment	6.50
(17) Carotenoid color	7.80
(18) Checked and broken macaroni units	5.20
(19) Clarity of oil involving heating	5.20
(20) Cold test—oil	5.20
(21) Coliform	15.60
(22) Color—bleached	7.80
(23) Color—gardner	2.60
(24) Color—lovibond	2.60
(25) Color—oil and shortening	2.60
(26) Congeal point	12.50
(27) Cooking test	5.20
(28) Crude fat	5.20
(29) Crude fiber	8.35
(30) Density	5.20
(31) Dextrose equivalent	14.85
(32) Diastatic activity of flour	15.60
(33) Enrichment—quick test	2.60
(34) Falling number	5.20
(35) Farinograph characteristics	19.50
(36) Fat—acid hydrolysis	10.40
(37) Fat acidity	7.80
(38) Fat stability—Aom	10.40
(39) Filth—heavy	12.90
(40) Filth—light	15.60
(41) Flash point—open and closed cup	7.80
(42) Foam test	15.60
(43) Foots—heated and/or chilled	5.20
(44) Foreign material—processed grain products	7.80
(45) Free fatty acids	5.20
(46) Heating test—oil and shortening	5.20
(47) Hydrogen ion concentration—pH	7.80
(48) Insoluble bromides	5.20
(49) Insoluble impurities—oil and shortening	5.20
(50) Iodine number or value	7.80
(51) Iron enrichment	10.40
(52) Linolenic acid (fatty acid profile)	10.00
(53) Lipid phosphorous	39.00
(54) Loaf volume	15.60
(55) Lysine from fortification	19.10
(56) Lysine from hydrolysis of protein	10.00
(57) Maltose value—flour	15.60
(58) Marine oil in vegetable oil—qualitative	5.20
(59) Melting point—Wiley	10.40
(60) Moisture—distillation	7.80
(61) Moisture—oven	3.65
(62) Moisture and volatile matter—oil and shortening	5.20
(63) Neutral oil loss	15.60
(64) Nitrogen solubility index	13.00
(65) Oven leak test—oil can	7.80
(66) Oil content—oilseed	7.80
(67) Particle size—flour	12.35

INSPECTION SERVICE—Continued

	Fee
(68) Performance test—prepared bakery mix	17.95
(69) Peroxide value	5.20
(70) Phosphorous	10.40
(71) Popping value—popcorn	15.60
(72) Potassium bromate—qualitative	2.60
(73) Potassium bromate—quantitative	7.80
(74) Protein dispersibility index	13.00
(75) Protein, Kjeldahl	6.00
(76) Purity—Monosodium glutamate	20.80
(77) Reducing sugars	15.60
(78) Refractive index	7.80
(79) Riboflavin	20.80
(80) Rope spore count	26.00
(81) Salmonella	30.55
(82) Salt content	7.80
(83) Saponification number	7.80
(84) Sedimentation	13.00
(85) Sieve test	3.65
(86) Smoke point	7.80
(87) Softening point	10.40
(88) Solid fat index	18.00
(89) Specific baking volume—cake mix	18.00
(90) Specific gravity—oils	10.40
(91) Starch damage—flour	12.35
(92) Staphylococcus aureas	20.25
(93) Sucrose	15.60
(94) Test weight per bushel—other than grain	2.15
(95) Tilletia contraversa Kuhn (TCK)	20.80
(96) Unsaponifiable matter	10.40
(97) Urease activity	7.80
(98) Viscosity	10.40
(99) Water soluble protein	13.00
(100) Xanthydrol test for rodent urine	16.40
(b) If a requested test is to be reported on a specified moisture basis, a fee for moisture test will also be assessed.	
Lentil inspection: (see Bean inspection).	
Minimum fee for services covered by the hourly rate—a minimum fee of 2 hours per individual, per service request, will be assessed at the applicable hourly rate.	
New inspection—fees based on service requested.	
Pea inspection: (see Bean inspection).	
Sampling, per man-hour	20.80
Special inspection service, per man-hour	20.80
Split pea inspection: (see Bean inspection).	
Standby time, per man-hour	20.80
Straw inspection: (see Hay inspection).	

[1] The applicable grading or laboratory testing fee. Minimum fee, if any, is $20.80, subject to [3] below.
[2] Applicable sampling fee, if any, plus applicable grading or laboratory testing fee.
[3] No fees shall be assessed if a material error is found in the inspection from which an appeal is taken.
[4] When graded according to the applicable U.S. Standards. Factors requested in addition to those that are in the U.S. Standards will be charged the factor fee for each additional factor. See Factor fee.
[5] Only one fee will be assessed for this service whether performed singly or concurrently (but see minimum fee requirements).
[6] Plus all travel costs associated with the performance of the demonstration grading service.

[FR Doc. 82-232 Filed 1-4-82; 8:45 am]
BILLING CODE 3410-EN-M

Soil Conservation Service

7 CFR Part 631

Great Plains Conservation Program; Correction

AGENCY: Soil Conservation Service (SCS), USDA.

ACTION: Final rule correction.

SUMMARY: This action revises 7 CFR Part 631 of the Great Plains Conservation Program (GPCP) regulations to make technical corrections.

EFFECTIVE DATE: January 1, 1982.

FOR FURTHER INFORMATION CONTACT: Guy D. McClaskey, SCS, P.O. Box 2890, Washington, D.C. 20013, telephone (202) 382–1868.

SUPPLEMENTARY INFORMATION: This action makes technical corrections and terminology changes in the final rule to allow entering into new GPCP contracts until September 30, 1991, and change the term "administrator" to "chief." The final rule limits new GPCP contracts to December 31, 1981. On June 6, 1980, Pub. L. 96–263 was approved that extended GPCP to September 30, 1991. The correction will update the extended date set by this law.

This proposed action has been reviewed under USDA procedures established in Secretary's Memorandum 1512–1 which implements Executive Order 12291 and has been determined to be "nonmajor."

This proposed action has been determined "nonmajor" since the annual effect on the economy is less than $100 million and there will be no increase in costs or prices for individuals, organizations, or other government agencies affected. There will be no significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States based enterprises in domestic or export markets.

Since this action only clarifies the final rule and makes minor technical corrections, SCS has determined that publication for public comment would not be in the public interest.

SCS certifies that this regulation will not have a significant impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

These corrections contain no new or amended requirements for recordkeeping, reporting, plans or procedures, applications, or any other type of information collection.

A complete review and revision of the GPCP regulations will be completed in fiscal year 1982. The rule correction in this action will allow the program to continue operations until the complete revision has been made. The Great Plains Conservation Program is authorized by section 16(b) of the Soil Conservation and Domestic Allotment Act (70 Stat. 115, as amended; 16 U.S.C. 590p(b), Pub. L. 96–263). Final program rules were revised and published November 18, 1975, and went into effect at once.

The program provides technical and financial assistance under long-term contracts to land users in 518 designated

counties of the 10 Great Plains States. It is designed to protect and improve soil, water, plant, and wildlife resources of the Great Plains area which is plagued with recurring drought and wind erosion. Installation of complete conservation treatment and management systems on farms and ranches helps stabilize individual enterprises and consequently the local economy.

PART 631—GREAT PLAINS CONSERVATION PROGRAM

Therefore, 7 CFR Part 631 is amended as follows:

At each place the word "administrator" appears it is changed to the word "chief."

§ 631.8 [Amended]

1. The date, December 31, 1981, in § 631.8(a) is changed to September 30, 1991.

(Catalog of Federal Domestic Assistance Program No. 10.900 Great Plains Conservation Program. Office of Management and Budget Circular A-95 regarding State and local clearinghouse review of Federal and federally assisted programs and projects is not applicable.)

David G. Unger,

Associate Chief.

December 24, 1981.

[FR Doc. 82-24 Filed 1-4-82; 8:45 am]

BILLING CODE 3410-01-M

Federal Grain Inspection Service

7 CFR Part 800

Grain Regulations; Revision of Rules

AGENCY: Federal Grain Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Federal Grain Inspection Service (FGIS) is adopting without change as a final rule, an interim final rule published in the Federal Register on July 27, 1981 (46 FR 38336), in which § 800.205 of the regulations was revised to restate and clarify the procedures to be followed where renewal of a designation of an official agency is involved and where a designation is revoked or suspended for cause.

EFFECTIVE DATE: January 5, 1982.

FOR FURTHER INFORMATION CONTACT: Lewis Lebakken, Jr., Regulations and Directives Management, 1400 Independence Avenue SW., Washington, D.C. 20250; telephone (202) 447-9172.

SUPPLEMENTARY INFORMATION: This final action has been issued in conformance with Executive Order 12291 and Secretary's Memorandum 1512-1 and has been determined to be "nonmajor," because it imposes no additional duties or obligations on persons subject to the regulations and its only purpose is to clarify existing regulations.

Kenneth A. Gilles, Administrator of FGIS, has determined that this action will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), because it applies only to a limited number of private and State grain inspection and weighing agencies which are designated under the Act.

The July 27, 1981, issue of the Federal Register (46 FR 38336) contained an interim final rule requesting comments on certain changes to the regulations which restated and clarified the procedures to be followed where renewal of a designation of an official agency is involved and where a designation is revoked or suspended for cause. Comments were to be submitted on or before September 25, 1981. No comments were received.

The procedure which an official agency must follow when it requests to have its designation renewed is set out in §§ 800.196 through 800.199 of the regulations. Section 800.205 was revised so that its provisions will be consistent with those of §§ 800.196 through 800.199 and with section 7(g)(1) of the United States Grain Standards Act (hereinafter the "Act").

Section 7(g)(1) of the Act provides that the designation of each official agency shall terminate at such time as specified by the Administrator but not later than 3 years after issuance. Designations of official agencies may be renewed in accordance with the criteria and the procedure for designation prescribed in section 7(f) of the Act. Further, certain technical changes have been made in § 800.205 so that the regulatory text will be aligned with the revocation and suspension provisions of section 7(g)(3) of the Act. These technical changes were not substantive in nature.

PART 800—GENERAL REGULATIONS

Accordingly § 800.205 of the regulations published as an interim final rule at 46 FR 38336 is adopted without change as a final rule, effective January 5, 1982.

(Sections 8, 18, Pub. L. 94-582, 90 Stat. 2870, 2884 (7 U.S.C. 79, 87e))

Dated: December 16, 1981.

Kenneth A. Gilles,

Administrator.

[FR Doc. 82-233 Filed 1-4-82; 8:45 am]

BILLING CODE 3410-EN-M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 238

Contracts With Transportation Lines; Addition of Air Afrique

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This rule adds Air Afrique to the list of carriers which have entered into agreements with the Service to guarantee the passage through the United States in immediate and continuous transit of aliens destined to foreign countries.

EFFECTIVE DATE: December 2, 1981.

FOR FURTHER INFORMATION CONTACT: Stanley J. Kieszkiel, Acting Instructions Officer, Immigration and Naturalization Service, 425 Eye Street, NW, Washington, D.C. 20536, Telephone: (202) 633-3048.

SUPPLEMENTARY INFORMATION: This amendment to 8 CFR 238.3 is published pursuant to 5 U.S.C. 552. The Commissioner of Immigration and Naturalization Service entered into an agreement with Air Afrique on December 2, 1981 to guarantee passage through the United States in immediate and continuous transit of aliens destined to foreign countries.

The agreement provides for the waiver of certain documentary requirements and facilitates the air travel of passengers on international flights while passing through the United States.

Compliance with 5 U.S.C. 533 as to notice of proposed rulemaking and delayed effective date is unnecessary because of the amendments merely make editorial changes to the listing of transportational lines.

In accordance with 5 U.S.C. 605(b), the Commissioner of Immigration and Naturalization certifies that the rule will not have a significant impact on a substantial number of small entities.

This order constitutes a notice to the public under 5 U.S.C. 552 and is not a rule within the definition of section 1(a) of E.O. 12291.

Accordingly, 8 CFR Part 238 is amended as follows:

PART 238—CONTRACTS WITH TRANSPORTATION LINES

§ 238.3 [Amended]

In § 238.3 Aliens in immediate and continuous transit, the listing of

transportation lines in paragraph (b) *Signatory lines* is amended by:

1. Adding in alphabetical sequence, "Air Afrique."

(Secs. 103, 66 Stat. 173 (8 U.S.C. 1103); 238, 66 Stat. 202 (8 U.S.C. 1228))

Dated: December 28, 1981.

Doris M. Meissner,

Acting Commissioner of Immigration and Naturalization.

[FR Doc. 82-110 Filed 1-4-82; 8:45 am]

BILLING CODE 4410-10-M

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8 CFR Part 316a

Residence, Physical Presence and Absence; Addition of Institute for Development Anthropology, Inc., and Environmental Research Laboratory of the University of Arizona

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This final rule adds to the list of organizations determined to be "American Institutions of Research" recognized by the Attorney General. The Institute for Development Anthropology, Inc., and the Environmental Research Laboratory of the University of Arizona were recognized as conferring constructive residence for naturalization purposes for their employees overseas.

EFFECTIVE DATE: March 3, 1981, as to the Institute for Development Anthropology, Inc., and December 4, 1981 as to the Environmental Research Laboratory of the University of Arizona.

FOR FURTHER INFORMATION CONTACT: For General Information: Stanley J. Kieszkiel, Acting Instructions Officer, Immigration and Naturalization Service, 425 Eye Street, NW., Washington, D.C. 20536, Telephone (202) 633-3048.

For Specific Information Keith C. Williams, Acting Assistant Commissioner, Naturalization, Immigration & Naturalization Service, 425 Eye Street, NW., Washington, D.C. 20536, Telephone (202) 633-3320.

SUPPLEMENTARY INFORMATION: Section 316(b) of the Immigration and Nationality Act, 8 U.S.C. 1427(b), allows for certain absences abroad by lawful permanent residents of the United States to preserve residence and be counted towards the residence requirements of naturalization. Among other things, employment overseas by a recognized American institute of research qualifies for this constructive residence benefit. 8 CFR 316a.2 lists those American institutions of research which have been recognized by the Attorney General. Absences abroad in the employment of these institutes will be counted as constructive residence in establishing the residence requirements of naturalization provided all conditions of 8 U.S.C. 1427(b), which lists the requirements of naturalization are satisfied. The Institute for Development Anthropology, Inc., and the Environmental Research Laboratory of the University of Arizona, each in requesting recognition as an American institution of research, have submitted documentation to support their requests. The Regional Commissioner, Eastern Region, Immigration and Naturalization Service, in accordance with Service Operations Instructions (0I 316a.4), has approved the request of the Institute for Development Anthropology, Inc. Similarly, the Regional Commissioner, Western Region, has approved the Environmental Research Laboratory of the University of Arizona.

Compliance with 5 U.S.C. 553 as to notice of proposed rulemaking and effective date is unnecessary because the amendment merely adds to the listing of recognized institutions.

In accordance with 5 U.S.C. 605(b) the Commissioner of Immigration and Naturalization certifies that this rule will not have a significant economic impact on a substantial number of small entities.

This order constitutes a notice to the public under 5 U.S.C. 552 and is not a rule within the definition of section 1(a) of E.O. 12291.

PART 316a—RESIDENCE, PHYSICAL, PRESENCE AND ABSENCE

§ 316a.2 [Amended]

In § 316a.2 American institutes of research, the listing of organizations is amended by adding in alphabetical sequence, "Environmental Research Laboratory of the University of Arizona" and "Institute for Development Anthropology, Inc."

(Sec. 316, 66 Stat. 163 (8 U.S.C. 1427))

Dated: December 28, 1981.

Doris M. Meissner,

Acting Commissioner of Immigration and Naturalization.

[FR Doc. 82-109 Filed 1-4-82; 8:45 am]

BILLING CODE 4410-10-M

DEPARTMENT OF THE TREASURY

Comptroller of the Currency

12 CFR Part 5

[Docket No. 81-21]

Rules, Policies and Procedures for Corporate Activities; Correction

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Final rule; correction.

SUMMARY: On December 4, 1981 (46 FR 59232), the Office of the Comptroller of the Currency (Office) published a correction document to Title 12 of the Code of Federal Regulations Part 5 (FR Doc. 81-34892). The December 4, 1981, correction document, at item #8, corrected § 5.21, Organization of an Interim National Bank, to change the designations of the paragraphs (f), (g), (h), (i), (j), and (k), to (e), (f), (g), (h), (i), and (j) respectively. This correction was unnecessary since the paragraphs were correctly designated prior to issuance of the December 4, 1981, correction document. Therefore, disregard the correction listed as #8 in the December 4, 1981, correction document.

DATE: Effective January 5, 1982.

FOR FURTHER INFORMATION CONTACT: James E. Brennan, Manager, Bank Organization and Structure Division, Office of the Comptroller of the Currency, 490 L'Enfant Plaza East, SW., Washington, D.C. 20219. Telephone: (202) 447-1184.

SUPPLEMENTARY INFORMATION: On 46 FR 59233, in the issue of December 4, 1981, disregard the correction in paragraph "8".

Dated: December 23, 1981.

C. T. Conover,

Comptroller of the Currency.

[FR Doc. 82-30 Filed 1-4-82; 8:45 am]

BILLING CODE 4810-33-M

CIVIL AERONAUTICS BOARD

14 CFR Part 201

[Reg. ER-1274; Amdt. No. 7]

Application for Certificates of Public Convenience and Necessity

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: The CAB eliminates the requirement that applicants for

certificates of public convenience and necessity to engage in domestic air transportation list the communities for which they seek authority in their applications. This action is taken because the CAB will no longer list the points that an airline is authorized to serve in the carrier's certificate. Airlines will be able to serve any community they wish after they obtain a certificate.

DATES: Adopted: December 22, 1981. Effective: December 31, 1981.

FOR FURTHER INFORMATION CONTACT: David Schaffer, Office of the General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue, NW, Washington, D.C. 20428; 202–673–5442.

SUPPLEMENTARY INFORMATION: In order to operate large aircraft in air transportation, a carrier must obtain from the Board a certificate of public convenience and necessity under section 401 of the Federal Aviation Act. Until now, these certificates listed all the terminal and intermediate points that the carrier was authorized to serve. (Section 401(e)(1) of the Act.) Part 201 of the Board's rules, 14 CFR Part 201, sets forth the requirements for applications for section 401 certificates. Section 201.4 of this rule requires applicants to identify the terminal and intermediate points for each route applied for and to submit an illustrative service proposal for the markets for which authority is sought.

Section 1601(a)(1)(C) of the Act prohibits the Board from continuing to list terminal and intermediate points on domestic certificates after December 31, 1981. This in intended to give certificated airlines the authority to serve any point in the United States without having to obtain authority from the Board for each one. After December 31, 1981, an applicant for a domestic 401 certificate will therefore not have to identify all the terminal and intermediate points it wishes to serve. This calls for conforming changes in Part 201.

The requirement in § 201.4 that an applicant specify routes and list terminal and intermediate points for which it seeks domestic authority is being eliminated. The requirement that it file an illustrative service proposal is being changed. This proposal will have to cover only the routes that the applicant intends to enter initially or similar markets if it does not want to reveal its actual plans. The purpose of this requirement is to demonstrate to the Board that the applicant has some idea of the costs and flight times involved in a given route and has basic managerial capability. The proposed scope of the carrier's initial operations is also essential in determining the amount of financing required to inaugurate the service proposed. It is thus relevant to the question of the applicant's fitness. An applicant would not be bound to commence service to the cities for which it submitted an illustrative service proposal nor would it be prohibited from serving other communities instead. A substantial change in the scope of operations that were proposed would, however, require the submission of additional fitness information under 14 CFR 204.4.

The above discussion does not apply to intra-Alaska and intra-Hawaii freighter air service or to foreign air transportation. For reasons more fully explained in Order 81–11–23 (Docket 40208), 46 FR 55294, November 9, 1981, the Board must continue to list terminal and intermediate points on certificates authorizing such service. Thus, an applicant for intra-Alaska and intra-Hawaii cargo-only or foreign air service will have to identify those points it wishes to serve on its application as well.

The elimination of terminal and intermediate points in domestic certificates also calls for changes in § 201.4(b). That paragraph currently distinguishes between interstate air transportation on the one hand and overseas and foreign air transportation on the other. It prohibits an applicant from including a request for interstate authority in the same application as requests for overseas or foreign authority. With the changes described above, however, this distinction is outmoded. Since certificates will list points for foreign air transportation but not for interstate and overseas service, it makes more sense to consider applications for interstate and overseas services together but to require applications involving foreign air transportation to be filed separately. The amendment to § 201.4(b) below does this.

We are also taking this opportunity to eliminate § 201.6. That section governs applications for authority to provide all-cargo (freighter) air service under paragraphs (a)(1) and (a)(2) of § 418. Those two paragraphs apply to carriers that were already providing all-cargo air service under a certificate or an exemption. They allow such carriers to apply for the broader authority available under section 418 within 45 days after enactment of the section. This 45-day period has long since passed so § 201.6 is now obsolete. Elimination of § 201.6 does not affect applications under § 418(a)(4) from any person seeking authority to provide all-cargo air service for the first time. Those applications are covered by 14 CFR Part 291.

Since this action is procedural in nature, is taken to conform our rules to the change in our statutory authority at the end of this year and relieves restrictions, we find good cause for dispensing with notice and public procedure and for making these amendments effective in less than 30 days.

PART 201—APPLICATIONS FOR CERTIFICATES OF PUBLIC CONVENIENCE AND NECESSITY

Accordingly, the Board amends 14 CFR Part 201, *Application for Certificates of Public Convenience and Necessity*, as follows:

1. The authority for Part 201 is:

Authority: Secs. 204, 401, 402, Pub. L. 85–726, as amended, 72 Stat. 743, 754, 757; 49 U.S.C. 1324, 1371, and 1372.

2. The Table of Contents is amended by removing § 201.6.

3. Paragraphs (b), (c)(3), and (e)(1) of § 201.4 are revised to read:

§ 201.4 General provisions concerning contents.

* * * * *

(b) Requests for authority to engage in interstate and overseas air transportation shall not be included in the same application with requests for authority to engage in foreign air transportation. Similarly, requests for authority to engage in scheduled air transportation shall not be included in the same application with requests for authority to engage in nonscheduled air transportation.

(c) * * *

(3) For cargo-only transportation within the States of Alaska or Hawaii and for foreign air transportation, an adequate identification of each route for which a certificate is desired and whether or not this transportation is to be rendered on scheduled operations. The identification of each route shall name the terminal and intermediate points to be included in the certificate for which application is made. For all applications, a specification of the type or types of service (mail, passengers, or property) to be rendered and whether such services are to be rendered on scheduled operations.

* * * * *

(e) * * *

(1) For scheduled carriers only, an illustrative service proposal for the type of markets that the applicant plans to serve initially showing the type and capacity of the equipment it would use and the elapsed trip time of flights in block hours over the segments.

* * * * *

§ 201.6 [Removed]

4. Section 201.6 is removed.

By the Civil Aeronautics Board:

Phyllis T. Kaylor,

Secretary.

[FR Doc. 82-170 Filed 1-4-82; 8:45 am]

BILLING CODE 6320-01-M

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14 CFR Part 207

[Reg. ER-1276; Amdt. No. 33; Docket No. 40236]

Charter Trips and Special Services; Part Charters

AGENCY: Civil Aeronautics Board.

ACTION: Final Rule.

SUMMARY: The CAB amends its charter rules to allow airlines to conduct "part charters," which are flights that carry both charter and scheduled-service passengers. The rule is designed to increase airlines' marketing flexibility and eliminate an unnecessary restraint on competition. Supplementary information about this action is set out in ER-1275, issued along with this rule.

DATES: Adopted: December 28, 1981. Effective: December 31, 1981.

FOR FURTHER INFORMATION CONTACT: Patti Szrom, Special Authorities & Administration, Bureau of Domestic Aviation, 202-673-5088, or Patricia DePuy, Regulatory Affairs Division, Bureau of International Aviation, 202-673-5878; Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428.

SUPPLEMENTARY INFORMATION:

PART 207—CHARTER TRIPS AND SPECIAL SERVICES

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 207, Charter Trips and Special Services, as follows:

1. The authority for Part 207 is:

Authority:—Secs. 101(3), 102, 204, 401, 403, 404, 407, 411, 416, 418, 1002, Pub. L. 85-726, as amended, 72 Stat. 737, 740, 743, 754, 758, 760, 766, 769, 771, 788, 91 Stat. 1284; 49 U.S.C. 1301, 1302, 1324, 1371, 1373, 1374, 1377, 1381, 1386, 1388, 1482.

2. In § 207.11, paragraph (a) is amended by revising the introductory language in paragraph (a)(2) and removing the last two sentences of paragraph (a)(3), and paragraph (b)(4) is removed, as follows:

§ 207.11 Charter flight limitations.

(a) Passenger charter flights in air transportation shall be limited to the following:

* * * * *

(2) Air transportation performed on a time, mileage, or trip basis where all or part of the capacity of an aircraft has been engaged by any of the following persons:

* * * * *

(3) Air transportation performed on a time, mileage, or trip basis by a direct air carrier in accordance with Subpart E of this part.

(4) [Removed]

* * * * *

3. In § 207.13, paragraph (b) is amended by removing "pursuant to § 207.11(a)(3)" from the proviso, so that the proviso is revised to read as follows:

§ 207.13 Terms of service.

* * * * *

(b) * * * *Provided, however,* That in the case of a passenger charter for less than the entire capacity of an aircraft, the carrier shall require full payment of the total charter price, including payment for the return portion of a round trip, from the passenger charterers not less than 10 days prior to the commencement of any portion of the transportation, and such payment shall not be refundable unless the charter is canceled by the carrier or unless the carrier accepts a substitute charterer for one which has canceled a charter, in which case the amount paid by the latter shall be refunded. For the purpose of this paragraph payment to the carrier's depository bank, as designated in the charter contract, shall be deemed payment to the carrier.

* * * * *

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 82-172 Filed 1-4-82; 8:45 am]

BILLING CODE 6320-01-M

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14 CFR Part 208

[Reg. ER-1277; Amdt. No. 34; Docket No. 40236]

Less-Than-Planeload Charters

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: The CAB amends its rule governing flights by U.S. airlines that have charter authority but no scheduled route authority, to allow flights where part of the aircraft is chartered and part is empty. The rule is designed to increase airlines' marketing flexibility and eliminate an unnecessary restraint on competition. Supplementary information about this action is set out in ER-1275, issued along with this rule.

DATES: Adopted: December 28, 1981. Effective: December 31, 1981.

FOR FURTHER INFORMATION CONTACT: Patti Szrom, Special Authorities & Administration, Bureau of Domestic Aviation, 202-673-5088, or Patricia DePuy, Regulatory Affairs Division, Bureau of International Aviation, 202-673-5878; Civil Aeronautics Board, 1825 Connecticut Avenue NW., Washington, D.C. 20428

SUPPLEMENTARY INFORMATION:

PART 208—TERMS, CONDITIONS AND LIMITATIONS OF CERTIFICATES TO ENGAGE IN CHARTER AIR TRANSPORTATION

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 208, Terms, Conditions and Limitations of Certificates to Engage in Charter Air Transportation as follows:

1. The authority for Part 208 is:

Authority: Secs. 101(3), 102, 204, 401, 403, 404, 407, 411, 416, 417, 1002, Pub. L. 85-726, as amended, 72 Stat. 737, 740, 743, 754, 758, 760, 766, 769, 771, 788, 76 Stat. 145; 49 U.S.C. 1301, 1302, 1324, 1371, 1373, 1374, 1377, 1381, 1386, 1387, 1482.

2. In § 208.6, paragraph (a) is amended by revising the introductory language in paragraph (a)(2) and removing the last two sentences of paragraph (a)(3), as follows:

§ 208.6 Charter flight limitations.

(a) Passenger charter flights in air transportation shall be limited to the following:

* * * * *

(2) Air transportation performed on a time, mileage, or trip basis where all or part of the capacity of an aircraft has been engaged by any of the following persons:

* * * * *

(3) Air transportation performed on a time, mileage, or trip basis by a direct air carrier in accordance with Subpart F of this part.

* * * * *

3. In § 208.32, paragraph (e) is amended by removing "pursuant to § 208.6(a)(3)" from the proviso, so that the proviso reads:

§ 208.32 Terms of service.

* * * * *

(e) * * * *Provided, however,* That in the case of a passenger charter for less than the entire capacity of an aircraft, the carrier shall require full payment of the total charter price, including payment for the return portion of a round trip, from the passenger charterers not less than 10 days prior to the commencement of any portion of the transportation, and such payment shall not be refundable unless the charter is canceled by the carrier or unless the carrier accepts a substitute charterer for

one which has canceled a charter, in which case the amount paid by the latter shall be refunded. For the purpose of this paragraph, payment to the carrier's depository bank, as designated in the charter contract, shall be deemed payment to the carrier.

* * * * *

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 82-173 Filed 1-4-82; 8:45 am]

BILLING CODE 6320-01-M

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14 CFR Part 212

[Reg. ER-1275; Amendment No. 43; Docket 40236]

Charter Trips by Foreign Air Carriers; Part Charters

AGENCY: Civil Aeronautics Board.

ACTION: Final Rule.

SUMMARY: The CAB amends its charter rules to allow airlines to conduct "part charters," which are flights that carry both charter and scheduled-service passengers. The rule is designed to increase airlines' marketing flexibility and eliminate an unnecessary restraint on competition.

DATES: Adopted: December 28, 1981. Effective: December 31, 1981.

FOR FURTHER INFORMATION CONTACT: Patti Szrom, Special Authorities & Administration, Bureau of Domestic Aviation, 202-673-5888, or Patricia DePuy, Regulatory Affairs Division, Bureau of International Aviation, 202-673-5078; Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428.

SUPPLEMENTARY INFORMATION:

The Proposal

A "part charter" is a flight that includes both charter and scheduled-service passengers. The Board's passenger charter rules, by authorizing charters to be performed on a planeload basis only, have long prohibited part charters. The prohibition was designed to preserve a distinction between charter service and scheduled service, and to protect planeload charters against competition from part charters. (Part charters should not be confused with split charters, whereby two or more charterers together engage the entire capacity of an aircraft and no scheduled-service passengers are carried. Split charters are already permitted.)

In the Airline Deregulation Act of 1978, Pub. L. 95-504, Congress amended section 401(n)(1) of the Federal Aviation Act to prohibit passenger part charters in domestic air transportation. In the International Air Transportation Competition Act (IATCA), Pub. L. 96-192, it amended section 401(n)(1) to extend the prohibition to foreign air transportation. Section 26(b) of IATCA, 94 Stat. 47, terminates the statutory prohibition on December 31, 1981.

The Board is thus free to amend its rules to allow part charters after December 31, 1981. The Board proposed to do that in EDR-435/SPDR-84, 46 FR 56425, November 17, 1981 ("the NPRM"). In the NPRM the Board noted that the original bases for the prohibition no longer exist, and there appears to be no good reason to continue it beyond the period mandated by Congress. When U.S. charter carriers were precluded from offering scheduled service the Board believed the part charter prohibition was necessary to protect those carriers from very low cost charters on scheduled service. Because the former charter carriers can now operate scheduled service, and in view of new forms of scheduled service that have many of the characteristics of charters, we concluded in the NPRM that the restriction is no longer necessary. Moreover, continuing to protect planeload charters against competition from part charters would be inconsistent with the clear Congressional policy to let competition be the primary determinant of the type of service that airlines provide.

The NPRM stated that allowing part charters would increase the travel options available to the public, especially in less popular markets where there is not enough traffic to support planeload charters. Part charter authority would also improve airlines' ability to make the most efficient use of their aircraft, by enabling them to offer the mix of services that best suits the demand in any given market and to sell seats that otherwise might fly empty.

To allow part charters the Board therefore proposed to amend 14 CFR Parts 207 and 212, which apply to direct carriers, and 380, which applies to charter operators, to make part charters a legal charter form. The Board also proposed a corresponding amendment of Part 208, which applies only to U.S. carriers that have no scheduled route authority. Eliminating the planeload requirement for charters by these carriers would not enable them to conduct part charters as described above, because they would still lack the authority to carry scheduled traffic. Even so, such an amendment would be worthwhile, the Board stated, because it would enable these carriers to perform flights where a portion of the space was chartered and the rest remained unsold. A carrier may find such a flight to be economically justified, and there is no need for the Board to supervise carriers' business judgment.

Under the proposed revisions to Part 207, a U.S. route carrier would be allowed to engage in part charters over any domestic or international route authorized by certificate or exemption. Foreign air carriers, however, would not automatically receive this authority. The proposed revisions to Part 212 would make part charters a legal charter form, but would require each foreign air carrier to apply for and obtain a statement of authorization before engaging in part charter services. The NPRM stated that the Board would also entertain applications for "blanket" statements of authorization, under which the grantee carrier could perform unlimited part charters as long as the authorization remained in force. The proposed procedures for applying for such authority were the same as those already employed by foreign carriers seeking to obtain fifth freedom charter authority, except that applications for individual statements of authorization would be required 45 days before the planned part charter.

Our proposal to impose a prior approval requirement for foreign air carriers stemmed directly from the potentially significant economic value of part charters. The NPRM stated that in our view such a valuable right, which is not universally available from foreign governments, should not be conferred automatically. Rather, it should be awarded only after a review of our aviation relations with the foreign carrier's homeland and the confirmation that economically reciprocal rights exist for U.S. air carriers.

The Comments

United Air Lines and Transamerica Airlines filed comments on the NPRM. United supported the proposal. It stated that part charters would be another ingredient in the mix of products that air carriers can market, which would help carriers to tailor group movements to the needs of the traveling public and tour operators. United also stated that charter agreements are often negotiated far in advance of actual operation, and urged the Board to make the amendments effective January 1, 1982, as proposed. United agreed with the Board that foreign carriers should not automatically receive the same part charter authority as domestic carriers. It suggested that the Board examine foreign carriers' applications on a flight-by-flight basis, and stated that the Board's willingness to grant blanket

authorizations for fifth freedom charters has worked to the detriment of U.S. carriers.

Transamerica's comment took no position on the legality or advisability of allowing part charters. The comment suggested, however, that the NPRM presented problems in three areas: technical details, reciprocity issues, and timing.

The technical problems that Transamerica suggested would arise would result from the different ways that scheduled and charter service have been regulated up to now. Transamerica noted that the NPRM's silence on this matter indicated that part charter traffic would move according to charter rules even when carried on scheduled flights commingled with differently-regulated as well as differently-priced traffic. In the case of overbooking, for example, it suggested that there may be a tendency for carriers to discriminate against part charter passengers by bumping them first since they will not be entitled to receive denied boarding compensation. And in cases of involuntary rerouting, the part charter passengers might find themselves worse off than if they were booked on either scheduled tickets or on a planeload charter. Transamerica cited the Public Charter rule's restrictions on cancellations (§§ 380.12, 380.32(h), and 380.43) and stated that their applicability to part charter passengers on scheduled flights would be unclear because scheduled flights are governed by tariff rules, which often differ from the Public Charter rules and which "will not necessarily apply to part charter passengers." It suggested that the responsibility for refunds when a flight is canceled, although clear on a scheduled flight or a planeload charter, would become muddled for a part charter passenger. It also questioned how the rules on payments for split charters would apply to part charters.

With regard to reciprocity in foreign markets, Transamerica agreed with the Board that foreign carriers should not be awarded part charter authority unless U.S. carriers have adequate reciprocal rights. It criticized the NPRM, however, for failing to state what would constitute sufficient reciprocity to support such an award. It urged that the Board, before allowing a foreign carrier to conduct part charters, make sure that the carrier's homeland allows not only part charters by U.S. carriers but also equal and nondiscriminatory access for planeload charters by U.S. carriers. This policy is necessary, Transamerica stated, because the protected flag carrier of a country that sharply restricts planeload charters could be expected to support part charters for itself combined with continued restrictions for planeload charters. If reciprocity were to be decided on the basis of part charter policy alone, the Board might be forced to allow such a carrier to perform part charters, giving up in the process bargaining leverage that could otherwise be used to obtain a more procompetitive charter policy for a broader range of carriers. Even for countries with which the United States has liberal bilateral agreements covering planeload charters, Transamerica cautioned, the Board should not authorize U.S.-origin part charters by a foreign carrier unless U.S. carriers can conduct foreign-origin part charters.

Finally, Transamerica urged that the Board delay action on part charters. It stated that the part charter form will offer a significant competitive advantage to those carriers with extensive scheduled route systems, and that carriers relying primarily on planeload charters will need more flexible charter rules in order to offer a more attractive product. It referred to the National Air Carrier Association's petition in Docket 40215, in which it has joined, seeking the removal of restrictions on charters to make them more competitive with scheduled service. Transamerica urged the Board to consider the part charter and charter liberalization rulemaking proceedings simultaneously, arguing that to do otherwise would "inevitably exacerbate the discriminatory harm to planeload charter services described in the NACA Petition." It stated that such a delay would also enable the Board to review or moot the technical problems described above.

Response to Comments

The Board has decided to adopt the part charter rules as proposed, with one clarifying addition in reponse to Transamerica's comment. The Board is not persuaded to delay this action pending the other rulemaking on charter liberalizations in general. The part charter ban is a regulatory restriction on air carriers' marketing flexibility that limits the services offered to the traveling public. Although it is possible that part charters may cause some change in market share between different segments of the industry, the Board does not consider that a sufficient reason to delay removal of a regulatory restraint. The basic policy underlying deregulation, embodied by Congress in section 102 of the Act, is that free market forces will produce the most efficient and beneficial allocation of resources. It is not necessary or called for to predict all outcomes before taking deregulatory action. In fact, the Board's inability to predict outcomes is one of the main reasons to prefer free competition to a closely regulated system.

The Board is sensitive to the reciprocity concerns raised by Transamerica, but this rulemaking proceeding is not the best forum in which to address them. As Transamerica itself noted, "the issue is complicated by the almost infinite number of variable factors at work in various bilateral markets." The question whether a particular country affords adequate reciprocity can be better addressed in individual cases when a carrier from that country applies to the Board for a statement of authorization for a part charter. Under § 212.5, interested persons may file memoranda in support of, or opposition to, any such application. And while the Board has not yet established specific procedures for considering requests for blanket statements of authorization, it will not grant such a request without affording an opportunity for public comments.

Several of Transamerica's technical points, such as those relating to overbooking and involuntary rerouting, are essentially speculative. There is no question that part charters, as a new form of marketing, may raise some problems that the carriers, charter operators, and passengers will have to work out. But at this point the Board has no reason to believe that the parties involved will need government intervention to resolve these problems. The best way to discover whether any of them would rise to the level of public policy questions is to let the rule go into effect. Part charters are a relatively complex form of air transportation. The thrust of the Board's action here is not to lay down new rules, but to remove regulatory impediments and see whether any problems arise that cannot be satisfactorily resolved by the private sector.

There should be no confusion about the applicability of rules tariffs. These apply to air carriers' scheduled passengers, but not their charter passengers, regardless of whether those passengers are on planeload or part charter flights. Similarly, cancellations and refunds are governed by tariff rules for scheduled passengers, but by the charter rules and operator-participant contracts for planeload and part charter passengers. In response to Transamerica's comment, the Board is amending the rules that require payments for split passenger charters to be made at least 10 days before departure (§§ 207.13(b), 208.32(e), and

212.8(a)), to eliminate a cross-reference that is made inaccurate by the other changes adopted here. The result is that those sections now apply to any passenger charter of less than an entire planeload, whether it be a split charter or a part charter. The Board will be reviewing these provisions in its forthcoming proposal on liberalized charter rules.

This rule amends Part 212, which governs charters by foreign air carriers. Issued along with this rule are ER–1276, which makes a corresponding amendment of Part 207 for U.S. route carriers; ER–1277, which amends Part 208 as described above to allow U.S. charter-only carriers to conduct charter flights that are part empty; and SPR–182, which makes a confronting amendment of Part 380, the Public Charter rule. Because these rules relieve restrictions and create no additional burdens, the Board finds that they may become effective less than 30 days after publication in the **Federal Register**.

Regulatory Flexibility Act

In accordance with 5 U.S.C. 605(b), as added by the Regulatory Flexibility Act, Pub. L. 96–534, the Board certifies that these rules will not have a significant economic impact on a substantial number of small entities. Few if any of the direct air carriers that are affected by the rules are small businesses. Charter operators, many of which are small businesses, will benefit from these rules because they eliminate a restriction on the type of flights on which operators may sell seats.

PART 212—CHARTER TRIPS BY FOREIGN AIR CARRIERS

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 212, *Charter Trips by Foreign Air Carriers*, as follows:

1. The authority for Part 212 is:

Authority.—Secs. 101(3), 102, 204, 401, 402, 403, 404, 407, 411, 416, 1002, Pub. L. 85–726, as amended, 72 Stat. 737, 740, 743, 754, 757, 758, 760, 766, 769, 771, 788; 49 U.S.C. 1301, 1302, 1324, 1371, 1372, 1373, 1374, 1377, 1381, 1386, 1482.

2. In § 212.3, the introductory language in paragraph (a)(1) is revised, the last two sentences of paragraph (a)(2) are removed, and paragraph (b)(3) is removed as follows. (The introductory text of paragraph (a) is included for the convenience of the user.)

§ 212.3 Charter flight limitations.

(a) Passenger charter flights by foreign air carriers in foreign air transportation shall be limited to the movement of persons or their baggage on a time, mileage, or trip basis—

(1) Where all or part of an aircraft has been engaged by any of the following persons:

* * * * *

(2) In accordance with Subpart E.

(b) * * *

(3) [Removed]

* * * * *

3. In § 212.4, paragraph (b) is amended by moving "or" from the end of paragraph (b)(2) to the end of paragraph (b)(3) and adding a new paragraph (b)(4), so that paragraph (b) is revised to read as follows:

§ 212.4 Prior authorization requirements.

* * * * *

(b) Foreign air carriers shall obtain a statement of authorization for each—

(1) Fifth freedom charter flight to or from the United States,

(2) Long-term wet lease to a direct air carrier or direct foreign air carrier,

(3) Charter flight for which the Board specially requires prior authorization under paragraph (e) or (f) of this section, or

(4) Flight carrying both charter and scheduled passenger traffic (hereafter "part charter").

* * * * *

4. In § 212.5, paragraph (a) is amended by removing the first sentence and adding two new sentences, and paragraph (d)(2) is amended by adding "a part charter or for" in the first sentence so that the revised sentence reads as follows:

§ 212.5 Application for authorization.

(a) Application for a statement of authorization shall be submitted on CAB Form 433 (Appendix C), except that for part charters or long-term wet leases the application may be submitted in letter form. An application for a long-term wet lease shall describe the purpose and terms of the wet lease agreement. * * *

* * * * *

(d) * * *

(2) Applications for a part charter or for a long-term wet lease to a direct air carrier or direct foreign air carrier shall be filed at least 45 days before the date of the first proposed flight.

* * * * *

5. In § 212.8, paragraph (a) is amended by removing "under § 212.3(a)(2)" from the proviso, so that the proviso is revised to read as follows:

§ 212.8 Terms of service.

(a) * * * *Provided, however,* that in the case of a passenger charter for less than the entire capacity of an aircraft, the carrier shall require full payment of the total charter price, including payment for the return portion of a round trip, from the passenger charterers not less than 10 days prior to the commencement of any portion of the transportation, and such payment shall not be refundable unless the charter is canceled by the carrier or unless the carrier accepts a substitute charterer for one which has canceled a charter, in which case the amount paid by the latter shall be refunded. For the purpose of this section, payment to the carrier's depository bank, as designated in the charter contract, shall be deemed payment to the carrier.

* * * * *

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 82–171 Filed 1–4–82; 8:45 am]

BILLING CODE 6320–01–M

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14 CFR Part 231

[Reg. ER–1279; Amendment No. 6]

Transportation of Mail; Elimination of Domestic Schedule Filing

AGENCY: Civil Aeronautics Board.

ACTION: Interpretative rule.

SUMMARY: The CAB amends its rule on the filing of airline schedules to cover only foreign air transportation and freighter service within Alaska and Hawaii, in order to conform to changes in the agency's statutory authority. This action is at the CAB's initiative.

DATES: Adopted: December 21, 1981. Effective: December 31, 1981.

FOR FURTHER INFORMATION CONTACT: Mark Schwimmer, Office of the General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428; 202–673–5442.

SUPPLEMENTARY INFORMATION: The first sentence of section 405(b) of the Federal Aviation Act requires each air carrier to file with the Board and the Postal Service a statement of the points that it is authorized to serve and all its schedules and schedule changes involving those points. The Board's rule implementing this statutory provision is found at 14 CFR Part 231. The statement of points and the schedules are referred to together in Part 231 as a "general schedule."

In the Airline Deregulation Act of 1978, Pub. L. 95–504, Congress added a new section 1601 to the Federal Aviation Act to provide for the termination of some Board functions and the transfer of others. In particular, section 1601(a)(1)(G) provides that—

(a)(1) The following provisions of this Act (to the extent such provisions relate to interstate and overseas air transportation of persons) and the authority of the Board with respect to such provisions (to the same extent) shall cease to be in effect on December 31, 1981:

. . . (G) Section 405(b) of this Act (insofar as such section requires the filing of any statement or schedule by any air carrier).

This section amounts to an amendment of section 405(b) effective December 31, 1981, and requires a corresponding amendment of Part 231. General schedules clearly must continue to be filed for all foreign air transportation. They will no longer be required to be filed for interstate or overseas passenger air transportation.

For interstate and overseas transportation of cargo (*i.e.*, property and mail), however, a question of interpretation arises. Because section 1601(a) refers only to transportation "of persons," a literal reading of that section would preserve the general schedule filing requirements for all interstate and overseas air transportation of cargo, even when carried in combination with passengers. As virtually all passenger carriers also carry cargo along with those passengers on combination aircraft, the practical effect of the literal interpretation would be to continue the schedule-filing requirement even for passenger service, making section 1601(a)(1)(G) virtually meaningless. Congress could not have intended such a result. The Board therefore concludes that section 405(b), as modified by section 1601(a)(1)(G), will no longer require the filing of general schedules for interstate or overseas passenger or combination service. This interpretation affects only the filing requirement of the first sentence of section 405(b). The remainder of that section, which concerns the authority of the Postal Service, is unchanged by section 1601(a)(1)(G).

For interstate and overseas cargo-only air transportation, *i.e.*, on freighter aircraft, the literal reading of section 1601(a)(1)(G) creates no similar problem. The Board therefore concludes that section 405(b) still requires the filing of general schedules for such service. In its rule on domestic cargo transportation (14 CFR Part 291), however, the Board has already exempted carriers from this filing requirement, except for service that is wholly within Alaska or wholly within Hawaii.

This amendment of Part 231 therefore adds a new provision limiting the applicability of the part to foreign air transportation and to cargo-only air transportation within Alaska or Hawaii. Since this amendment is interpretative in nature and creates no additional burdens, the Board finds that notice and public procedure are unnecesary and that it may become effective less than 30 days after publication in the **Federal Register.**

PART 231—TRANSPORTATION OF MAIL; MAIL SCHEDULES

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 231, *Transportation of Mail; Mail Schedules*, as follows:

1. The authority citations for individual sections within Part 231 are removed and the authority for Part 231 is revised to read:

Authority—Secs. 204, 405, 1601, Pub. L. 85-726, as amended, 72 Stat. 743, 760, 92 Stat. 1744; 49 U.S.C. 1324, 1375, 1551.

2. In § 231.1, the current text is designated as paragraph (b) and a new paragraph (a) is added, to read:

§ 231.1 Filing of general schedules.

(a) This part applies only to:

(1) Foreign air transportation, and

(2) Cargo-only air transportation within the States of Alaska or Hawaii.

(b) * * *

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 82-202 Filed 1-4-82; 8:45 am]

BILLING CODE 6320-01-M

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14 CFR Part 302

[Reg. PR-238; Amdt. No. 65]

Rules of Practice in Board Proceedings

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: The CAB limits the number of persons upon whom domestic certificate applications must be served. This action is taken because these applications will no longer have to include the points that the applicant seeks authority to serve.

DATES: Adopted: December 22, 1981. Effective: December 31, 1981.

FOR FURTHER INFORMATION CONTACT: David Schaffer, Office of General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428; 202-673-5442.

SUPPLEMENTARY INFORMATION: Under section 401 of the Federal Aviation Act, any person may apply for a certificate of public convenience and necessity. These certificates authorize carriers to provide air transportation. They may contain terms, conditions, or limitations and, under section 401, an air carrier may also apply to have these terms modified or removed. Subpart Q of Part 302 (14 CFR 302.1705) specifies the persons upon whom these applications must be served. That provision is tied to the points listed in the application or certificate. The application and any responsive documents must be served on the carriers and State agencies at the points listed on the carrier's application or certificate.

After December 31, 1981, domestic certificates will no longer list the points that an air carrier is authorized to serve. Section 1601(a)(1)(C). Carriers will have authority to serve all points in the United States. By ER-1274, issued today, we have amended Part 201 so that carriers will no longer have to list the points they wish to serve in their section 401 applications. This calls for conforming changes in the service requirements of Subpart Q of Part 302 (§ 302.1705(a)). Since a carrier's application for new domestic authority will no longer list points, that cannot be the basis for the service requirement. It will also be too burdensome to require a carrier to serve its application on persons at all points that it will receive authority to serve, as that encompasses all points in the United States, its territories and possessions. Instead, the rule as changed will require an applicant to serve officials and carriers only at the points that it plans initially to serve. These will be the points for which it has filed an illustrative service proposal under 14 CFR 201.4(e)(1), and that are of most immediate interest in the carrier's application.

An application to modify or remove terms or conditions in a certificate will be served on officials and carriers at the points actually affected by the application.

The service requirements for section 401 applications to provide cargo-only air service within Alaska and Hawaii have not been changed. These applications will still have to be served on all points listed in the applicant's application or certificate since these certificates will continue to list points that the carrier will be authorized to serve. (See Docket 40208, 46 FR 55294, November 9, 1981, for a full explanation of why certificates must continue to list points for which intra-Alaska and intra-Hawaii cargo-only air service is authorized.)

The service requirements for applicants for foreign air carrier (402) permits and foreign air transportation (401) certificates have not been changed, but the paragraph governing foreign permits has been renumbered. The requirements of § 302.1705(b)(3) to (b)(6) have not been changed.

A conforming change in Subpart I has been made in light of the amendments to § 201.4 made by ER–1274, issued today.

Since this action is procedural in nature, relieves restrictions, and should be in effect when the Board's route authority expires at the end of this year, we find that notice and public procedure on this rule are unnecessary and that it may take effect in less than 30 days.

PART 302—RULES OF PRACTICE IN BOARD PROCEEDINGS

Accordingly, the Board revises 14 CFR Part 302, *Rules of Practice in Board Proceedings*, as follows:

1. The authority for Part 302 is:

Authority.— Secs. 101, 203, 204, 401, 402, 403, 404, 406, 412, 901, 1001, 1002, 1005, Pub. L. 85–726, as amended, 72 Stat. 737, 742, 743, 754, 757, 758, 760, 763, 770, 783, 788, 794; 49 U.S.C. 1301, 1323, 1324, 1371, 1372, 1373, 1374, 1376, 1382, 1471, 1481, 1482, 1485; Reorganization Plan No. 3, 75 Stat. 837, 26 FR 5989; E.O. 11514, Pub. L. 91–90, 42 U.S.C. 4321; 84 Stat. 772, 39 U.S.C. 5402.

2. In § 302.1705 paragraphs (a), (b)(1), and (b)(2) are revised to read:

§ 302.1705 Service of documents.

(a) *General requirements.* (1) In certificate proceedings involving domestic applications under sections 401(d)(1), 401(d)(2), and 401(d)(3) of the Act, the application and all documents filed before the issuance of the order establishing further procedures (§ 302.1750) shall be served on the persons listed in paragraph (b) of this section for each point for which the applicant has submitted an illustrative service proposal under § 201.4(e)(1) of this chapter, and on any other person who has filed a pleading in the docket.

(2) In certificate proceedings involving applications under section 401(g), 401(h), and 401(e)(7)(B) of the Act, all documents filed before the issuance of the order establishing further procedures (§ 302.1750) shall be served on the persons listed in paragraph (b) of this section for each point that is actually affected by the application, and on any other person who has filed a pleading in the docket.

(3) In certificate proceedings under section 401 of the Act involving the provision of cargo-only air service within the States of Alaska or Hawaii or foreign air transportation, all documents filed before the issuance of the order establishing further procedures (§ 302.1750) shall be served on the persons listed in paragraph (b) of this section for each point listed in the carrier's application or certificate, and on any other person who has filed a pleading in the docket.

(4) After the order establishing further procedures under § 302.1750 has been issued, documents need only be served on the persons listed in the service list accompanying the order.

(5) In foreign air carrier permit proceedings described in § 302.1701(c), applicants shall serve on the persons listed in paragraph (b) of this section and the U.S. Department of State a notice that such application has been filed and, upon request, shall promptly provide those persons with copies of the actual documents. All later documents shall be served on any person that has filed a pleading in the docket.

(b) *Persons to be served.* Documents shall be served for each point as described in paragraph (a) of this section, on the following persons:

(1) All air carriers certificated under section 401 of the Act and authorized to engage in the type of air transportation (scheduled or charter) applied for at one or more of the points;

(2) All other air carriers operating at least five flights per week to or from one of the points according to the "Official Airline Guide";

* * * * *

3. Section 302.930 is revised by removing "pursuant to § 201.4(c)(3) and (4)" at the end thereof so that it reads:

§ 302.930 Evidence in route proceedings.

Route authority not specifically applied for. Applicants for certificate authority under section 401 of the Act may not introduce, in support of awards to them of such authority, evidence that does not support service to the points, routes, or areas specifically described in their applications.

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 82–200 Filed 1–4–82; 8:45 am]

BILLING CODE 6320–01–M

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14 CFR Part 321

[Reg. PR–239; Amdt. No. 3]

Unused Authority Procedures; Contents and Service of Applications

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: The CAB changes the description of active carriers that must be listed in, and served with copies of, applications for unused authority. The CAB also eliminates the requirement that inactive air carriers be listed or served. These changes simplify the application procedure.

DATES:

Adopted: December 23, 1981.

Effective: December 31, 1981.

FOR FURTHER INFORMATION CONTACT: Mark Schwimmer, Office of the General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428; 202–673–5442.

SUPPLEMENTARY INFORMATION: Part 321 of the Board's rules (14 CFR Part 321) sets out procedures governing the unused or "dormant" authority program established by section 401(d)(5) of the Federal Aviation Act. Under that program, if a certificated air carrier does not provide a specified minimum level of service between a domestic pair of points for which it has non-stop operating authority, the Board must ordinarily award a certificate within 15 or 60 days to the first applicant who certifies that it complies with FAA regulations and is able to comply with Board regulations. The deadline is 15 days for markets that have zero or one active incumbent air carrier. The deadline is 60 days for markets that have two or more active incumbents, and the Board may deny an application for such a market if it finds that granting the application would be inconsistent with the public convenience and necessity. In each market, the Board can grant unused authority certificates to as many new applicants as there are inactive incumbent certificated carriers.

Most certificated air carriers will have no need for the unused authority program beginning December 31, 1981, because they will then have virtually unlimited domestic route authority as a result of section 1601(a)(1)(C) of the Act, which eliminates the Board's authority to specify terminal and intermediate points in certificates for domestic passenger transportation. The program will still be useful, however, for new carriers, uncertificated carriers, and certain carriers whose only certificate authority was obtained under section 401(d)(5). For these carriers it is a device to obtain authority quickly and without an initial fitness finding. Because the program will continue, some technical changes in Part 321 are necessary.

An applicant for unused authority is required by the current § 321.11(a)(3) to list the active air carriers, whether or not certificated, in each market covered by the application. This list was originally intended to enable the Board to determine whether the application would be subject to the 15- or 60-day processing deadline. Paragraph (a)(4) of § 321.11 calls for the listing of the inactive carriers in each market, but only those with certificate authority.

This list was intended to enable the Board to verify that there was in fact enough unused certificate authority in each market for all the applicants. And § 321.10(d)(1) requires the applicant to serve copies of the application on all of these carriers.

In each market covered by the unused authority program there will be dozens of certificated carriers beginning December 31 that have certificate authority but are not using it. There will be no doubt, therefore, that there is enough unused authority available for all applicants. Under these circumstances the Board will have no need for applicants to list inactive carriers as currently required by § 321.11(a)(4), so that provision is being removed from the rule. And it would be an undue burden on applicants, with no accompanying benefit, for them to have to serve copies of their applications on virtually all certificated carriers. The Board is therefore amending the service requirement in § 321.10(d)(1) to cover only the active incumbents described in § 321.11(a)(3).

The Board is also amending § 321.11(a)(3) to require applications to list only those active incumbent carriers that are certificated, rather than all active incumbents. The Board has long interpreted section 401(d)(5) as requiring the counting only of certificated active incumbents for the purpose of determining whether to use the 15- or 60-day procedure. A listing in unused authority applications of those active incumbent carriers that do not have certificates is therefore unnecessary.

Because these amendments are procedural in nature, and because there is a need to avoid unnecessary burdens that would otherwise arise on December 31, 1981, the Board finds that notice and public procedure are unnecessary, impracticable, and contrary to the public interest, and that the amendments may become effective less than 30 days after publication in the **Federal Register.**

PART 321—UNUSED AUTHORITY PROCEDURES

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 321, *Unused Authority Procedures,* as follows:

1. The authority for Part 321 is:

Authority: Secs. 204, 401, 1001, Pub. L. 85–726, as amended, 72 Stat. 743, 754, 788; 49 U.S.C. 1324, 1371, 1481.

2. In § 321.10, paragraph (d)(1) is amended by removing "or (4)" so that it reads:

§ 321.10 General requirements for applications.

* * * * *

(d) Applications and amendments of applications shall be served on:

(1) All air carriers named in the application in accordance with § 321.11(a)(3).

* * * * *

3. In § 321.11, paragraph (a)(3) is revised and paragraph (a)(4) is removed and reserved as follows:

§ 321.11 Contents of applications.

Each application shall:

(a)* * *

(3) *Active carriers.* The Official Airline Guide's 2-letter carrier code for each certificated air carrier that has provided the minimum level of service between the points during the period or season described in paragraph (a)(2) of this section.

(4) [Reserved]

* * * * *

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 82–199 Filed 1–4–82; 8:45 am]

BILLING CODE 6320–01–M

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14 CFR Part 380

[Reg. SPR–182; Amdt. No. 14; Docket 40236]

Public Charters; Part Charters

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: The CAB amends its charter rules to allow airlines to conduct "part charters," which are flights that carry both charter and scheduled-service passengers. The rule is designed to increase airlines' marketing flexibility and eliminate an unnecessary restraint on competition. Supplementary information about this action is set out in ER–1275, issued along with this rule.

DATES:

Adopted: December 28, 1981.

Effective: December 31, 1981.

FOR FURTHER INFORMATION CONTACT: Patti Szrom, Special Authorities & Administration, Bureau of Domestic Aviation, 202–673–5088, or Patricia DePuy, Regulatory Affairs Division, Bureau of International Aviation, 202–673–5878; Civil Aeronautics Board, 1825 Connecticut Avenue, NW, Washington, D.C. 20428.

SUPPLEMENTARY INFORMATION:

PART 380—PUBLIC CHARTERS

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 380, *Public Charters,* as follows:

1. The authority for Part 380 is:

Authority: 101(3), 204, 401, 402, 407, 416, and 1102, Pub. L. 85–726, as amended, 72 Stat. 737, 743, 754, 757, 766, 771, 797; 49 U.S.C. 1301, 1324, 1371, 1372, 1377, 1386, 1502.

§ 380.10 [Amended]

2. In § 380.10, *Public Charter general requirements,* paragraph (e) is removed.

By the Civil Aeronautics Board:

Phyllis T. Kaylor,

Secretary.

[FR Doc. 82–196 Filed 1–4–82; 8:45 am]

BILLING CODE 6320–01–M

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14 CFR Part 399

[PS–106; Amdt. No. 82]

Statements of General Policy; Removal of Obsolete Policy Statements

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: The CAB removes two obsolete policy statements about local service air carriers' operating authority.

DATES:

Adopted: December 23, 1981;

Effective: December 31, 1981.

FOR FURTHER INFORMATION CONTACT: Mark Schwimmer, Office of the General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428; 202–673–5442.

SUPPLEMENTARY INFORMATION: Section 399.10 of the Board's rules (14 CFR 399.10) states that it is the policy of the Board to include in the certificates of local service carriers a provision "to make it clear that their operations are definitely local air transportation, as distinguished from the service rendered by scheduled trunkline air carriers." The local service carriers no longer exist as a separate classification of air carriers, however, and some of them already have route systems that are nationwide in scope. Moreover, they will all have unlimited domestic operating authority beginning December 31, 1981, as a result of the sunset of the Board's authority to name terminal and intermediate points in certificates authorizing domestic passenger air transportation (section 1601(a)(1)(C) of the Federal Aviation Act). The policy statement in § 399.10 has therefore become obsolete, and the Board is now removing it.

Section 399.11 sets out a "use it or lose it" policy for local service carriers receiving subsidy under section 406 of the Act. Under this policy, the Board would take steps to determine whether certain service or route authority should be suspended or terminated if prescribed minimum traffic standards were not met. This policy statement has also become obsolete in light of the

Airline Deregulation Act of 1978, which (1) restricted the Board's authority to reduce subsidy under section 406 of the Federal Aviation Act, and (2) established in section 419 a new program for guaranteeing essential air service. The Board is therefore removing § 399.11 along with § 399.10.

Because this rule merely eliminates obsolete policy statements, the Board finds that notice and public procedure are unnecessary, and that the rule may become effective less than 30 days after publication in the **Federal Register.**

PART 399—STATEMENTS OF GENERAL POLICY

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 399, *Statements of General Policy,* as follows:

1. The authority for Part 399 is:

Authority: Secs. 101, 102, 105, 204, 401, 402, 403, 404, 405, 406, 407, 408, 409, 411, 412, 416, 801, 1001, 1002, 1102, 1104, Pub. L. 85-726, as amended, 72 Stat. 737, 740, 743, 754, 757, 758, 760, 763, 766, 767, 768, 769, 770, 771, 782, 788, 797, 92 Stat. 1708; 49 U.S.C. 1301, 1302, 1305, 1324, 1371, 1372, 1373, 1374, 1375, 1376, 1377, 1378, 1379, 1381, 1382, 1386, 1461, 1481, 1482, 1502, 1504.

2. The Table of Contents is amended by removing §§ 399.10 and 399.11.

§ 399.10 and § 399.11 [Removed]

3. Sections 399.10, *Local service carrier certificates to indicate nature of operations specifically,* and 399.11, *"Use it or lose it" policy for subsidized local service carriers,* are removed and reserved.

By the Civil Aeronautics Board:

Phyllis T. Kaylor,

Secretary.

[FR Doc. 82-201 Filed 1-4-82; 8:45 am]

BILLING CODE 6320-01-M

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Parts 379, 385, and 399

Controls on Exports of Petroleum Transmission and Refining Equipment to the U.S.S.R.

AGENCY: Office of Export Administration, International Trade Administration, Commerce.

ACTION: Interim Rule.

SUMMARY: Under current regulations, a validated export license is required for foreign policy purposes for the export to the U.S.S.R. (including Estonia, Latvia, and Lithuania) of specified oil and gas exploration and production equipment, and technical data related to oil and gas exploration and production. This rule imposes new foreign policy controls on exports to the U.S.S.R. (including Estonia, Latvia, and Lithuania) of commodities for transmission (including transportation) and refinement of petroleum or natural gas and technical data related to oil and gas transmission or refinement. These controls also apply to Afghanistan.

DATES: These rules are effective December 30, 1981. Comments must be received by the Department by March 1, 1982. However, these regulations may be revised before the close of the comment period.

ADDRESS: Written comments (six copies when possible) should be sent to: Richard J. Isadore, Director, Operations Division, Office of Export Administration, U.S. Department of Commerce, P.O. Box 273, Washington, D.C. 20044.

FOR FURTHER INFORMATION CONTACT: Mr. Archie Andrews, Director, Exporters' Service Staff, Office of Export Administration, Department of Commerce, Washington, D.C. 20230 (Telephone: (202) 377-5247 or 377-4811).

SUPPLEMENTARY INFORMATION:

Regulatory Changes

At the direction of the President and pursuant to section 6 of the Export Administration Act of 1979, the Department of Commerce is expanding the existing oil and gas controls applicable to the U.S.S.R. to include commodities and technical data for transmission (including transportation) or refinement of petroleum or natural gas for energy usage, excluding petrochemical feedstocks. This action is in response to the Soviet Union's heavy and direct responsibility for the repression in Poland. Presently, under 15 CFR 385.2(c) the Department of Commerce controls exports of specified oil and gas exploration and production equipment, technical data (other than GTDA) related to oil and gas exploration and production, and other commodities that require a validated export license for shipment to the Soviet Union and that are intended for use in oil or gas exploration or production. This rule expands the existing controls by applying the controls to the areas of refinement for energy usage and transmission. The commodities and technical data covered by this rule are also subject to the rule, effective December 30, 1981, which suspended the processing of all licensing for export to the U.S.S.R.

Further, the regulations affecting exports of technical data to other destinations are revised. Most types of technical data that are not generally available to the public presently may be exported under General License *GTDR* to all destinations except Cuba, North Korea, Vietnam, Cambodia, the U.S.S.R., East European communist countries, Laos, and the People's Republic of China. For technical data related to oil and gas exploration and production, use of General License *GTDR* is conditioned on the exporter receiving written assurance from the importer that neither the data nor the direct product thereof is intended to be shipped, directly or indirectly, to the U.S.S.R. This rule imposes on the export of technical data related to the transmission and refining of petroleum or natural gas, the condition that General License *GTDR* not be used unless the exporter has received written assurance from the importer that neither the technical data nor the direct product thereof is intended to be shipped, directly or indirectly, to the U.S.S.R.

Pursuant to section 6 of the Export Administration Act of 1979 and following consultation with the Department of State, it has been determined that this rule is necessary to further significantly the foreign policy of the United States. Appropriate persons in industry and the Congress have been consulted, and the criteria set forth in section 6(b) of the Act have been considered.

Pursuant to section 4(c), it has been determined that, notwithstanding foreign availability, failure to take this action would be detrimental to the foreign policy of the United States.

Pursuant to section 6(d), it has been determined that there are no feasible alternative means of achieving the purpose of this action. As provided in section 6(g), efforts are being made to obtain cooperation of countries that produce comparable items.

Saving Clause

This rule places a validated license requirement on certain commodities and technical data that previously could be exported under a general license. Therefore, shipments of commodities or technical data removed from general license as a result of changes set forth in this rule that were on dock for lading, on lighter laden aboard an exporting carrier, or in transit to a port of export pursuant to actual orders for export prior to 8:00 a.m., E.S.T., December 30, 1981, may be exported under the previous general license provisions up to and including January 14, 1982. Any such shipments not laden aboard the exporting carrier on or before January

14, 1982 require an individual validated license for export.

Rulemaking Requirements

The Office of Export Administration has determined that:

1. Under section 13(a) of the Export Administration Act of 1979 (50 U.S.C. app. 2401 *et seq.* (Supp. III 1979) ("the Act")), this rule is exempt from the public participation in rulemaking procedures of the Administrative Procedure Act.

However, because of the importance of the issues raised by these regulations and the intent of Congress set forth in section 13(b) of the Act, these regulations are issued in interim form and comments will be considered in developing any final regulations. These regulations may be revised before the end of the comment period. Accordingly, interested persons who desire to comment are encouraged to do so at the earliest possible time to permit the fullest consideration of their views.

2. This rule does not impose a burden under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

3. This rule is not subject to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 3501 *et seq.*

4. This rule is exempt from the requirements of Executive Order 12291 (46 FR 13193, February 19, 1981), "Federal Regulation" because it relates to a foreign affairs function of the United States.

The period for submission of comments will close on March 1, 1982. Comments received after the close of the comment period cannot be assured consideration in the development of the final regulations. Public comments that are accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature, or for any other reason, will not be accepted. Such comments and materials will be returned to the submitter and will not be considered in the development of the final regulations. All public comments to be considered in any revision to these regulations will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, comments in written form are preferred. If oral comments are received, they must be followed by written memoranda which will also be a matter of public record and will be available for public review.

Accordingly, the Export Administration Regulations (15 CFR 368, *et seq.*) are amended as follows:

PART 379—TECHNICAL DATA

1. Section 379.4(f)(1)(i)(*p*) is revised to read:

§ 379.4 General License GTDR: Technical Data Under Restriction.

* * * * *

(f) * * *

(1) * * *

(i) * * *

(*p*) Machinery, equipment, instruments and other commodities utilized for the exploration, production, transmission or refinement of petroleum or natural gas up to and including refinery operations directed to energy usage but excluding petrochemical feedstock processes.

* * * * *

PART 385—SPECIAL COUNTRY POLICIES AND PROVISIONS

2. Section 385.2(c) is revised to read:

§ 385.2 Country Groups Q, W, and Y[1]; U.S.S.R., Other Warsaw Pact Countries, Albania, Mongolian People's Republic, and Laos.

* * * * *

(c) As authorized by section 6 of the Export Administration Act of 1979, a validated license is required for foreign policy reasons for the export to the U.S.S.R. of oil and gas exploration, production, transmission or refinement equipment as defined in CCL entries 6098F, 6191F, 6198F, 6388F, 6389F, 6390F, 6391F, 6431F, 6491F, 6598F, 6685F, 6779F, and 6780F. Also included in the scope of this control are technical data (other than that authorized under General License (GTDA) related to oil and gas exploration, production, transmission and refinement and other commodities that require a validated export license for shipment to the Soviet Union and that are intended for use in oil or gas exploration, production, transmission or refinement. The term "refinement" includes refinery operations directed to energy usage, but excludes petrochemical feedstock processes.

* * * * *

PART 399—COMMODITY CONTROL LIST AND RELATED MATTERS

Supplement 1 to 399.1 [Amended]

3. The Commodity Control List (Supplement No. 1 to § 399.1) is amended by adding the following new entries in numerical order, disregarding the first digit:

* * * * *

Export control commodity number and commodity description	Unit	Validated license required	GLV's value limits T&V	Processing code	Reason for control
* * * * *				* *	
6198F Equipment utilized in the petroleum and natural gas transmission and transportation, and in refining of petroleum and natural gas for energy usage (excluding petrochemical feedstock); and specially designed parts and accessories therefor (see Interpretation 31).		SZ, Afghanistan, and the U.S.S.R.[2,3]		MG	3
* * * * *				* *	
6388F Industrial gas turbine engines; and specially designed parts, n.e.s.		SZ, Afghanistan and the U.S.S.R.[3]		MG	3
6389F Compressors specially designed for or intended for the compression and transmission of natural gas, and specially designed parts therefor.		SZ, Afghanistan, and the U.S.S.R.[3]		MG	3
* * * * *				* *	
6431F Gas turbine engines for aero, marine or other vehicular use, n.e.s., and specially designed parts.		SZ, Afghanistan and the U.S.S.R.[6]		MG	3
* * * * *				* *	
6491F Equipment specially designed for or utilized in the transmission or transportation of petroleum or natural gas; and specially designed parts and accessories therefor.		SZ, Afghanistan and the U.S.S.R.[6]		MG	3

Export control commodity number and commodity description	Unit	Validated license required	GLV's value limits T&V	Processing code	Reason for control
6685F Pipe, tube, and fittings therefor, specially intended for use in the production or transmission of petroleum or natural gas, or in refining of petroleum or natural gas for energy usage (excluding petrochemical feedstock).		SZ, Afghanistan and the U.S.S.R.		MG	3
6780F Chemicals specially intended for use in refining processes for the production of petroleum, petroleum products, and natural gas for energy usage (excluding petrochemical feedstock).		SZ, Afghanistan and the U.S.S.R.		MG	3

4. The following entries on the Commodity Control List (Supplement No. 1 to 399.1) are revised to read as follows:

Export control commodity number and commodity description	Unit	Validated license required	CLV's value limits T&V	Processing code	Reason for control
6098F Other machinery and equipment (including tools, fixtures and jigs) specially designed or modified for the manufacture of equipment utilized in the exploration for, production of, transmission of, or transportation of petroleum or natural gas, or refining of petroleum or natural gas for energy usage (excluding petrochemical feedstock); and specially designed parts and accessories therefor, as follows:		SZ, Afghanistan and the U.S.S.R.[1 2]		MG	3
Dowel hole drilling machines, Cone bit drilling machines, Cone bit milling machines, Bit-arm milling machines, Pipe perforating machines, Liner mills, Casing mills, Cone buster mills, Collar mills, Packer mills and Machinery and equipment—n.e.s., specially designed or modified for the manufacture of equipment utilized in the exploration for, production of, transmission of, or transportation of petroleum or natural gas, or refining of petroleum or natural gas for energy usage (excluding petrochemical feedstock).					
6390F Other machinery and equipment (including tools, fixtures and jigs) specially designed or modified for the manufacture of equipment utilized in the exploration for, production of, transmission of, or transportation of petroleum or natural gas, or for refining petroleum or natural gas; for energy usage (excluding petrochemical feedstock); and specially designed parts and accessories therefor, as follows:		SZ, Afghanistan and the U.S.S.R.[1]		MG	3
Pipe coating equipment, Pipe laying equipment, Pipe wrapping equipment; and Machinery and equipment—n.e.s., specially designed or modified for the manufacture of equipment utilized in the exploration for, production of, transmission of, or transportation of petroleum or natural gas, or for refining of petroleum or natural gas for energy usage (excluding petrochemical feedstock).					
6391F Other equipment utilized for the exploration for, production of, transmission of, or transportation of petroleum or natural gas, or refining of petroleum or natural gas for energy usage (excluding petrochemical feedstock); and specially designed parts and accessories therefor. (See Supplement No. 1 to § 399.2, Interpretations 30 and 31, for illustrative list of commodities included in this entry.).		SZ, Afghanistan and the U.S.S.R.[1]		MG	3
6598F Geophysical and mineral prospecting instruments; and other instruments and equipment specially designed or modified for the examination or testing of equipment utilized in the exploration for, production of, transmission of, or transportation of petroleum or natural gas, or refining of petroleum or natural gas for energy usage (excluding petrochemical feedstock); and specially designed parts and accessories therefor. (See Supplement No. 1 to § 399.2, Interpretations 30 and 31 for illustrative list of commodities included in this entry.		SZ, Afghanistan and the U.S.S.R.[3]		MG	3

Supplement 1 to § 399.2 [Amended]

5. The Commodity Interpretations (Supplement 1 to § 399.2) are amended as follows:

a. Footnote 1 to Interpretation 29 is revised to read:

[1] A validated license is required for this equipment and any equipment utilized in the exploration for, production of, transmission of, or transportation of petroleum or natural gas, or refining of petroleum or natural gas for energy usage (excluding petrochemical feedstock), as well as specially designed parts and accessories therefor, to the USSR, Afghanistan, Estonia, Latvia, and Lithuania.

b. A footnote No. 1 is added behind the following listings in interpretation 29:

Air or Gas Compressors, n.e.s.
Gas or Liquid Supply Meter, n.e.s.
Gas Turbine Engines, n.e.s.

Internal pneumatic line-up clamps for welding transmission line pipe
Line-travelling coating and wrapping for pipes and tubes
Mechanical instruments, n.e.s., for measurement, transmission, or control of temperature, pressure, or other variables of liquids or gases
Metering and mixing, n.e.s.
Pipe-line cleaning

c. A new interpretation 31 is added to § 399.2, Supplement No. 1 to read as follows:

Interpretation 31: Petroleum and Natural Gas Transportation and Refining Equipment

The following is an illustrative list of petroleum and natural gas transportation and refining equipment subject to validated license control for export to the USSR, Estonia, Latvia, Lithuania, and Afghanistan. This list is illustrative only. It does not include all commodities covered by CCL entry 6198.

Reactors (Crackers)
Separators
Extraction Columns
Exchangers
Agitators
Pipes
Valves
Filtration Units
Electronic Controls
Air or Gas Compressors
Gas or Liquid Supply Meters
Gas Turbine Engines
Internal pneumatic line-up clamps for welding transmission line pipe
Line-travelling coating and wrapping equipment for pipes and tubes
Instruments for measurement, transmission, or control of temperatures, pressure, or other variables of liquids or gases
Metering and mixing equipment
Pipe-line cleaning equipment
Specialized land-based and seaborne petroleum and natural gas transportation equipment

(Sections 4, 6, 13, 15, and 21, Pub. L. 96–72, 93 Stat. 503, 50 U.S.C. app. 2401 *et seq.*; Executive Order No. 12214 (45 FR 29783, May 6, 1980); Department Organization Order 10–3 (45 FR 6141, January 25, 1980); International Trade Administration Organization and Function Orders 41–1 (45 FR 11862, February 22, 1980) and 41–4 (45 FR 65003, October 1, 1980))

Dated: December 30, 1981.

Bohdan Denysyk,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 81–37468 Filed 12–30–81; 4:05 pm]

BILLING CODE 3510–25–M

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15 CFR Part 390

General Orders; Suspension of All Licensing for Exports to the U.S.S.R.

AGENCY: Office of Export Administration, International Trade Administration, Commerce.

ACTION: Interim rule.

SUMMARY: This issuance announces a General Order of the Department of Commerce suspending the processing of all licensing for exports to the U.S.S.R. to further U.S. foreign policy objectives in light of the Soviet Union's heavy and direct responsibility for the repression in Poland. This issuance provides notice that no new licenses or other authorizations for export to the U.S.S.R. will be issued by the Department of Commerce. Outstanding validated licenses and authorizations may be reviewed to determine whether suspension or revocation may be necessary to be consistent with the objectives of this action.

DATES: These rules are effective December 30, 1981. Comments must be received by the Department by March 1, 1982. However, these regulations may be revised before the close of the comment period.

ADDRESS: Written comments (six copies when possible) should be sent to: Richard J. Isadore, Director, Operations Division, Office of Export Administration, U.S. Department of Commerce, P.O. Box 273, Washington, D.C. 20044.

FOR FURTHER INFORMATION CONTACT: Mr. Archie Andrews, Director, Exporters' Service Staff, Office of Export Administration, Department of Commerce, Washington, D.C. 20230 (Telephone: (202) 377–5247 or 377–4811).

SUPPLEMENTARY INFORMATION:

Regulatory Changes

At the direction of the President, the Department of Commerce has suspended the processing of applications for validated licenses and other authorizations for export to the U.S.S.R. No changes in the General License provisions of the Export Administration Regulations are being made by this announcement.

Pursuant to section 6 of the Export Administration Act of 1979 and following consultation with the Department of State, it has been determined that this rule is necessary to further significantly the foreign policy of the United States. Appropriate persons in industry and the Congress have been consulted, and the Departments of Commerce and State have considered the criteria set forth in section 6(b) of the Act.

Pursuant to section 4(c), it has been determined that, notwithstanding foreign availability, failure to take this action would be detrimental to the foreign policy of the United States.

Pursuant to section 6(d), it has been determined that there are no feasible alternative means of achieving the purpose of this action. As provided in section 6(g), efforts are being made to obtain cooperation of countries that produce comparable items.

Accordingly, exporters are placed on notice that the processing of validated licenses and other requests for export or reexport authorization for shipments to the U.S.S.R. has been suspended.

This action affects validated export license applications, parts and components applications, special bulk license applications (to the extent they would authorize exports to the U.S.S.R.) and reexport requests that are currently pending, as well as any new applications or requests. This will serve as notice to exporters that pending applications or requests, as well as any that may be submitted in the future, will be returned without action.

The Department may review outstanding validated licenses and other authorizations for exports to the U.S.S.R. to determine if they should be suspended or revoked as a result of the President's announcement.

Rulemaking Requirements

The Office of Export Administration has determined that:

1. Under section 13(a) of the Export Administration Act of 1979 (50 U.S.C. app. 2401 *et seq.*) (Supp. III 1979) ("the Act"), this rule is exempt from the public participation in rulemaking procedures of the Administrative Procedure Act.

However, because of the importance of the issues raised by these regulations and the intent of Congress set forth in section 13(b) of the Act, these regulations are issued in interim form and comments will be considered in developing any final regulations. These regulations may be revised before the end of the comment period. Accordingly, interested persons who desire to comment are encouraged to do so at the earliest possible time to permit the fullest consideration of their views.

2. This rule does not impose a burden under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

3. This rule is not subject to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 3501 *et seq.*

4. This rule is exempt from the requirements of Executive Order 12291 (46 FR 13193, February 19, 1981), "Federal Regulation" because it relates

to a foreign affairs function of the United States.

PART 390—GENERAL ORDERS

The period for submission of comments will close on March 1, 1982. Comments received after the close of the comment period cannot be assured consideration in the development of the final regulations. Public comments that are accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature, or for any other reason, will not be accepted. Such comments and materials will be returned to the submitter and will not be considered in the development of the final regulations. All public comments to be considered in any revision to these regulations will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, comments in written form are preferred. If oral comments are received, they must be followed by written memoranda which will also be a matter of public record and will be available for public review. Therefore, the Export Administration Regulations (15 CFR 368, *et seq.*) are amended by adding a new § 390.8 to read:

§ 390.8 General order suspending all licensing for exports to the U.S.S.R.

Effective December 30, 1981, the processing of all applications for validated licenses, reexport authorizations, and parts and components authorizations for shipment of any commodities or transfer of any technical data to the Union of Soviet Socialist Republics (U.S.S.R.) has been suspended. Furthermore, outstanding validated licenses and authorizations to export may be reviewed to determine whether suspension or revocation is necessary.

(Sections 4, 6, 13, 15, and 21, Pub. L. 96–72, 93 Stat. 503, 50 U.S.C. app. 2401 *et seq.*; Executive Order No. 12214 (45 FR 29783, May 6, 1980); Department Organization Order 10–3 (45 FR 6141, January 25, 1980); International Trade Administration Organization and Function Orders 41–1 (45 FR 11862, February 22, 1980) and 41–4 (45 FR 65003, October 1, 1980)

Dated: December 30, 1981.

Bohdan Denysyk,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 81-37346 Filed 12-30-81; 4:05 pm]

BILLING CODE 3510-25-M

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

15 CFR Part 535

Notice to Account Parties With Standby Letters of Credit in Favor of an Iranian Entity

Cross Reference: For a notice that calls to the attention of account parties who have standby letters of credit in favor of an Iranian entity, including instruments against which no demand has been made, relevant factors concerning the purposes of certain sections of the Iranian Assets Control Regulations (15 CFR 535) and the approach of the January 19, 1982, deadline for filing claims with the Iran-United States Claims Tribunal, see FR Doc. 81-37480 appearing in the notices section of this issue.

BILLING CODE 4810-25-M

DEPARTMENT OF LABOR

Office of the Secretary

20 CFR Chs. I, V, VI

29 CFR Subtitle A and Chs. V and XVII

41 CFR Chs. 50 and 60

Display of Office of Management and Budget Control Numbers for Recordkeeping Requirements

AGENCY: Office of the Secretary, Labor.

ACTION: Technical amendments.

SUMMARY: This document amends certain Department of Labor regulations to include OMB control numbers approved prior to December 31, 1981, at the places in the regulations where current information collection requirements are described. It includes items listed in the December 29, 1981, **Federal Register** (46 FR 62844) and thereby updates that list. It also removes obsolete references to previous GAO and OMB approvals of information collection requirements. OMB control numbers for other DOL recordkeeping requirements will be published in a subsequent issue of the **Federal Register**.

EFFECTIVE DATE: January 5, 1982.

FOR FURTHER INFORMATION CONTACT: Paul Larson, Director, Office of Management Reports and Analysis, Directorate of Management Policy and Systems, Room S–5526, Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, D.C. 20210, Telephone 202–523–6331.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The information collection requirements contained in the regulatory sections listed below have been approved by the Office of Management and Budget under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96–511) and assigned the control numbers contained in the listing.

Guide to Agency Abbreviation Code

BLS— Bureau of Labor Statistics
ESA—Employment Standards Administration
ETA—Employment and Training Administration

Text of Amendments

Following the text of each paragraph cited in the second column of the table, add parenthetically the corresponding OMB number listed in the third column:

Agency	Regulatory citation	OMB No.
BLS	29 CFR 1904.2, 1904.4, and 1904.5.	1220-0029
	29 CFR 1904.5	1220-0045
ESA	20 CFR 702.111	1215-0117
	29 CFR 575.3	1215-0120
	20 CFR 10.145	1215-0115
	20 CFR 702.148	1215-0118
	29 CFR 549.1	1215-0122
	20 CFR 725.531	1215-0124
	29 CFR 516 Subpart A and B	1215-0017
	29 CFR 3.4(b), 4.6(g), 5.5(a)(3), and 5.5(e).	1215-0017
	41 CFR 50-201.501	1215-0017
	41 CFR Parts 60-1, 60-2, 60-4, 60-20, 60-30, 60-40, 60-50, 60-60, 60-250, and 60-741.	1215-0072
	41 CFR Part 60-3	3046-0017
	29 CFR 547.1	1215-0019
	29 CFR 570.35(b)(3)(vi)	1215-0121
	29 CFR 4.6(b)(2)(1)	1215-0126
	29 CFR 4.6(1)(i)	1215-0127
	29 CFR 40.51, 40.52, 40.53	1215-0128
	20 CFR 10.410(a)	1215-0133
ETA	20 CFR 653.103, 653.106, 653.107, 653.108, 653.109, 653.111, 653.112, 653.501, 653.503.	1205-0039
	20 CFR 658.410 and 658.413	1205-0039
	29 CFR 56.63	1205-0175

Signed at Washington, D.C. this 31st day of December 1981.

Raymond J. Donovan,

Secretary of Labor.

[FR Doc. 81-37481 Filed 12-31-81; 3:04 pm]

BILLING CODE 4510-23-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 80F-0482]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Ethyl Acetate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the food additive regulations to provide for the safe use of ethyl acetate as a solvent in the decaffeination of coffee. This action is based on data contained in a petition filed by the General Foods Corp.

DATES: Effective January 5, 1982; objections by February 4, 1982.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James B. Lamb, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 16, 1981 (46 FR 3983), FDA announced that a petition (FAP 8A3353) had been filed by General Foods Corp., White Plains, NY 10625, proposing to amend Part 173—Secondary Direct Food Additives Permitted in Food for Human Consumption (21 CFR Part 173) to provide for the safe use of ethyl acetate as a solvent for the decaffeination of coffee. In response to the notice of filing, FDA received one comment. The comment and FDA's response are summarized below.

The petition asked that FDA approve ethyl acetate for use as the extraction solvent for moisturized green coffee beans. The comment expressed the belief that the petition is too narrow because it limits the extraction of caffeine to moisturized green coffee beans. According to the comment, ethyl acetate can be used to remove caffeine from whole roasted coffee beans, ground roasted coffee, or aqueous extracts of coffee beans as well as from moisturized green coffee beans. The comment further stated that the good manufacturing practices involved in producing the finished product would limit solvent residues. Thus, there is no reason to restrict the forms of coffee in which ethyl acetate may safely be used, so that manufacturers may have flexibility in their choice of decaffeination processes.

FDA has evaluated the comment, data in the petition, and other relevant material and has concluded that ethyl acetate has a wide margin of safety. Further, the data submitted in support of the petition demonstrate that ethyl acetate effectively decaffeinates coffee. In sum, the agency agrees with the comment that it is not necessary to limit the use of ethyl acetate in the decaffeination of coffee to moisturized green coffee beans, and that ethyl acetate may safely be used in accordance with good manufacturing practice as a solvent in the decaffeination of coffee. Accordingly, Part 173 is amended to provide for the safe use of ethyl acetate as set forth below.

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

Therefore, under the Federal Food, Drug, and Cosmetic Act (Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Part 173 is amended in Subpart C by adding new § 173.228, to read as follows:

§ 173.228 Ethyl acetate.

Ethyl acetate (CAS Reg. No. 141–78–6) may be safely used in food in accordance with the following conditions:

(a) The additive meets the specifications of the Food Chemicals Codex,[1] (Ethyl Acetate; p. 372, 3d Ed., 1981), which are incorporated by reference.

(b) The additive is used in accordance with good manufacturing practice as a solvent in the decaffeination of coffee.

Any person who will be adversely affected by the foregoing regulation may at any time on or before February 4, 1982, submit to the Dockets Management Branch (address above), written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective January 5, 1982.

(Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348).)

Note.—Incorporation by reference was approved by the Director, Office of the Federal Register, September 23, 1981.

Dated: December 21, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82–23 Filed 1–4–82; 8:45 am]

BILLING CODE 4160–01–M

[1] Copies may be obtained from: National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418 or examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

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21 CFR Parts 510 and 522

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a canine, narcotic antagonist (naloxone hydrochloride injection) from Endo Laboratories, Inc., to Endo Pharmaceuticals, Inc. Endo Pharmaceuticals, Inc., filed a supplemental new animal drug application (NADA) providing for the change.

EFFECTIVE DATE: January 5, 1982.

FOR FURTHER INFORMATION CONTACT: John R. Markus, Bureau of Veterinary Medicine (HFV–104), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4313.

SUPPLEMENTARY INFORMATION: Endo Pharmaceuticals, Inc., P.O. Box 363, Manati, PR 00701, filed a supplemental NADA (035–825) providing for its sponsorship of a naloxone hydrochloride injection. By letter of October 6, 1981, Endo Laboratories, Inc., the former sponsor, confirmed the transfer of sponsorship.

The supplemental NADA for the change of sponsor is approved and the regulations are amended to reflect the approval.

Under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), the intracorporate transfer of an NADA is a Category I change that does not require reevaluation of the safety and effectiveness data in the parent application.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This action is governed by the provision of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 21 CFR 5.1; see 46 FR 26052; May 11, 1981)) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. In Part 510, § 510.600 is amended by adding a new sponsor alphabetically to paragraph (c)(1) and numerically to (c)(2) to read as follows:

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

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Endo Pharmaceuticals, Inc., P.O. Box 363, Manati, PR 00701	000060
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
000060	Endo Pharmaceuticals, Inc., P.O. Box 363, Manati, PR 00701.
* * * * *	

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

§ 522.1462 [Amended]

2. In Part 522, § 522.1462(b) is amended by removing sponsor number "000056" and inserting in its place "000060".

Effective date. This amendment is effective January 5, 1982.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: December 23, 1981.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 82-16 Filed 1-4-82; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 7801]

Income Tax; Taxable Years Beginning After December 31, 1953; Treatment of Certain Interests in Corporations as Stock or Indebtedness

AGENCY: Internal Revenue Service, Treasury.

ACTION: Amendment of final regulations.

SUMMARY: This document amends final regulations relating to the treatment of certain interests in corporations as stock or indebtedness by generally changing the effective date of the regulations from January 1, 1982, to July 1, 1982.

EFFECTIVE DATE: December 31, 1981.

FOR FURTHER INFORMATION CONTACT: Carolyn Swift of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224 (Attention: CC:LR:T, 202-566-3458, not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

Section 385 of the Internal Revenue Code relates to the treatment of certain interests in corporations as stock or indebtedness. Final regulations under section 385 were published in the **Federal Register** for Wednesday, December 31, 1980 (45 FR 86438) as T.D. 7747. These regulations generally would have applied to certain interests in corporations created after April 30, 1981. However, at the invitation of the Treasury and Internal Revenue Service, several public comments on the final regulations were received after December 31, 1980. The comments recommended changes in several areas of these regulations. In order for the Treasury and Internal Revenue Service to have sufficient time to examine these comments and determine whether changes should be made, the regulations were amended to apply to certain interests in corporations only if they were created after December 31, 1981. (T.D. 7774, published in the **Federal Register** for May 1, 1981, (46 FR 24945)). After further examination of the comments and re-evaluation of the regulations, a decision was made to revise provisions of the regulations under section 385. In order to allow Treasury and the Internal Revenue Service additional time to prepare and publish revisions to certain provisions of the regulations, the regulations are amended so that, in general, they will apply to certain interests in corporations only if they are created after June 30, 1982. It is expected that the revisions to the regulations will be published in the near future as proposed changes with opportunity for public comment.

Drafting Information

The principal author of this regulation is Carolyn Swift of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, both on matters of substance and style.

Waiver of Certain Procedural Requirements of Final Treasury Directive

A determination has been made by Roscoe L. Egger, Jr., Commissioner of Internal Revenue, that there is need for an immediate amendment to the regulations under section 385 of the Code in order to postpone the January 1, 1982, effective date of the regulations. Because of the immediate need for this regulation, compliance with the procedural requirements of paragraphs 8 through 14 of the final Treasury directive (43 FR 52121), relating to improving regulations, would be impractical, and therefore, these requirements have not been followed.

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Adoption of Amendments to the Regulations

Accordingly, 26 CFR Part 1 is amended as follows:

Paragraph (a)(1) of § 1.385-1 is revised to read as follows:

§ 1.385-1 Stock or indebtedness.

(a) *Effective date*—(1) *In general.* The regulations under section 385 apply to instruments (as defined in § 1.385-3(c)) and preferred stock issued after June 30, 1982, and to loans described in § 1.385-7 and guaranteed loans made after June 30, 1982.

* * * * *

There is a need for immediate guidance with respect to the provisions

contained in this Treasury decision. For this reason, it is found impractical to issue it with notice and public procedure under subsection (b) of section 553 of Title 5 of the United States Code or subject to the effective date limitation of subsection (d) of that section.

This Treasury decision is issued under the authority contained in section 385 and 7805 of the Internal Revenue Code of 1954 (83 Stat. 613 and 68A Stat. 917; 26 U.S.C. 385 and 7805).

Roscoe L. Egger, Jr.,

Commissioner of Internal Revenue.

Approved: December 30, 1981.

David G. Glickman,

Acting Assistant Secretary of the Treasury.

[FR Doc. 81-37419 Filed 12-30-81; 3:04 pm]

BILLING CODE 4830-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 762

[OPTS-62010B; TSH FRL-1980-1]

Fully Halogenated Chlorofluoroalkanes; Essential Use Exemption for Pharmaceutical Rotary Tablet Press Punch Lubricants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In the **Federal Register** of January 21, 1981 (46 FR 6019), EPA proposed amending the chlorofluorocarbon (CFC) rule (40 CFR Part 762) to add an essential use exemption for pharmaceutical rotary tablet press punch lubricants. EPA has concluded that an essential use exemption is necessary because there are no effective alternatives to this use of CFCs, and removal of the CFC-propelled product would have an adverse economic impact and a potentially unfavorable health impact on the public. EPA now promulgates a final rule which amends its CFC rule to include an essential use exemption for pharmaceutical rotary tablet press punch lubricants.

EFFECTIVE DATE: This exemption becomes effective January 5, 1982.

ADDRESS: The official record for this rulemaking is available for public inspection from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays, in the office of: Document Control Officer, Management Support Division (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-107, 401 M St., SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M St., SW., Washington, D.C. 20460, Toll free (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator 202-544-1404).

SUPPLEMENTARY INFORMATION:

I. Background

In 1978, EPA promulgated a rule (40 CFR Part 762) which prohibited almost all manufacture, processing, and distribution in commerce of fully halogenated chlorofluoroalkanes (hereinafter referred to as chlorofluorocarbons or CFCs) for aerosol propellant uses that are subject to the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601). This rule was published in the **Federal Register** of March 17, 1978 (43 FR 11318). This rule consisted of two separate parts. Part 712 dealt with recordkeeping while Part 762 addressed specific regulation of the substances. In the interest of making the Code of Federal Regulations easier for users to read and reference, EPA promulgated a rule published in the **Federal Register** of June 30, 1980 (45 FR 43721) consolidating both Parts into a revised Part 762. EPA has granted exemptions from this general prohibition for uses determined by the Agency to be "essential" according to certain criteria described in "Essential Use Determination—Revised," a support document to the March 17, 1978 CFC rule.

The criteria upon which an exemption is evaluated include: the availability of alternative propellants and/or the availability of alternative products; the health and environmental impact of CFC substitutes; and the possibility of severe economic consequences on industry if a CFC aerosol product cannot be used. The absence of an available alternative does not alone qualify a product for an essential use exemption.

In the **Federal Register** of January 21, 1981 (46 FR 6019), EPA proposed amending its chlorofluorocarbon rule to add an essential use exemption for pharmaceutical rotary tablet press punch lubricants. Pharmaceutical rotary tablet press punch lubricants are used to lubricate various moving parts of machines used in the production of medicine tablets. The bases for this proposed exemption were the lack of alternatives to the use of CFCs, the adverse economic and potentially unfavorable health impacts of nonavailability of the CFC-propelled product, and the fact that the release of CFCs into the environment would be small. EPA received one comment on this proposed rule supporting the proposed acton.

II. New Exemption

EPA, therefore, is amending the CFC rule in accordance with its proposal to include an essential use exemption for pharmaceutical rotary tablet press punch lubricants.

III. Regulatory Impacts

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. This regulation is not "Major" because it would have an annual impact on the economy of less than $100 million. It would also have the effect of reducing costs for the affected users of CFC-propelled pharmaceutical rotary tablet press punch lubricants, and it would not have adverse effects on factors such as competition, employment, or investment.

The proposed rule was published prior to the establishment of Executive Order 12291, and therefore was not considered under the terms of the Order. However, this final rule was submitted to the Office of Management and Budget (OMB) for review as required by section 7(f) of Executive Order 12291. As mandated by the Regulatory Flexibility Act, EPA is certifying that this regulation will not have a significant impact on a substantial number of small business entities. This certification is being made because it was determined that this rule will provide an economic benefit to companies using pharmaceutical rotary tablet press punch lubricants, regardless of their size.

This exemption becomes effective immediately pursuant to the authority of section 553(d) of the Administrative Procedure Act, 5 U.S.C. 553, which allows rules granting an exemption to become effective less than 30 days after promulgation.

IV. Public Record

The rulemaking record for this action consists of the rulemaking record for EPA's CFC rule (40 CFR Part 762) published in the **Federal Register** of March 17, 1978 (43 FR 11318), and the following documents:

(1) **Federal Register** of January 21, 1981 (46 FR 6019). USEPA. "Fully Halogenated Chlorofluoroalkanes; Proposed Essential Use Exemption for Pharmaceutical Rotary Tablet Press Punch Lubricants."

(2) CIBA-GEIGY, Main Comment, February 17, 1981.

(3) Key Industries, Communication, February 20, 1979.

(4) Key Industries, Communication, March 4, 1979.

(5) Key Industries, Communication, June 8, 1979.

(6) Key Industries, Communication, June 25, 1979.

(7) Key Industries, Communication, July 9, 1979.

(8) Key Industries, Communication, August 28, 1979.

(9) USDHEW, PHS, FDA, Bureau of Foods, Letter from Ralph Stafko to James Silverman, USEPA, OTS, CAD, November 28, 1979.

(10) USEPA, IERL, Memo from C. Frank to James Silverman, USEPA, OTS, CAD, August 16, 1979.

(11 USEPA, OTS, CAD, Letter from James Silverman to C. Frank, USEPA, IERL, August 7, 1979.

(12) USEPA, OTS, CCD, Telephone conversation between Kathleen Ehrensberger and Charlie Kumkumian, FDA, BD, NDE, February 22, 1980.

In addition, any comments from OMB to EPA and any EPA response to those comments are available for public inspection in the Public Record for this rulemaking.

(Sec. 6, 90 Stat. 2020., (15 U.S.C. 2065)).

Dated: December 23, 1981.

Anne M. Gorsuch,

Administrator.

PART 762—FULLY HALOGENATED CHLOROFLUOROALKANES

Therefore, 40 CFR Part 762 is amended by adding a new paragraph (h) to § 762.58 to read as follows:

§ 762.58 Essential use exemption.

* * * * *

(h) Pharmaceutical rotary tablet press punch lubricants.

* * * * *

[FR Doc. 82-122 Filed 1-4-82; 8:45 am]

BILLING CODE 6560-31-M

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40 CFR Part 762

[OPTS-66005D; TSH-FRL 1980-2]

Fully Halogenated Chlorofluoroalkanes; Essential Use Exemption for Spinnerette Release Agents

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA proposed in the **Federal Register** of August 25, 1981 (46 FR 42880), a rule reinstating the essential use exemption for spinnerette release agents to the chlorofluorocarbon (CFC) rule under 40 CFR Part 762. EPA took this action based on new information indicating that adequate substitutes do not exist and that substitutes could not be developed and used for all applications or by all man-made fiber producers. EPA now promulgates a final rule to reinstate the spinnerette release agents exemption to the CFC rule.

EFFECTIVE DATE: This exemption becomes effective January 5, 1982.

ADDRESS: The official record for this rulemaking is available for public inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in the office of: Document Control Officer, Management Support Division (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E–107, 401 M St., SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, Rm. E–511, 401 M St., SW., Washington, D.C. 20460, Toll free (800–424–9065), In Washington, D.C.: (554–1404), Outside the USA: (Operator 202–554–1404).

SUPPLEMENTARY INFORMATION:

I. Background

In 1978, EPA promulgated a rule (40 CFR Part 762) which prohibited almost all manufacturing, processing, and distribution in commerce of fully halogenated chlorofluoroalkanes (hereinafter referred to as chlorofluorocarbons or CFC's) for aerosol propellant uses. This rule was published in the **Federal Register** of March 17, 1978 (43 FR 11318). This rule consisted of two separate parts. Part 712 dealt with recordkeeping while Part 762 addressed specific regulation of the substances. In the interest of making the Code of Federal Regulations easier for users to read and reference, EPA promulgated a rule published in the **Federal Register** of June 30, 1980 (45 FR 43721) consolidating both Parts into a revised Part 762.

EPA has granted exemptions from this general prohibition for uses determined by the Agency to be "essential" according to certain criteria described in "Essential Use Determination—Revised," a support document to the March 17, 1978 CFC rule.

The criteria upon which an exemption is evaluated include: the availability of alternative propellants and/or the availability of alternative products; the health and environmental impact of CFC substitutes; and the possibility of severe economic consequences on industry if a CFC aerosol product cannot be used. The absence of an available alternative does not alone qualify a product for an essential use exemption.

EPA promulgated a rule published in the **Federal Register** of January 21, 1981 (46 FR 5981) revoking the spinnerette release agents exemption. This rule would have become effective on March 1, 1982. The rule was based upon information EPA received indicating that the development of adequate substitutes for CFCs in spinnerette release agents had progressed to the point where they would be widely available by March 1, 1982.

Following promulgation, the Man-Made Fiber Producers Association and several companies that manufacture man-made fibers presented EPA with convincing evidence that adequate substitutes will not be available for all processes and applications by March 1, 1982. Information provided indicated that companies manufacture many products using different designs, sizes, and shapes of spinnerettes which use different spinning cabinet designs and extrusion methods. Consequently, a release agent that works for one type of process or product line may not be suitable for another. Some man-made fiber companies indicated that if the CFC prohibition became effective in March 1982, they would be forced to use considerably less effective and possibly less safe substitutes in some processes and product lines.

EPA believes that the information and concerns presented by industry are sufficient to warrant reinstatement of the exemption for spinnerette release agents. EPA proposed in the **Federal Register** of August 25, 1981 (46 FR 42880) a rule to reinstate the essential use exemption for spinnerette release agents. EPA received six comments supporting reinstatement of this exemption.

II. Reinstatement of Exemption

EPA, therefore, is amending its CFC rule in accordance with its proposed rule to reinstate the essential use exemption for CFCs used as an aerosol propellant for spinerette release agents. CFC release as a result of this use is an estimated 152,000 kilograms, or only .04 percent of the total U.S. CFC production in 1980. EPA encourages the use of substitutes where feasible.

III. Regulatory Impacts

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. This regulation is not "Major." It does not have an annual effect on the economy of $100 million or more. Although EPA has not quantified the regulation's potential effect on the man-made fiber industry, the impact of this rule will be to decrease cost to the

industry compared with the former rule, which would have increased costs by prohibiting the use of CFCs as an aerosol propellant for spinnerette release agents. In addition, the present rule will not create significant adverse effects on factors such as competition, employment, or investment. This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

As mandated by the Regulatory Flexibility Act, EPA is certifying that this regulation will not have a significant impact on a substantial number of small business entities. This certification is made because this rule will provide an economic benefit to companies using CFC-propelled spinnerette release agents, regardless of their size.

This exemption becomes effective immediately pursuant to the authority of section 553(d) of the Administrative Procedure Act, 5 U.S.C. 553, which allows rules granting an exemption to become effective less than 30 days after promulgation.

IV Public Record

The rulemaking record for this action consists of the rulemaking records for the CFC rule published in the **Federal Register** of March 17, 1978 (43 FR 11318); the rule revoking the exemption published in the **Federal Register** of January 21, 1981 (46 FR 5981); and the following documents:

(1) **Federal Register** of August 25, 1981 (46 FR 42880). USEPA. "Fully Halogenated Chlorofluoroalkanes; Essential Use Exemption Spinnerette Release Agents."
(2) Allied Chemical, Communication, January 30, 1981.
(3) Allied Chemical, Communication, June 29, 1981.
(4) Allied Chemical, Main Comment, September 8, 1981.
(5) American Enka Company, Communication, January 28, 1981.
(6) American Enka Company, Communication, February 5, 1981.
(7) American Enka Company, Communication, March 5, 1981.
(8) American Enka Company, Main Comment, September 15, 1981.
(9) American Hoechst Corporation, Communication, April 13, 1981.
(10) Badische Corporation, Communication, May 7, 1981.
(11) Badische Corporation, Main Comment, September 28, 1981.
(12) D.B. Powers Corporation, Communication, April 6, 1981.
(13) E. I. du Pont de Nemours and Company, Communication, August 3, 1981.
(14) Eastman Kodak, Communication, February 25, 1981.
(15) Eastman Kodak, Communication, June 29, 1981.
(16) Eastman Kodak, Main Comment, September 10, 1981.
(17) Fiber Industries, Inc., Main Comment, September 22, 1981.
(18) Man-Made Fiber Producers Association, Inc., Communication, February 26, 1981.
(19) Man-Made Fiber Producers Association, Inc., Communication, May 21, 1981.
(20) Man-Made Fiber Producers Association, Inc., Communication, May 29, 1981.
(21) Man-Made Fiber Producers Association, Inc., Communication, June 9, 1981.
(22) Monsanto Textiles Company, Main Comment, September 14, 1981.
USEPA, OTS, CCD, Telephone conversations between Kathleen Ehrensberger and:
(23) C.T. Handy, E. I. du Pont de Nemours and Company, March 12, 1981.
(24) Mike Kemp, Textile Economics Bureau, June 4 and 5, 1981.
(25) Mr. Betts, Wyn-Tex, June 4 and 5, 1981.
(26) Abdul Jalil, Fibers and Plastics of Georgia, June 4, 1981.
(27) Everett Smith, Wellman Industries, June 5, 1981.
(28) Guy Osterneck, Osterneck Company, June 5, 1981.
(29) Ernie Rockwood, American Manufacturing Co., Inc., June 5 and 8, 1981.
(30) Thomas A. Mayberry, Concord Fibers, June 5, 1981.
(31) Herb Wolfgang, ACS Industries, Inc., June 8, 1981.
(32) Scott Allison, IMS Corp., June 8, 1981.

In addition, any comments from OMB to EPA and any EPA response to those comments are available for public inspection in the Public Record.

(Sec. 6, 90 Stat. 2020; (15 U.S.C. 2605))

Dated: December 23, 1981.

Anne M. Gorsuch,

Administrator.

PART 762—FULLY HALOGENATED CHLOROFLUOROALKANES

Therefore, 40 CFR Part 762 is amended by revising § 762.58(b) to read as follows:

§ 762.58 Essential use exemptions.

* * * * *

(b) Release agent for molds used in the production of plastic and elastomeric materials.

* * * * *

[FR Doc. 82-121 Filed 1-4-82; 8:45 am]
BILLING CODE 6560-31-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 74

[FCC 81-570]

Television and Radio; Amendment Regarding Five and Seven Year License Periods

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its rules implementing the five year renewal periods for television and seven year renewal periods for radio as mandated by the Omnibus Budget Reconciliation Act.

DATES: Effective December 16, 1981.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Israel Teitelbaum, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

Order

Adopted: December 16, 1981.
Released: December 17, 1981.

In the matter of Amendment of §§ 73.733 and 74.15 of the Commission's Rules: Five and Seven Year License Periods; FCC 81-570.

1. On October 30, 1981, the Commission amended § 73.1020 of its Rules to extend the maximum three year license terms for television and radio stations (46 FR 57050; November 20, 1981). *Station License Period,* FCC 81-497, released November 2, 1981. This amendment was mandated by the Omnibus Budget Reconciliation Act enacted into law on August 13, 1981. Public Law 97-35, 95 Stat. 357. Under that Act, radio license terms were extended to seven years and television license terms to five years. Our October 30 *Order* inadvertently failed to amend all pertinent FCC rules. Those amendments are, therefore, being made in this *Order.*

2. The license terms of all independently authorized broadcast facilities will comport with the five year term for television facilities and seven year term for radio facilities. The license terms of auxiliary facilities will run with the terms of the parent facility. (See 47 CFR 74.15(b).) Thus, international stations will be licensed for seven years. (See 47 CFR 73.733.) FM booster licenses will be issued for a period running concurrently with the license of the FM radio broadcast station with which it is used. (See 47 CFR 74.15(c).) Television broadcast translator stations will be

licensed for five years and FM translators for seven years. (See 47 CFR 74.15(d).)

3. Consistent with the actions taken in our October 30 *Order*, this *Order* implements the longer license terms, commencing with affected broadcast authorizations expiring on or after October 1, 1981. Section 4 of the Administrative Procedure Act, 5 U.S.C. 553, requires that a general notice of proposed rulemaking be published in the **Federal Register** and interested parties be given an opportunity to comment upon or participate in any rule making. However, these requirements do not apply when the agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b)(B). The rules revised herein merely implement the intent of Congress in passing the subject legislation. Moreover, in that Congress determined that extended license renewal terms are in the public interest, immediate implementation of the subject revised rules is appropriate. Thus good cause is established for waiver of the 30 day effective period. 5 U.S.C. 553(d)(3).

4. Accordingly, it is ordered, That effective as of the adoption date of this *Order*, the Commission's Rules are amended in the manner set forth in the attached Appendix.

(Secs. 4, 303, 307, 48 Stat., as amended, 1066, 1082, 1083; 47 U.S.C. 154, 303, 307)

Federal Communications Commission.

William J. Tricarico,

Secretary.

Appendix

PART 73—RADIO BROADCAST SERVICES

1. 47 CFR Part 73, § 73.733 is revised to read as follows:

§ 73.733 Normal license period.

All international broadcasting station licenses will be issued so as to expire at the hour of 3 a.m. local time and will be issued for a normal license period of 7 years expiring November 1.

PART 74—EXPERIMENTAL, AUXILIARY, AND SPECIAL BROADCAST AND OTHER PROGRAM DISTRIBUTIONAL SERVICES

2. 47 CFR Part 74, § 74.15(d) is amended by revising the introductory text of (d) and paragraphs (d)(1)–(10) to read as follows:

§ 74.15 License period.

* * * * *

(d) Initial licenses for television broadcast translator stations and FM broadcast translator stations will ordinarily be issued for a period running until the date specified in this Section for the State or territory in which the station is located or, if issued after such date, to the next renewal date determined in accordance with this Section. When renewed, television broadcast translator stations will ordinarily be renewed for 5 years and FM broadcast translator stations for 7 years; *Provided, however,* That, if the Commission finds that the public interest, convenience, or necessity will be served, it may issue either an initial license or a renewal thereof for a lesser term. The time of expiration of normally issued initial and renewal licenses will be 3 a.m., local time, on the following dates, and, thereafter, at 5-year intervals for television broadcast translator stations and at 7-year intervals for FM broadcast translator stations:

(1) For stations located in Nevada, February 1, 1983.

(2) For stations located in California, April 1, 1983.

(3) For stations located in Maine, Vermont, New Hampshire, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, Maryland, Delaware, West Virginia, Ohio, and the District of Columbia, June 1, 1983.

(4) For stations located in Virginia, North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, Arkansas, Missouri, Kentucky, Tennessee, Indiana, Illinois, Michigan, Wisconsin, Puerto Rico, and the Virgin Islands, August 1, 1983.

(5) For stations located in Oklahoma and Texas, October 1, 1983.

(6) For stations located in Kansas and Nebraska, December 1, 1983.

(7) For stations located in Iowa and South Dakota, February 1, 1984.

(8) For stations located in Minnesota and North Dakota, April 1, 1984.

(9) For stations located in Wyoming, June 1, 1984.

(10) For stations located in Montana, August 1, 1984.

* * * * *

3. 47 CFR Part 74, § 74.15 is amended by renumbering § 74.15(f) as § 74.15(e) and removing the reference to any reservation of § 74.15(e).

[FR Doc. 82-204 Filed 1-4-82; 8:45 am]

BILLING CODE 6712-01-M

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1033

[Twenty-ninth Rev. S.O. No. 1473; Amdt. No. 1]

Various Railroads Authorized To Use Tracks and/or Facilities of the Chicago, Rock Island and Pacific Railroad Co., Debtor (William M. Gibbons, Trustee)

AGENCY: Interstate Commerce Commission.

ACTION: Amendment No. 1 to Twenty-ninth Revised Service Order No. 1473.

SUMMARY: Pursuant to Section 122 of the Rock Island Transition and Employee Assistance Act, Pub. L. 96–254, this order authorizes various railroads to provide interim service over the Chicago, Rock Island and Pacific Railroad Company, Debtor (William M. Gibbons, Trustee), and to use such tracks and facilities as are necessary for operations. This order permits carriers to continue to provide service to shippers which would otherwise be deprived of essential rail transportation.

EFFECTIVE DATE: 11:59 p.m., December 31, 1981, and continuing in effect until 11:59 p.m., January 31, 1982, unless otherwise modified, amended or vacated by order of this Commission.

FOR FURTHER INFORMATION CONTACT:

M. F. Clemens, Jr., (202) 275–7840 or 275–1559.

SUPPLEMENTARY INFORMATION:

Decided December 29, 1981.

Upon further consideration of Twenty-ninth Revised Service Order No. 1473 (46 FR 62860), and with respect to the duration of this amendment, the limited extension of time is to permit the Commission additional time to consider the matter of further extensions as indicated by the Commission's Notice of September 21, 1981, and good cause appearing therefor:

It is ordered, that § 1033.1473 *Various railroads authorized to use tracks and/or facilities of the Chicago, Rock Island and Pacific Railroad Company, debtor (William M. Gibbons, trustee),* Twenty-ninth Revised Service Order No. 1473 is amended by substituting the following paragraph (n) for paragraph (n) thereof:

* * * * *

(n) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., January 31, 1982, unless otherwise modified, amended, or vacated by order of this Commission.

Effective date. This order shall become effective at 11:59 p.m., December 31, 1981.

(49 U.S.C. 10304–10305 and Sec. 122, Pub. L. 96–254)

This amendment shall be served upon the Association of American Railroads, Transportation Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms to that agreement and upon the American Short Line Railroad Association. Notice of this amendment shall be given to the general public by depositing a copy in the office of the Secretary of the Commission at Washington, D.C., and by filing a copy with Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members John H. O'Brien, William F. Sibbald, Jr., and Melvin F. Clemens, Jr.

Agatha L Mergenovich,

Secretary.

[FR Doc. 82-186 Filed 1-4-82; 8:45 am]

BILLING CODE 7035-01-M

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49 CFR Part 1033

[Tenth Rev. S.O. No. 1474, Amdt. No. 1]

Various Railroads Authorized To Use Tracks and/or Facilities of Chicago, Milwaukee, St. Paul and Pacific Railroad Co., Debtor (Richard B. Ogilvie, Trustee)

AGENCY: Interstate Commerce Commission.

ACTION: Amendment No. 1 to Tenth Revised Service Order No. 1474.

SUMMARY: Pursuant to Section 122 of the Rock Island Railroad Transition and Employee Assistance Act, Pub. L. 96–254, this order authorizes various railroads to provide interim service over the Chicago, Milwaukee, St. Paul and Pacific Railroad Company, Debtor (Richard B. Ogilvie) Trustee, and to use such tracks and facilities as are necessary for operations. This order permits carriers to continue to provide service to shippers which would otherwise be deprived of essential rail transportation.

EFFECTIVE DATE: 11:59 p.m., December 31, 1981, and continuing in effect until 11:59 p.m., March 31, 1982, unless otherwise modified, amended or vacated by order of this Commission.

FOR FURTHER INFORMATION CONTACT: M. F. Clemens, Jr., (202) 275–7840 or 275–1559.

SUPPLEMENTARY INFORMATION:

Decided December 29, 1981.

Upon further consideration of Tenth Revised Service Order No. 1474 (45 FR 54747), and good cause appearing therefor:

It is ordered, that § 1033.1474 *Various Railroads Authorized to Use Tracks and/or Facilities of the Chicago, Milwaukee, St. Paul and Pacific Railroad Company, debtor, (Richard B. Ogilvie, trustee),* Tenth Revised Service Order No. 1474 is amended by substituting the following paragraph (n) for paragraph (n) thereof:

* * * * *

(n) *Expiration date.* The provisions of this order are extended for an additional ninety (90) days, and shall expire at 11:59 p.m., March 31, 1982, unless otherwise modified, amended or vacated by order of this Commission.

Effective date. This amendment shall become effective at 11:59 p.m., December 31, 1981.

(49 U.S.C. 10304–10305 and (Sec. 122, Pub. L. 96–254)

This amendment shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. Notice of this amendment shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members John H. O'Brien, William F. Sibbald, Jr., and Melvin F. Clemens, Jr.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-188 Filed 1-4-82; 8:45 am]

BILLING CODE 7035-01-M

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49 CFR Part 1033

[Fifth Rev. S.O. No. 1495; Amdt. No. 3]

Burlington Northern Railroad Co. and Fort Worth and Denver Railway Co. Authorized To Use Tracks and/or Facilities of the Chicago, Rock Island and Pacific Railroad Co., Debtor (William M. Gibbons, Trustee)

AGENCY: Interstate Commerce Commission.

ACTION: Amendment No. 3 to Fifth Revised Service Order No. 1495.

SUMMARY: Pursuant to Section 122 of the Rock Island Transition and Employee Assistance Act, Pub. L. 96–254, this order authorizes the Burlington Northern and Fort Worth and Denver to provide interim service over the Chicago, Rock Island and Pacific Railroad Company, Debtor (William M. Gibbons, Trustee), and to use such tracks and facilities as are necessary for operations. This order permits carriers to continue to provide service to shippers which would otherwise be deprived of essential rail transportation.

EFFECTIVE DATE: 11:59 p.m., December 31, 1981, and continuing in effect until 11:59 p.m., January 31, 1982, unless otherwise modified, amended or vacated by order of this Commission.

FOR FURTHER INFORMATION CONTACT: M. F. Clemens, Jr., (202) 275–7840, 275–1559.

SUPPLEMENTARY INFORMATION:

Decided December 29, 1981.

Upon further consideration of Fifth Revised Service Order No. 1495 (46 FR 48212, 54559 and 57691), and with respect to the duration of this amendment, the limited extension of time is to permit the Commission additional time to consider the matter of further extensions as indicated by the Commission's Notice of September 21, 1981, and good cause appearing therefor:

It is ordered, that § 1033.1495 *Burlington Northern Railroad Company and Fort Worth and Denver Railway Company Authorized To Use Tracks and/or Facilities of the Chicago, Rock Island and Pacific Railroad Company, debtor, (William M. Gibbons, trustee),* Fifth Revised Service Order No. 1495 is amended by substituting the following paragraph (n) for paragraph (n) thereof:

* * * * *

(n) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., January 31, 1982, unless otherwise modified, amended or vacated by order of this Commission.

Effective date. This amendment shall become effective at 11:59 p.m., December 31, 1981.

(49 U.S.C. 10304–10305 and Sec. 122, Pub. L. 96–254)

This amendment shall be served upon the Association of American Railroads, Transportation Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms

of that agreement and upon the American Short Line Railroad Association. Notice of this amendment shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members John H. O'Brien, William F. Sibbald, Jr., and Melvin F. Clemens, Jr.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-187 Filed 1-4-82; 8:45 am]

BILLING CODE 7035-01-M

Proposed Rules

Federal Register
Vol. 47, No. 2
Tuesday, January 5, 1982

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.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Chapter I

Regulatory Agenda

AGENCY: Office of Personnel Management.

ACTION: Semiannual agenda of regulations.

SUMMARY: The following Office of Personnel Management regulations are scheduled for review or development during the 6-month period from November 1, 1981 through April 30, 1982. This agenda carries out OPM's responsibilities to publish semiannual agenda under E.O. 12291, Federal Regulation, and the Regulatory Flexibility Act (5 U.S.C. Chapter 6). This publication in the **Federal Register** does not impose a binding obligation on the Office of Personnel Management with regard to any specific item on the Agenda. Regulatory action in addition to the items listed is not precluded.

FOR FURTHER INFORMATION CONTACT: Beverly McCain Jones, Issuance System Office, Office of Planning and Evaluation (202) 254–5966.

Office of Personnel Management.

Donald J. Devine,

Director.

REGULATIONS SCHEDULED FOR REVIEW OR DEVELOPMENT

[Nov. 1, 1981 through Apr. 30, 1982]

CFR part (and subpart or section number if applicable) or other authority	Title of affected part	Brief description and justification	Knowledgeable official, responsible office, and telephone number	Major rule; E.O. 12291	Affects small entities; RFA
1. 5 CFR Part 274 [1]	Corrective Actions	Proposed new regulations to establish procedures for OPM initiated corrective actions, in cases of violations of civil service rules and regulations. *Justification:* Establish regulatory base for compliance oriented corrective actions. Target Date: 4/30/82.	Terry Evans, Compliance Branch, ACE, AR (202) 632-4540.	No	No.
2. 5 CFR Part 293	Personnel Records and Files	Final regulations to establish an Employee Performance File, analogous to the existing regulations for the Official Personnel Folder, as part of overall agency performance appraisal systems. *Justification:* These reguations provide minimum essential Privacy Act requirements for sensitive employee records while preserving maximum agency flexibility in designing their own recordkeeping systems. Note: Adoption of these final rules was originally targeted for 8/81. Delayed due to the necessity to devote resources to a special high priority project. Target Date: 10/81.	William H. Lynch, Work Force Information Division, ACE, AR, (202) 254-9790, (202) 254-9793.	No	No.
3. 5 CFR Part 294 and 5 CFR Part 293.	Availability of Official Information	Guidance for obtaining information from OPM, under the Freedom of Information Act. Note: Have received comments from agencies; making changes to regulations based on comments. Will send revised regulations through clearance process then forward to the FEDERAL REGISTER. *Justification:* The Freedom of Information Act requires agencies to publish regulations describing how to obtain information from them. Implementation of SES raises questions about availability of data on members, and institution of performance evaluation raises a question of availability of performance standards and/or evaluations. Target Date: Proposed regulations 12/81.	William C. Duffy, Chief, Information Systems Plans and Policies Branch, Office of Budget and Management, (202) 632-7714.	No	No.
4. 5 CFR Part 307, § 307.105	Veterans Readjustment Appointments.	To clarify the right of VRAs to appeal from termination during their first year of service on the same basis as employees in the competitive service (5 CFR 315.804, 815, 806) and to include reference to the right of VRAs who have completed 1 year of service to appeal removal under 5 CFR 432 and 5 CFR 752C. *Justification:* To assure that VRAs have access to appeal rights to which entitled. If not issued, MSPB may continue to dismiss VRA appeals for lack of jurisdiction. Target Date: 10/81 for final regs.	John Schultz, Office of Policy Analysis and Development, Staffing Services, (202) 632-6817.	No	No.

REGULATIONS SCHEDULED FOR REVIEW OR DEVELOPMENT—Continued

[Nov. 1, 1981 through Apr. 30, 1982]

CFR part (and subpart or section number if applicable) or other authority	Title of affected part	Brief description and justification	Knowledgeable official, responsible office, and telephone number	Major rule; E.O. 12291	Affects small entities; RFA
5. 5 CFR Part 307	Veterans Readjustment Appointments.	Proposed extension of VRA Program beyond 9/30/81 contingent on legislation. *Justification:* Extension of VRA authority until 9-30-84 under consideration in Congress. If enacted and signed by the President, regulations will have to be revised to reflect change in law. Target Date: 3/82.	A. Diane Graham, Office of Affirmative Employment Programs, (202) 632-4420.	No	No.
6. 5 CFR Part 316, § 316.302 and § 316.402.	Temporary and Term Employment	Regulations to permit noncompetitive temporary and term appointment of persons eligible for career appointment under 5 USC 3304(c). *Justification:* To give Ramspeck Act eligibles the opportunity to be considered for temporary or term appointment when permanent jobs are not available. This would equalize their benefits and those of eligibles under other special appointing authorities. Target Date: Final regulations 11/81.	Tracy Spencer, Noncompetitive Staffing and College Relations, Staffing Services, (202) 632-6000.	No	No.
7. 5 CFR Part 316	Kinds of Employment for Veterans Readjustment Appointment Eligibles.	Proposed extension affecting temporary and term employment for VRA eligibles beyond 9/30/81 contingent on legislation. *Justification:* Extension of VRA authority until 9/30/84 under consideration in Congress. If enacted and signed by the President, regulations will have to be revised to reflect change in law. Target Date: 3/82.	A. Diane Graham, Office of Affirmative Employment Programs, (202) 632-4420.	No	No.
8. 5 CFR Part 317, Subpart G	SES Career Appointment by Reinstatement.	Final regulations on reinstatement to an SES career appointment following (a) a voluntary separation from SES, or (b) a Presidential appointment. *Justification:* These reinstatements are authorized by law. The regulations set the procedures for implementing the law. Interim regulations were issued on 12/5/80. Need to make regulations final, based on comments on interim. Target Date: 2/82.	Ann Ugelow, SES Division, EPG, (202) 632-6821.	No	No.
9. 5 CFR Part 317, Subpart H	Career Appointees: Retention of SES Provisions Following a Presidential Appointment.	Regulations to implement 5 U.S.C. 3392(c) regarding the right of SES career appointes to retain certain SES provisions while serving under a Presidential appointment made by and with the advice and consent of the Senate. *Justification:* Regulations are needed to insure uniformity in the implementation of the law. Target Date: Proposed regulations 2/82.	Ann Ugelow, SES Division, EPG, (202) 632-6821.	No	No.
10. 5 CFR Part 330, Subpart C.	Displaced Employee Program	Revise regulations to provide limited benefits to spouses of transferred Federal employees; reaffirm agency's primary responsibility to assist its own employees; remove requirement that disability annuitant be under age 60; clarify ineligibility of Schedule C employees; modify conditions under which employee eligibility can be terminated; recognize role of agency delegated examining units. *Justification:* To make provisions of the Displaced Employee Program more responsive to current agency staffing requirements and needs, and to bring eligibility of disability annuitants into conformance with a recent court ruling. Target Date: Final regulations 10/81.	Cathy Lundblad, Noncompetitive Staffing and College Relations, Staffing Services, (202) 632-6000.	No	No.
11. 5 CFR Parts 339, 432, 752, and 831.	Medical Qualification Requirements; Reduction in Grade and Removal Based on Unacceptable Performance; Adverse Action, Retirement.	Final regulation governing medical examinations of Federal employees and agency filed disability retirement applications. *Justification:* Regulations are needed to correct problems that have resulted from misuse of mandatory fitness-for-duty examinations (particularly psychiatric examinations). Present procedures governing medical examination have received much criticism from Congress and employee organization. See #22 for additional information. Target Date: 1/82.	Gay Gardner, Office of Pay and Benefits Policy, Compensation, (202) 632-4684.	No	No.
12. 5 CFR Part 351 [1]	Reduction in Force	Clarification of existing OPM policy on RIF assignment rights and the identification of employees with a transferring function. *Justification:* These proposed regulation are intended to both (1) clarify and simplify existing policy concerning employee retention rights, and (2) as indicated, make needed revisions to longstanding policy. Target date for proposed regulatios: 12/81.	Theodore Dow or Thomas Glennon, Office of Policy Analysis and Development, Staffing Services, (202) 632-6817.	No	No.
13. 5 CFR Part 352	Reemployment Rights after Service with Panama Canal Commission.	Proposed Subpart I for reemployment rights for Federal employees who accept assignment with the Panama Canal Commission. *Justification:* To implement Pub. L. 96-70 which authorizes OPM to prescribe regulations to put reemployment rights into effect. Target Date: 11/81.	Leota Shelkey, Office of Policy Analysis and Development, Staffing Services (202) 632-6817.	No	No.

REGULATIONS SCHEDULED FOR REVIEW OR DEVELOPMENT—Continued

[Nov. 1, 1981 through Apr. 30, 1982]

CFR part (and subpart or section number if applicable) or other authority	Title of affected part	Brief description and justification	Knowledgeable official, responsible office, and telephone number	Major rule; E.O. 12291	Affects small entities; RFA
14. 5 CFR Part 352	Reemployment Rights after Service with U.S.Senate Committee on Appropriations.	Add new subpart covering reemployment following service with the U.S. Senate Committee on Appropriations under provisions of 2 USC 67a. Delete Subpart F covering reemployment after service in the Economic Stabilization Program because applicable law has been repealed. *Justification:* New subpart needed to implement 2 U.S.C. 67a. Deletion of Subpart F needed because statutory authority for it no longer exists. Target date for proposed regulations is 10/81; final regulations 4/82.	Tracy Spencer, Noncompetitive Staffing and College Relations, Staffing Services, (202) 632-6000.	No	No.
15. 5 CFR Part 353 [1]	Restoration to Duty	The proposed changes would (1) give agencies greater flexibility in placing an emnployee entitled to restoration by exempting them (agencies) from the present requirement that they restore a veteran to his/her previous position even though it was occupied by an employee in the same retention subgroup under Part 351; (2) clarify an agency's rights and responsibilities in cases when the DOL takes excessive time to decide a claim or the claimant appeals DOL's decision to stop compensation; and (3) state an agency has discretion to carry an injured employee on LWOP for whatever period it considers appropriate, or separate the employee who is unable to work. *Justification:* Several recent MSPB cases have revealed gaps in the regulations on these issues which have led to ambiguous and contradictory decisions. If we do not move into the vacuum by effecting a fair solution, we may have the Board force something on OPM that is unworkable. Target Date 1/82.	Raleigh Neville, Office of Policy Analysis and Development, Staffing Services, (202) 632-6817.	Yes	No.
16. 5 CFR Part 359 [1]	Removal, Reinstatement, and Guaranteed Placement in the Senior Executive Service.	Final regulations on (1) the removal of SES career appointees during probation or for less than fully successful executive performance, (2) the removal of other SES appointees, and (3) placement rights of certain SES career appointees. *Justification:* These actions are authorized by law. The regulations establish procedures for implementing the law. Interim regulations were issued on July 31, 1979. Target Date: 3/82.	Ann Ugelow, SES Division, EPG, (202) 632-6821.	No	No.
17. 5 CFR Part 410, § 410.302.	Training: Selection and Assignment of Trainees.	Final regulation concerning when merit promotion procedures must be used in selecting employees for training. Present regulation applies to an excessive number of training instances. *Justification:* Proposed regulation will be more economical. Agency comments indicate that it will improve training management. Proposed regulation issued on 2/20/81. Target Date: Final Regulation 12/81.	Constance Guitian, Training Policy Division, WED, (202) 653-6171.	No	No.
18. 5 CFR Part 410, § 410.503.	Training: General Prohibitions on Training Through Non-Government Facilities.	Final regulations to clarify requirement to consider already qualified employees for positions before providing training in non-government facilities. Present regulation applies to an excessive number of training instances. *Justification:* Proposed regulation will be more economical. Agency comments indicate that it will improve training management. Proposed regulations issued on 2/20/81. Target Date: Final regulations 12/81.	Constance Guitian Training Policy Division WED, (202) 653-6171.	No	No.
19. 5 CFR Part 410, § 410.508 and § 410.509.	Training: Agreement to Continue in Service and Failure to Fulfill Agreement to Continue in Service.	Proposed regulations to clarify procedures governing continued service agreement and provide due process procedures when an agency recovers expenses from employee who fails to continue in service after training. *Justification:* Simplify the administration of continued service agreements making them less costly. In order to avoid having agency heads vulnerable to personal liability suits, due process provisions have been added. Target Date: Proposed regulations 11/81; Final regulations 1/82.	Constance Guitian Training Policy Division WED, (202) 653-6171.	No	No.
20. 5 CFR Part 430 Subpart B.	Performance Appraisal	Proposed amendment to include a statutory requirement regarding the use of performance standards in appraising employee performance on individual elements and to define the term "non critical element." *Justification:* Title 5, U.S.C., Section 4302(b)(1) requires that agencies establish performance standards which will, to the maximum extent feasible, permit the accurate evaluation of job performance. Since some agencies question this requirement it is essential that the requirement be specifically described in OPM regulations. See FPM Letter 430-4 dated 3/80. Target Date: Proposed regulations by 11/81.	Nat Brown, Performance Appraisal Service Division, WED, (202) 632-8950.	No	No.

REGULATIONS SCHEDULED FOR REVIEW OR DEVELOPMENT—Continued

[Nov. 1, 1981 through Apr. 30, 1982]

CFR part (and subpart or section number if applicable) or other authority	Title of affected part	Brief description and justification	Knowledgeable official, responsible office, and telephone number	Major rule; E.O. 12291	Affects small entities; RFA
21. 5 CFR Part 432	Reduction in Grade and Removal Based on Unacceptable Performance.	Final amendment clarifying agency's obligations when an employee's health is an issue. *Justification:* This amendment is intended to define agency and employee obligations to avoid harmful errors by agencies in taking actions based on unacceptable performance resulting in costly reversal by review bodies. See #11 for additional information. Target Date: Final regulations 1/82.	Wilma Lehman, Employee Relations, Policy Coordination Division, OPE, (202) 254-5134.	No	No.
22. 5 CFR Part 451 Subpart B, § 451.207.	Incentive Awards: Eligibility	Proposed revision to regulation would exclude members of the Senior Executive Service from eligibility for lump sum cash awards for sustained superior job performance. *Justification:* Cash awards for sustained superior performance authorized by Chapter 45 of Title 5, U.S.C. are duplicative of performance bonuses for career SES members, authorized under 5 USC 5384. This has led to questions regarding possible misuse of incentive awards authorities to circumvent the intent of Congressional and OPM restrictions on performance bonuses to SES members. Revision of the incentive awards regulations would preclude both misuse and speculation. Target Date: Final regulations 10/81.	Richard P. Brengel, Office of Productivity Programs, WED, (202) 632-4596.	No	No.
23. 5 CFR Part 470	Personnel Research Programs and Demonstration Projects.	Add new Part 470 to implement programs for conducting research and demonstration projects. *Justification:* Implement 5 U.S.C. 4706 (CSRA). Proposed regulation was issued 9/81. Target Date for final: 1/82.	Donald Hill, Office of Planning and Evaluation, (202) 254-6486.	No	No.
24. 5 CFR Part 511, § 511.605, 5 CFR Part 511, § 511.703.	Classification Under the General Schedule.	Clarify retroactive effective date for employees with retained grade. *Justification:* OPM published final rules on classification appeals under the general schedule on 12/30/80. At that time, it was decided that for employees in retained grade there would be no need for retroactive adjustments since neither their title, series or grade would be affected during the retained grade. However, several agencies have raised questions concerning the consequences of a reclassification action when the employee is re-eligible for retained grade and suffers a subsequent RIF. Under current regulations the correct title, series or grade would be used for RIF purpose as opposed to the retained grade. To deny employees in this situation the possibility of retroactive adjustment, if unwarranted, would place them at a disadvantage when compared to other employees. Target Date: Final regulations 1/11.	Gust Pappas, Chief, Classification Appeals Office, ACE, AR, (202) 632-7744.	No	No.
25. 5 CFR Part 531, § 531.204.	Pay under the General Schedule	Regulation to provide pay determination rule for loss of merit pay status. *Justification:* Current regulations do not provide for the possibility of a change in an employee's merit pay status without a change in position. A regulatory change is necessary to ensure an appropriate pay determination is made when this situation occurs. Proposed regulation was issued 8/81. Target Date for final: 11/81.	Donald J. Winstead, Office of Pay and Benefits Policy, Compensation, (202) 632-4634 or Peter G. Rymshaw, Merit Pay Development Division, Compensation, (202) 632-6127.	No	No.
26. 5 CFR Part 531, Subpart B.	Determining Rate of Basic Pay	Proposed revised regulations concerning use of highest previous rate, pay on promotion, pay schedule conversion rules, and movement between pay systems. *Justification:* Present regulations difficult to understand and are the subject of a case pending before the U.S. Supreme Court. Target Date: 7/82.	Donald J. Winstead, Office of Pay and Benefits Policy, Compensation, (202) 632-4634.	No	No.
27. 5 CFR Part 531, Subpart C.	Pay Adjustments for Supervisory	Proposed revised regulations. *Justification:* Revisions necessary to reflect Comptroller General decision and enactment of grade and pay retention statutes. Target Date: 7/82.	Donald J. Winstead, Office of Pay and Benefits Policy, Compensation Group, (202) 632-4634.	No	No.
28. 5 CFR Part 536	Grade and Pay Retention: Termination When Employee Transfers to Another Agency.	Proposed revised regulations to provide for termination of grade and pay retention benefits and eligibility for these benefits upon transfer to a new agency, and to clarify appeal rights to OPM when an employee loses eligibility for benefits by declining an offer of another position. *Justification:* Current policy permits the hiring agency to establish its own policy on whether or not to continue grade and pay retention benefits of employees hired by transfer from another agency. Agencies have questioned the appropriateness of this policy. Target Date: 11/81.	Roger Menke, Office of Pay and Benefits Policy, Compensation, (202) 632-4684.	No	No.

REGULATIONS SCHEDULED FOR REVIEW OR DEVELOPMENT—Continued

[Nov. 1, 1981 through Apr. 30, 1982]

CFR part (and subpart or section number if applicable) or other authority	Title of affected part	Brief description and justification	Knowledgeable official, responsible office, and telephone number	Major rule; E.O. 12291	Affects small entities; RFA
29. 5 CFR Part 540 [1]	Merit Pay System	Revised regulations to clarify policies and implement changes prompted by merit pay program evolution and development. *Justification:* Modification required by program evolution and change to implement status. Target Date for proposed 1/82.	Peter G. Rymshaw, Merit Pay Development Division, Compensation, (202) 632-6127.	No	No.
30. 5 CFR Part 550	Pay Administration (General)	Final regulations on the installment collection of indebtedness because of erroneous payment made by an agency. *Justification:* Required to implement section 8(1) of E.O. 11609, 7/22/71, as revised by E.O. 12107, 12/28/78. Target Date: 2/82.	Patricia Rochester, Office of Pay and Benefits Policy, Compensation, (202) 632-4634.	No	No.
31. 5 CFR Part 550, Subpart G [1].	Severance Pay	Proposed revision of regulations on severance pay as it applies to separated employees who decline offers of equivalent positions in other agencies, to employees who accept jobs with contractors, and to employees receiving compensation for on-the-job injuries. *Justification:* Recent reductions in force and contracting out emphasize need to clarify present regulations in regard to these particular kinds of cases. Target Date: 6/82.	Margaret Goodell, Office of Pay and Benefits Policy, Compensation, (202) 632-4684.	No	No.
32. 5 CFR Part 550, Subpart H.	Back Pay	Final regulations to provide for payment of reasonable attorney fees in back pay cases. *Justification:* Necessary to implement 5 USC 5596(b). Target Date: 11/81.	Donald J. Winstead, Office of Pay and Benefits Policy, Compensation, (202) 632-4634.	No	No.
33. 5 CFR Part 550, Subpart J.	Pay Administration, Adjustment of Work Schedules for Religious Observances.	Proposed regulations to implement title IV of the Federal Employee Flexible and Compressed Work Schedule Act of 1978. *Justification:* Regulations will provide methods for agencies to control the adjustment of work schedules for this purpose and for conditions that constitute a basis for denying an employee's request due to interference with the agency's mission. Target Date: 11/81.	Gus Ghessie, Office of Pay and Benefits Policy, Compensation, (202) 632-4684.	No	No.
34. 5 CFR Parts 550 and 610.	Pay Administration and Hours of Work.	Final regulations to clarify the definition of the phrase "regularly scheduled workweek" under chapters 55 and 61 of title 5, U.S.C. *Justification:* Regulations clarify the meaning of the phrase "regularly scheduled" and reestablish the proper relationship between an agency's responsibility to schedule work under chapter 61 and an employee's entitlement to premium pay for such work under subchapter V of chapter 55 of title 5, U.S.C. GAO has concurred in OPM's issuance of these regulations, which will greatly simplify this aspect of pay administration. Target Date: 4/82.	Dwight W. Brown, Office of Pay and Benefits Policy, Compensation (202) 632-4634.	No	No.
35. 5 CFR Parts 550 and 610.	Pay Administration and Hours of Duty.	Proposed regulations to allow agencies to "round up" and "round down" to nearest quarter hour (or fractions less than a quarter of an hour) for crediting irregular, unscheduled overtime work. *Justification:* Regulation needed to equalize treatment of fractional hours of overtime work and time spent in preshift and post-shift activities. Target Date: 12/81.	Mary Angel, Office of Pay and Benefits Policy, Compensation, (202) 632-4684.	No	No.
36. 5 CFR Part 551	Pay Administration under the FLSA-Exemptions.	Proposed revised regulations to simplify the exemption determination process. *Justification:* These revisions would reduce the costs to agencies of administering the FLSA. Target Date: 3/82.	Mario Caviglia, Compliance Branch, ACE, AR, (202) 632-4540.	No	No.
37. 5 CFR Part 551, Subpart F.	Pay Administration under the FLSA-Compliance.	Proposed new regulation to implement the FLSA Compliance Program. *Justification:* Required by 29 U.S.C. 204(f) and by changes made by 5 USC 1103a5. Target Date: 3/82.	Mario Caviglia, Compliance Branch, ACE, AR, (202) 632-4540.	No	No.
38. 5 CFR Part 630, Subpart I.	Court Leave	Proposed new regulations on court leave and revision of annual and sick leave and home leave regulations. *Justification:* Needed for clarification and elimination of discrepancies in application. Target Date: 6/82.	Margaret Goodell, Office of Pay and Benefits Policy, Compensation, (202) 632-4684.	No	No.

REGULATIONS SCHEDULED FOR REVIEW OR DEVELOPMENT—Continued

[Nov. 1, 1981 through Apr. 30, 1982]

CFR part (and subpart or section number if applicable) or other authority	Title of affected part	Brief description and justification	Knowledgeable official, responsible office, and telephone number	Major rule: E.O. 12291	Affects small entities; RFA
39. 5 CFR Part 715	Actions in the Interest of the Employee.	Final regulation covering voluntary personnel actions and other actions in the interest of the employee, including cancellation and correction of separations, reductions in pay, suspensions, furloughs, etc. *Justification:* The current regulation has an obsolete title and covers only the employee's right to resign and to withdraw a resignation before the effective date. Other requirements are contained in FPM Chapter 715 and FPM Supplement 831-1 which should be in regulations. Since the regulations and FPM chapter are used both by agencies and by MSPB (in adjudicating appeals of alleged involuntary actions), we believe it is necessary to reorganize the regulation and FPM chapter to place all mandatory requirements in the regulation, and only guidance, including court and MSPB decisions, in the FPM Chapter. Target Date: Final regulations 2/82.	Cynthia Field, Employee Relations, Policy Coordination Division, OPE, (202) 254-5517.	No	No.
40. 5 CFR Part 720	Federal Equal Opportunity Recruitment Program (Race, sex, handicap, and national origin systems).	Regulations codify EEOC delegations to OPM for operational control of agency information systems implementing affirmative recruitment programs and statistical reports to OPM. *Justification:* Required by Reorganization Plan No. 1 of 1978. OPM presently operates under a one paragraph interim delegation from EEOC. Published for comment 6/6/80. Proposed regulation for 60-day comment. Target Date: 1/82.	Dr. Philip, A. D. Schneider, Work Force Information Division, AR, (202) 632-6808.	No	No.
41. 5 CFR Part 720	Federal Equal Opportunity Recruitment Program (FEORP).	Final regulations to revise Part 720 to simplify data requirements relating to FEORP. *Justification:* To make possible maximum consistency with data requirements contained in EEOC's "Final Instructions for Federal Agency Affirmative Action Plans" and therefore reduce paperwork and calculation burdens on agencies. Target Date: 11/81.	A. Diane Graham, Office of Affirmative Employment Programs, (202) 632-4420.	No	No.
42. 5 CFR Part 731	Suitability for Federal Employment	Proposed new part to reflect delegation of suitability rating authority. *Justification:* Part 731 suitability rating authority has been delegated by the OPM to a number of agencies upon request of those agencies. Part 731 needs to be revised to address suitability rating actions of agencies with delegated authority. Current Current Status: Proposed regulation ready for internal clearance and approval. Target Date: Proposed regulations 12/81.	Robert Hubbard, Division of Personnel Investigations, Staffing Services, (202) 632-6152.	No	No.
43. 5 CFR Part 732	Personnel Security and Related Programs.	Proposed new part to address recent and possibly proposed changes in the personnel security program *Justification:* there has been a lack of consistency among agencies in designating position sensitivity based on national security and ADP security considerations. Contributing to this problem is the fact that the designation standards appear as *guidance* in the FPM rather than as regulatory *requirements*. Part 732 needs revision to incorporate the designation standards as regulatory requirements. Subject to OPM approval of the five-level security designation standards for positions, proposed by the interagency task force on GAO recommendations, new standards would be incorporated into Part 732 in lieu of the current criteria. Status: Completion pending receipt of published task force report and decision by Director on implementation. Target Date: 12/81.	Robert Hubbard, Division of Personnel Investigations, Staffing Services, (202) 632-6152.	No	No.
44. 5 CFR Part 736	Investigations	Proposed new part to reflect changes in the personnel investigations program. *Justification:* Investigative coverage for persons entering positions designated at the same level of sensitivity varies from agency to agency. Specific investigative requirements currently appear only as *guidance* in the FPM. In the interest of promoting greater uniformity in investigations, Part 736 needs to be revised to establish regulatory standards on investigative coverage at each level of sensitivity. Subject to OPM approval of the five levels of investigations proposed by the interagency task force on GAO recommendations, new investigative standards would be incorporated into Part 736 in lieu of the current coverage appearing in the FPM. Status: Completion pending receipt of published task force report and decision by Director on implementation. Target Date: 12/81.	John Crandell, Division of Personnel Investigations, Staffing Services, (202) 632-6152.	No	No.

REGULATIONS SCHEDULED FOR REVIEW OR DEVELOPMENT—Continued

[Nov. 1, 1981 through Apr. 30, 1982]

CFR part (and subpart or section number if applicable) or other authority	Title of affected part	Brief description and justification	Knowledgeable official, responsible office, and telephone number	Major rule; E.O. 12291	Affects small entities; RFA
45. 5 CFR Part 752 Subpart F [1].	Regulatory Requirements for Taking Adverse Actions Under the Senior Executive Service.	Final regulations on (1) suspensions for more than 14 days and (2) removal from the civil service of SES career appointees. *Justification:* These actions are authorized by law. The regulations establish procedures for implementing the law. Interim regulations were issued on July 31, 1979. Need to publish final regulations. Target Date: 3/82.	Ann Ugelow, SES Division, EPMD, (202) 632-6820.	No	No.
46. 5 CFR Part 752	Adverse Actions.	Final amendment clarifying the agency's obligations when an employee's health is an issue. *Justification:* Intended to define agency and employee obligations by OPM regulation to avoid harmful errors by agencies in effecting adverse actions resulting in costly reversals by appeals bodies. Target Date: 1/82.	Cynthia Field, Employee Relations, Policy Coordination Division, OPE, (202) 254-5517.	No	No.
47. 5 CFR Part 754	Adverse Actions by OPM	Proposed regulations revising 5 CFR 754 to apply to all specific adverse actions directed by OPM against agency employees. *Justification:* Currently, Part 754 applies only to actions based on suitability and fraud in examination; no procedures have been provided by regulations for other actions under section 5.3 of Civil Service Rule V. The revised part would additionally define the appropriate uses of cancellation of personnel actions. Changes are necessary to permit the proper usage of OPM's enforcement authority. Target Date: Proposed regulation 3/82.	Wilma Lehman, Employee Relations, Policy Coordination Division, OPE, (202) 254-5134.	No	No.
48. 5 CFR Part 790 [1]	Federal Employee Alcoholism and Drug Abuse Programs.	This rule is to implement and clarify the requirements for Federal civilian employees alcoholism and drug abuse programs contained in Pub. L. 91-616 and Pub. L. 92-255. *Justification:* These regulations are needed because MSPB no longer view FPM language as a firm legal basis for determining agency obligation in cases under appeal. MSPB recently overturned two agency actions for removal, citing that alcoholism and drug abuse are legal handicaps and that agencies must offer assistance to employees as a "reasonable accommodation" to their handicap. Target Date: 4/82.	Arthur J. Purvis, Employee Health Services Branch, WED, (202) 523-4550.	No	No.
49. 5 CFR Part 831	Government Claims for Recovery of Indebtedness.	Final regulations prescribing procedures for submission of agency claims for recovery of an indebtness against benefits due form the Civil Service Retirement System. *Justification:* Required in conjunction with a pending court case—*Rhinehart v. Seneca, et al.* Target Date: 2/82.	Patricia Rochester, Office of Pay and Benefits Policy, Compensation, (202) 632-4634.	No	No.
50. 5 CFR Part 831, Subpart S [1].	Withholding State Income Tax from Annuitants.	Final regulations on withholding of state income tax. *Justification:* New item required to implement section 1705 of Omnibus Reconcilation Act of 1981 (Pub. L. 97-35) to provide for withholding of state income taxes from civil service annuities. Target Date: 2/82.	Eugene Littleford, Office of Pay and Benefits Policy, Compensation, (202) 632-4634.	No	No.
51. 5 CFR Part 831, Subpart M.	Retirement; Recovery of Annuity Overpayments.	Proposed regulation revising right to a hearing in certain situations when there has been an overpayment of annuity form the Civil Service Retirement System. *Justification:* As a result of Shannon v. *U.S.C.S.C.*, OPM is required to give a right to a hearing in a certain annuity overpayment cases. The final court order in this case restricts the circumstances in which hearing must be offered. The proposed regulatory change will reflect the final decision of the court. Target Date: 12/81.	Patricia Rochester, Office of Pay and Benefits Policy, Compensation, (202) 632-4634.	No	No.
52. 5 CFR Part 831, 870, 871, and 890.	Retirement; Retention of Benefits upon Employment by Indian Tribal Organizations.	To provide for retention of CSR, FEHB, and FEGLI coverages by certain Federal employees who transfer to tribal organization employment. *Justification:* Regulations implement Pub. L. 93-638. Target Date: 3/82.	Beverly Carter, Office of Pay and Benefits Policy, Compensation, (202) 632-4634.	No	No.
53. 5 CFR Parts 870, 871, 872, and 873.	Life Insurance and Optional Life Insurance.	Final regulations to implement the Federal Employees Group Life Insurance Act of 1980. Regulations were necessitated by enactment of Pub. L. 96-427. *Justification:* Interim regulation now in effect; final regulation must be issued for permanent operation of life insurance program. Target Date: 11/81.	John Landers, Office of Pay and Benefits Policy, Compensation, (202) 632-4634.	No	No.

REGULATIONS SCHEDULED FOR REVIEW OR DEVELOPMENT—Continued

[Nov. 1, 1981 through Apr. 30, 1982]

CFR part (and subpart or section number if applicable) or other authority	Title of affected part	Brief description and justification	Knowledgeable official, responsible office, and telephone number	Major rule; E.O. 12291	Affects small entities; RFA
54. 5 CFR Part 890	Federal Employees Health Benefits (FEHB).	To reinstate or eliminate the two deductibles an enrollee had to meet when the enrollee changed health plans during and open season and incurred covered expenses subject to a deductible before the open season change became effective at the beginning of the first pay period in January. *Justification:* To repeal interim regulations published 12/30/80 and reestablish original two deductible requirement. Target Date for final regulations: 11/81.	Lauretta R. Hall, Office of Pay and Benefits Policy, Compensation, (202) 632-4684.	No	No.
55. 5 CFR Part 890	Federal Employees Health Benefits (FEHB).	Final regulations to define medically underserved areas for FEHB contract year 1982. *Justification:* Mandated by Pub. L. 96-179. Target Date: 12/81.	Lauretta R. Hall, Office of Pay and Benefits Policy, Compensation, (202) 632-4684.	No	No.
56. 5 CFR Part 890, Subpart C.	Federal Employees Health Benefits (FEHB) (Registration and Enrollment).	Proposed change to enable Federal employees enrolled for high option FEHB coverage to elect low option coverage upon becoming eligible under the Civilian Health and Medical Program of the Uniformed Services. *Justification:* FEHB high option enrollees who become eligible for CHAMPUS coverage would not be able to switch to low option FEHB coverage until next open season which could be several months. During this time the enrollee as well as the Federal Government would be contributing to high option premium rather than a lesser low option premium, while the enrollee would be overinsured. Target Date: 11/81.	Mary Ann Mercer, Office of Pay and Benefits Policy, Compensation, (202) 632-4634.	No	No.
57. 5 CFR Part 900, Subpart F [1].	Intergovernmental Personnel Act Programs.	Modification of the Merit Standards for personnel administration. *Justification:* To ease the administrative burden placed on State and local governments by the merit system standards for personnel administration. Target Date: Proposed regulation 11/81.	Joseph W. Howe, Policy Coordination Division, OPE, (202) 254-5134.	No	No.
58. 5 CFR Part 930, Subpart B [1].	Appointment, Pay and Removal of Administrative Law Judges.	Proposed regulations to repeal outdated text in light of opinion of Attorney General, dated 12/8/76; and add text to reflect procedures for appeals by ineligible applicants per advice of OGC. Will clarify procedures for applicants who are dissatisfied with their rating obtained from the Office of Administrative Law Judges after completion of the examination process. *Justification:* This change in the regulations is intended to assure greater availability of information concerning appeals procedure and to minimize any confusion concerning the subject. Target Date: 1/82.	Marvin H. Morse, Director, Office of Administrative Law Judges, (202) 632-4604.	No	No.
59. 5 CFR Part 1001, Subpart C.	Regulations Governing Employees of the Office of Personnel Management: Employee Responsibilities and Conduct.	Remove Part 1001 from 5 CFR and publish internal Ethics standards in OPM administrative manual or supplement. *Justification:* Part 1001 is applicable solely to OPM employees and, as such, inclusion in the Code of Federal Regulations is not required. Internal ethics standards of OPM will be published, instead, in the agency administrative manual or supplement. Target Date: Proposed regulations 2/82.	Llewellyn Fischer, Office of the General Counsel, (202) 632-4518.	No	No.

[1] New Item.

[FR Doc. 82-17 Filed 1-4-82; 8:45 am]

BILLING CODE 6325-01-M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

10 CFR Parts 500, 501, and 503

[Docket No. ERA-R-81-12]

Powerplant and Industrial Fuel Use Act of 1978; Administrative Procedures and Exemption Criteria; Extension of Comment Period

AGENCY: Economic Regulatory Administration, Energy.

ACTION: Extension of public comment period on proposed revisions to final rules.

SUMMARY: On November 30, 1981, the Department of Energy (DOE) revised its final rules implementing the Powerplant and Industrial Fuel Use Act of 1978 (FUA) to simplify the administrative procedures and exemption criteria applicable to owners or operators of new and existing electric powerplants and major fuel burning installations (MFBI's) which are subject to the prohibitions of the Act (46 FR 59872 (December 7, 1981)). On the same date, DOE also issued a notice of proposed rulemaking (NOPR), proposing several additional revisions to its final rules implementing FUA. The NOPR provided for a 30-day period for the submission of public comments, which would expire on January 6, 1982.

DOE's Economic Regulatory Administration (ERA) has received several motions for extension of the foregoing public comment period. The motions are based upon the fact that the 30-day comment period originally provided coincides with the holiday season, interfering with coordination of comments for companies and trade associations.

The issues addressed in the NOPR represent refinements of the basic evidentiary and eligibility rules finalized on November 30, 1981. ERA agrees that grant of the foregoing motions for extension is in the public interest, and would not unreasonably impede the effort to reduce unnecessary regulatory burdens under FUA. Therefore, for good cause shown, ERA hereby grants the motions to extend the public comment period on the November 30, 1981, NOPR, and will consider any public comments filed on or before February 4, 1982.

DATE: Comments should be filed with DOE on or before February 4, 1982.

ADDRESSES: All written comments should be addressed to Public Hearing Management, Department of Energy, Room 7146, Federal Building, 12th and Pennsylvania Ave. NW., Washington, D.C. 20461, and identified on the outside envelope and on each document with the designation: "Powerplant and Industrial Fuel Use Act, Docket No. ERA–R–81–12." Fifteen copies should be submitted. All comments received will be available for public inspection in the ERA Office of Public Information, Room 7120, Federal Building, 12th and Pennsylvania Ave. NW., Washington, DC., between the hours of 8 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Robert L. Davies, Office of Fuels Programs, Economic Regulatory Administration, Department of Energy, Room 6114, 2000 M St. NW., Washington, D.C. 20461, (202) 653–3372

Henry Garson, Office of General Counsel, Department of Energy, Room 6B–178, Forrestal Bldg., 1000 Independence Ave. SW., Washington, D.C. 20585, (202) 252–2967.

SUPPLEMENTARY INFORMATION: Any information or data considered to be confidential must be submitted in compliance with the DOE freedom of information regulations (10 CFR Part 1004). DOE reserves the right to determine the confidential status of the information or data and to treat it according to its determination.

Issued in Washington, D.C., on December 29, 1981.

Robert L. Davies,

Director, Fuels Conversion Division, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 82-206 Filed 1-4-82; 8:45 am]

BILLING CODE 6450-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 20

[Docket No. 81N–0043]

Freedom of Information Files

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the FDA regulation on record retention of files on freedom of information requests. The amendment would allow for a reasonable record retention and destruction plan and relieve FDA of the burden of keeping these files indefinitely.

DATE: Comments by March 8, 1982.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gerald Deighton, Freedom of Information Staff (HFI–30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1813.

SUPPLEMENTARY INFORMATION: FDA issued and adopted comprehensive freedom of information (FOI) regulations in 1974 (21 CFR Part 20, 39 FR 44602; December 24, 1974). Included in these rules was 21 CFR 20.31, which reads:

The Food and Drug Administration shall maintain a permanent file of all requests for Food and Drug Administration records and all responses thereto, including a copy of all of the records furnished in response to a request. This file is available for public review during working hours.

In 1974, when a total of 2,600 FOI requests were received, such a rule appeared to place no undue burden on the agency. However, it soon became apparent that interest in obtaining FDA records had been drastically underestimated. In 1975 the total number of requests increased five-fold to 13,000, a total which has steadily increased before leveling off at about 32,000 in 1979 and nearly 34,000 in 1980.

As a result, the agency is now burdened with approximately 123,000 files occupying some 1,700 linear feet of space. With a few exceptions, which will be provided for, these files merely occupy space, serving no useful administrative, regulatory, or even historical purpose.

Thus, despite Federal Property Management regulations authorizing destruction of routine FOI request files in 2 years after date of reply, FDA has, by its own regulation, created a file system with no perceivable growth limit.

Therefore, FDA proposes an amendment of Part 20 which will (1) allow a reasonable record retention and destruction plan, (2) free a substantial amount of filing space, and (3) realize a considerable savings to the government. Except where denials and appeals are involved, the proposal would authorize FDA to dispose of FOI request files 2 years from the date of FDA's final response to the request. Adoption of the proposal would have the immediate effect of permitting FDA to dispose of a large number of unnecessary files and the long-term effect of permitting the agency to keep its FOI files to a more manageable size. It would also provide FDA an immediate savings of $42,000 per year at current storage rates and an additional $20,000 each year based on current yearly volume and storage rates. The proposal would provide for the retention, for longer periods of time, of files concerning FOI requests that FDA wholly or partially denied.

The agency has determined pursuant to 21 CFR 25.24(b)(12) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

PART 20—PUBLIC INFORMATION

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), it is proposed that Part 20 be amended by revising § 20.31 to read as follows:

§ 20.31 Retention schedule of request for Food and Drug Administration records.

(a) Unless unusual circumstances dictate otherwise, the Food and Drug Administration shall maintain and dispose of files of requests and responses furnished thereto within the time limits authorized by GSA General Records Schedule 14, FPMR 101–11–4, January 10, 1977, as follows:

(1) Files created by the receipt of and response to freedom of information requests, except denials and/or appeals, may be destroyed 2 years from date of final response.

(2) Files created by a freedom of information request which was wholly

or partially denied may be destroyed 5 years after the denial letter was issued.

(3) Files created by a freedom of information request which was wholly or partially denied and which denial was subsequently appealed to the Department of Health and Human Services may be destroyed 4 years after final determination by FDA or 3 years after final adjudication by courts, whichever is later.

(b) This destruction schedule will automatically be revised whenever the time limits pertaining to these records are revised by the GSA General Records Schedule.

Interested persons may, on or before March 8, 1982 submit to the Dockets Management Branch (address above), written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with the Regulatory Flexibility Act, FDA has carefully analyzed the economic effects of this proposal and has determined that the proposal would not have a significant economic impact on a substantial number of small entities. The basis for this determination is that the proposal would have no impact, adverse or beneficial, on the public. Because the proposed rule concerns agency management, it is not subject to Executive Order 12291.

Dated: December 22, 1981.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-15 Filed 1-4-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 168

[Docket No. 81N-0238]

Fructose; Advance Notice of Proposed Rulemaking on the Possible Establishment of a Standard

Corrections

In FR Doc. 81-35421 appearing at page 60625 in the issue for Friday, December 11, 1981, make the following changes:

1. On page 60625, third column, under 2.1, the formula should read as follows:

$$[\alpha]\ \frac{20}{D} = \frac{100\alpha}{1c} \quad -89° \text{ to } -93.5°$$

2. On page 60626, first column, under 7.1, the formula and the first line under "Where:" should read as follows:

$$[\alpha]\ \frac{20}{D} = \frac{100\alpha}{1c}$$

where: α is the observed rotation

3. On page 60626, second column, second line under 7.9, insert "method" before "(ICUMSA"; and in the fifth line, the hyphen between "lead" and "kg" should be replaced by a slash.

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21 CFR Part 168

[Docket No. 81N-0256]

Powdered Dextrose (Icing Dextrose); Advance Notice of Proposed Rulemaking on the Possible Establishment of a Standard

Corrections

In FR Doc. 81-35425 appearing at page 60626 in the issue for Friday, December 11, 1981, make the following changes:

1. On page 60627, second column, 3.2 *Anti-caking agents,* should read as follows:

"3.2 *Anti-caking agents:* The following may be used, singly or in combination, provided that starch is not present:

Calcium silicate not more than 1.5% m/m
Calcium phosphate, tribasic not more than 1.5% m/m
Magnesium carbonate not more than 1.5% m/m
Magnesium stearate not more than 1.5% m/m
Silicon dioxide, amorphous (dehydrated silica gel) not more than 1.5% m/m
Silicates:
Magnesium trisilicate not more than 1.5% m/m
Sodium calcium alumino-silicate not more than 1.5% m/m"

2. On page 60627, second column, 4.3, "***(PB)***" should read "***(Pb)***"; and in 6.1, fifth line, insert "as" after *"monohydrate".*

BILLING CODE 1505-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[LR-75-81]

Treatment of Certain Interests in Corporations as Stock or Indebtedness

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of public hearing on proposed regulations.

SUMMARY: This document provides notice of a public hearing on proposed amendments to the regulations relating to treatment of certain interests in corporations as stock or indebtedness.

DATES: The public hearing will be held on March 10, 1982, beginning at 10 a.m. Outlines of oral comments must be delivered or mailed by March 8, 1982.

ADDRESS: The public hearing will be held in the I.R.S. Auditorium, Seventh Floor, 7400 Corridor, Internal Revenue Building, 1111 constitution Avenue NW., Washington, D.C. The outlines should be submitted to the Commissioner of Internal Revenue, Attn: CC:LR:T (LR-75-81), Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT: Charles Hayden of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 111 Constitution Avenue NW., Washington, D.C. 20224, 202-566-3935, not a toll-free call.

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed amendments to the regulations under section 385 of the Internal Revenue Code of 1954. The proposed regulations appears in the Proposed Rules section of this issue of the **Federal Register.**

The rules of § 601.601(a)(3) of the "Statement of Procedural Rules" (26 CFR Part 601) shall apply with respect to the public hearing. Persons who have submitted written comments within the time prescribed in the notice of proposed rulemaking and also desire to present oral comments at the hearing on the proposed rugulations should submit an outline of the comments to be presented at the hearing and the time they wish to devote to each subject by March 8, 1982.

Each speaker will be limited to 10 minutes for an oral presentation exclusive of time consumed by

questions from the panel for the government and answers to these questions.

Because of controlled access restrictions, attendees cannot be admitted beyond the lobby of the Internal Revenue Building until 9:45 a.m.

An agenda showing the scheduling of the speakers will be made after outlines are received from the speakers. Copies of the agenda will be available free of charge at the hearing.

This document does not meet the criteria for signficant regulations set forth in paragraph 8 of the Treasury Directive for improving government regulations appearing in the **Federal Register** for Wednesday, November 8, 1978.

By direction of the Commissioner of Internal Revenue:

David E. Dickinson,

Director, Legislation and Regulations Division.

[FR Doc. 81-37469 Filed 12-30-81; 3:03 pm]

BILLING CODE 4830-01-M

26 CFR Parts 1 and 15A

[LR-75-81]

Treatment of Certain Interests in Corporations as Stock or Indebtedness

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed revisions to regulations relating to the treatment of certain interests in corporations as stock or indebtedness. The Tax Reform Act of 1969 authorized the Secretary of the Treasury to prescribe the regulations that are proposed to be revised by this document. This document also contains proposed conforming regulations relating to the allocation of income and deductions among taxpayers and certain other matters. The regulations would affect corporations and their shareholders and creditors.

DATES: Written comments must be delivered or mailed by March 1, 1982. The regulations are proposed to apply to interests in corporations created after June 30, 1982.

ADDRESS: Send comments and requests for a public hearing to: Commissioner of Internal Revenue, Attention: CC:LR:T (LR-75-81). Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT: Carolyn Swift of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. 20224. Attention: CC:LR-T (202-566-3458, not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

Section 385 of the Internal Revenue Code relates to the treatment of certain interests in corporations as stock or indebtedness. Final regulations under section 385 were filed with the Federal Register on December 29, 1980 and were published as T.D. 7747 in the **Federal Register** for Wednesday, December 31, 1980 (45 FR 86438). These regulations generally would have applied to certain interests in corporations created after April 30, 1981. However, at the invitation of the Treasury and Internal Revenue Service, a number of public comments on the final regulations were received after December 31, 1980. The comments recommended changes in several areas of those regulations. In order to give the Treasury and Internal Revenue Service sufficient time to fully examine these comments and determine whether changes should be made, the regulations were amended by a Treasury decision (published in the **Federal Register** as T.D. 7774 on May 1, 1981) to apply to certain interests in corporations only if they were created after December 31, 1981.

Treasury and the Internal Revenue Service have now evaluated the comments received after publication of the regulations filed on December 29, 1980 (the "December 29 regulations"). In response to these comments, a number of changes have been made. In addition to these substantive changes, many minor conforming changes (for example, changes in cross-references) have been made. To facilitate making these changes, the December 29 regulations are being amended by T.D. 7801 to apply to certain interests in corporations only if they are created after June 30, 1982. The document making this change appears in the final rules section of this issue of the **Federal Register.** In this document, changes are being proposed as amendments to the December 29 regulations. It is anticipated that the regulations under section 385, as amended, will apply to certain interests in corporations created after June 30, 1982.

The more important of the changes made in response to the public comments are discussed below.

Section 1.385-0—Purpose and General Explanation.

In order to aid taxpayers in getting an overview of the section 385 regulations, a general explanation of the regulations has been added. This explanation is intended to summarize the rules in relatively nontechnical way and to point out where the taxpayers may be outside the scope of the regulations or may be able to use various safe harbors. This new explanation is in addition to the summary of rules set forth in § 1.385-2 which is a more technical explanation serving as a source of references to the body of the regulations.

Section 1.385-1—Effective Date and Scope.

A number of comments raised questions about the application of the regulations in the international context. In order to provide Treasury and the Internal Revenue Service a further opportunity to study these questions, the proposed amendments will not apply to certain interests created in international transactions (see § 1.385-1(b)(3)). However, it should be emphasized that this exclusion of certain interests created in international transactions is only an interim measure pending further study and that the issuance of regulations applicable to such interests is contemplated. The public is encouraged to submit comments on what the regulations under section 385 should provide with respect to international transactions.

Several comments asked about the application of the regulations to interests created by cooperatives. The proposed regulations provide specific rules governing their application to interests created by cooperatives (see § 1.385-1(b)(2); § 1.385-6(a)(2)(v) and (h)(6)(viii)).

The proposed amendments also contain a new provision coordinating the hybrid instrument provisions under section 385 with the new installment sales provisions under section 453. This provision replaces the provision on this subject in the temporary installment sales regulations, § 15A.453-1(c)(8). Under the new provision, a hybrid instrument is outside the scope of the section 385 regulations if it is issued in exchange for property (other than money) and § 1.385-6 (relating to proportionality) does not apply to the instrument (see § 1.385-1(b)(4)). In effect, if a hybrid instrument issued in exchange for property is not issued proportionately, it will be treated as stock or debt under applicable principles of law outside the section 385 regulations. If a hybrid instrument is issued proportionately in exchange for property, it is treated as stock or debt under § 1.385-6(d) (including, where applicable under new § 1.385-6(d)(2), discussed below).

The December 29 regulations provided an exception to the effective date for instruments issued pursuant to a plan filed in a bankruptcy proceeding. To qualify for the exception, the instrument had to be issued pursuant to a plan of reorganization filed with the court on or

before December 29, 1980 in a proceeding under the Federl bankruptcy laws (Title 11, U.S.C.) or under the Regional Rail Reorganization Act of 1973. One comment pointed out that this standard might be difficult to apply where the bankruptcy court ultimately adopted a plan which drew from several different plans filed with the court at different times. To elminate this potential problem, under the proposed regulations, an instrument will qualify for this exceptin if it is issued pursuant to a plan of reorganization confirmed by the court in a proceeding under the Federal bankruptcy laws or under the Regional Rail Reorganization Act of 1973 and the proceeding is commenced on or before the date this notice of proposed rulemaking is filed with the **Federal Register** (see 1.385–1(a)(2)(i)).

The December 29 regulations also provided an exception to the effective date for certain instruments issued pursuant to a pre-existing binding written contract. This exception has been updated and clarified. In particular, under the provision in the proposed amendments, the contract must specify all the material terms and conditions of the instrument. The purpose of this requirement is to prevent a sole shareholder, e.g., from avoiding the effective date of the regulations by a pre-existing general commitment to provide funds to his or her corporation.

Section 1.385–2—Summary of Rules.

Only conforming changes have been made in the summary of rules.

Section 1.385–3—Definition of Terms.

A number of commenters expressed concern that the excessive or inadequate consideration rules (§ 1.385–3(a) of the December 29 regulations)—which applied to any instrument issued to a "shareholder"—might be applied to lenders owning relatively small amounts of stock or warrants. As a result, the interest rate on instruments issued to such lenders with small equity interests might have been adjusted through the application of § 1.385–3(a) of the December 29 regulations in conjunction with section 1232 or § 1.61–12(c)(2). Other commenters were unsure about how the excessive or inadequate consideration rules would apply to instruments issued to nonshareholders to whom stock ownership would customarily be attributed (e.g., the spouse or children of a shareholder).

In order to clarify the regulations on these points, Treasury decided to apply the excessive or inadequate consideration rules only to proportionately-held instruments rather than to instruments issued to shareholders (see § 1.385–6(c)). It was felt that this change was in keeping with the overall focus of the regulations on proportionate debt because shareholders have no economic incentive to set or enforce arm's length terms on proportionate debt.

Three points should be clarified, however, in connection with this change. First, under the December 29 regulations, there were situations where nonproportinate debt was treated as being held proportionately (§ 1.385–6(a)(7) of the December 29 regulations). In general, these are situations where, because of compensating arrangements involving the other shareholders, a shareholder holding debt nonproportionately may not have an economic incentive to act like an independent creditor. For example, if a 50-percent shareholder who owns all of the corporations' debt agrees to forego $5,000 of interest as part of an arrangement where the other 50-percent shareholder agrees to forego a $5,000 salary payment due from the corporation, the first shareholder's debt will be treated as held proportionately.

These rules will continue to apply as part of the proposed regulations (see § 1.385–6(a)(7)). Indeed, these rules will play an even more important role as a result of the restriction of the application of the excessive or inadequate consideration rules to proportionate debt.

Second, it is not intended that restricting the excessive or inadequate consideration rules to proportionate debt will affect the applicability under current law of section 301, section 1232 or the regulations thereunder to nonproportionate debt. For example, the investment unit rules of § 1.1232–3(b)(2)(ii) will continue to apply to an investment unit consisting of an obligation and shares of stock even if the class of obligations is not held proportionately. See examples (7), (8), and (9) of § 1.385–6(a)(6).

Third, it should be noted that the proposed amendments add a new provision which treats an instrument as if it were issued proportionately if (1) the instrument is held by a person who owns, actually or constructively, at least 25 percent of the value or voting power of the issuing coporation's stock and (2) the issuing corporation's debt-to-equity ratio, at the end of the year of issuance, exceeds 10:1. In effect, such an instrument (assuming it is a straight debt instrument) is subject to the independent creditor standard of § 1.385–6(g)(2) and to the "second look" rules of § 1.385–6 (k), (l), and (m). The reason for this provision is that when a lender owns a substantial amount of a corportion's stock and lends to the corporation when it has a very high debt-to-equity ratio, Treasury felt that this was evidence that the lender was acting more like a stockholder than a creditor with respect to the debt instrument. Thus, it was felt that, under these circumstances, the burden should shift to the lender to demonstrate that it is acting as an independent creditor with respect to the debt instrument.

Two additional changes have been made in the excessive or inadequate consideration provisions. First, under the December 29 regulations, the excessive or inadequate consideration provisions applied to all instruments, whether they were treated as indebtedness or stock under the section 385 regulations. Under the proposed amendments, the excessive or inadequate consideration provisions apply only to instruments treated as indebtedness under the regulations. If an instrument is initially treated as stock under the section 385 regulations, then the treatment of the excess of the consideration paid for the instrument over its fail market value (or the excess of the instrument's fair market value over the consideration paid therefor) will be determined outside the section 385 regulations (see § 1.385–6(c) (1), (2) and (3)).

Second, under the December 29 regulations, the excess of the consideration paid for an instrument over its fair market value was automatically treated as a capital contribution and the excess of the instrument's fair market value over the consideration paid therefor was automatically treated as a section 301 distribution. Under the proposed amendments, such excesses will *ordinarily* be treated, respectively, as a capital contribution and a section 301 distribution but, under appropriate circumstances, may be treated as a gift followed by a capital contribution, as a section 301 distribution followed by a gift, as compensation for services, or as otherwise determined under general principles of tax law.

There was a provision in the December 29 regulations which enabled the Commissioner to disregard a noncommercial term of an instrument, in determing the fair market value of the instrument or the reasonableness of an interest rate, if the principal purpose of the term was to increase or decrease the instrument's fair market value or a reasonable rate of interest for the instrument. One comment pointed out that, in some sense, the purpose of *any* term of an instrument may be to increase or decrease its fair market value. Accordingly, this provision has been clarified to enable the

Commissioner to disregard a noncommercial term if its principal purpose is to increase or decrease the instrument's fair market value or a reasonable rate of interest for the instrument *for Federal tax purposes (see § 1.385–3 (a) (1) (iii)).*

Also, the example in this provision has been changed to make the sole shareholder an individual with large net operating loss carryovers rather than a nonresident alien. The only purpose of this change is to make the sole shareholder a U.S. person who would have an incentive to charge an above-market interest rate on a loan to the corporation. In view of the exclusion in connection with international transactions, all references to non-U.S. persons have been deleted. There is no significance to the fact that the shareholder has large net operating loss carryovers other than that it would give the shareholder an incentive to charge an above-market interest rate. See also example (3) of § 1.385–6(h)(5).

Finally, with the transfer of the excessive or inadequate consideration provisions from § 1.385–3 to § 1.385–6, § 1.385–3, has been reorganized and retitled "Definition of terms" instead of "Preliminary rules."

Section 1.385.4—Instruments generally.

Under § 1.385–4, (c) (1) (ii), if an instrument becomes stock under § 1.385–6, (k), (l), or (m), then the instrument is treated as having been exchnged (without recognition of gain or loss) for preferred stock in a recapitalization to which section 368(a)(1)(E) applies. This provision has been clarified concerning its application to an instrument which is reclassified as preferred stock because of a change in terms. If the change in terms is sufficiently substantial so that the changes in terms is treated as an exchange of instruments under applicable principles of tax law (without reference to the section 385 regulations), then § 1.385–4(c)(1)(ii) does not apply and the tax treatment of the constructive exchange is determined outside the section 385 regulations. However, if the change in terms is not treated as an exchange of instruments under applicable principles of the tax law, then § 1.385–4(c)(1)(ii) applies.

Section 1.385–5—Certain hybrid instruments.

Under the December 29 regulations, a hybrid instrument was treated as stock if, on the day of issue, the fair market value of the instrument without its equity features was less than 50 percent of the actual fair market value of the instrument (with those features). Several commenters were unsure about how to compute the fair market value of a hybrid instrument without its equity features.

In order to clarify the regulations on this point, the rules for determining whether a hybrid instrument should be treated as stock or indebtedness have been revised in the proposed amendments. Under § 1.385–5, as revised, a hybrid instrument is treated as stock, if on the day of issue, the fair market value of the "straight debt payments" with respect to the instrument is less than 50 percent of the fair market value of the instrument (see § 1.385–5(a)). The proposed amendments set forth a series of operating rules for determining these straight debt payments (see § 1.385–5(d)). For example, to the extent a hybrid instrument provides for a contingent payment that is contingent in amount, the straight debt payments are computed assuming the occurrence of the contingency resulting in the smallest possible payment under the instrument. To the extent the hybrid instrument provides for a contingent payment that is contingent as to timing, the straight debt payments are computed assuming the occurrence of the contingency providing for payment on the latest possible date under the instrument.

In computing the fair market value of the straight debt payments with respect to a hybrid instrument, the present value of each of the straight debt payments must be computed. The proposed amendments provide additional guidance for arriving at a discount rate for this present value calculation. On this point, the proposed amendments provide that the discount rate to be used in computing the present value of a straight debt payment payable at a future date is a reasonable rate of interest (determined without regard to the safe harbor of § 1.385–6(f)(2)) for an instrument in the amount of the straight debt payment payable on the date that the straight debt payment must be made and payable on the terms and conditions of such fixed payment (see § 1.385–5(d)(3)). An example illustrating this rule has also been added.

Also, the proposed amendments provide that, with respect to an instrument issued in a redemption of stock, the instrument will not be considered a hybrid instrument solely because amounts designated as principal or interest (or both) are, by operation of local law, payable only out of earned surplus (see § 1.385–5(c)(5)(v) and example (12) of § 1.385–5(f)). It should be emphasized that this provision applies only when the earned surplus restriction is imposed by state law and not when it arises by agreement of the parties.

In addition, in response to comments on this point, the proposed amendments clarify the circumstances under which a nonrecourse obligation will be considered a hybriud instrument (see § 1.385–5(c)(5)(iv) and example (13) of § 1.385–5(f)).

Finally, the definitions of "contingent payment" and related terms (fixed payments of interest, fixed payments of principal, and definitely ascertainable) have been retained from the December 29 regulations. The public is encouraged to submit comments on whether these definitions are satisfactory for the purpose of isolating "equity-like" payments (e.g., in the case of bonds subject to extensive covenants).

Section 1.385–6—Proportionality.

Several very important changes have been made in the provisions relating to proportionality.

Definition of proportionality. Many comments expressed the view that proportionality should be defined objectively. In view of the central role played by proportionality in the section 385 regulations, Treasury agrees that an objective definition for proportionality is appropriate.

Under a new provision in the proposed regulations, holdings of stock and a class of instruments will be considered substantially proportionate if the total overlap of ownership of stock and a class of instruments exceeds 50 percent (see § 1.385–6(a)(2)). Thus, for example, if the sole shareholder of a corporation owns 50 percent of a class of instruments and an independent creditor owns the other 50 percent of the class of instruments, the holdings of the corporation's stock and the class of instruments are not substantially proportionate. However, if the sole shareholder owned more than 50 percent of the class of instruments, the holdings of the stock and the class of instruments would be substantially proportionate.

Similarly, if a 50 percent shareholder of a corporation owns 100 percent of a class of instruments, holdings of the corporation's stock and the class of instruments are not substantially proportionate. However, if a more-than-50-percent shareholder of a corporation owns 100 percent of a class of instruments, then holdings of the corporation's stock and the class of instruments are substantially proportionate.

In connection with this objective test for proportionality, it should be emphasized that the fact that a class of instruments is proportionate does not

mean that the instruments are automatically treated as stock. It means only that the instruments are subject to the more stringent tests of § 1.385–6 in determining whether the instruments are treated as stock or indebtedness.

The objective test for determining whether there is proportionality contains several additional rules:

(1) *Attribution rules.* With some important modifications, the attribution rules of section 318 (a) apply to attribute the ownership of both stock and instruments (see § 1.385–6(a)(2)(ii) and the examples in § 1.385–6(a)(2)(vii)).

(2) *Definition of stock.* There is a definition of the term "stock" for purposes of determining proportionality (see § 1.385–6(a)(2)(iii) and examples (7) and (12) of § 1.385–6(a)(6)).

(3) *Special rule for certain redemptions.* There is a special rule for straight debt instruments issued proportionately in redemption of stock if section 302(a) would apply to the redemption (if the instrument were treated as indebtedness) and the section 483(c) interest rate is charged. Such instruments are initially treated as indebtedness and there is no adjustment of the interest rate under § 1.385–6(c) and section 1232 or § 1.61–12(c)(2); however, they are subject to the "second look" rules of § 1.385–6 (k), (l), and (m).

(4) *Rules for cooperatives.* There is a special rule for determining proportionality with respect to holdings in cooperatives (see § 1.385–6(a)(2)(v)).

Safe harbor. The December 29 regulations provided a safe harbor for a straight debt instrument if, in general, (i) the debt-to-equity ratio of the issuing corporation did not exceed 1:1; (ii) the instrument had a fixed maturity and provided for annual payments of interest at the section 6621 rate, a local prime rate, a rate determined by the Secretary of the Treasury taking into account the yield on U.S. obligations of comparable maturity, or any rate in between; and (iii) all principal and interest were paid when due. Many commenters urged that the debt-to-equity requirement for the safe harbor should be increased and that additional safe harbor interest rates should be added.

The proposed amendments increase the debt-to-equity limit from 1:1 to 3:1 (see § 1.385–6(f)(2)(ii)). In addition, they add as safe harbor interest rates the safe haven interest rates under section 482 (see § 1.385–6(f)(2)(i)(A)). As a result, the section 385 regulations now contain an extremely broad safe harbor enabling most taxpayers to assure that significant amounts of proportionate straight debt will be treated as debt for tax purposes. This increased safe harbor should be particularly beneficial for small businesses.

The interest rate two points above the prime rate has also been added as a safe harbor interest rate. The purpose of this addition is to allow taxpayers the certainty and simplicity of the safe harbor even if they choose to charge an interest rate somewhat above the prime rate—a rate that may more closely resemble the rate at which the corporation could borrow from independent creditors.

Reasonable rate of interest. The general rule of § 1.385–6(f)(1) provides that an interest rate on an instrument issued by a corporation is reasonable if it is within the normal range of rates paid to independent creditors on similar instruments by corporations of the same general size and in the same general industry, geographical location, and financial condition on the date the determination is made. This rule has been clarified to make explicit that the interest rate determined by the Secretary pursuant to § 1.385–6(f)(2)(i)(A) for instruments of comparable maturity is a floor for the reasonable interest rate as determined under this general rule. Of course, higher rates may well be appropriate for this purpose. (The interest rate might be lower, however, if the safe harbor of § 1.385–6(f)(2) is applicable).

Independent creditors. Several commenters requested that the regulations set forth the factors to be taken into account in determining whether a creditor will be considered an independent creditor for purposes of the regulations. Accordingly, the proposed amendments now set forth some of these factors (see § 1.385–6(b)(1)).

In addition, the safe harbor requirements for classification as an independent creditor have been substantially revised (see § 1.385–6(b)(2)–(4)).

Hybrid instruments issued proportionately. Under the December 29 regulations, a hybrid instrument was treated as stock if it was issued proportionately. Under the new proposed regulations, a class of hybrid instruments issued proportionately is not automatically treated as stock if, immediately after the class is issued, independent creditors (determined without regard to the "safe harbor" definition of independent creditor and without taking into account the creditor's holdings of the hybrid instruments at issue) own at least 20 percent of such class. In this case, the treatment of the hybrid instrument as debt or stock is determined under the general rule of § 1.385–5. It should be emphasized, however, that, even if the class is treated as debt under § 1.385–5, it remains subject (except for instruments held by independent creditors) to the "second look" rules of § 1.385.6 (k), (l), and (m).

Excessive debt. Under the December 29 regulations, a corporation's debt is considered "excessive" if (i) all of the instrument's terms and conditions and (ii) the corporation's financial structure, taken together, would not be satisfactory to a bank, insurance company or similar lending institution which makes ordinary commercial loans. (The taxpayer can avoid this test by meeting a safe harbor.) Under the proposed amendments, this rule is changed in one respect and is clarified in two additional respects (see § 1.385–6(f) (2) and (6)). First, the proposed amendments require the transaction to be satisfactory to an independent creditor (determined without regard to the "safe harbor" definition of independent creditor) rather than just to a bank, insurance company or similar lending institution which makes ordinary commercial loans.

Second, the proposed amendments clarify that the stated interest rate is one of the "terms and conditions" of the instrument. Thus, if the interest rate would not be acceptable to an independent creditor, then the issuing corporation's debt is excessive (unless the safe harbor is met). However, the proposed amendments provide that an interest rate will be considered acceptable to an independent creditor for this purpose if a rate one point lower or one point higher would be acceptable to such creditor.

Third, the proposed amendments clarify that the instrument's terms and conditions (including the interest rate) are to be considered as a whole for purposes of this test. This means that slight nonmaterial deviations from particular terms or conditions that would be required by an independent creditor will not cause the instrument to fail this test if, considered as a whole, the terms and conditions would be acceptable to an independent creditor.

Debt-to-equity ratio. The debt-to-equity ratio of the issuing corporation is computed using the adjusted basis of the corporation's assets. For the reasons stated in the "Explanation of Changes" in the December 29 regulations (45 FR 86443), Treasury believes that, for the purposes of the section 385 regulations, adjusted basis of assets (and not fair market value) should be used in the debt-to-equity ratio computation. Accordingly, this rule is retained in the proposed regulations.

However, several commentators pointed out that, as a result of the new Accelerated Cost Recovery System ("ACRS") enacted as part of the Economic Recovery Tax Act of 1981, the adjusted basis of recovery property (within the meaning of section 168) will decline so rapidly that it will no longer be a sensible way to compute a corporation's equity in its assets. Treasury agrees that the adjusted basis of recovery property should not be used in computing debt-to-equity ratio. Moreover, it was felt that if a change were made in the method for computing adjusted basis for recovery property for purposes of computing debt-to-equity ratio, simple fairness dictated that a parallel change be made in making the calculation for older property that had been depreciated on an accelerated method. Accordingly, the proposed regulations compute the adjusted basis of property subject to an allowance for depreciation by computing depreciation deductions in the same manner as the adjustments to earnings and profits for depreciation under section 312(k) (see § 1.385–6(h)(6)(i)). Thus, for example, under current section 312(k)(3), depreciation deductions for recovery property would be computed, in general, using the straight-line method with no salvage value and using a recovery period determined in accordance with the following table:

In the case of—	The applicable recovery period is (years)
3-year property	5
5-year property	12
10-year property	25
15-year real property	35
15-year public utility property	35

For depreciable property acquired before 1981 and depreciated using an accelerated method of depreciation, adjusted basis (for purposes of computing debt-to-equity ratio) would generally be computed using straight line depreciation.

The proposed amendments also provide a rule for computing the debt-to-equity ratio when the excessive or inadequate consideration provisions apply. Under this rule, the debt-to-equity ratio is computed before the excessive or inadequate consideration rules are applied (see § 1.385–6(h)(4)). Thus, for example, if an instrument is issued bearing an unreasonably low interest rate and, as a result, a capital contribution would be imputed under § 1.385–6(c), the debt-to-equity ratio of the issuing corporation is computed before imputation of the capital contribution.

The regulations provide special rules for computing the debt-to-equity ratio of an affiliated group of corporations. In the December 29 regulations, the term "affiliated group" was defined by reference to section 279(g). Under section 279(g), the term "affiliated group" has the same definition as in section 1504(a) except that (i) the exclusions of section 1504(b) are not applicable and (ii) the "acquired corporation" is not considered an includible corporation. The latter departure from the definition in section 1504(a) was inadvertent. Accordingly, § 1.385–6(j)(1) has been modified to clarify that the definition of "affiliated group" for purposes of the regulations under section 385 shall be the same as in section 1504(a) except that no corporation shall be excluded from the group by the exclusions of section 1504(b).

Finally, an example has been added to clarify further the application of the rules for computing the debt-to-equity ratio of an affiliated group of corporations (see example (4) of § 1.385–6(j)(2)).

Nonpayment of interest. In the December 29 regulations, payment of interest with property other than money (*e.g.*, a note) was considered actual payment to the extent of the fair market value of the property. Under the proposed amendments, payment of interest with property other than money is considered actual payment to the extent such property is includible in the income of the holder of the instrument (see § 1.385–6(l)(3); § 1.385–7(c)(2)). For this purpose, interest is considered includible in the income of a tax-exempt entity (*e.g.*, a charitable organization) if it would be subject to tax if the entity were not tax-exempt.

Section 1.385–7—Certain Other Obligations.

Under the December 29 regulations, there was an exception to § 1.385–7 for loans which were repaid within 6 months but only to the extent that the outstanding balance of such loans (and demand instruments) did not exceed $25,000. A number of comments expressed the view that unwritten loans in excess of $25,000 which were repaid within a short period should also not be treated as capital contributions merely because a reasonable interest rate was not charged. Other comments noted that this provision might be burdensome for small businesses.

Treasury agrees that an unwritten loan which is actually repaid within a short period (and not renewed or offset in some manner) should not be treated as a capital contribution because of the failure to pay interest at a reasonable rate. Treasury also wanted to provide a rule that small businesses could comply with. Accordingly, this exception has been substantially expanded to exclude from § 1.385–7 all loans (regardless of amount) which are repaid within 120 days after the end of the taxable year in which the loan is made (see § 1.385–7(a)(2) and examples (3) and (4) of § 1.385–7(e)).

By providing that the loan can be repaid within 120 days after the end of the taxable year in which the loan is made, this provision allows the accountant for a small corporate business, upon an annual review of the corporation's books, to advise the corporation to repay the loan before it is irrevocably classified as a contribution to capital. Although there is a strong policy to treat cash advances by shareholders as capital contributions where there is neither the observance of the requisite formality of a written instrument nor the payment of interest at a reasonable rate, it was felt that this policy could be mitigated to provide this practical solution for small businesses.

Treasury believes that at least some significant amount of interest should be paid with respect to these short-term loans, particularly in view of the extention in the permissible period of repayment from 6 months to as long as 16 months. It was felt, however, that an interest rate requirement (e.g., a requirement that the loan be repaid with interest at the rates specified under section 482) would be a proverbial "trap for the unwary" for small businesses when noninterest bearing advances may be made for a few days. Accordingly, rather than treat all noninterest-bearing advances automatically as equity, Treasury decided that interest should be imputed at the section 482 rate as a condition for being able to use the exception for loans repaid within 120 days after the end of the taxable year of the loan. Therefore, the new rule provides that if a loan within the exception for loans repaid within 120 days after the end of the taxable year of the loan is not repaid with interest at an arm's length rate (within the meaning of § 1.482–2(a)(2)), then interest at the rate set forth in § 1.482–2(a)(2)(iii)(B)(2) shall be imputed.

In addition, there is a provision clarifying when a loan will be considered to be renewed or offset (and therefore not actually repaid) (see § 1.385–7(a)(2)(iii)).

Section 1.385–8—Locked Interests.

Only conforming changes have been made to § 1.385–8.

Section 1.385–9 of the December 29 Regulations—Guaranteed Loans.

Section 1.385–9 of the December 29 regulations, relating to guaranteed loans, has been omitted from the proposed regulations. The reason is to clarify—it is hoped beyond doubt—that the section 385 regulations are not intended to change existing case law relating to the circumstances under which a third party loan to a corporation which is guaranteed by a shareholder will be recharacterized as a loan to the shareholder followed by a capital contribution by the shareholder to the corporation. Thus, the existing case law, including such cases as *Plantation Patterns, Inc.*, v. *Commissioner*, 462 F.2d 712 (5th Cir. 1972), cert. denied, 404 U.S. 1076 (1972), aff'g T.C. Memo Dec. 1970–82 (1970), will continue to govern whether such recharacterization is appropriate.

Section 1.385–10 of the December 29 Regulations—Certain Preferred Stock.

Section 1.385–10 of the December 29 regulations, relating to preferred stock, has been omitted from the proposed regulations. Accordingly, the existing case law will continue to govern whether a preferred stock bears a sufficient substantive resemblance to debt for it to be treated as debt for tax purposes.

Treasury and the Internal Revenue Service are continuing to study whether further guidance in this area should be provided to taxpayers. The public is thus encouraged to submit comments relating to this area.

Provision Relating to Section 171.

If a corporation issues an instrument proportionately for its face amount and the interest rate on the instrument is unreasonably high, then the fair market value of the investment would exceed the consideration paid for the instrument. If the instrument is treated as indebtedness, this excess is treated as a section 301 distribution. In addition, the shareholder's basis for the instrument is increased by the amount of the section 301 distribution. See § 1.301–1 (j); § 1.385–6 (c) (3) example (5). As a result, the basis of the note would exceed the face amount of the note and the note would be considered to be issued at a premium. See section 171 (b); § 1.61–12 (c) (2). The corporation would be required to amortize the premium, resulting in an effective reduction of its interest deduction with respect to the instrument. Correspondingly, it would generally be advantageous to the shareholder to elect to amortize the premium and thereby effectively reduce the amount of interest to be included in the shareholder's income.

However, the shareholder can amortize the premium only if an election has been made in accordance with § 1.171–3. Under this section, the election must be made by claiming a deduction for bond premium on the return for the first taxable year to which the taxpayer wishes the election to apply. Thus, if a final determination that the instrument had been issued at a premium is not made until several years after the instrument is issued (e.g., as a result of a settlement between the Service and the taxpayer or a final court decision), it may be too late to elect to amortize the premium for the year of issue and interim years.

To allow the shareholder the benefit of amortizing this premium for these years (to the extent such years are open years for the shareholder), the regulations under section 171 have been amended to provide that the election under section 171 shall (unless the taxpayer elects otherwise) be deemed to apply to these years (see new § 1.171–3 (d)).

Initial Regulatory Flexibility Analyses

The proposed amendments to the regulations under section 385 are being issued in response to the public comments on the December 29 regulations that have been received at Treasury's invitation and as a result of further study of the regulations by Treasury and the Internal Revenue Service. The objective of the proposed amendments is to provide further guidance on the treatment of certain interests in corporations as stock or indebtedness for Federal tax purposes. The proposed amendments are prescribed pursuant to authority granted in section 385 of the Internal Revenue Code.

The proposed amendments relate to the treatment of certain interests in corporations as stock or indebtedness. Thus, they have potential application to all small entities which are corporations, and to their shareholders and creditors.

The proposed amendments do not create new reporting, or recordkeeping, or other similar compliance requirements.

The proposed amendments do not duplicate, overlap or conflict with any existing Federal regulations.

The purpose of the regulations under section 385 is to replace the voluminous and uncertain case law with a set of rules that will enable taxpayers to plan their transactions with the knowledge of the likely treatment of certain interests as debt or equity for Federal tax purposes. It is not feasible to exempt small corporations from these rules because, as an examination of the case law will readily demonstrate, the principal problem addressed by the regulations—the extent to which proportionate debt should be treated as debt for Federal tax purposes—is a problem arising most often in the context of a small, closely held corporation.

However, the proposed amendments would make several changes which are particularly beneficial for small business. For example, the safe harbor provided by the December 29 regulations has been significantly expanded. The safe harbor under the December 29 regulations applied only if the issuing corporation's debt-to-equity ratio was 1:1 or less and certain specified interest rates were charged. Under the proposed amendments, the boundary of the safe harbor has been expanded to 3:1. Also, several additional safe harbor interest rates have been added—most notably the safe haven rates under section 482. The existence of a broad safe harbor is of particular significance to small businesses.

As another example, a general, nontechnical explanation of the regulations has been added. This will also be of particular benefit to small businesses.

The proposed amendments fall into two main categories:

(1) Proposed changes that would liberalize the December 29 regulations (e.g., broadening of the safe harbor); and

(2) Proposed changes that would replace subjective rules with objective rules (e.g., definition of proportionality).

Since, as explained above, it is not feasible to exempt small entities from the section 385 regulations, the main alternatives considered were making particular rules more or less liberal (e.g., making the safe harbor debt-to-equity ratio either greater or less than 3:1) and leaving particular rules subjective rather than objective. As to the first type of alternative, it was concluded that the rules ultimately proposed struck an appropriate balance between preventing abuses in the debt-equity area and providing workable rules for small business. As to the second type of change, it was decided that, in the situations where objective rules were proposed, the advantage of objective rules in providing certainty outweighed the disadvantage of not providing the theoretically correct outcome in every case.

The actual changes are discussed in greater detail in the balance of the preamble.

Comments and Requests for a Public Hearing: Before these proposed regulations are adopted, consideration

will be given to any written comments that are submitted (preferably six copies) to the Commissioner of Internal Revenue. All comments will be available for public inspection and copying. A public hearing has been scheduled and will be held on March 10, 1982. Notice of the time and place of this hearing appears in the notice of hearing section of the issue of the **Federal Register**.

Drafting Information: The principal author of these proposed regulations is Carolyn Swift of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, both on matters of substance and style.

Proposed Amendments to the Regulations: The proposed amendments to 26 CFR Part 1 are as follows:

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

§ 1.166–9 [Amended]

Paragraph 1. Section 1.166–9(c) is amended by removing "(see § 1.385–9)" from subparagraph (1).

Paragraph 2. Section 1.171–3 is amended by adding the phrase "except as provided in paragraph 9d) of this section" at the end of the forth sentence of paragraph (a) and by adding paragraph (d) to read as follows:

§ 1.171–3 Election with respect to taxable and partially taxable bonds.

* * * * *

(d) *Coordination with regulations under section 385.* If a corporation issues an instrument (as defined in § 1.385–3(b)) to a taxpayer and

(1) The election described in paragraph (a) of this section is not otherwise in effect with respect to the instrument for one or more of the taxable years during which the instrument is outstanding; and

(2) As a result of a determination (as defined in section 1313(a)) with respect to the taxpayer, the instrument is found to have been issued at a premium pursuant to § 1.385–6(c)(2) (see also example (5) of § 1.385–6(c)(4) and section 171(b)), then such election shall be deemed to have been made with respect to the instrument as of the taxpayer's first open taxable year during which the instrument is outstanding. Such deemed election shall apply only to such instrument. The rules set forth in paragraph (a) of this section shall remain applicable to any other bonds owned by such taxpayer. Such deemed election shall not apply with respect to an instrument if, within 120 days of the determination described in paragraph (d)(2) of this section, the taxpayer files a statement to this effect with the Internal Revenue Service Center at which the taxpayer is required to file its return.

Paragraph 3. Sections 1.385–1 through 1.385–10 are amended by removing §§ 1.385–9 and 1.385–10, by adding § 1.385–0, and by revising § 1.385–1 through § 1.385–8. The added and revised sections read as follows:

§ 1.385–0 Purpose and general explanation.

(a) *Purpose.* Section 385(a) authorizes the promulgation of regulations to determine whether the creation of an interest in a corporation results in a debtor-creditor or corporation-shareholder relationship. Section 385(a) contemplates regulations that will determine not only when an interest in a corporation that is labeled debt will be treated as debt for tax puroses but also when such an interest will be treated as stock. However, not every interest in every corporation is subject to the regulations under section 385 because section 385(a) authorizes regulations only as they may be necessary or appropriate.

(b) *Focus of regulations; initial inquiries*—(1) *Instruments.* Under the section 385 regulations, certain interests in a corporation are characterized as stock or indebtedness immediately after the interest is created. If, under local law, an interest in a corporation is treated as indebtedness and if the interest is evidenced by a writing such as a bond, note or debenture, the writing is called an "instrument." Unwritten loans and loans not evidenced by an instrument (e.g., appearing on a corporation's books or in a board of directors' resolution) are distinguished from instruments and may be treated differently under the section 385 regulations

(2) *Straight debt instruments and hybrid instruments.* The section 385 regulations distinguish between straight debt instruments and hybrid instruments. Instruments that are either convertible into stock or provide for any contingent payment are "hybrid instruments." (For redemptions, earned surplus limitations imposed by local law do not cause a payment to be contingent). All other instruments are "straight debt instruments."

(3) *Proportionality.* The section 385 regulations focus on instruments that are held in substantially the same proportions as the corporation's stock. Generally, proportionality is considered to exist when there is a greater than 50 percent overlap between the ownership of stock and the class of instruments being characterized under these regulations. For this purpose, holdings of certain persons (e.g., family members) may be aggregated under attribution rules.

(c) *Operation of regulations; no proportionality.*—(1) *Straight debt instruments.* Straight debt instruments not issued proportionately are ordinarily treated as indebtedness under the regulations. However, if an instrument is issued to a 25 percent shareholder and the corporation's debt-to-equity ratio exceeds 10:1, then the instrument is treated as if it were issued proportionately.

(2) *Hybrid instruments.* Hybrid instruments not issued proportionately are generally treated as indebtedness if the present value of straight debt payments with respect to the instrument is at least half of the fair market value of the instrument. However, if a hybrid instrument is issued nonproportionately in exchange for property (e.g., a sale of a business to a corporation unrelated to the seller in exchange for a note providing for payments contingent on the profits of the business), the instrument is outside the scope of the section 385 regulations.

(d) *Operation of regulations; proportionality.*—(1) *Straight debt instruments.* The following fules apply to straight debt instruments issued proportionately:

(i) *Ratio not exceeding 3:1.* If the issuing corporation's debt-to-equity ratio does not exceed 3:1, then the instrument may qualify for the safe harbor described below in paragraph (d)(2)(iv) of this section.

(ii) *Inside ratio not exceeding 3:1 and outside ratio not exceeding 10:1.* If the issuing corporation's debt-to-equity ratio exceeds 3:1 (or the safe harbor is otherwise not satisfied) but the corporation's inside debt-to-equity ratio (excluding liabilities held by independent creditors) does not exceed 3:1 and its outside debt-to-equity ratio (including such liabilities) does not exceed 10:1, then:

(A) The instrument is treated as indebtedness;

(B) If the stated rate on the instrument is not reasonable this interest rate may, in effect, be adjusted to a reasonable rate. In general, this is done by treating an instrument as issued for an amount equal to its fair market value (rather than the amount purportedly paid for the instrument) and then applying the original issue discount or bond premium provisions; and

(C) The instrument, even though initially classified as indebtedness, may subsequently be reclassified as stock under the "second look" rules. Under these "second look" rules, an instrument may be reclassified as stock if there is a failure to pay interest or principal when due, there is a change in terms, or interest on a demand instrument is not paid at a reasonable rate.

(iii) *Inside ratio exceeds 3:1 or outside ratio exceeds 10:1.* If the issuing corporation's inside debt-to-equity ratio exceeds 3:1 or its outside debt-to-equity ratio exceeds 10:1, then the interest rate is not adjusted and the instrument is classified as stock unless the terms and conditions of the instrument coupled with the issuing corporation's financial structure would have been acceptable to an independent creditor (determined without regard to the independent creditor "safe harbor"). Even if the instrument is treated as indebtedness under this test, the instrument may subsequently be reclassified as stock under the "second look" rules described above in paragraph (d)(2)(ii)(C) of this section

(iv) *Safe harbor.* In general, the regulations under section 385 provide a safe harbor for a straight debt instrument issued by a corporation for its face amount whenever all of the following conditions are satisfied:

(A) *Principal and interest.* The instrument has a fixed maturity date and provides for annual payments of interest at (*1*) the rate in effect under section 6621, (*2*) the prime rate in effect at any local commercial bank (or the rate two points above such rate, (*3*) a rate determined from time to time by the Secretary taking into consideration the average yield on outstanding marketable obligations of the United States of comparable maturity, (*4*) the endpoints of the range of rates set forth in § 1.482–2(a)(2)(iii)(B)(1), or (*5*) any rate in between.

(B) *Debt-to-equity.* The debt-to-equity ratio of the corporation does not exceed 3:1.

(C) *Paid when due.* All principal and interest on the instrument are paid when due.

If a straight debt instrument falls within the safe harbor, then it will be treated as indebtedness when issued, the interest rate will not be adjusted through the imputation of original issue discount or bond premium, and (assuming its terms are not changed) it will not be subsequently reclassified as stock.

(2) *Absolute safe harbor for independent creditors.* Even if a class of straight debt instruments is issued proportionately, if one (or more) of the instruments in the class is issued to an independent creditor, the instrument will be treated as indebtedness and the interest rate will not be adjusted through the imputation of original issue discount or bond premium.

(3) *Hybrid instruments.* A hybrid instrument issued proportionately is generally treated as stock. However, if a class of hybrid instruments is issued proportionately but at least 20 percent of the class is owned by independent creditors (determined without regard to the independent creditor "safe harbor"), then the class of hybrid instruments is not automatically treated as stock; rather, the instruments will initially be treated as stock only if the present value of the straight debt payments with respect to the instruments is less than 50 percent of the fair market value of the instruments. The "second look" rules will also apply to the instruments not held by independent creditors.

(4) *Special rule for redemptions.* If a shareholder receives a proportionately-issued straight debt instrument in a redemption that would qualify for non-dividend treatment under section 302 if the instrument were treated as debt, the regulations under section 385 initially treat the straight debt instrument as indebtedness, subject to subsequent application of the "second look" rules. For redemptions only, earned surplus limitations imposed by local law do not affect the treatment of an instrument as a straight debt instrument.

(e) *Cross reference.* See 1.385–2 for a more detailed, technical summary of the regulations under section 385.

(f) *Cautionary note.* This section is merely a summary of the regulations under section 385 and is subject to all respects to the more complete rules contained in §§ 1.385–1 and §§ 1.385–3 through 1.385–8.

§ 1.385–1 Stock or indebtedness.

(a) *Effective date*—(1) *In general.* The regulations under section 385 apply to instruments (as defined in § 1.385–3(b)) issued after June 30, 1982 and to loans described in § 1.385–7 made after June 30, 1982.

(2) *Exceptions.* The regulations under section 385 do not apply to—

(i) Instruments issued pursuant to a plan of reorganization confirmed by the court in a proceeding under the Federal bankruptcy laws (Title 11, U.S.C.) or under the Regional Rail Reorganization Act of 1973, if the proceeding is commenced on or before December 30, 1981; or

(ii) Instruments issued pursuant to a written contract which specifies all the material terms and conditions of the instrument and which is binding on December 30, 1981 and at all times thereafter, provided that the lender does not have an option not to acquire the instrument.

(b) *Scope*—(1) *In general.* The regulations under section 385 contain rules under which certain interests in corporations are treated as stock or indebtedness. All other interests (such as bank deposits, insurance policies, claims for wages, and trade accounts payable) are outside the scope of the regulations.

(2) *Cooperatives.* The regulations under section 385 apply to cooperatives described in section 1381(a). However, interests that constitute written notices of allocation under 1388(b), per-unit retain certificates under section 1388(g), or membership paper are outside the scope of the regulations under 385. For purposes of the regulations under section 385, "membership paper" means any evidence of a fee (payable in cash or other property) charged to a member or a patron for participation in the cooperative regardless of whether the fee is to be paid once or periodically or whether the fee is returnable in whole or part. See § 1.385–6(a)(2)(v) for the characterization of the interests described in this subparagraph for purposes of determining proportionality of holdings in a cooperative. See § 1.385–6(h)(6)(viii) for the characterization of these interests in computing the debt-to-equity ratio of a cooperative.

(3) *International transactions.* Until such time as further regulations relating to the application of the section 385 regulations to international transactions are issued, any instrument issued in an international transaction or any loan described in § 1.385–7 made in an international transaction is outside the scope of the section 385 regulations. For purposes of the preceding sentence, an instrument or loan described in § 1.385–7 is issued or made in an international transaction if it is an instrument issued by or to, or a loan described in § 1.385–7 made to or by, (i) a person that is not a United States person or (ii) a domestic corporation dividends from which are or would be treated under section 861(a)(2)(A) as income from sources without the United States.

(4) *Certain hybrid instruments issued for property.* A hybrid instrument (as defined in § 1.385–3(d)) is outside the scope of the regulations under section 385 if it is issued in exchange for property (other than money) and § 1.385–6 (relating to proportionality) does not apply to such instrument. For purposes of this paragraph (a)(4), § 1.385–6 will be considered to apply to

an instrument if, but for the exception provided by § 1.385–6(d)(2), § 1.385–6(d)(1) would apply to such instrument.

(5) *Consequences if outside scope.* Any interest outside the scope of the regulations under section 385 will be treated as stock or indebtedness under applicable principles of law without reference to the regulations under section 385.

(6) *Similar distinctions.* Certain other sections of the Internal Revenue Code make distinctions that are similar to (but not the same as) the one between stock and indebtedness. Section 385 does not necessarily govern these distinctions. Thus, for example, an interest in an organization may be treated as indebtedness under section 385, but the net profits of the organization may, by reason of the indebtedness, inure to the benefit of the holder within the meaning of section 501(c). Similarly, section 385 does not affect the availability of the investment tax credit with respect to a loan treated as an ownership interest within the meaning of section 48(k)(1)(C) (relating to the investment credit for movies). See § 1.48–8(a)(4)(iii).

(c) *Authority.* Sections 1.385–1 through 1.385–8 are prescribed under the authority of section 385. In addition, certain provisions in these sections derive additional authority under section 7805, because they interpret other sections of the Internal Revenue Code, including section 301 (relating to distributions of property), section 1012 (relating to basis), and section 1232 (relating to original issue discount).

§ 1.385–2 Summary

(a) *Instruments issued proportionately*—(1) *Straight debt instruments.* Straight debt instruments (as defined in § 1.385–3(e)) issued proportionately to the issuing corporation's shareholders are ordinarily treated as indebtedness. Exceptions may apply where the issuing corporation has excessive debt (see § 1.385–6(g)), or where the instruments are not issued for money, (see § 1.385–6(e)) or are payable on demand (see § 1.385–6(m)). Additionally, straight debt instruments initially treated as debt may be reclassified as stock where there is a failure to pay interest or principal when due (see § 1.385–6 (l) and (m)(3)) or where there is a change in terms (see § 1.385–6(k)).

(2) *Hybrid instruments.* Hybrid instruments (*e.g.*, income bonds or convertible debentures) are generally treated as stock if they are issued proportionately (see § 1.385–6(d)). There is an exception, however, if at least 20 percent of the class of hybrid instruments is held by independent creditors (determined without regard to the independent creditor safe harbor) (see § 1.385–6(d)(2)).

(b) *Instruments not issued proportionately*—(1) *Straight debt instruments.* Straight debt instruments not issued proportionately are ordinarily treated as indebtedness. However, if an instrument is issued to a 25-percent shareholder and the corporation's debt-to-equity ratio exceeds 10:1, then the instrument is treated as if it were issued proportionately (see § 1.385–6(a)(2)(vi)).

(2) *Hybrid instruments.* Hybrid instruments not issued proportionately are generally treated as stock if the value of the straight debt payments with respect to the instrument is less than half of the fair market value of the instrument (see § 1.385–5). Otherwise, they are generally treated in the same manner as straight debt instruments.

(c) *Ancillary rules*—(1) *In general.* In addition to the primary rules described in paragraphs (a) and (b) of this section, the regulations under section 385 also contain a variety of significant ancillary rules. These rules are subordinate in the sense that they do not apply directly to treat any interest as stock or indebtedness. However, they are essential to the working of the regulations.

(2) *Proportionality.* Section 1.385–6(a)(2) defines when holdings of a corporation's stock and a class of instruments are substantially porportionate. This definition is significant—

(i) When instruments are issued for excessive or inadequate consideration (see § 1.385–6(c));

(ii) When hybrid instruments are issued (see § 1.385–6(d));

(iii) When instruments are issued other than in consideration for money (see § 1.385–6(e));

(iv) When an instrument is issued by a corporation with excessive debt (see § 1.385–6(g));

(v) When there is a change in an instrument's terms (see § 1.385–6(k));

(vi) When there is nonpayment of interest on an instrument (see § 1.385–6(l));

(vii) When an instrument is payable on demand (see § 1.385–6(m)).

(3) *Adjustment of interest rate.* If instruments issued proportionately are treated as indebtedness but do not carry a reasonable rate of interest, § 1.385–6(c) provides a mechanism to adjust the rate to a reasonable rate by comparing the fair market value of the instrument with the cash consideration paid for it. If there is a difference between the value of the instrument and the cash consideration paid therefor, the amount deemed to be paid for the instrument is adjusted and this ordinarily results in the creation of either original issue discount (see section 1232) or amortizable bond premium (see section 171(b)). This result ensures that the holders take a reasonable amount into income as interest received, and that the issuing corporation takes a reasonable deduction for interest paid on the instruments each year (see § 1.61–12(c)(2)).

(4) *Reasonable rate of interest.* Section 1.385–6(f) contains rules for determining whether a rate of interest is reasonable. These rules are significant—

(i) Where instruments are issued proportionately other than in exchange for money (see § 1.385–6(e));

(ii) Where instruments are held proportionately and there is a change in terms (see § 1.385–6(k)) or nonpayment of principal (see § 1.385–6(l)(3));

(iii) Where instruments held proportionately are payable on demand (see § 1.385–6(m));

(iv) Where loans of money made to a corporation by persons other than independent creditors are not evidenced by an instrument (see § 1.385–7); and

(v) In determining the fair market value of an instrument (see § 1.385–3(a)(2)).

(5) *Debt-to-equity ratio.* Paragraphs (h) and (j) of § 1.385–6 contain rules for determining a corporation's debt-to-equity ratio. These rules are significant in determining—

(i) Whether a rate of interest is presumptively reasonable (see § 1.385–6(f)(2)); and

(ii) Whether a corporation has excessive debt (see § 1.385–6(g)).

(6) *Fair market value.* Section 1.385–3(a) contains rules for determining the fair market value of an instrument. These rules are significant in determining—

(i) Whether the interest rate will in effect be adjusted under § 1.385–6(c) (and section 1232 or § 1.61–12(c)(2)); and

(ii) Whether a hybrid instrument is treated as stock (see § 1.385–5).

(d) *Safe harbor.* In general, the regulations under section 385 provide a safe harbor for a straight debt instrument (as defined in § 1.385–3(e)) issued by a corporation for its face amount whenever all of the following conditions are satisfied:

(1) *Principal and interest.* The instrument has a fixed maturity date and provides for annual payments of interest at (i) the rate in effect under section 6621, (ii) the prime rate in effect at any local commercial bank (or a rate two points above such rate), (iii) a rate determined from time to time by the Secretary taking into consideration the

average yield on outstanding marketable obligations of the United States of comparable maturity, (iv) either of the endpoints of the range of rates set forth in § 1.482–2(a)(2)(iii)(B)(1),or (v) any rate in between.

(2) *Debt-to-equity ratio.* The debt-to-equity ratio of the corporation does not exceed 3:1.

(3) *Paid when due.* All principal and interest on the instrument are paid when due.

If a straight debt instrument falls within the safe harbor, then it will be treated as indebtedness when issued, no original issue discount or bond premium will be imputed with respect to it and (assuming its terms are not changed) it will not be subsequently reclassified as stock.

(e) *Other provisions*—(1) *Certain other loans.* Sections 1.385–7 contains rules that apply to certain loans of money made to a corporation by persons other than independent creditors that are not evidenced by an instrument within 120 days after the end of the taxable year in which they are made.

(2) *Locked interests.* Section 1.385–8 contains rules that treat locked interests (such as a bond with a nondetachable warrant) as separate and distinct.

(f) *Cautionary note.* This section is merely a summary of the regulations under section 385, and is subject in all respects to the more complete rules contained in §§ 1.385–3 through 1.385–8.

§ 1.385–3 Definition of terms.

(a) *Fair market value.* The following rules apply for purposes of the regulations under section 385:

(1) *In general.* (i) The fair market value of an instrument is the price at which it would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy or to sell and both having reasonable knowledge of all relevant facts.

(ii) The fair market value of an instrument may be determined by using present value and standard bond tables. See § 1.1232–3(b)(2)(ii)(*d*) for examples in which the fair market values of instruments are determined by the use of these tables.

(iii) (A) In determining the fair market value of an instrument (or the reasonableness of an interest rate), the Commissioner may disregard a noncommercial term of the instrument if the principal purpose of the inclusion of the term is to increase or decrease the fair market value of the instrument (or a reasonable rate of interest for the instrument) for Federal tax purposes. See also section 482.

(B) The following example illustrates the application of this subdivision (iii):

Example. A, an individual with large net operating loss carryovers, is the sole shareholder of corporation W. On January 1, 1987, W issues a $100,000, 28-percent debenture to *A* in exchange for $100,000. Under provision P of the debenture, an action to enforce the terms of the debenture can be maintained only in the village court of village V, located in foreign country Q. Assume that the principal purpose of the inclusion of provision P is to reduce the fair market value of the debenture for Federal tax purposes. Based on these facts, provision P will be disregarded in determining the fair market value of the debenture.

(2) *Rules of convenience.* (i) On the day of issue, the fair market value of a straight debt instrument is considered to be equal to the face amount if—

(A) The stated annual rate of interest on the instrument is reasonable (within the meaning of § 1.385–6(f)), and

(B) The consideration paid for the instrument is equal to the face amount.

(ii) Notwithstanding any other provision of this paragraph (a), if an instrument is registered with the Securities and Exchange Commission and sold to the public for money, then the fair market value of the instrument on the day of issue is the issue price (as defined in section 1232(b)(2)).

(3) *Examples.* The following examples illustrate the application of paragraph (a)(2) of this section:

Example (1). On March 1, 1985, corporation M issues a $1,000, 8-percent, 5-year note at par. Assume that on that date, 10 to 12 percent is the range of rates of interest paid to independent creditors on similar instruments issued by corporations of the same general size and in the same general industry, geographic location, and financial condition; that the rate of interest in effect under section 6621 is 6 percent; that the interest rate for 5-year obligations determined by the Secretary pursuant to § 1.385–6(f)(2)(i) is 7 percent; but the lowest prime rate at any local commercial bank is 9 percent; and the range of rates set forth in § 1.482–2(a)(2)(iii)(B)(1) is 8–10 percent. Also assume that M's debt-to-equity ratio at the end of the taxable year is 3:2. Based on these facts, any rate between 6 and 12 percent is a reasonable rate of interest within the meaning of § 1.385–6(f). In particular, 8 percent is a reasonable rate of interest, and the fair market value of the note is therefore considered to be $1,000.

Example (2). The facts are the same as in example (1) except that M's debt-to-equity ratio at the end of the taxable year is 4:1. Based on these facts, paragraph (a)(2)(i) of this section does not apply.

Example (3). The facts are the same as in example (2) except that the note provides for annual payments of interest at a rate of 11 percent. Since 11 percent is within the range of rates of interest paid to independent creditors on similar instruments issued by corporations of the same general size and in the same general industry, geographic location and financial condition, the fair market value of the note is considered to be $1,000.

(b) *Instrument.* The term "instrument" means any bond, note, debenture, or similar written evidence of an obligation.

(c) *Obligation.* The term "obligation" means an interest in a corporation that is treated as indebtedness under applicable nontax law.

(d) *Hybrid instrument.* The term "hybrid instrument" means an instrument that is convertible into stock or one (such as an income bond or a participating bond) that provides for any contingent payment to the holder (other than a call premium).

(e) *Straight debt instrument.* The term "straight debt instrument" means any instrument other than a hybrid instrument.

(f) *Table of terms.* The following table indicates where some other important terms referred to in the section 385 regulations are defined.

Subject	§ 1.385–
Contingent payment	5(d)(1).
Debt-to-equity ratio	6(h).
Excessive debt	6(g)(2).
Failure to pay interest	6(l)(3).
Fixed payments; interest	5(d)(2).
Fixed payments; principal	5(d)(3).
Independent creditor	6(b).
Reasonable rate of interest	6(f).

§ 1.385–4 Instruments generally.

(a) *General rule.* Except as otherwise provided in the regulations under section 385, all instruments (as defined in § 1.385–3(b)) are treated as indebtedness for all purposes of the Internal Revenue Code. For exceptions, see § 1.385–5 (relating to certain hybrid instruments) and § 1.385–6 (relating to proportionality).

(b) *Operating rules*— (1) *In general.* The regulations under section 385 determine the status of each instrument (i.e., as stock or indebtedness) at the time the instrument is issued. Except as provided in paragraphs (k), (l), and (m) of § 1.385–6 (relating to proportionality), the status of an instrument can never change. Thus, for example, the status of an instrument is not affected by a mere change in ownership.

(2) *Special rule.* Under § 1.385–6 (k), (l), and (m), the status of an instrument can change from indebtedness to stock (e.g., in the event of a failure to pay interest when due).

(c) *Effect of classification*— (1) *In general.* (i) If an instrument is treated as stock under section 385, then the

instrument is treated as preferred stock for all purposes of the Internal Revenue Code. In particular, all payments of "interest" on the instrument are treated as distributions to which section 301 applies, and all payments of "principal" are treated as distributions in redemption of stock. Such preferred stock is considered to have the same terms (e.g. voting rights) as the instrument has under applicable local law. Each class of instruments classified as preferred stock is treated as a separate class of preferred stock. (See, however, § 1.1371–1(h) for the effect on an election made under Subchapter S. Also see § 1.992–1(d)(2) for an exception to this rule.)

(ii) If an instrument becomes stock under § 1.385–6 (k), (l), or (m), then the instrument is treated as having been exchanged (without recognition of gain or loss) for preferred stock in a recapitalization to which section 368(a)(1)(E) applies. For this purpose, if there is a change in the terms of an instrument and the change in terms is sufficiently substantial to be considered an exchange of instruments under applicable principles of tax law (ascertained without reference to the regulations under section 385), then the change in terms is treated under § 1.385–6(e) (relating to instruments issued for property) rather than under § 1.385–6(k) (relating to changes in terms). Thus, in the situation described in the preceding sentence, the tax consequences of the constructive exchange are determined without regard to the regulations under section 385 rather than under the first sentence of this paragraph (c)(1)(ii).

(2) *Illustrations.* The following examples illustrate the application of this paragraph (c):

Example (1). On January 1, 1983, corporation X issues a $100,000 note to A. The note is due on January 1, 1993, and pays interest at a rate of 10 percent a year. Assume that the note is initially treated as indebtedness under paragraph (a) of this section. However, on January 1, 1987, the note becomes stock under § 1.385–6(l) (relating to nonpayment of interest). A is treated as having exchanged the note for preferred stock on January 1, 1987, in a recapitalization to which section 368(a)(1)(E) applies. Moreover, A does not recognize gain or loss merely because the note is reclassified.

Example (2). The facts are the same as in example (1). In addition, on July 1, 1988, A receives $15,000 in interest on the note. The entire $15,000 payment is treated as a distribution to which section 301 applies.

Example (3). Individuals B and C each own 50 percent of the stock of corporation Y. On January 1, 1990, Y distributes one convertible debenture each to B and C as a dividend. The convertible debentures are treated as stock under § 1.385–6(d) (relating to hybrid instruments). Assume that Y has accumulated earnings and profits of $5 million at the time of the distribution. Based on these facts, the debentures are treated as section 306 stock unless their distribution is taxable under section 305(b)(5).

§ 1.385–5 Certain hybrid instruments.

(a) *In general.* A hybrid instrument is treated as stock if, on the day of issue—

(1) The fair market value of the straight debt payments (as defined in paragraph (d)(2) of this section) with respect to the instrument is less than

(2) fifty percent of the fair market value of the instrument.

(b) *Special rule.* Paragraph (a) of this section shall be applied by substituting "Forty-five percent" for "Fifty percent" if clear and convincing evidence shows that, on the day of issue, both the issuer and holder reasonably believed that—

(1) The fair market value of the straight debt payments (as defined in paragraph (d)(2) of this section) with respect to the instrument is not less than

(2) Fifty percent of the fair market value of the instrument.

(c) *Meaning of terms.* The following rules apply for purposes of the regulations under section 385:

(1) *Contingent payment.* The term "contingent payment" means any payment other than a fixed payment of principal or interest.

(2) *Fixed payments; interest.* An instrument provides for fixed payments of interest if both of the following conditions are satisfied:

(i) Interest at a definitely ascertainable rate is due on definitely ascertainable dates.

(ii) Except as provided in paragraph (c)(5) of this section, the holder's right to receive interest when due (or within 90 days thereafter) cannot be impaired without the holder's consent.

(3) *Fixed payments; principal.* An instrument provides for the fixed payment of principal if both of the following conditions are satisfied:

(i) A definitely ascertainable principal sum is payable on demand or due on definitely ascertainable dates.

(ii) Except as provided in paragraph (c)(5) of this section, the holder's right to receive principal when due cannot be impaired without the holder's consent.

(4) *Definitely ascertainable.* (i) A rate of interest is definitely ascertainable if it is applied to a definitely ascertainable principal sum and it is—

(A) An invariable rate or

(B) A variable rate determined according to an external standard that is not subject to the borrower's control and that is not related to the success or failure of the borrower's business or activities.

(ii) A principal sum is definitely ascertainable if it is—

(A) An invariable sum or

(B) A variable sum determined according to an external standard that is not subject to the borrower's control and that is not related to the success or failure of the borrower's business or activities.

A principal sum is not variable simply because it is within the borrower's control to prepay all or a portion of the principal sum.

(5) *Exceptions.* The classification of a payment as fixed is not affected by the fact that:

(i) The instrument is issued under an indenture that satisfies the requirements of section 316 of the Trust Indenture Act of 1939 (15 U.S.C. 77ppp);

(ii) A holder's right to receive interest or principal may be impaired by the operation of the Federal bankruptcy laws (Title 11, U.S.C.), the Railroad Modification Act (47 U.S.C. 20b), or a similar provision of law;

(iii) A holder's right to receive interest or principal may be impaired in the event of the insolvency of the issuing corporation (either in the sense that the corporation is not able to pay its debts as they become due or in the sense that its liabilities exceed its assets);

(iv) The obligation to make the payment is a nonrecourse obligation, but only if the face amount of the obligation would, if the obligation were issued in exchange for property, be includable upon issuance as part of the purchaser's adjusted basis for the property; or

(v) With respect to an instrument issued in a redemption of stock, amounts designated as interest or principal (or both) are, by operation of local law, payable only out of earned surplus.

(6) *Illusory contingencies.* For purposes of this paragraph (d), the Commissioner may disregard a contingency where there is no reasonably foreseeable circumstance in which it could affect the likelihood of payment.

(7) *Certain guarantees. If—*

(i) A payment does not satisfy the requirements of paragraph (c) (2) or (3) fo this section, but

(ii) The payment is guaranteed (directly or indirectly) by any person, then (depending on the facts and circumstances) the Commissioner may treat the payment as fixed.

(8) *Examples.* For examples that illustrate the application of this paragraph (c), see paragraph (a) of each of the examples in paragraph (f) of this section.

(9) *Other terms.* (i) For the definition of the term "fair market value", see § 1.385–3(a).

(ii) For the definition of the term "hybrid instrument", see § 1.385–3(d).

(iii) For the definition of the term "instrument", see § 1.385–3(b).

(d) *Operating rules.*—(1) *In general.* Paragraph (a) of this section requires a comparison of the fair market value of the straight debt payments with respect to a hybrid instrument with the instrument's fair market value at the time it is issued. The rules in this paragraph (d) apply in determining the fair market value of the straight debt payments.

(2) *Straight debt payments.* The straight debt payments with respect to a hybrid instrument are determined as follows:

(i) The straight debt payments with respect to the right to fixed payments of principal or interest are the fixed payments themselves;

(ii) The straight debt payments with respect to the right to contingent payments (other than a call premium) are the payments that must be made on the occurrence of the contingencies resulting in the lowest possible fair market value of payments under the instruments. To the extent the payments are contingent in amount, the straight debt payments are computed assuming the occurrence of the contingency providing the smallest possible payment under the instrument. To the extent the payments are contingent as to timing, the straight debt payments are computed assuming the occurrence of the contingency providing payment on the latest possible date under the instrument. To the extent the payments are contingent on the exercise of discretion by the issuer of the instrument, the straight debt payments are computed assuming the smallest and latest possible discretionary payments. If the instrument is convertible into stock, the straight debt payments are computed without regard to the convertibility feature.

(3) *Valuation.* The fair market value of the straight debt payments with respect to a hybrid instrument is the sum of the present value (at the time of the instrument's issuance) of each of the straight debt payments.

(4) *Discount rate.* (i) The discount rate to be used in computing the present value of a straight debt payment payable at a future date is a reasonable rate of interest (within the meaning of § 1.385–6(f)(1) for an instrument in the amount of the straight debt payment, payable on the date that the straight debt payment must be made and payable on the terms and conditions of such straight debt payment.

(ii) Paragraph (d)(4)(i) of this section may be illustrated by the following example:

Example. (a) Corporation X issues a class of 10-year, 10-percent $1,000 subordinated income bonds to the public. Interest on the bonds is payable only if earned. The bonds have a fair market value of $1,000 each. At approximately the same time as the issuance of the income bonds, X issues to the public a class of 8-percent subordinated bonds which are substantially identical to the income bonds except that (1) they bear interest at 8 percent and (2) the interest is payable at all events. Both classes of bonds are issued at their face amount and are registered with the Securities and Exchange Commission.

(b) The income bonds will be treated as indebtedness if the fair market value of the straight debt payments with respect to the bonds is at least 50 percent (or, in some cases, 45 percent) of the fair market value of the bonds. See paragraphs (a) and (b) of this section. In order for this test to be applied, the present value of the straight debt payments with respect to a bond (i.e., a $1,000 subordinated payment of principal payable 10 years after issuance) must be determined. Based on the facts set forth in paragraph (a) of this example, it is appropriate to use an 8 percent discount rate in determining the present value of the straight debt payment of $1,000, payable on a subordinated basis 10 years from the date of the issuance of the bonds.

(e) *Cross reference.* See § 1.385–1(b)(4) under which certain hybrid instruments issued in exchange for property (other than money) are excluded from the scope of the regulations under section 385.

(f) *Illustrations.* The following examples illustrate the application of this section. It is assumed that § 1.385–6 does not apply to the instruments described in these examples.

Example (1). (a) On July 1, 1987, corporation J issues subordinated income debenture bonds in the principal amount of $1,000 each. The bonds pay interest at the rate of 8 percent a year. However, interest is payable only if earned. The bonds are due on December 31, 2006. Based on these facts, each bond provides for a fixed payment of $1,000 in principal on December 31, 2006, but for contingent payments of interest.

(b) Assume that the fair market value of the 8-percent subordinated income debenture bonds is $1,000 each. The straight debt payments with respect to a subordinated income debenture bond are a $1,000 subordinated payment of principal due on December 31, 2006. Assume that the present value of such a payment on July 1, 1987 would be $261. Based on these facts, the subordinated income debenture bonds are treated as stock because the fair market value of the straight debt payments with respect to a debenture bond (i.e., $261) is less than 50 percent of the bond's fair market value (i.e., $1,000/2=$500).

Example (2). (a) On March 1, 1988, corporation M issues 6-percent subordinated income debentures in the principal amount of $1,000 each due on March 1, 2038. Annual payment of interest is mandatory if net income is available and optional otherwise. Accumulated interest must be paid in all events at maturity. Based on these facts, each debenture provides for fixed payments of $1,000 in principal and $3,000 in simple interest on March 1, 2038.

(b) Assume that the fair market value of the 6-percent subordinated income debentures is $1,000 each. The straight debt payments with respect to a debenture are payments of $4,000 (total principal and interest) on March 1, 2038, with the payments being subordinated to the general creditors of M. Assume that the present value on March 1, 1988 of such payments with respect to a debenture would be $265. Based on these facts, the income debentures are treated as stock because the fair market value of the straight debt payments with respect to an income debenture (i.e., $265) is less than 50 percent of the income debenture's fair market value (i.e., $1,000/2=$500.

Example (3). (a) On February 7, 1987, corporation P issues written obligations called "debenture preference stock" in the principal amount of $50 each. The debenture preference stock bears interest at 6 percent a year. In addition, at the discretion of the board of directors of P, the holders of the debenture preference stock may share in the profits of P after a dividend of $6 has been paid on each share of P's common stock. The debenture preference stock matures on December 31, 2017, except that the maturity may be extended from time to time (but in no event beyond December 31, 2037) at the discretion of P's board of directors. Based on these facts, the debenture preference stock provides for fixed payments of interest at a rate of 6 percent and a fixed payment of $50 in principal on December 31, 2037.

(b) Assume that the fair market value of the debenture preference stock is $50 each. The straight debt payments with respect to a share of debenture preference stock are annual payments of 6 percent interest and a $50 payment principal due on December 31, 2037. Assume that the present value on February 7, 1987 of such payments would be $20.12. Based on these facts, the debenture preference stock is treated as stock because the fair market value of the straight debt payments with respect to a share of the debenture preference stock (i.e., $20.12) is less than 50 percent of the share's fair market value if (i.e., $50/2=$25).

Example (4). (a) On December 1, 1989, corporation T issues variable interest notes in the principal amount of $1,000 each. The notes pay interest at a rate that may vary between 2 percent and 10 percent, depending on the earnings of T. The board of directors of T may, in its discretion, defer all payments of interest until the notes mature on December 1, 2014, and may subordinate the notes to other debts of T. Based on these facts, each provides for fixed payments of $1,000 in principal and $500 in interest (i.e., 2 percent × $1,000 × 25 years) on December 1, 2014.

(b) Assume that the fair market value of the variable interest notes is $1,000 each. The straight debt payments with respect to a note are payments of $1500 (total principal and interest) on December 1, 2014, with such payments being subject to subordination at the discretion of the board of directors of T. Assume that the present value on December 1, 1989 of such payments would be $219. Based on these facts, the variable interest notes are treated as stock because the fair market value of the straight debt payments with respect to a note (i.e., $219) is less than 50 percent of the note's fair market value (i.e., $1,000/2=$500).

Example (5). (a) On April 1, 1984, corporation U issues inflation provision notes in the principal amount of $557,700. The notes pay interest at a fixed rate of 6 percent on a fluctuating maturity value and are due on April 1, 1994. The maturity value if determined according to the Consumer's Price Index, published monthly by the Bureau of Labor Statistics. Based on these facts, the inflation provision notes provide for fixed payments of both principal and interest. See paragraph (c)(4)(i)(A) and (ii)(B) of this section.

(b) The inflation provision notes are treated as indebtedness because they are straight debt instruments.

Example (6). (a) Corporation W owns a track of land and is building 350 houses there. On August 15, 1985, P lends $300,000 to W pursuant to a written agreement. The agreement provides that W will pay $175,000 to P "in lieu of interest," with $500 payable on the sale of each house. In addition, W is obligated to return P's $300,000 investment on demand at any time after December 31, 1990. The loan is secured by the general credit of W, and the written agreement contains appropriate protective provisions. Assume that the agreement is an instrument within the meaning of § 1.385–3(b). Based on these facts, the agreement provides for the fixed payment of $300,000 in principal and for a contingent payment of $175,000.

(b) Assume that the fair market value of the obligation to P is $300,000. The straight debt payments with respect to the obligation are a $300,000 payment of principal due on December 31, 1990. Assume that the present value on August 15, 1985 of such a payment would be $170,000. Based on these facts, the obligation to P is treated as indebtedness because the fair market value of the straight debt payments with respect to the obligations (i.e., $170,000) is not less than 50 percent of the obligation's fair market value (i.e., $300,000/2=$150,000).

Example (7). (a) On May 1, 1984, corporation X issues subordinated debentures due on May 1, 1994, in the principal amount of $1,000 each. Interest is payable annually at the fixed rate of 7 percent a year. Additional interest, which is contingent on the net profits of X, is payable at a maximum rate of 1 percent a year. Default in payment of interest, while not accelerating the maturity of the debenture, gives rise to a cause of action which the debenture holder may maintain against X for nonpayment or interest. Based on these facts, each debenture provides for a fixed $1,000 payment of principal and for fixed payments of interest at the rate of 7 percent a year.

(b) Assume that the fair market value of the subordinated debentures is $1,000 each. The straight debt payments with respect to a debenture are the same payments as the debenture provides without the provision for additional interest. Assume that the present value on May 1, 1984 of such payments would be $949. Based on these facts, the subordinated debentures issued by X are treated as indebtedness because the fair market value of the straight debt payments with respect to a debenture (i.e., $949) is not less than 50 percent of the debenture's fair market value (i.e., $1,000/2=$500).

Example (8). (a) Corporation Z owns a large tract of land and is engaged in the business of developing, subdividing, and selling the land. On January 25, 1986, Z issues noninterest-bearing debenture bonds having a face value of $500,000 and a maturity date of January 25, 2011. The retirement of the bonds will be secured by the deposit of 10 percent of Z's gross receipts into a special bank account. However, if Z is liquidated after all of its lands have been sold, it will have no further obligation to retire any of the outstanding bonds unless the 10 percent payments have not been made as required. Based on these facts, the bonds do not provide for fixed payments of either principal or interest.

(b) The straight debt payments with respect to the debenture bonds are zero payments. Therefore, the debenture bonds are treated as stock.

Example (9). (a) On August 1, 1983, U, a domestic industrial corporation, issues debentures in the principal amount of 1,000 German marks each. The debentures pay interest at a fixed rate of 8 percent, are due on August 1, 1993, and provide for the payment of principal and interest in German marks. U immediately converts the proceeds from the issuance of the debentures into U.S. dollars and uses the money for its domestic business needs. Based on these facts, the debentures provide for fixed payments of both principal and interest. See paragraph (c)(4)(i)(B) and (ii)(E) of this section.

(b) The debentures are treated as indebtedness because they are straight debt instruments.

Example (10). (a) On September 1, 1984, corporation W issues floating rate notes in the principal amount of $100,000. The notes pay interest at 3 percentage points above the prime rate. Based on these facts, the floating rate notes provide for fixed payments of both principal and interest. See paragraph (c)(4)(i)(B) and (ii)(A) of this section.

(b) The floating rate notes are treated as indebtedness because they are straight debt instruments.

Example (11). (a) Unrelated individuals A and B each own 50 percent of the only class of stock of corporation X. In addition to the outstanding stock, X has outstanding debentures held by independent creditors. On January 1, 1988, X redeems all of A's stock in exchange for a 10-year note with a principal amount of $500,000. Under the terms of the note, interest on outstanding principal is payable annually at a rate of 10 percent. Under applicable local law, the note is treated as indebtedness. However, under local law, each payment of principal and interest is subject to the restriction that no payment may be made at a time when the corporation is (or would be rendered) insolvent (i.e., unable to pay its debts as they become due). The insolvency restriction does not affect the classification of the principal or interest payments as fixed payments. See paragraph (d)(5)(iii) of this section. Therefore, the note provides for fixed payments of both principal and interest.

(b) The note is treated as indebtedness because it is a straight debt instrument. The result would be the same if, under local law, payments could not be made when X's liabilities exceeded its assets.

Example (12). (a) The facts are the same as in example (11) except that, under local law, the payments of principal and interest on the note are subject to the additional restriction that each payment can only be made out of X's earned surplus. Based on these facts, the earned surplus limitation does not affect the classification of the principal or interest payments as fixed payments. See paragraph (c)(5)(v) of this section. Therefore, the note provides for fixed payments of both principal and interest.

(b) The note is treated as indebtedness because it is a straight debt instrument.

Example (13). (a) On January 1, 1990, Corporation R purchases an office building from unrelated corporation S for a purchase price of $20 million. R pays $5 million in cash and issues a 15 year, 12-percent note for the remaining $15 million of the purchase price. The note is secured by a first mortgage on the office building but is otherwise nonrecourse with respect to R. Assume that under applicable principles of tax law (determined without reference to the regulations under section 385), R's adjusted basis for the building immediately after the purchase is $20 million (i.e., the face amount of the note is includible in R's basis for the building). Based on these facts, the note provides for fixed payments of principal and interest.

(b) The note is treated as indebtedness because it is a straight debt instrument.

(g) *Additional illustrations.* The following examples are additional illustrations of the application of this section. It is assumed that § 1.385–6 does not apply to the instruments described in these examples.

Example (1). On January 1, 1990, corporation M issues 7-percent Series A bonds in the principal amount of $1,000 each. The bonds are due on January 1, 2015, and are secured by the general credit of M. They are registered with the Securities and Exchange Commission and sold to the public at par. Because the Series A bonds are straight debt instruments, they are treated as indebtedness.

Example (2). The facts are the same as in example (1), except that the instruments issued by M are 9-percent Series B income bonds. Interest is not payable on the Series B income bonds unless earned and is noncumulative. The straight debt payments with respect to a Series B income bond are a $1,000 payment of principal due on January 1, 2015. Assume that the present value on January 1, 1990 of such a payment would be

$184. Based on these facts, the Series B income bonds are treated as stock because the fair market value of the straight debt payments with respect to a Series B income bond (i.e., $184) is less than 50 percent of the bond's fair market value (i.e., $1,000/2=$500).

Example (3). The facts are the same as in example (2), except that the Series B income bonds are due on January 1, 2000. The straight debt payments with respect to a Series B income bond are a $1,000 payment of principal due on January 1, 2000. Assume that the present value, on January 1, 1990 of such a payment would be $508. Based on these facts, the Series B income bonds are treated as indebtedness because the fair market value of the straight debt payments with respect to a Series B income bond (i.e., $508) is not less than 50 percent of the bond's fair market vlaue (i.e., $1,000/2=$500).

Example (4). The facts are the same as in example (3), except that the Series B income bonds bear 10-percent interest and are subordinated to the general creditors of M. The straight debt payments with respect to a Series B income bond are a $1,000 payment of principal due on January 1, 2000, with such payment being subordinated to the general creditors of M. Assume that the present value on January 1, 1990 of such a payment would be $463. Based on these facts, the Series B income bonds are treated as stock because the fair market value of the straight debt payments with respect to a Series B income bond (i.e., $463) is less than 50 percent of the bond's fair market value (i.e., $1,000/2=$500).

Example (5). The facts are the same as in example (2), except that the Series B income bonds pay 8-percent cumulative interest, and accumulated interest become unconditionally due at maturity. the straight debt payments with respect to a Series B income bond are payments of $3,000 (total principal and interest) due on January 1, 2015. Assume that the present value on January 1, 1990 of such payments would be $553. Based on these facts, the Series B income bonds are treated as indebtedness because the fair market value of the straight debt payments with respect to a Series B income bond (i.e., $553) is not less than 50 percent of the bond's fair market value (i.e., $1,000/2=$500).

Example (6). The facts are the same as in example (1), except that the instruments issued by M are 6-percent Series C convertible bonds. Each Series C bond is convertible into two shares of common stock of M. The straight debt payments with respect to a Series C bond are the same payments as the bond provides without the conversion feature. Assume that the present value on January 1, 1990 of such payments (in effect, the value of the bond without the conversion feature) would be $883. Based on these facts, the Series C convertible bonds are treated as indebtedness because the fair market value of the straight debt payments with respect to a Series C bond (i.e., $883) is not less than 50 percent of the bond's fair market value (i.e., $1,000/2=$500).

Example (7). The facts are the same as in example (6), except that the Series C convertible bonds pay 2-percent interest and are convertible into four shares of stock of M. The straight debt payments with respect to a Series C bond are the same payments as the bond provides without the conversion feature. Assume that the present value on January 1, 1990 of such payments (in effect, the value of the bond without the conversion feature) would be $417. Based on these facts, the Series C convertible bonds are treated as stock because the fair market value of the straight debt payments with respect to a Series C bond (i.e., $417) is less than 50 percent of the bond's fair market value (i.e., $1,000/2=$500).

Example (8). The facts are the same as in example (1), except that the instruments issued by M are 7-percent Series D convertible income bonds due on January 1, 2015. The Series D bonds are convertible into two shares of common stock of M, and accumulated interest on the Series D bonds is unconditionally due at maturity. The straight debt payments with respect to a Series D bond are payments of $2,750 (total principal and interest) due on January 1, 2015 (and also disregarding the conversion feature). Assume that the present value on January 1, 1990 of such payments would be $506. Based on these facts, the Series D convertible income bonds are treated as indebtedness because the fair market value of the straight debt payments with respect to a Series D bond (i.e., $506) is not less than 50 percent of the bond's fair market value (i.e., $1,000/2=$500).

Example (9). The facts are the same as in example (4), except that the Series B income bonds are privately placed with corporation X. In reliance on an independent appraisal, both X and M reasonably believe that the fair market value of the straight debt payments with respect to a Series B income bond is $510. Based on these facts, the Series B income bonds are treated as indebtedness. See paragraph (b) of this section.

§ 1.385-6 Proportionality.

(a) *In general*—(1) *Scope.* This section applies to a class of instruments if holdings of stock and the class of instruments are substantially proportionate. This section affects instruments issued for inadequate or excessive consideration, hybrid instruments, instruments not issued for money, instruments that are payable on demand, and certain other instruments where there is a change in terms or a failure to pay principal or interest, or where a corporation's debt-to-equity ratio is excessive.

(2) *Proportionality*—(i) *In general.* Holdings of stock and a class of instruments are substantially proportionate if the "total overlap factor" with respect to the class of instruments is greater than 50 percent. The "total overlap factor" is the sum of the overlap factors of each person with respect to the class of instruments. The overlap factor of a person with respect to a class of instruments is the lesser of the percentage of stock or the percentage of the class of instruments owned, actually or constructively, by the person.

(ii) *Constructive ownership rules.* For purposes of computing the overlap factors under paragraph (a)(2)(i) of this section, the constructive ownership rules of section 318(a) shall be applied to attribute the ownership of stock and instruments in accordance with the following special rules:

(A) For purposes of section 318(a)(1)(ii), an individual shall also be considered to own stock or instruments owned, directly or indirectly, by or for his or her brothers and sisters (whether by the whole or half blood).

(B) Stock or an instrument constructively owned under section 318(a)(4) (relating to options) shall be taken into account only to the extent that (whether or not the options are currently exercisable) it is reasonable to expect, as of the time the relevant determination is made, that the options may be exercised.

(C) Section 318(a)(2)(C) shall be applied without regard to the 50 percent minimum percentage ownership requirement.

(D) If, in applying the attribution rules of section 318(a) (as modified by this subdivision (ii)) to both stock and a class of instruments, stock owned by one or more shareholders of a corporation or instruments owned by one or more holders would be attributed to one or more other persons, then the total overlap factor shall be determined by taking the largest total overlap factor that can be produced (without double counting) by computing holdings of stock and instruments under this subdivision (ii).

(E) A person's overlap factor shall be taken into account whether or not the person actually owns any stock or instruments of a corporation.

(iii) *Definition of "stock."* For purposes of paragraphs (a)(2) (i) and (ii) of this section, the term "stock" is defined as follows:

(A) If the issuing corporation has only one class of stock, then "stock" means all outstanding shares of this class of stock.

(B) If the issuing corporation has more than one class of stock, then the classes of stock which constitute "stock" will be determined based on the facts and circumstances. In general, a class of stock will be considered "stock" if it participates in corporate growth or has other characteristics which would reduce the incentive of holders of such class to establish or enforce arm's length terms on instruments issued to such holders. See examples (7) and (12) of paragraph (a)(6) of this section.

(iv) *Special rule for redemptions.* (A) If—

(*1*) A corporation issues a straight debt instrument to a shareholder in

redemption of all or part of the shareholder's stock in the corporation,

(2) Section 302(a) would apply to the redemption if the instrument were treated as indebtedness,

(3) The stated interest rate on the instrument is not less than the rate prescribed by the Secretary pursuant to section 483(c); and

(4) This section would, but for this paragraph (a)(2)(iv), apply to the instrument,

then the instrument is initially classified as indebtedness upon issuance and paragraph (c) of this section does not apply to the instrument. However, the instrument may subsequently be reclassified as stock under paragraphs (k), (l), and (m) of this section.

(B) For purposes of paragraph (a)(2)(iv)(A) of this section, an instrument will be treated as a straight debt instrument notwithstanding that amounts designated as interest or principal (or both) are, by operation of local law, payable only out of earned surplus.

(v) *Special rule for cooperatives.* In determining proportionality for holdings in a cooperative, interests described in § 1.385–1(b)(2) will be treated as stock.

(vi) *Special rule for major shareholders.* Notwithstanding paragraph (a)(2)(i) of this section, holdings of an instrument and the issuing corporation's stock will be treated as substantially proportionate if—

(A) The instrument is held by a person who owns (actually or constructively by application of section 318(a) as modified by paragraphs (a)(2)(ii) (A), (B), and (C) of this section) stock possessing at least 25 percent of the total combined voting power of all classes of stock entitled to vote or at least 25 percent of the total value of shares of all classes of the corporation's stock; and

(B) The corporation's debt-to-equity ratio, computed in accordance with paragraphs (h) and (j) of this section, exceeds 10:1 at the end of the taxable year in which the insrument is issued.

(vii) *Examples.* The following examples illustate the application of this paragraph (a)(2):

Example (1). The only class of stock of corporation X and a class of its instruments are owned as follows by unrelated individuals A, B, C, and I:

[In percent]

	A	B	C	I
Stock	40	10	50	0
Instruments	20	60	10	10

The "total overlap factor" with respect to the class of instruments is 20%+10%+10%, or 40%, and, accordingly, holdings of the X stock and the class of instruments are not substantially proportionate.

Example (2). Individuals B, BW (B's wife), BC (B's child, S (B's sister) and SH (S's husband) own the only class of stock of corporation Y and a class of its debentures as follows:

[In percent]

	B	BW	BC	S	SH
Stock	0	100	0	0	0
Debentures	0	0	50	25	25

The largest overlap factor that can be produced by computing holdings of stock and instruments under the section 318(a) attribution rules, as modified by paragraph (a)(2)(ii) of this section, is 75 percent, produced as follows:

[In percent]

	B (including holdings of BW, BC, and S)	SH
Stock	100	0
Debentures	75	25

Therefore, holdings of the Y stock and the class of debentures are substantially proportionate. If, however, B were deceased, the total overlap factor would be 50 percent and, accordingly, holdings of the Y stock and the class of debentures would not be substantially proportionate.

Example (3). Twenty-five unrelated individuals each own 4 percent of the only class of stock of corporation P which, in turn, owns 100 percent of the only class of stock of corporation S. The same individuals each own 4 percent of a class of debentures issued by S. Under section 318(a)(2)(C), as modified by paragraph (a)(2)(ii)(C) of this section, each individual shareholder of P is considered to own 4 percent of the stock of S. Thus, the overlap factor of each P shareholder with respect to the debentures issued by S is 4 percent. Therefore, the total overlap factor with respect to the debentures is 100 percent and holdings of the S stock and the debentures are substantially proportionate.

Example (4). The only class of stock of corporation Z and a class of its instruments are owned as follows:

[In percent]

	Corporation		
	W	X	Y
Stock	30	10	60
Instruments	40	60	0

Individual A owns all of the stock of corporations W and X. Individual B owns all of the stock of corporation Y. A owns 100 percent of a class of straight debt instruments issued by Y. A, B, W, X and Y are otherwise unrelated.

The largest overlap factor that can be produced by computing holdings under the section 318 attribution rules (as applied to both stock and instruments) is 40 percent, computed as follows:

[In percent]

	A (including holdings of W and X)	Y
Stock	40	60
Instruments	100	0

Therefore, holdings of the Z stock and the class of instruments are not substantially proportionate.

(3) *Exceptions.* (i) This section does not apply if a corporation's stock and instruments are widely held and the instruments are separately traded and readily marketable.

(ii) This section does not apply to any instrument held by an independent creditor (as defined in paragraph (b) of this section).

(4) *Two classes treated as one.* Depending on the facts and circumstances, two or more classes of instruments may be considered together. For example:

(i) If—

(A) Two or more classes of instruments are issued pursuant to a plan, and

(B) Holdings of stock and the instruments will be substantially proportionate on completion of the plan,

then this section applies to each instrument immediately after it is issued.

(ii) If (regardless of whether issued pursuant to a plan)—

(A) Subsequent to their issuance, two or more classes of instruments are treated as a single class, and

(B) Considered as a single class, holdings of stock and such class are substantially proportionate,

then this section applies to each class beginning at the time of such treatment.

(5) *One class treated as two.* If two portions of a class of instruments are treated differently (e.g., interest in paid on one portion but not on the other), then each portion is treated as a separate class beginning at the time of such treatment.

(6) *Illustrations.* The following examples illustrate the application of this paragraph (a). Except as otherwise provided, all persons in these examples are unrelated.

Example (1). A, B, and C each own 100 shares of common stock in corporation Y. Y

has no other stock of any class outstanding. However, Y does have outstanding subordinated 8-percent debentures in the prinicpal amount of $100,000. A owns $40,000 of the debentures, B owns $30,000, C owns $20,000, and an independent creditor owns the remaining $10,000. Based on these facts, the total overlap factor with respect to the debentures is 83⅓ percent and holdings of the debentures and holdings of stock in Y are thus substantially proportionate. Therefore, this section applies to the debentures held by A, B and C. However, this section does not apply to the debentures held by the independent creditor.

Example (2). A, B, and C each own ⅓ of the common stock of corporation Z. Pursuant to a plan, Z issues $100,000 of 10-year, 8-percent debentures to A, $100,000 of 12-year, 8½-percent debentures to B, and $100,000 of 15-year, 9-percent debentures to C. Based on these facts, upon completion of the plan, the total overlap factor with respect to the debentures is 100 percent and holdings of the debentures and Z's stock are thus substantially proportionate. See paragraph (a) (4) (i) of this section. Therefore this section applies to the debentures.

Example (3). Corporation P owns all the stock of corporations S and T. In addition, S owns 80 percent of a class of debentures issued by T. The other 20 percent of the debentures is owned by an independent creditor. Based on these facts, the total overlap factor with respect to the debentures is 80 percent and holdings of the T stock and debentures are thus substantially proportionate. Therefore, this section applies to the debentures held by S but not to those held by the independent creditor.

Example (4). Corporation V has move than 100,000 shareholders. On January 1, 1990, V issues $10 of debentures on each share of stock as a dividend. The stock and debentures are traded separetely on a national securities exchange. Based on these facts, this section does not apply to the debentures.

Example (5). A owns all 100 shares of stock in Corporation Y. A also owns 50 percent of a class of senior debentures issued by Y, and B owns the remaining 50 percent. In addition, B owns all of a class of junior debentures issued by Y, which are convertible into a total of 100 shares of Y stock. Further, it is reasonable to expect that B may ultimately exercise the conversion privilege. Based on these facts, the total overlap factor with respect to the senior debentures is 100 percent and holdings of stock in Y and the senior debentures are thus treated as substantially proportionate under paragraph (a)(2) of this section. Consequently, this section applies to the senior debentures. However, the total overlap factor with respect to the junior debenture is 50 percent and, therefore, holdings of Y stock and the junior debentures are not substantially proportionate.

Example (6). A owns all 100 shares of stock of corporation U. In addition, B owns $100,000 of convertible debentures issued by U. The debentures are convertible into 1,000 shares of U's common stock. Assume that it is reasonable to expect that B may ultimately exercise the conversion privilege. Based on these facts, B is treatred as owning 1,000 shares of U common stock. Thus, the total overlap factor with respect to the convertible debentures is 90.9 percent and holdings of the convertible debentures and stock in U are thus substantially proportionate. Therefore, this section applies, and the convertible debentures are treated as stock under paragraph (d) of this section (relating to hybrid instruments.)

Example (7). Corporation M is a large manufacturing company whose products are sold through independent dealers. In order to assist individuals who do not have enough capital to become dealers, M has established a dealer investment plan. Pursuant to the dealer investment plan, M and unrelated individual I organize corporation D on January 1, 1982. M transfers $900,000 to D in exchange for 10-percent notes in the principal amount of $500,000 and 400 shares of class A stock. I transfers $100,000 to D in exchange for 1,000 shares of class B stock. The class B stock is nonvoting until all the class A shares are redeemed for $1,000 each. At least 70 percent of D's earnings and profits must be used each year to retire the notes and to redeem the class A stock. I has no control over the redemption of stock and no right to have his stock redeemed while any of the class A stock is outstanding. M's investment will thus be systematically eliminated, and I will become the sole owner of D. Because the plan is akin to a security arrangement and is not intended to give M a meaningful interest in the corporate growth of D, the class A stock is not considered "stock" within the meaning of paragraph (a)(2)(iii) of this section. Therefore, holdings of the stock and notes are not substantially proportionate. Cf. example (14) of § 1.305–3(e). Therefore, this section does not apply to the notes. However, for purposes of section 1232 (relating to original issue discount), the issue price of the notes is equal to their fair market value. See § 1.1232–3(b)(2)(ii) (relating to investment units).

Example (8). Corporation S is a small business investment company operating under the Small Business Investment Act of 1958 (15 U.S.C. 661 and following). Individual J is an electrical engineer. On January 1, 1983, S and J, who are otherwise unrelated, form corportation X to manufacture high technology electrical components. X has a total authorized capital of 2,000 shares of common stock. S transfers $810,000 to X for 9-percent subordinated debentures in the principal amount of $800,000, 100 shares of common stock, and warrants to acquire an additional 900 shares of common stock at $100 a share. Assume it is reasonable to expect that the warrants may be exercised. J transfers $100,000 to X for 1,000 shares of common stock. Based on these facts, the total overlap factor with respect to the subordinated debentures is 50 percent and holdings of the stock and debentures thus are not substantially proportionate. Therefore, this section does not apply to the subordinated debentures. However, for purposes of section 1232 (relating to original issue discount), the issue price of the debentures is equal to their fair market value. See § 1.1232–3(b)(2)(ii) (relating to investment units).

Example (9). Corporation T is a medium-sized supplier of computer software. Individual K is the manager of T's military applications division. On January 1, 1984, K forms corporation Y to acquire the assets of T's military applications division. K transfers $100,000 to Y for all 100 shares of Y's outstanding common stock. In addition, Y obtains financing from the following sources: $2 million from a small business investment company for 8-percent junior subordinated debentures and warrants to acquire 100 shares of common stock, $3 million from an insurance company for 14-percent senior subordinated debentures, and $2,500,000 from a bank for 10-percent secured notes. K is not otherwise related to T, the small business investment company, the insurance company, or the bank. Based on these facts, there is no substantial proportionality between holdings of stock and any class or classes of instruments. Therefore, this section does not apply to any of the instruments. However, for purposes of section 1232 (relating to original issue discount), the issue price of the junior subordinated debentures is equal to their fair market value. See § 1.1232–3(b)(2)(ii) (relating to investment units).

Example (10). A is the sole shareholder of corporation X. On January 1, 1987, X issues $50,000 of class B debentures to A and $50,000 of class B debentures to independent creditor K. Based on these facts, the total overlap factor with respect to the class B debentures is 50 percent and holdings of the X stock and the class B debentures are thus not substantially proportionate. However, on January 1, 1989, A voluntarily subordinates his debentures to K's. Based on these facts, under paragraph (a)(5) of this section, A's debentures are treated as a separate class beginning on January 1, 1989. Thus, this section applies to A's debentures and they may be treated as stock under paragraph (k) of this section (relating to a change in terms). The result would be the same if, on January 1, 1989, X missed an interest payment due on A's debentures, but made the payment on K's debentures. In this event, A's debentures might be treated as stock under paragraph (l) of this section (relating to nonpayment of interest).

Example (11). (a) A and B each own 50 percent of the stock of corporation Z, a calendar year taxpayer. Pursuant to a plan, Z issues $100,000 of class A convertible debentures to A on January 1, 1983 and issues $100,000 of class B convertible debentures to B on January 1, 1985. Based on these facts, the two classes of debentures are considered together. Therefore, holdings of the debentures and the stock are substantially proportionate and each class of debentures is treated as stock upon issuance under paragraph (d) of this section (relating to hybrid instruments issued proprtionately).

(b) The facts are the same as in paragraph (a) of this example except that the two classes of debentures are not issued pursuant to a plan. Based on these facts, this section does not apply to either class of debentures upon their issuance.

(c) The facts are the same as in paragraph (b) of this example except that Z fails to pay interest on the debentures accrued during 1989. Based on these facts, the two classes of debentures are treated as one class as of January 1, 1989 and the debentures may be treated as stock under paragraph (l) of this section (relating to nonpayment of interest). See paragraph (a)(4)(ii) of this section.

Example (12). E owns all of the common stock of corporation X. In addition, F owns all of the preferred stock of X. The preferred stock is an 8 percent nonparticipating, nonconvertible, nonvoting preferred stock. Further, E owns a class of debentures issued by X. Based on these facts, this preferred stock is not treated as stock for purposes of determining proportionality and, accordingly, the total overlap factor with respect to the debentures is 100 percent. Therefore, holdings of the X stock and debentures are substantially proportionate and, thus, this section applies to the debentures. However, if F owned all of the debentures, the total overlap factor with respect to the debentures would be zero and this section would not apply.

(7) *Special rule.* (i) If, pursuant to an agreement or arrangement—

(A) The terms of an instrument issued to a shareholder are not fixed at arm's length or the instrument is not enforced according to its terms, and

(B) There are related, compensating non-arm's length transactions,

then the Commissioner may treat holdings of the instrument and the corporation's stock as substantially proportionate.

(ii) The following examples illustrate the application of this subparagraph (7):

Example (1). A and B each own 50 percent of the common stock of corporation X. On January 1, 1985, A lends $500,000 to X in exchange for a 10-year 10-percent $500,000 note. B is the general manager of X. During 1987, pursuant to an arrangement between A and B, X does not pay the $50,000 of interest on A's note and X pays B $50,000 less compensation than he would be entitled to under B's employment contract with X. Based on these facts, holdings of X's stock and the note will be treated as substantially proportionate. Therefore, this section applies to the note and the note may be reclassified as stock under paragraph (l) of this section (relating to nonpayment of interest).

Example (2). C and D each own 50 percent of the stock of corporation Y. On January 1, 1987, C leases a townhouse to Y for a ten-year term. Y agrees to pay an annual rent of $10,000 and additional rent equal to 20 percent of the net annual rentals from the townhouse. Also on January 1, 1987, as part of the same arrangement, D lends $100,000 to Y in exchange for a 10-year debenture. Ten percent annual interest is payable on the debenture. In addition, the holder of the debenture is entitled to contingent annual interest equal to 20 percent of the net annual rentals from the townhouse. Based on these facts, holdings of the debenture and Y's stock shall be treated as substantially proportionate. Accordingly, the debenture will be treated as stock under paragraph (d) of this section (relating to hybrid instruments issued proportionately).

(b) *Independent creditor*—(1) *In general.* For purposes of the regulations under section 385, all relevant facts and circumstances must be taken into account in determining whether a creditor is independent. Relevant factors that may be taken into account include (but are not limited to) the following:

(i) Whether the creditor has stock holdings (direct or attributable) in the issuing corporation and, if so, the size of such holdings;

(ii) Whether the creditor has a relationship with the corporation other than that of a creditor, e.g., as an employee, supplier, or customer; and

(iii) Whether the creditor is related to the individual shareholders of the issuing corporation or of a corporation related to the issuing corporation, including (but not limited to) the relationships described in section 318(a).

(2) *Safe harbor.* In applying this section to a class of instruments issued by a corporation, a creditor is deemed to be independent if—

(i) The creditor does not own, directly or by attribution under the constructive ownership rules of section 318(a), as modified by paragraph (b)(3) of this section, at least 5 percent of the total combined voting power of all classes of stock entitled to vote or at least 5 percent of the total value of shares of all classes of the corporation's stock;

(ii) The creditor does not own, directly or by attribution under the constructive ownership rules of section 318(a) as modified by paragraph (b)(3) of this section, at least 5 percent of the stock owned by the corporation; and

(iii) the creditor's (actual or constructive) percentage ownership of the class of instruments is at least twice as great as the greater of the creditor's (actual or constructive) percentage ownership of (A) the total combined voting power of all classes of stock entitled to vote or (B) the total value of shares of all classes of the corporation's stock.

(3) *Constructive ownership.* For purposes of subparagraph (2) of this paragraph (b), the attribution rules of section 318(a) shall be applied with the following modifications—

(i) For purposes of section 318(a)(1)(ii), an individual shall also be considered to own stock or instruments owned, directly or indirectly, by for his or her brothers and sisters (whether by the whole or half blood);

(ii) Section 318(a)(2)(C) shall be applied without regard to the 50 percent minimum percentage ownership requirement;

(iii) Section 318(a)(3)(C) shall be applied by substituting "5 percent" for "50 percent"; and

(iv) In determining whether any person owns 5 percent or more of the stock of a corporation, stock constructively owned under section 318(a)(4) (relating to options) by a person whose interests in the corporation would not be attributed under section 318(a) to the person whose interests are being tested is not taken into account.

(4) *Illustrations.* The following examples illustrate the application of this paragraph (b):

Example (1). Individual C owns (actually or under the constructive ownership rules of section 318(a) as modified by paragraph (b)(3) of this section) 5 percent or more in value of the stock of corporation Y. Based on these facts, C does not satisfy the conditions of either paragraph (b)(2)(i) or paragraph (b)(2)(ii) of this section. Consequently, C does not come within the safe harbor of paragraph (b)(2) of this section with respect to instruments issued by Y.

Example (2). Individual A owns all 100 outstanding shares of stock and an option to acquire an additional 1,000 shares of stock in corporation X. Individual B owns an option to acquire 10 shares of stock in X. Applying the constructive ownership rules of section 318(a) as modified by paragraph (b)(3) of this section, B is considered to own 10 out of 110 outstanding shares of stock in X. Therefore, B does not come within the safe harbor of paragraph (b)(2) of this section. The result would be the same if the option owned by B were owned by B's spouse.

Example (3). Corporation Y obtains a $100,000 loan from C, an unrelated commercial bank. As a condition for making a loan, C obtains the right to designate one of Y's directors. Based on these facts, C is an independent creditor of Y.

Example (4). Individual E owns 97 percent of the only class of stock of corporation Z, and unrelated individual F owns the remaining 3 percent. In addition, E owns 96.2 percent of a class of debentures issued by Z, and F owns the remaining 3.8 percent. Because F's percentage ownership of the class of debentures is not at least twice as great as F's percentage ownership of the Z stock, F does not come within the safe harbor of paragraph (b)(2) of this section.

(c) *Excessive or inadequate consideration*—(1) *Excessive consideration.* If, immediately after an instrument is issued by a corporation, this section applies to the instrument and the instrument is treated as indebtedness, then the excess of—

(i) The consideration paid, over

(ii) The fair market value of the instrument, is treated as not paid in exchange for the instrument. Ordinarily, such excess is treated as a contribution to capital. However, under appropriate

circumstances, it may be treated as a gift followed by a capital contribution or as compensation for services or as otherwise determined under general principles of tax law.

(2) *Inadequate consideration.* If, immediately after an instrument is issued by a corporation, this section applies to the instrument and the instrument is treated as indebtedness, then the excess of—

(i) The fair market value of the instrument, over

(ii) the consideration paid, is treated as not transferred in exchange for the consideration paid. Ordinarily, such excess is treated as a distribution to which section 301 applies. See § 1.301–1(d), (j) and (k). However, under appropriate circumstances, it may be treated as a distribution to which section 301 applies followed by a gift or as compensation for services or as otherwise determined under general principles of tax law.

(3) *Consequences if instrument treated as stock.* If, immediately after an instrument is issued by a corporation the instrument is treated as stock, then the treatment of amounts described in paragraphs (c) (1) and (2) of this section shall be determined outside the regulations under section 385.

(4) *Illustrations.* The following examples illustrate the application of this paragraph (c) and related provisions:

Example (1). Corporation S is organized in 1985 for the purpose of constructing, owning, and operating a professional office building. Fifteen persons, all medical doctors, subscribe for the capital stock of S at $100 a share. On January 1, 1988, the doctors agree to advance $300 to S for each share of stock subscribed. These advances are represented by 19-year, 7-percent debentures in the principal amount of $300 each. Assume that the debentures are treated as indebtedness under § 1.385–4(a) (relating to instruments generally), and that the fair market value of each debenture is $246. Based on these facts, $54 of each $300 advance is treated as a contribution to capital. Therefore, the doctors' basis in each debenture is $246, and there is an original issue discount of $54 on each debenture. See section 1232.

Example (2). The facts are the same as in example (1), except that the doctors pay $200 for each debenture. Based on these facts, the doctors are treated as receiving a $46 distribution to which section 301 applies on each share of stock. Therefore, the doctors' basis in each debenture is $246 (see § 1.301–1(j)), and there is an original issue discount of $54 on each debenture.

Example (3). The facts are the same as in example (1), except that the debentures bear interest at 9 percent a year. Assume that the fair market value of each 9-percent debenture is $300. Based on these facts, the doctors are not treated as making a contribution to capital or as receiving a distribution to which section 301 applies. Therefore, the doctors' basis in each debenture is $300, and there is no original issue discount on the debentures.

Example (4). The facts are the same as in example (1), except that S issues the debentures together with the capital stock in 1985, and the doctors pay $400 for each unit consisting of one debenture and one share of stock. Based on these facts, the doctors' basis in each debenture is $246 (see § 1.1012–1(d)), their basis in each share of stock is $154, and the original issue discount on each debenture is $54 (see § 1.1232–3(b)(2)(ii)).

Example (5). Individuals A and B each own ½ the common stock of corporation M, which is the only class of stock outstanding. On January 1, 1983, M issues two 12-percent $1,000 notes, one to A and one to B, each for $1,000 in cash. Assume that the fair market value of each note is $1,250 and that the notes are treated as indebtedness under § 1.385–4(a) (relating to instruments generally). Based on these facts, on January 1, 1983, A and B each receive a $250 distribution to which section 301 applies. Thus, each note has a basis of $1,250 and is issued at a premium of $250 (see section 171(b), § 1.171–3(d) and § 1.61–12(c)(2)).

(d) *Hybrid instruments*—(1) *In general.* If this section applies to a hybrid instrument immediately after it is issued, then, except as provided in paragraph (d)(2) of this section, the instrument is treated as stock.

(2) *Exception.* If, immediately after a class of hybrid instruments is issued, independent creditors (determined without regard to paragraph (b)(2) of this section and without taking into account the creditor's holdings of the hybrid instrument at issue) own at least 20 percent of the class, then paragraph (d)(1) of this section does not apply to the class. However, even if the exception provided by this paragraph (d)(2)(ii) applies to a class of hybrid instruments, the instruments remain subject to § 1.385–5 and (except for the instruments held by independent creditors) remain subject to paragraphs (k), (l), and (m) of this section.

(3) *Hybrid instrument.* For the definition of the term "hybrid instrument," see § 1.385–3(d).

(4) *Illustration.* The following example illustrates the application of this paragraph (d):

Example. Corporation X's only outstanding stock is 100 shares of common stock. Individual A owns 40 shares, individual B owns 30 shares, and individual C owns 30 shares. On January 1, 1990, X issues $100,000 of convertible debentures. Sixty thousand dollars of the convertible debentures are issued to A, $25,000 are issued to B, and the remaining $15,000 are issued to C. Based on these facts, the convertible debentures are treated as stock.

(e) *Instruments not issued for money*—(1) *In general.* An instrument issued by a corporation is treated as stock if—

(i) This section applies to the instrument immediately after it is issued,

(ii) The stated annual rate of interest on the instrument is not reasonable (within the meaning of paragraph (f) of this section), and

(iii) The issuance of the instrument does not give rise to original issue discount under section 1232(a)(3) or amortizable bond premium under § 1.61–12(c)(2).

(2) *Special rule.* For purposes of this paragraph (e), the reasonableness of a rate of interest is determined on the day an instrument is issued.

(3) *Exception.* (i) This paragraph (e) does not apply to an instrument that is issued in exchange for an equal or greater principal amount of indebtedness of the issuing corporation if—

(A) An independent creditor holding the outstanding indebtedness would, in the exercise of ordinary diligence, have agreed to the exchange, and

(B) The issuing corporation would, in the exercise of ordinary diligence, have agreed to make the exchange with an independent creditor holding the outstanding indebtedness.

(ii) For purposes of subdivision (i) of this subparagraph (3), the principal amount of indebtedness includes interest accrued but unpaid up until the date of the exchange, but only to the extent that such interest is paid with principal in the exchange.

(4) *Illustrations.* The following examples illustrate the application of this paragraph (e):

Example (1). J organizes corporation W on December 10, 1985 to operate a distributorship of radios, television sets, and other types of electrical appliances. On the same day, J transfers certain franchises, and other assets to W in exchange for all of W's capital stock and $100,000 of 10-year, 9-percent debenture bonds. Assume that on December 10, 1985, 9 percent is not a reasonable rate of interest (within the meaning of paragraph (f) of this section). Based on these facts, the debenture bonds are treated as stock.

Example (2). Corporation X operates a wholesale electrical supply business. In the course of a recapitalization on December 30, 1990, X issues 2,100 of new class B debentures (the entire class) to L in exchange for X common stock. Immediately after the recapitalization, L holds 90 percent of the common stock of X. The principal amount of each class B debenture is $100, and each debenture pays $50 a year in interest. Assume that on December 30, 1990, 50 percent is not a reasonable rate of interest (within the meaning of paragraph (f) of this section). Based on these facts, the class B debentures issued to L are treated as stock.

Example (3). On January 1, 1987, individuals A, B and C transfer a tract of undeveloped land and $4,500 in cash to newly formed corporation X. In exchange, each receives 100 shares of stock and a 2-year, 10-percent promissory note for $110,000. Assume that 10 percent is not a reasonable rate of interest (within the meaning of paragraph (f) of this section). Based on these facts, the promissory notes are treated as stock for all purposes of the Internal Revenue Code. In particular, the notes are not treated as "other property" within the meaning of section 351(b). Thus, no gain or loss is recognized on the transfer of the land to X (see section 351), and X's basis in the land is the same as it was in the hands of A, B, and C (see section 362(a)(1)).

Example (4). B is the sole shareholder of corporation Y. On January 1, 1990, Y issues a $30,000, 10 percent note to B in exchange for $30,000. The note is due on January 1, 2000 and is treated as indebtedness under § 1.385–4(a). Interest on the note is paid according to its terms through 1999. During 1999, Y encounters business difficulties. On December 11, 1999, Y issues a new note to B in exchange for the outstanding note. The terms of the new note are identical to those of the outstanding note except that the new note is due on January 1, 2002 and is subordinated to a new bank loan being made at the time of the exchange. Assume that an independent creditor holding the outstanding note would, in the exercise of ordinary diligence, have agreed to exchange the outstanding note for the new note. Assume also that Y would, in the exercise of ordinary diligence, have agreed to the exchange even if the outstanding note were held by an independent creditor. Based on these facts, the exception of paragraph (e)(3) of this section applies and, therefore, this paragraph (e) does apply to the new note. However, the new note is subject to paragraphs (k), (l), and (m) of this section.

(f) *Reasonable rate of interest*—(1) *In general.* The annual rate of interest on an instrument issued by a corporation is reasonable if it is within the normal range of rates paid to independent creditors (determined without regard to paragraph (b)(2) of this section) on similar instruments by corporations of the same general size and in the same general industry, geographic location, and financial condition on the date the determination is made. In no event will the rate of interest on an instrument (other than an instrument to which paragraph (f)(2) of this section applies) be considered reasonable for purposes of this paragraph (f)(1) if it is less than the rate determined by the Secretary pursuant to paragraph (f)(2)(i)(A) of this section for instruments of comparable maturity.

(2) *Rule of convenience.* For purposes of the regulations under section 385, an annual rate of interest on an instrument is considered to be reasonable if—

(i) On the date the determination is made, (A) it is equal to the rate in effect under section 6621, the prime rate in effect at any local commercial bank (or a rate two points above such rate), either of the end points of the range of rates set forth in § 1.482–2(a)(2)(iii)(B)(1), or a rate determined from time to time by the Secretary taking into consideration the average yield on outstanding marketable obligations of the United States of comparable maturity or (B) it is in between any two of the rates described in subdivision (A) of this subdivision (i), and

(ii) At the end of the taxable year in which the determination is made, the debt-to-equity ratio of the issuing corporation is not greater than 3:1. For rules relating to the computation of the debt-to-equity ratio, see paragraphs (h) and (j) this section.

(3) *Exception.* Paragraph (f)(2) of this section does not apply to an instrument that evidences a nonrecourse liability.

(4) *Local commercial bank.* The term "local commercial bank" includes any commercial bank at which the issuing corporation ordinarily does business.

(5) *Illustrations.* The following examples illustrate the application of this paragraph (f):

Example (1). Individual A is the sole shareholder of corporation X. On January 1, 1990, A lends $100,000 to X in exchange for a 10 percent note. At about the same time, a local commercial bank lends $100,000 to X in exchange for a 10-percent note with approximately the same terms. The bank loan is personally guaranteed by A. However, the guarantee is required pursuant to the bank's normal lending practice as a substitute for detailed covenants, and the bank loan was made principally on X's credit (and not A's). Based on these facts, 10 percent is a reasonable rate of interest.

Example (2). A is the sole shareholder of corporation X. On July 1, 1989, A lends $100,000 to X in exchange for a 10-year note bearing annual interest at 10 percent. On December 31, 1989, X's debt-to-equity ratio, computed in accordance with the principles of paragraphs (h) and (j) of this section, is 3:1. On July 1, 1989, the section 6621 rate is 12 percent; the prime rate is 14 percent; the endpoints of the range of rates set forth in § 1.482–2(a)(2)(iii)(B)(*1*) are 11 percent and 13 percent and the rate determined by the Secretary for 10-year instruments taking into consideration the average yield on outstanding U.S. obligations of comparable maturity is 10 percent. Based on these facts, the rate of interest on the note is considered to be reasonable.

(6) *Cross-reference.* For circumstances where the Commissioner may disregard a noncommercial term of an instrument in determining a reasonable interest rate, see § 1.385–3(a)(1)(iii).

(g) *Excessive debt*—(1) *In general.* If, immediately after an instrument is issued by a corporation—

(i) This section applies to the instrument, and

(ii) The corporation's debt is excessive, then the instrument is treated as stock.

(2) *Excessive debt.* The corporation's debt is "excessive" if (i) all of the instrument's terms and conditions (including the stated interest rate), considered as a whole, and (ii) the corporation's financial structure, taken together, would not be satisfactory to an independent creditor (determined without regard to paragraph (b)(2) of this section). For this purpose, the corporation's size, industry, geographic location, and financial condition must be taken into account. Also, for this purpose, the stated interest rate will be considered satisfactory to an independent creditor if an interest rate one point higher or one point lower than the stated interest rate would be satisfactory to such creditor.

(3) *Safe harbor.* Notwithstanding paragraph (g)(1) of this section, a corporation's debt is not excessive if—

(i) The corporation's outside ratio is less than or equal to 10:1, and

(ii) The corporation's inside ratio is less than or equal to 3:1.

(4) *Ratios.* The corporation's outside ratio is the debt-to-equity ratio determined under paragraphs (h) and (j) of this section. Its inside ratio is determined in the same manner by excluding liabilities to independent creditors (except in computing stockholders' equity). Both ratios are determined at the end of the taxable year in which the instrument is issued.

(5) *Exception.* This paragraph (g) does not apply to instruments issued in exchange for an equal or greater principal amount of indebtedness. For purposes of the preceding sentence, the prinicpal amount of indebtedness includes interest accrued but unpaid up until the date of the exchange, but only to the extent that such interest is paid with principal in the exchange.

(6) *Illustrations.* The following example illustrates the application of this paragraph (g):

Example. Individual B forms corporation Y on December 31, 1982. Y uses the calendar year as the taxable year. On December 31, 1982, Y acquires rental property from an unrelated third party for $100,000. It obtains the $100,000 from the following sources: $10,000 from B for common stock, $10,000 from C on a second mortgage note, and $80,000 from D on a first mortgage note. Assume that C and D are B's father and mother. Also assume that the terms and conditions of the mortgage notes and Y's financial structure would be satisfactory to an unrelated commercial bank. Based on these facts, the mortgage notes are not treated as stock under this paragraph (g).

(h) *Debt-to-equity ratio.* The following rules apply for purposes of the regulations under section 385:

(1) *In general.* The debt-to-equity ratio of a corporation is the ratio that—

(i) The corporation's liabilities (excluding trade accounts payable, accrued operating expenses and taxes, and other similar items) bears to

(ii) The stockholders' equity.

(2) *Stockholders' equity.* The stockholders' equity in a corporation is the excess of—

(i) The adjusted basis of its assets (less reserves for bad debts, if applicable, and other similar asset offsets) over

(ii) Its liabilities (including liabilities excluded under paragraph (h)(1)(i) of this section).

(3) *Operating rules.* Except as provided in paragraph (h)(6) of this section, the adjusted basis of a corporation's assets and the amount of its liabilities are determined—

(i) In accordance with the tax accounting principles properly used by the corporation in determining taxable income; and

(ii) Without regard to the treatment of any interest as stock or indebtedness by reason of section 385.

(4) *Coordination with excessive or inadequate consideration rules.* For purposes of meeting the requirements of paragraph (f)(2) of this section (relating to the interest rate rule of convenience) and the requirements of paragraph (g)(3) of this section (relating to the excessive debt safe harbor), the debt-to-equity ratio of the corporation will be determined without application of the provisions of paragraph (c) of this section.

(5) *Illustrations.* The following examples illustrate the application of paragraph (h) (1)–(4) of this section:

Example (1). On December 31, 1990, corporation M has assets with an adjusted basis of $150,000 and liabilities of $100,000. The stockholder's equity in M is $50,000 (i.e., $150,000—$100,000). Assume that M has no trade accounts payable, accrued taxes and operating expenses, etc., and that the special rules in paragraph (h)(6) of this section do not apply. Based on these facts, the debt-to-equity ratio of corporation M on December 31, 1990 is 2:1 (i.e., $100,000:$50,000).

Example (2). On December 31, 1990, corporation N has assets with an adjusted basis of $150,000. In addition, N has liabilities of $100,000, including $30,000 of trade accounts payable, accrued taxes and operating expenses, etc. The stockholders' equity in N is $50,000 (i.e., $150,000—$100,000). Assume that the special rules in paragraph (h)(6) of this section do not apply. Based on these facts, N has a debt-to-equity ratio on December 31, 1990 of 7:5 (i.e., $70,000:$50,000).

(6) *Special rules.* (i)(A) In computing the adjusted basis of property of a character subject to the allowance for depreciation for purposes of this section, the deductions for depreciation shall be determined in the same manner as under section 312(k) for purposes of computing earnings and profits.

(B) The following example illustrates the application of this subdivision (i):

Example. Corporation X purchases a new machine for $240,000 and places it in service on January 1, 1983. Assume the machine is "5-year property" within the meaning of section 168(c)(2)(B). Also assume that, under section 312(k)(3)(A), the adjustment to earnings and profits for depreciation with respect to the machine is computed under the straight-line method using a half-year convention and no salvage value and using a recovery period of 12 years. Based on these facts, for purposes of computing X's debt-to-equity ratio on December 31, 1984, X is treated as having an adjusted basis of $210,000 in the machine (240,000—(3/24) (240,000)).

(ii) In the case of a corporation that uses the cash method of accounting, the adjusted basis of trade accounts receivable shall be deemed to be equal to the face amount of the receivables (less an appropriate reserve for uncollectibles).

(iii)(A) In determining the debt-to-equity ratio of a corporation at the end of a taxable year, the stockholders' equity shall be increased by the amount of any net operating loss (determined without regard to sections 1211(a) and 1212) sustained by the corporation during the taxable year.

(B) The following example illustrates the application of this subdivision (iii):

Example. On January 1, 1985, individual A organizes corporation T and transfers $100,000 to it for $50,000 of stock and a $50,000 note. At the end of T's first taxable year, T has assets with an adjusted basis of $120,000 and liabilities of $480,000 including $30,000 of trade accounts payable, accrued taxes and operating expenses, etc. T also has a net operating loss (determined without regard to sections 1211(a) and 1212) for the taxable year of $10,000. Based on these facts, T's stockholders' equity at the end of the taxable year is $50,000 (i.e., ($120,000—$80,000)+$10,000). Consequently, T's debt-to-equity ratio is 1:1 (i.e., $50,000:$50,000).

(iv) In determining the debt-to-equity ratio of a corporation that is a bank (as defined in section 581) or is primarily engaged in a lending or finance business (as defined in sections 279(c)(5)), adjustments shall be made in accordance with the principles of section 279(c)(5)(A).

(v) In determining the debt-to-equity ratio of an insurance company (as defined in § 1.801–1(b)), insurance reserves shall be treated in the same manner as trade accounts payable.

(vi) A liability is treated in the same manner as a trade account payable if it is—

(A) Incurred under a commercial financing agreement (such as an automobile "floorplan" agreement) to buy an item of inventory,

(B) Secured by the item, and

(C) Due on (or before) sale of the item.

(vii)(A) The debt-to-equity ratio shall be computed without regard to distortions created by a temporary contribution to equity or any similar contrivance.

(B) The following example illustrates the application of this subdivision (vii):

Example. Individual A organizes corporation X on December 31, 1985. X uses the calendar year as the taxable year. A contributes $100,000 in cash and property with a basis of $40,000 to X in exchange for 1,000 shares of common stock and a 10-percent note worth $40,000. On January 4, 1986, X redeems 900 shares of stock for $90,000 in cash. Based on these facts, X's debt-to-equity ratio on December 31, 1985 is determined by not treating the $90,000 paid in redemption of stock on January 4, 1986 as an asset of X. Therefore, the debt-to-equity ratio is 4:1 (i.e., $40,000:$10,000).

(viii) In determining the debt-to-equity ratio of a cooperative, interests described in § 1.385–1(b)(2) will be treated as equity except that, if a cooperative treats such an interest as a liability for financial reporting purposes, that interest is treated in the same manner as a trade account payable.

(i) [Reserved]

(j) *Affiliated groups*—(1) *In general.* For purposes of the regulations under section 385, the debt-to-equity ratio of a member of an affiliated group of corporations is determined in accordance with paragraph (h) of this section and this paragraph (j)(1). For purposes of this paragraph (j), the term "affiliated group of corporations" will have the same meaning as in section 1504(a) except that no exclusions will be made under section 1504(b). If one includible corporation ("X") owns stock in another includible corporation ("Y"), then X's debt-to-equity ratio is determined as follows:

(i) X is treated as having a ratable share of Y's assets and liabilities. This ratable share is determined by dividing—

(A) The fair market value of the Y stock owned by X, by

(B) The fair market value of all of Y's stock.

(ii) X's investments in Y and Y's liabilities to X are eliminated. In addition, any other duplication in the

amount of X's money and other assets and liabilities resulting from the application of this subparagraph (l) (for example, resulting from Y's ownership of stock in X) is eliminated.

(2) *Illustrations.* The following examples illustrate the application of this paragraph (j):

Example (1). Corporations P and S–1 comprise an affiliated group, P owning all the stock of S–1. On December 31, 1985, P's only asset is stock in S–1, and P has no liabilities. In addition, S–1 has assets with an adjusted basis of $200,000 and liabilities of $150,000. Assume that S–1 has no trade accounts payable, accrued taxes and operating expenses, etc. and that the special rules in paragraph (h)(6) of this section do not apply. Based on these facts, P is treated as having assets with an adjusted basis of $200,000 and liabilities of $150,000. Therefore, P's debt-to-equity ratio is 3:1 (i.e., $150,000:$50,000).

Example (2). The facts are the same as in example (1), except that S–1's liabilities include a $50,000 note payable to P and P's assets consist of this note and the S–1 stock. Eliminating this note, S–1's liabilities are only $100,000. Based on these facts, P is treated as having liabilities of $100,000 and assets with an adjusted basis of $200,000. Therefore, P's debt-to-equity ratio is 1:1 (i.e., $100,000:$100,000).

Example (3). (a) The facts are the same as in example (1), except that S–1's assets include 80 percent of the only class of stock of corporation S–2, which also is a member of the affiliated group. S–1's adjusted basis in the stock of S–2 is $15,000. In addition, S–2 has assets with an adjusted basis of $50,000 and no liabilities.

(b) Based on these facts, S–1 is treated as having $40,000 (i.e., 80 percent of $50,000) of S–2's assets instead of the S–2 stock. Therefore, S–1 is treated as having assets with an adjusted basis of $225,000 and liabilities of $150,000. This S–1's debt-to-equity ratio is 2:1 (i.e., $150,000:$75,000). P's debt-to-equity ratio is also 2:1.

Example (4). Corporations W, X, Y, and Z comprise an affiliated groups. W owns all of the stock of X and X owns all of the stock of each of Y and Z. In addition ot the stock of Y and Z, X has assets with an adjusted basis of $100 and no liabilities. Y has assets with an adjusted basis of $800 and liabilities of $700. These liabilities include a liability of $200 to W and a liability of $100 to Z. Z has, in addition to its obligation from Y, assets with an adjusted basis of $300 and liabilities of $200. Assume that X, Y, and Z have no trade accounts payable, accrued taxes and operating expenses, etc. and that the special rules in paragraph (h)(6) of this section do not apply. Based on these facts, for the purpose of computing X's debt-to-equity ratio, X is teated as having Y's assets with an adjusted basis of $800 and Y's liabilities of $600 (the liability of Y to Z is eliminated for this purpose but the liability to W is not). Also, for this purpose, X is treated as having Z's assets with an adjusted basis of $300 and Z's liabilities of $200 (Z's obligation from Y is eliminated for this purpose). Therefore, X is treated as having assets with an adjusted basis of $1,200 and liabilities of $800 and X's debt-to-equity ratio is 2:1.

(k) *Change in terms*—(1) *In general.* If—

(i) The holder agress to postpone the maturity date or otherwise to make a substantial change in the terms of an instrument,

(ii) the instrument is treated as indebtedness under the regulations under section 385, and

(iii) This section applies to the instrument on the day of agreement.

then (for purposes of the regulations under section 385) the instrument is treated as newly issued in exchange for property on the day of agreement. Thus, beginning on the day of agreement the instrument may be treated as stock under paragraph (d) of this section (relating to hybrid instruments), paragraph (e) of this section (relating to certain instruments not issued for money) or paragraph (m) of this section (relating to instruments payable on demand). However, paragraph (g) of this section (relating to excessive debt) does not apply unless there is an increase in the principal amount of the instrument within the meaning of paragraph (g)(5) of this section.

(2) *Substantial.* For purposes of this paragraph (k), each change in the terms of an instrument is substantial if the fair market value of the instrument could be materially affected by that change. Thus, for example, subordination (however effected or a change in interest rate is ordinarily a substantial change. On the other hand, a mere substitution of collateral need not be a substantial change. In addition, prepayment will not be considered a substantial change in terms.)

(3) *Day of agreement.* For purposes of this paragraph (k), the "day of agreement" is the day the issuer and the holder enter into a binding contract to change the terms of an instrument.

(4) *Illustrations.* The following examples illustrate the application of this paragraph (k):

Example (1). A is the sole shareholder of corporation X. On January 1, 1990, X issues a $10,000, 9-percent note to A for $10,000 in cash. The note is due on January 1, 2000, and is treated as indebtedness under § 1.385–4(a). However, on December 10, 1999, A and X agree to extend the maturity of the note until January 1, 2015. Assume that under the terms of the agreement the note will continue to pay 9-percent interest, and that on December 10, 1999, 9-percent is not a reasonable rate of interest (within the meaning of paragraph (f) of this section) for a note due on January 1, 2015. Also assume that an independent creditor holding the note would not, in the exercise of ordinary diligence, have agreed to the extension of maturity and that, therefore, the exception of paragraph (e)(3) of this section is not applicable. Based on these facts, the note would be treated as stock under paragraph (e) of this section if it were newly issued in exchange for property on December 10, 1999. Therefore, the note is reclassified as stock on December 10, 1999.

Example (2). A is the sole shareholder of corporation X. X issues a $20,000, 10-percent note to A for $20,000 in cash on January 1, 2005. The note is due on January 1, 2007, and is treated as indebtedness under § 1.385–4(a). On December 10, 2005, A and X agree to extend the maturity of the note until January 1, 2037, and to increase the interest rate from 10 to 11 percent. For purposes of this paragraph (k), both changes in terms made on December 10, 2005 are substantial because both could materially affect the fair market value of the note. The result is the same even if the two changes are mutually offsetting in the sense that, taken together, they have no material effect on the fair market value of the note.

Example (3). B is the sole shareholder of corporation Y. On January 1, 1990, Y issues a $30,000, 10-percent note to B in exchange for $30,000. The note is due on January 1, 2000 and is treated as indebtedness under § 1.385–4(a). Interest on the note is paid according to its terms through 1999. During 1999, Y encounters business difficulties. On December 11, 1999, B agrees to extend the note until January 1, 2002 and also agrees to subordinate the note to a new bank loan being made at this time. Based on these facts, the note is treated (for purposes of the regulations under section 385) as newly issued in exchange for an equal principal amount of indebtedness. Assume that an independent. Assume that an independent creditor holding the note would, in the exercise of ordinary diligence, have agreed to both the extension of maturity and the subordination to the new bank loan. Assume also that Y would, in the exercise of ordinary diligence, have agreed to the extension and the subordination even if the note were held by an independent creditor. Based on these additional facts, the note continues to be treated as indebtedness notwithstanding the extension of maturity and the subordination to the new bank loan. See paragraph (e)(3) and example (4) of paragraph (e)(4) of this section. However, the note continues to be subject to this paragraph (k) and to paragraphs (l) and (m) of this section.

(l) *Nonpayment of interest*—(1) *In general.* If—

(i) A corporation fails to pay all or part of the interest due and payable on an instrument during a taxable year,

(ii) This section applies to the instrument on the last day of the taxable year, and

(iii) The owner of the instrument fails to exercise the ordinary diligence of an independent creditor,

then the instrument is treated as stock beginning on the later of the first day of the taxable year during which the failure to pay occurs or the first day on which this section applied to the instrument.

(2) *Illustrations.* The following examples illustrate the application of paragraph (l)(1) of this section:

Example (1). N is the sole shareholder of corporation Y. On January 1, 1986, Y issues $100,000 of 10-year, 10-percent debentures. Interest on the debentures is payable semiannually. Eighty thousand dollars of the debentures are issued to N and are treated as indebtedness under § 1.385–4(a). The remaining debentures are issued to independent creditors. Y pays all interest accrued on the debentures semiannually until 1991. Because of adverse business conditions, Y does not pay the interest accrued in 1991 on either the debentures held by N or the debentures held by the independent creditors. Both N and the independent creditors decide not to bring suit against Y in the hope that conditions will improve and that Y will be able to meet its obligations. Based on these facts, the debentures held by N continue to be treated as indebtedness because N has not failed to exercise the ordinary diligence of an independent creditor.

Example (2). (a) M is the sole shareholder of X, a corporation that uses the calendar year as the taxable year. On January 1, 1985, X issues $100,000 of 10-year, 9-percent debentures. Interest on the debentures is payable semiannually. Ten thousands dollars of the debentures are issued to M and are treated as indebtedness under § 1.385–4(a). The remaining debentures are issued to independent creditors. X pays all interest accrued on the debentures semiannually until 1990. Because of adverse business conditions, X does not pay the interest accrued in 1990 on the debentures held by M. However, X continues to pay interest on the debentures held by the independent creditors. Based on these facts, the debentures held by M are treated as a separate class of instruments beginning on January 1, 1990. See paragraph (a)(5) of this section. Since the debentures held by M are treated as a separate class of instruments, the holdings of M's debentures and the stock of X are substantially proportionate as of January 1, 1990.

(b) M has failed to take the steps that a reasonably diligent independent creditor would take to secure payment of interest. Based on these facts, the debentures held by M are treated as stock beginning on January 1, 1990. However, the debentures held by the independent creditors are not affected.

Example (3). L owns 80 percent of the stock of Z, a coporation that uses the calendar year as the taxable year. On January 1, 1985, Z issues $200,000 of 10-year, 10-percent unsecured notes to L. Interest on the notes is payable semiannually. Z pays all interest accrued on the notes semiannually until 1990. Because of adverse business conditions, Z does not pay the interest accrued in 1990 on the notes. On February 1, 1991, L agrees to postpone $10,000 of the interest accrued in 1990 until the notes mature on January 1, 1995. In addition, Z agrees to pledge certain collateral as security for the debentures. Taking into account Z's prior record of paying all interest accrued until 1990, the pledge of collateral, and all other relevant facts and circumstances, it is assumed that L has exercised the ordinary diligence of an independent creditor. Based on these facts, the notes continue to be treated as indebtedness.

(3) *Failure to pay interest.* For purposes of this section, a corporation fails to pay interest on an instrument during a taxable year of the corporation if the interest is not actually paid within 90 days after the end of such taxable year. For this purpose, payment of interest with property other than money will be considered actual payment, but only to the extent such property is includible in the income of the holder of the instrument. For example, payment of interest with a note will be considered actual payment, but only to the extent the note is includible in the income of the holder of the note. For this prupose, property is considered to be includible in the income of a tax-exempt entity (e.g., a charitable organization) if it would be includible if the entity were not tax-exempt.

(4) *Special rule.* (i) For purposes of this paragraph (l), interest accrued while this section does not apply to the instrument is disregarded.

(ii) The following example illustrates the application of this subparagraph (4):

Example. Individual A owns all the stock of X, a corporation that uses the calendar year as the taxable year. On January 1, 1983, X issues $10,000 of 8-percent debentures to B, an independent creditor. The debentures are treated as indebtedness under § 1.385–4(a) (relating to instruments generally). Interest on the debentures is payable semiannually on January 1 and July 1 of each year. X fails to make the $400 payment of interst due on July 1, 1986, and A then buys the debentures from B. X actually pays the $400 interest due on January 1, 1987, but A forgives the $400 payment that was due on July 1, 1986. Based on these facts, the debentures are not treated as stock under this paragràph (l). There is no requirement that interest accrued while B held the debentures must be paid. However, X may have income under § 1.61–12(a) (relating to discharge of indebtedness).

(m) *Payable on demand*—(1) *Initial classification.* If immediately after it is issued—

(i) This section applies to an instrument,

(ii) By its terms, the instrument is payable on demand, and

(iii) The stated annual rate of interest on the instrument is not reasonable (within the meaning of paragraph (f) of this section),

then the instrument is treated as stock.

(2) *Reclassification.* If for any taxable year (or portion thereof)—

(i) Either by its terms or by operation of paragraph (m)(3) of this section, an instrument is payable on demand,

(ii) This section applies to the instrument, and

(iii) The issuing corporation fails to pay interest on the instrument at a reasonable rate, then the instrument is treated as stock beginning on the the first day of that taxable year (or portion thereof). For purposes of this subparagraph (2), a rate of interest is considered reasonable if it is reasonable (within the meaning of paragraph (f) of this section) as of any day of the taxable year.

(3) *Nonpayment of principal.* If—

(i) The issuing corporation fails to make a scheduled payment of principal on an instrument within 90 days after the payment is due, and

(ii) The holder of the instrument fails to exercise the ordinary diligence of an independent creditor, then, for purposes of this paragraph (m), the instrument is considerd to be payable on demand beginning on the day after the day the principal is due.

(4) *Exceptions.* (1) This paragraph (m) (other than subparagraph (4)(ii) thereof) does not apply to an instrument that is actually retired within 120 days after the end of the taxable year of issue.

(ii) If an instrument payable on demand described in paragraph (m)(4)(i) of this section is not retired with interest at an arm's length rate within the meaning of § 1428–2(a)(2), then interest at the rate set forth in § 1.482–2(a)(2)(iii)(B)(*2*) shall be imputed.

(iii) For purposes of paragraph (m)(4)(i) of this section an instrument is not considered to be actually retired if it is reissued, renewed or offset in any manner. An instrument will be presumed not to be reissued, renewed or offset to the extent that the holder (or any person from whom the ownership of stock would be attributed to the holder under section 318(a)) does not make any loan described in § 1.385–7(a)(1) within the prohibited period and the corporation does not issue to the holder (or to any such person) an instrument payable on demand within the prohibited period. The prohibited period begins on the date the instrument is retired and extends for the number of days the instrument was outstanding. The Commissioner may rebut this presumption by evidence tending to show that the instrument, when considered with other loans or instruments, is used for purposes other than temporary and nonperiodic needs of the corporation's business. For example, this presumption may be rebutted by evidence tending to show that the corporation has a seasonal need for working capital and that there is a pattern of funding this need with instruments payable on demand or loans described in § 1.385–7(a).

(iv)(A) If a failure to pay interest on an instrument at a reasonable rate results solely from a failure to pay interest when due, then paragraph (m)(2) of this section does not apply. See, however, paragraph (l) of this section

(relating to nonpayment of interest when due).

(B) The following example illustrates the application of this subdivision (iv):

Example. Individual A owns 100 percent of the stock of corporation X. On January 1, 1990, X issues a 14-percent demand note to A. X uses the calendar year as its taxable year. Assume that 14 percent is a reasonable rate of interest (within the meaning of paragraph (f) of this section) on January 1, 1990, but that X fails to pay any part of the interest due on the note for the taxable year 1990. Based on these facts, paragraph (m)(2) of this section does not apply. However, if A has failed to exercise the ordinary diligence of an independent creditor, the note will be treated as stock under paragraph (l) of this section.

(5) *Illustrations.* The following examples illustrate the application of this paragraph (m) and related provisions. It is assumed in these examples, that the demand instruments are not retired within 120 days after the end of the taxable year in which they are issued:

Example (1). J and N operate a partnership that distributes beer. On April 1, 1989, J and N organize corporation T and transfer the assets of the partnership to the corporation. In exchange for the assets of the partnership, J and N each receive half of the common stock of T and a 8-percent demand note for $45,000. Assume that 8 percent is not a reasonable rate of interest (within the meaning of paragraph (f) of this section) on April 1, 1989. Based on these facts, the demand notes are treated as stock.

Example (2). On August 24, 1986, F organizes corporation G to own and operate an outdoor amusement business. G uses the calendar year as its taxable year. On August 25, 1986, F transfers trucking equipment, mechanical rides, and other assets to G in exchange for all the capital stock of G and a 6 percent note for $200,000. The note is due on August 25, 1990, and is classified as indebtedness under § 1.385–4(a). However, G does not pay the principal within 90 days after it is due, and F does not pursue such payment with the ordinary diligence of an independent creditor. Based on these facts, beginning on August 26, 1990, the note is considered to be payable on demand. Assume that during 1990 the lowest reasonable rate of interest on a demand note issued by G (taking into account the financial condition of G) is 12-percent a year, and that under applicable local law the note continues to pay 6 percent interest after maturity. Based on these facts, the note is treated as stock on August 26, 1990.

Example (3). The facts are the same as in example (2) except that G agrees to pay 12 percent interest on the note. In addition, assume that 12 percent is a reasonable rate of interest on August 26, 1990. Based on these facts, the note is not treated as stock under this paragraph (m).

Example (4). The facts are the same as in example (3), except that G issues a 12-percent demand note for $200,000 to F in payment for the 6-percent note due on August 25, 1990. Based on these facts, the 6-percent note is not treated as stock. In addition, the 12-percent note may be treated as an indebtedness under § 1.385–4(a).

(n) *Meaning of terms*—(1) *Debt-to-equity ratio.* For the definition of the term "debt-to-equity ratio", see paragraphs (h) and (j) of this section.

(2) *Failure to pay interest.* For the definition of the term "failure to pay interest," see paragraph (l)(3) of this section.

(3) *Fair market value.* For the definition of the term "fair market value", see § 1.385–3(a).

(4) *Instrument.* For the definition of the term "instrument", see § 1.385–3(b).

§ 1.385–7 Certain other obligations.

(a) *Scope*—(1) *In general.* This section applies to any loan of money (*e.g.*, a cash advance) made to a corporation unless—

(i) The loan is made by an independent creditor (within the meaning of § 1.385–6(b)), or

(ii) The loan is evidenced by an instrument within 120 days after the end of the taxable year in which the loan is made.

If the loan is evidenced by an instrument within 120 days after the end of the taxable year in which the loan is made, the instrument is considered to be issued in consideration of the loan. For treatment of the instrument as stock or indebtedness, see §§ 1.385–4 through 1.385–6.

(2) *Exceptions.* (i) This section (other than paragraph (a)(2)(ii) thereof) does not apply to a loan repaid within 120 days after the end of the taxable year in which the loan is made.

(ii) If a loan described in paragraph (a)(2)(i) of this section is not repaid with interest at an arm's length rate within the meaning of § 1.482–2(a)(2), then interest at the rate set forth in § 1.482–2(a)(2)(iii)(B)(*2*) shall be imputed.

(iii) For purposes of paragraph (a)(2)(i) of this section, a loan is not considered to be actually repaid if it is renewed or offset in any manner. A loan will be presumed not to be renewed or offset to the extent that the lender (or any person from whom the ownership of stock would be attributed to the lender under section 318(a)) does not make any loan described in paragraph (a)(1) of this section within the prohibited period and the corporation does not issue to the lender (or such person) an instrument payable on demand within the prohibited period. The prohibited period begins on the day the loan is repaid and extends for the number of days the loan was outstanding. The Commissioner may rebut this presumption by evidence tending to show that the loan, when considered with other loans or instruments, is used for purposes other than temporary and nonperiodic needs of the corporation's business. For example, this presumption may be rebutted by evidence tending to show that the corporation has a seasonal need for working capital and that there is a pattern of funding this need with loans described in paragraph (a)(1) of this section.

(b) *Initial classification*—(1) *In general.* Except as provided in paragraph (b)(2) of this section, a loan to which this section applies is treated as indebtedness.

(2) *Exception.* A loan to which this section applies is treated as a contribution to capital if the debtor corporation has excessive debt when the loan is made (under the principles of § 1.385–6(g)).

(c) *Reclassification*—(1) *In general.* If a loan is treated as indebtedness under paragraph (b)(1) of this section and if the debtor corporation fails to pay interest on the loan at a reasonable rate during any taxable year, then the loan is reclassified as a contribution to capital as of the later of the first day of the taxable year or the date of the loan. For purposes of this subparagraph (1), a rate is considered reasonable if it is reasonable (under the principles of § 1.385–6(f)) as of any day of the taxable year.

(2) *Special rule.* For purposes of paragraph (c)(1) of this section, a corporation is not considered to pay interest on a loan during a taxable year unless the interest is actually paid within 90 days after the end of such taxable year. For this purpose, payment of interest with property other than money will be considered actual payment, but only to the extent such property is includible in the income of the lender. For example, payment of interest with a note will be considered actual payment, but only to the extent such note is includible in the income of the lender. For this purpose, property is considered to be includible in the income of a tax-exempt entity (e.g., a charitable organization) if it would be includible if the entity were not tax-exempt.

(d) *Effect of this section*—(1) *Initial classification.* If a loan is treated as a contribution to capital under paragraph (b)(2) of this section, then all payments of principal and interest on the loan are treated as distributions to which section 301 applies.

(2) *Reclassification.* If a loan is reclassified as a contribution to capital under paragraph (c) of this section, then all payments of principal and interest made on the loan after the beginning of

the year of reclassification are treated as distributions to which section 301 applies. In addition, once a loan is reclassified under paragraph (c) of this section, its status as a contribution to capital can never change.

(e) *Illustrations.* The following examples illustrate the application of this section:

Example (1). Corporation M uses the calendar year as the taxable year. A is the sole shareholder of M. On March 1, 1986, A advances $73,000 to M, and M establishes an account payable to A in the amount of $73,000. The account payable is entered on the books of M but is not evidenced by an instrument. The account payable is not repaid within 120 days after the end of 1986. In addition, M has excessive debt within the meaning of § 1.385–6(g). Based on these facts, the account payable is classified as a contribution to capital.

Example (2). The facts are the same as in example (1), except that M does not have excessive debt. The account payable is classified as indebtedness. However, if M fails to pay (before April 1, 1987) interest at a reasonable rate on the account payable for the last 10 months of 1986, the account payable will be reclassified as a contribution to capital (effective retroactively to March 1, 1986).

Example (3). Corporation X, which has excessive debt, uses the calendar year as the taxable year. On January 1, 1985, X's sole shareholder advances $60,000 to X. The advance is entered on the books of X but is not evidenced by an instrument. X repays $40,000 of the advance on April 1, 1985 and the remaining $20,000 on October 1, 1986. The advance is not renewed or offset in any manner. Based on these facts, this section (other than paragraph (a)(2)(ii) thereof) does not apply to the $40,000 of the advance that was repaid on April 1, 1985. See paragraph (a)(2)(i) of this section. The remaining $20,000 is treated as a contribution to capital. Therefore, the $20,000 repaid on October 1, 1986 is treated as a distribution to which section 301 applies. Also, interest on the $40,000 repaid on on April 1 is imputed at the rate set forth in § 1.482–2(a)(2)(iii)(B)(*2*).

Example (4). B is the sole shareholder of corporation Y. On June 1, 1988, B makes a $40,000 noninterest-bearing unwritten advance to Y. The advance is repaid on November 30, 1988 and is not renewed or offset in any manner. Based on these facts, interest is imputed on the advance of the rate set forth in § 1.482–2(a)(2)(iii)(B)(*2*). Assume that the rate set forth in § 1.482–2(a)(2)(iii)(B)(*2*) is 12 percent per annum simple interest. Then $2,400 is imputed with respect to the period of the advance as interest income to B and as an interest expense of Y. However, apart from this imputation of interest, this section does not apply to the advance.

Example (5). Corporations S and T are wholly owned subsidiaries of corporation P. P, S, and T use the calendar year as their taxable year. On July 1, 1990, S makes a noninterest bearing advance of $50,000 to T. The advance is entered on the books of T but it is not evidenced by an instrument. The advance is not repaid within 120 days after the end of 1990. Based on these facts, S is treated as distributing $50,000 to P, and P is then treated as contributing this amount to the capital of T.

§ 1.385–8 Locked interests.

(a) *In general.* For purposes of the regulations under section 385, two or more distinct interests in a corporation are treated as separate even though title to one cannot be transferred without transferring title to the others. Thus, for example, if a corporation issues a bond with a nondetachable warrant, the bond and the warrant are treated as two separate interests in the corporation.

(b) *Illustrations.* The following examples illustrate the application of this section:

Example (1). On January 1, 1989, corporation X issues 20-year, $1,000 debentures with nondetachable warrants. Each warrant entitles the holder to buy 100 shares of common stock in X for $10 a share. Based on these facts, the debentures and the warrants are treated as separate interests.

Example (2). The facts are the same as in example (1), except that each debenture can be surrendered on the exercise of a warrant in lieu of cash. The result is the same as in example (1).

Example (3). On January 1, 1990, corporation Y issues a 25-year, $1,000 debenture to individual A for $1,000 in cash. Y has no other debentures outstanding. The debenture pays interest at a rate of $100 a year; $50 is payable in all events and the other $50 is noncumulative and payable only if earned. Individual A owns 90 percent of the stock in Y, and the fair market value of the debenture is $1,000. Based on these facts, the debenture is treated as stock under § 1.385.6(d) (relating to hybrid instruments held proportionately).

Example (4). The facts are the same as in example (3), except that Y issues a $600 debenture together with four shares of preferred stock to A. The debenture pays fixed interest of $50 a year and has a fair market value of $600. Each share of preferred stock has a liquidation value of $100 and pays a noncumulative dividend of $12.50 a year if earned. In addition, Y is required to redeem the preferred stock at $100 a share at the end of 25 years. Assume that § 1.385–6(g) (relating to excessive debt) does not apply to the debenture. Based on these facts, the debenture is treated as indebtedness under § 1.385–4(a). The result is the same even if A cannot transfer title to the debenture without also transferring title to the preferred stock.

PART 15A—TEMPORARY INCOME TAX REGULATIONS UNDER THE INSTALLMENT SALES REVISION ACT

Par. 4. Section 15A.453–1(c)(8) is revised to read as follows:

§ 15A.453–1 Installment method reporting for sales of real property and casual sales of personal property.

* * * * *

(c) * * *

(8) *Coordination with section 385.* For rules regarding coordination with section 385, see § 1.385–1(b)(4).

PART I [AMENDED]

§ 1.482–2 [Amended]

Par. 5. Paragraph (a)(4)(ii) of § 1.482–2 is amended by removing "§ 1.61–12(c)(2)" and inserting in lieu thereof "section 171."

Par. 6. Paragraph (a)(5) of § 1.482–2 is amended by adding, immediately after the first sentence in the flush material following (ii), "(See, however, § 1.385–6(f)(2), under which the safe haven rates of paragraph (a)(2)(iii) of this section may, under certain circumstances, be safe harbor rates under the regulations under section 385.)"

Par. 7. The example in § 1.482–2(a)(6) is amended:

1. By removing "(see § 1.385–3(a)(1))" from the fourth sentence and inserting in lieu thereof "(see § 1.385–6(c)(1))"; and

2. By inserting immediately after the second sentence, "Assume that S's debt-to-equity ratio, determined under § 1.385–6 (h) and (j), exceeds 3:1 on the last day of the taxable year of issue."

Roscoe L. Egger, Jr.,

Commissioner of Internal Revenue.

[FR Doc. 81–37400 Filed 12–30–81; 3:04 pm]

BILLING CODE 4830–01–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1990

[Docket No. H090C]

Identification, Classification and Regulation of Potential Occupational Carcinogens

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Advance notice of proposed rulemaking and proposal for partial stay pending completion of rulemaking proceedings.

SUMMARY: The Occupational Safety and Health Administration is considering rulemaking proceedings, under Section 6 of the Occupational Safety and Health Act of 1970 and pursuant to 29 CFR 1990.106(b)(3), to reevaluate certain provisions of the generic standard, Identification, Classification and Regulation of Potential Occupational Carcinogens—the "Carcinogen Policy"—29 CFR Part 1990. This reevaluation is to determine the need for modification based on recent Supreme Court

decisions, public requests for review and the Agency's own experience. The Agency is considering possible changes to improve the cost-effectiveness of regulation under the Policy to coordinate the Policy with relevant portions of Executive Order 12291. The provisions for scientific review, for setting priorities and making the selection of substances public, and for limiting the use of certain kinds of scientific evidence are also being evaluated. Comments are invited on the scope of the reevaluation of the Carcinogen Policy.

OSHA also proposes to stay the requirements of the Policy relating to the establishment and pubication of the Candidate List and Priority Lists for the duration of the comment period on this advance notice and during any rulemaking proceedings which may follow. Other provisions of the Policy will continue in effect under the terms of this proposed stay.

DATES: Comments on suggested changes to the standard must be submitted by April 5, 1982. Comments concerning the issuance of a stay on the requirements to establish and publish the Candidate and Priority Lists must be submitted by February 19, 1982.

ADDRESSES: Comments, data and information should be submitted to the Docket Officer, Occupational Safety and Health Administration, Docket No. H090C, Room S6212, U.S. Department of Labor, 3rd St. and Constitution Avenue NW., Washington, D.C. 20210, where they will be available for inspection and copying.

FOR FURTHER INFORMATION CONTACT: James Foster, Occupational Safety and Health Administration, Room N3637, U.S. Department of Labor, 3rd St. and Constitution Avenue NW., Washington, D.C. 20210, telephone (202) 523–8148.

SUPPLEMENTARY INFORMATION:

Background

OSHA published the standard, Identification, Classification and Regulations of Potential Occupational Carcinogens—the "Carcinogen Policy"—as 29 CFR Part 1990 on January 22, 1980 (45 FR 5001 *et seq.*) The stated purposes of the Policy are to streamline the regulatory process and provide predictable an uniform criteria for identifying and regulating substances as occupational carcinogens.

The Policy includes criteria and scientific policies for identifying and classifying a substance as a potential occupational carcinogen. It includes a screening and priority setting process to be followed in determining whether a proposed standard on a potential carcinogen should be issued. Guidelines are included on the substantive provisions of a proposed standard and are generally non-binding except for provisions giving preference to engineering and work practice controls. Certain procedures are included for issuing advance notices of proposed rulemaking, and for considering new scientific information and for setting time periods for comments and actions. Provisions are also included for amending the Policy and for scientific review by government scientists outside OSHA. The Policy does not, by itself, regulate specific substances. For a detailed explanation of the Policy see 29 CFR Part 1990, 45 FR 5001, January 22, 1980, as amended by 46 FR 4889, January 19, 1981.

On August 12, 1980, OSHA published a Candidate List (45 FR 53672) as part of the priority setting process. OSHA listed the substances which were candidates for further scientific review after conducting a brief scientific review of "available positive data" (as defined in the Policy, 45 FR 5209 and § 1990.121).

Since its effective date of April 21, 1980, the Policy has been modified in light of the Supreme Court's decision in *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute (IUD* v. *API)* 448 U.S. 607 (1980). Provisions of the Policy that were inconsistent with that decision regarding OSHA's benzene standard, were deleted (46 FR 4889, January 19, 1981). Among the deleted provisions was one that required worker's exposure to carcinogins automatically to be set at the lowest feasible levels. Another provision that was deleted automatically characterized all carcinogens as presenting a grave danger. Furthermore, the Agency published additional proposed amendments to the Policy on January 23, 1981, (46 FR 7402), which were later withdrawn (46 FR 19000, March 27, 1981).

The Carcinogen Policy remains the subject of several court challenges. These challenges have been consolidated in the United States Court of Appeals for the Fifth Circuit in *American Petroleum Institute et al.* v. *OSHA et al.*, Nos. 80–3018, et al. The litigation is still in a preliminary stage, and no decision on the legal merits of the Policy has issued, nor is expected in the near future.

Reasons for Considering a Proposed Rulemaking

OSHA is considering reevaluating the Carcinogen Policy for a number of reasons, including the following:

1. To assure consistency with Supreme Court decisions.

2. To consider more cost-effective means of achieving the regulation of occupational carcinogens.

3. To consider modifications based on OSHA's experience under the existing policy e.g., the priority system, and additional policy considerations.

4. To consider and respond to any advances or changes in the science of carcinogenesis, including quantitative risk assessment, occurring since the closing of the record in 1979.

5. To respond to the requirements of Executive Order 12291.

Summary of Issues for Which Submissions of Comments, Data and Information are Requested

This summary is representative only. OSHA invites the submission of comments and data on all aspects of the Policy.

1. How should OSHA consider the cost-effectiveness of provisions which are incorporated into a standard regulating carcinogens under the Policy?

The Policy preamble and standard do not explicitly address methods of obtaining required levels of employee protection at lower cost. Appropriate areas for consideration of cost-effective approaches may include methods of compliance with the exposure limits in a standard. One such approach might utilize a combined strategy of engineering controls, work practices, personal protective equipment and medical surveillance. Greater use of action levels, percentage exclusions (see the discussion at 45 FR 5242) and performance language in the model standard, if one is to be retained, also may increase cost-effectiveness. In addition, more performance oriented standards may encourage cooperative efforts between employees and employers, which should lead to better protection in a more cost-effective manner. OSHA solicits comments on the approaches suggested, and any other suggestions to incorporate considerations of cost-effectiveness into this Policy.

2. Is it proper or appropriate for OSHA to retain the requirement for setting a no-exposure level where a suitable substitute exists for a use or a process of a potential occupational carcinogen?

The Policy now requires OSHA to assess whether the significance of the carcinogenic risk warrants the imposition of a no-exposure level for uses or processes involving a carcinogen, where a suitable substitute exists. Industrial hygienists generally state that substitution is a preferred compliance strategy because it

precludes the possibility of exposure from mechanical breakdown or human error. Some commenters suggest that it is difficult to evaluate the suitability of substitutes and that considerable disruption to industrial processes may occur when substitutes originally deemed to be suitable replacements are not actually adequate. It is also argued that this provision is unnecessary, since market pressure would generally force substitution when it is feasible. OSHA invites additional comments on these issues.

3. Should OSHA amend the provisions for the review and utilization of negative (non-positive) animal and human data?

Under the current policy, negative (non-positive) data are given less evidentiary value than positive data in making Agency decisions on identifying, classifying and regulating substances as potential occupational carcinogens. The basis for this preference is the scientific generalization that positive studies are mot persuasive than negative studies. Moreover, it is alleged that negative studies typically have a low degree of sensitivity for detecting an increased risk of cancer.

The Policy provides that only positive data will be used in the initial screening of the large number of chemicals in order to determine which will be placed on the Candidate List for further scientific review. The preamble states that for purposes of creating Priority Lists the Secretary is "to thoroughly review all of the relevant and meaningful scientific and technological evidence" (45 FR 5210).

The Policy also provides that (except for significant risk determinations) negative studies in humans must meet stringent criteria before consideration. Negative animal studies are to be evaluated in relationship to positive studies in the same species, but not in relationship to positive studies in different species.

Comments are requested on the appropriate procedures for evaluating the relationship between positive and negative data. Should these procedures, which currently give positive and negative data different weights at different stages in the regulatory process, be modified? If so, what scientific criteria are appropriate for evaluating negative studies and for determining their relative weight in the decision-making process?

4. Should OSHA alter or continue its process for reviewing data on the substantial number of substances for which there is some evidence of carcinogenicity, and for setting priorities?

The Policy establishes a three stage review process for screening the substantial number of substances for which there is some evidence of carcinogenicity. The first stage, limited to a brief review of certain available data, culminates in the preparation and publication of a Candidate List. OSHA completed that stage and published the first Candidate List of approximately 200 substances in August, 1980. Public comment was requested and reviewed.

At the second stage, OSHA performs a more searching scientific review, and applies priority factors set out in § 1990.132, which include the estimated number of employees exposed, their levels of exposure, and the levels reported to cause an increased incidence of neoplasms. The second stage culminates in the selection of ten Category I and ten Category II substances for inclusion on two Priority Lists. OSHA has not yet prepared these lists for public comment.

At the third stage, the Assistant Secretary for Occupational Safety and Health selects high priority substances for rulemaking, as appropriate, based on the application of the priority factors, scientific judgment, policy considerations and public comment received after publication of the Priority Lists.

Suggestions have been received which argue that the review process should be divided into separate scientific and regulatory stages, and that an outside panel should perform the scientific evaluation. In addition, required publication of the Candidate List, and especially the Priority Lists, has been seriously questioned. The basis of the concern is that the Lists are preliminary since they are published before OSHA fully evaluates all available evidence. A serious concern is that the public will perceive the Lists as the Government's conclusions that substances are carcinogens, possibly leading to undue and unwarranted concern or "cancer scares."

Comments are also requested on the screening and priority setting process, established in the current Policy. What have been the effects of the publication of the Candidate List in August 1980? Suggestions are requested on methods of involving the public in the screening and review process prior to rulemaking, without publication of the lists (or results) at varying stages of the process.

5. How should OSHA incorporate the provisions of Executive Order 12291, including cost/benefit analysis, in its priority setting process?

The Supreme Court, in *American Textile Manufacturers Institute (ATMI)* v. *Donovan*, 101 S. Ct. 2478 (1981) permits OSHA to utilize cost/benefit analysis in setting priorities. Executive Order 12291 (46 FR 13193, February 19, 1981) sets an analytic framework for performing cost/benefit analysis and evaluating regulatory alternatives. Some of the factors listed in the Policy for setting priorities would be relevant to performing cost/benefit analysis. They include whether controlling a carcinogen would reduce other occupational and environmental risks and the costs. Comments are requested on the appropriate framework for incorporating a cost/benefit approach in the prioritization process. Comments are also requested on incorporating the analytic framework of Executive Order 12291 in the priorities setting process of the Policy consistent with *ATMI* v. *Donovan*.

6. Should the Policy specify methods or techniques of quantitative risk assessment and significant risk determinations?

The Policy preamble has an extensive discussion of risk assessment techniques and uncertainties (45 FR 5178–5201). As amended in light of *IUD* v. *API*, the Policy permits OSHA to consider all relevant evidence in making risk assessments §1990.111(j) as amended at 46 FR 4889) for purposes of priority setting and to assess the significance of the risk in rulemaking. However no specific methods of performing risk assessments or significant risk determinations are contained in the language of the Policy.

Comments are requested on techniques of quantitative risk assessment, and their reliability. In addition, comments are requested on methods of assessing the significance of the risk, and the value of incorporating guidelines on these matters into the Policy.

Other Matters

In addition to specific responses to the questions posed in this notice and to other relevant issues, and in accordance with the provisions of the Regulatory Flexibility Act (Pub. L. 96–354, 95 Stat. 1164, 5 U.S.C. 601 *et seq.*) and Executive Order No. 12291, OSHA also requests information regarding the economic impact which any changes might have on affected industries and, in particular, small businesses.

The preamble to the final Carcinogen Policy concluded that economic analysis would be performed at the later stage of regulating specific carcinogens. This conclusion was based on the availability of data at that time and on the argument that no direct cost burdens are imposed by the Policy.

Representatives of industry argued that economic analysis should be performed at the earlier policy stage to indicate possible overall economic effects, and that this would show that a cost-benefit approach to regulation should be adopted.

Subsequently, in two major decisions, the Supreme Court substantially changed the legal context of this debate. In *IUD* v. *API, supra,* the Court held that the Agency had to demonstrate significant risk before regulating hazards. Consequently, OSHA eliminated provisions of the Policy which would automatically require the Agency to reduce workers' exposure to the lowest feasible level without consideration of the significance of the risk. In *ATMI* v. *Donovan, supra,* the Court held that the OSH Act requires that exposure levels be reduced to levels limited by the significance of the risk and by feasibility but not by cost-benefit considerations.

Within this changed context, and the applicable Administration policies stated in Executive Order 12291, OSHA requests comment on what is the appropriate kind of economic analysis for an amended Policy? If the Policy should concentrate on scientific issues and leave specific regulatory policy issues to individual rulemakings, would the same comments apply? Should modifications to the Policy be made to facilitate economic analysis at all stages and, if so, what changes are recommended?

OSHA concluded that environmental issues are to be considered in the context of regulation of specific carcinogens. The Agency prepared an environmental impact statement, however, which generally and qualitatively assessed the impact of specific policies on the internal and external environment (see discussion at 45 FR 5254, January 22, 1980). OSHA requests the public to submit comments and data concerning the environmental impact of any suggested changes to the Policy.

Proposed Partial Stay Pending Reevaluation and Rulemaking

Pending the reconsideration of the entire Policy, including any related rulemaking, OSHA hereby proposes to stay the provisions of the Policy requiring OSHA to establish and publish in the **Federal Register** the Candidate List and the Priority Lists. These provisions of the Carcinogen Policy are found in 29 CFR 1990.121, 122, 131 and 133. OSHA believes that these provisions should be stayed so that the Agency can fully evaluate the actual impact of the published Candidate List, the possible impact of publishing the Priority Lists (before any further publication occurs), and the underlying criteria for inclusion of substances of these Lists.

At this time OSHA believes that a stay should be limited to the provisions concerning the Candidate and Priority Lists, and that all other provisions of the Cancer Policy should continue in effect during this period of reconsideration.

OSHA invites the public to comment on this proposal to issue a partial stay. OSHA will carefully evaluate all comments, which are submitted on time, before it determines whether such a stay should be issued.

Comments on the proposed partial stay must be submitted by February 19, 1982. Comments on possible changes to the Policy must be submitted by April 5, 1982. All comments should be sent to the Docket Officer, Occupational Safety and Health Administration, Docket H090C, Rm. S6212, U.S. Department of Labor, 3rd St. and Constitution Ave. NW., Washington, D.C. 20210.

Authority

This document was prepared under the direction of Thorne G. Auchter, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, D.C. 20210. It is issued pursuant to Sections 6(b), 6(c) and 8(g) of the Occupational Safety and Health Act (84 Stat. 1593; 29 U.S.C. 655), 29 CFR 1990.106(b)(3), and the Administrative Procedure Act.

Signed at Washington, D.C., this 29th day of December 1981.

Thorne G. Auchter,

Assistant Secretary of Labor.

[FR Doc. 81-37473 Filed 12-31-81; 8:45 am]

BILLING CODE 4510-26-M

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 585

Army General Counsel's Honors Program; Policy and Procedures

AGENCY: Department of the Army, DOD.

ACTION: Proposed rule.

SUMMARY: This regulation would establish policy and procedures governing the Army General Counsel's Honors Program. This program selects highly qualified attorneys to file vacancies that occur periodically in the Army General Counsel's Office. This regulation describes the program requirements and application procedures.

DATE: Written comments submitted on or before February 4, 1982, will be considered.

ADDRESSES: Written comments should be addressed to Office of the General Counsel, Department of the Army, Washington, D.C. 20310.

FOR FURTHER INFORMATION CONTACT: LTC Thomas W. Taylor, (202) 695-0562.

(10 U.S.C. 3012, 3065)

December 23, 1981.

John O. Roach, II,

The Department of the Army Liaison Officer with the Federal Register.

Part 585 is proposed to be added as follows:

PART 585—THE ARMY GENERAL COUNSEL'S HONORS PROGRAM

Sec.

585.1 Purpose.
585.2 Applicability.
585.3 Ralated references.
585.4 Responsibility.
585.5 Program criteria.
585.6 Acceptance.
585.7 Grade.
585.8 Service obligations.
585.9 Submission of applications.

Authority: 10 U.S.C. 3012, 3065

§ 585.1 Purpose.

This regulation prescribes policy, acceptance criteria, and procedures for applicants applying for the Army General Counsel's Honors Program.

§ 585.2 Applicability.

(a) This regulation applies to all qualified individuals, with or without military status, who may be considered for active duty as commissioned officers under Army General Counsel's Honors Program.

(b) This regulation applies to the Active Army, the Army National Guard, and the US Army Reserve.

§ 585.3 Related references.

Related publications are listed below. (A related publication is merely a source of additional information. The user does not have to read it to understand this regulation.)

(a) AR 40-501 (Standards of Medical Fitness).

(b) AR 135-100 (Appointment of Commissioned and Warrant Officers of the Army).

(c) AR 381-20 (US Army Counterintelligence (CI) Activities).

§ 585.4 Responsibility.

The Office of the General Counsel will consider all qualified applicants for the Army General Counsel's Honors

Program and make selections as vacancies occur.

§ 585.5 Program criteria.

Periodically, a limited number of attorney positions become available under the Army General's Honors Program. Individuals meeting the program criteria may apply whether or not they already have military status. To be accepted in the program, an applicant must:

(a) Have a J.D. or LL.B. degree from a law school approved by the American Bar Association. A senior in such a law school may apply for admission to the Honors Program, but must receive a degree before acceptance.

(b) Have an outstanding undergraduate and law school record.

(c) Be potentially qualified for a Reserve appointment (see AR 135–100) if not already a reserve or Regular Army (RA) commissioned officer.

(d) Meet the medical fitness standards prescribed in chapter 2, AR 40–501. Required medical examinations will be conducted at an Armed Forces medical facility.

(e) Successfully undergo a National Agency Check or personnel security investigation of broader scope, as prescribed in AR 381–20.

(f) Be admitted to practice before a Federal court, or the highest court of a State or of the District of Columbia. The applicant must also be a member in good standing of the bar. A law school graduate may be accepted into the Honors Program, conditionally, before admission to the bar. However, failure to gain such admission in due course, by failing a bar examination or otherwise, will result in removal from the program.

§ 585.6 Acceptance.

Successful applicants without commissioned status will be appointed as Reserve commissioned officers and ordered to active duty. Successful applicants who are Reserve commissioned officers not on active duty will be ordered to active duty. Successful applicants who are Reserve or RA commissioned officers on active duty will be reassigned in coordination with their career management activity. Successful applicants are designated as Assistants to the General Counsel.

§ 585.7 Grade.

(a) Successful applicants without commissioned status will be appointed in the Reserve grade for which they are eligible under AR 135–100. They will be ordered to active duty in that grade.

(b) Reserve officers not on active duty will be ordered to active duty in their Reserve grade.

(c) Officers on active duty at the time of acceptance will retain their present grade.

§ 585.8 Service obligations.

Applicants accepted in the Honors Program incur an active duty service obligation of 3 years from the effective date of assignment to the Office of the General Counsel. This obligation runs concurrently with, but does not reduce, any previously incurred service obligation. Assignment to the Office of the General Counsel may be curtailed at the discretion of the General Counsel. However, this does not affect any service obligation incurred under this or any other regulation.

§ 585.9 Submission of applications.

(a) Applications for the Honors Program will be submitted directly to the General Counsel, Department of the Army, Washington, D.C. 20310.

(b) Applicants not holding a current appointment as a commissioned officer will submit the following:

(1) Application in letter form.

(2) DA Form 61 (Application for Appointment) in duplicate. (See AR 135–100, AR 145–1, AR 351–1, and AR 601–100 for guidance in preparing this form).

(3) DA Form 160 (Application for Active Duty) in one copy. (See AR 135–10 for guidance in preparing this form). Item 9b of the form will be annotated as follows: See Item 13, "Remarks." Item 13 will be annotated as follows: "If selected, I volunteer to serve on active duty for 3 years following assignment to the Army General Counsel's Honors Program."

(4) Standard Form 88 (Report of Medical Examination) in one copy. (See AR 40–501 for guidance in filling out this form.)

(5) FD Form 258 (Fingerprint Card) in two copies. This form may be completed at any military facility or law enforcement agency.

(6) Transcripts of all undergraduate and law school work, prepared by the schools where such work was completed. The transcripts should show class standing, if available.

(7) Law School Aptitude Test score.

(8) A certificate or statement:

(i) From the clerk of the highest court of a State or of the District of Columbia showing admission to practice and good standing before the bar; or

(ii) By the applicant that he or she has taken a bar examination, the date thereof, and the expected date of admission to the bar; or

(iii) By the applicant of his or her intent to take a bar examination, if one is required for admission to practice, as soon as the applicant becomes eligible; the date of such examination; and the expected date of admission to the bar.

(9) Letters based on personal acquaintance from at least three judges, lawyers, law school professors, or other knowledgeable persons concerning the applicant's reputation and professional standing. Letters should be forwarded by the writers directly to the General Counsel, Department of the Army, Washington, D.C. 20310.

(10) A description of the applicant's full-time or part-time legal experience. Legal experience includes private practice; Governmental, judicial, academic, and military legal experience; and legal clerkships.

(11) Any additional information concerning the special qualifications of the applicant which would contribute to program appointment.

(c) An applicant holds a Reserve commission, but not on active duty, will submit the documents listed in paragraph (b) of this section, except for DA Form 61 and FD Form 258. An applicant will submit these documents through Cdr. U.S. Army Reserve Components and Administration Center, and his or her career management activity.

(d) An applicant serving on active duty will submit the documents listed in paragraphs (b)(1) and (b)(6) through (b)(11) of this section as well as a signed statement acknowledging and agreeing to the 3-year active duty service obligation described in § 585.7 of this regulation through the applicant's career management activity.

[FR Doc. 82–197 Filed 1–4–82; 8:45 am]
BILLING CODE 3710–08–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A–4–FRL 2013–2]

Approval and Promulgation of Implementation Plans; Tennessee: Proposed 1979 Plan Revisions

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve State Implementation Plan (SIP) revisions submitted by the Tennessee Department of Public Health, pursuant to the requirements of Part D of Title I of the Clean Air Act (CAA) of 1977, for the Kingsport secondary particulate nonattainment area and the Copperhill secondary sulfur dioxide (SO_2) nonattainment area. EPA is also

proposing to remove the conditions on the approval given earlier to the Part D plans for the Kingsport and Nashville primary particulate nonattainment areas. The public in invited to submit written comments on these proposed actions.

DATE: To be considered, comments must be received on or before February 4, 1982.

ADDRESS: Written comments should be addressed to Raymond S. Gregory of EPA Region IV's Air Programs Branch (see EPA Region IV address below). Copies of the materials submitted by Tennessee may be examined during normal business hours at the following locations:

Public Information Reference Unit, Library Systems Branch, Environmental Protection Agency, 401 M Street SW, Washington, D.C. 20460
Environmental Protection Agency, Region IV, Air Programs Branch, 345 Courtland Street NE, Atlanta, Georgia 30365
Tennessee Air Pollution Control Division, 150 9th Avenue North, Nashville, Tennessee 37203
Air Pollution Section, Metropolitan Health Department, 1600 Hayes Street, Nashville, Tennessee 37203

FOR FURTHER INFORMATION CONTACT: Raymond S. Gregory of EPA Region IV's Air Programs Branch, 345 Courtland Street NE, Atlanta, Georgia 30365, telephone 404/881-3286 (FTS 257-3286).

SUPPLEMENTARY INFORMATION: In the March 3, 1978, **Federal Register** (43 FR 8962 at 9035), the September 11, 1978 **Federal Register** (43 FR 40412 at 40432), and the August 27, 1979 **Federal Register** (44 FR 50098), a number of areas within the State of Tennessee were designated as not attaining certain national ambient air quality standards (NAAQS).

Portions of Nashville and Kingsport were designated as nonattainment for the primary and secondary NAAQS for particulate matter. Implementation plan revisions for attainment of the primary particulate matter MAAQS were conditionally approved for Nashville on August 13, 1980 (45 FR 53809 at 532818), and for Kingsport on November 17, 1980 (45 FR 75660 at 75661).

Nashville Particulate

The conditional approval for the Nashville plan required the submittal by October 1, 1980, of a detailed listing of measures to be investigaed concerning nontraditional source control. The required listing (which included completion of a microscale emission inventory, a study of transportation measures to reduce vehicle miles traveled, microscopic analysis of sampler filters, and an impact modeling analysis) was submitted on September 30, 1980, and it meets the requirement of the conditional approval.

Kingsport Primary Particulate

The conditional approval for Kingsport required two actions, the first of which was the submittal of plans for the control of nontraditional sources and the showing that resultant controls would be sufficient to meet the requirement of Reasonable Further Progress (RFP). The State submittal of December 17, 1980, satisfies the requirement for the control of nontraditional sources. The required plans included provisions for wetting of unpaved traffic areas, a 15 miles per hour speed limit on plant grounds, a wheel wash for trucks and wetting of products on trucks to prevent blowoff. The reductions in particulate emissions from these control measures for fugitive dust were quantified in the control strategy demonstration. The plan for attainment of the secondary NAAQS submitted by the State on May 8, 1980, provided a showing of RFP sufficient to fulfill the requirement of this part of the conditional approval.

The second requirement was the submittal of permits without expiration dates for sources, or certification by the State that the same permits will be renewed and resubmitted to EPA before expiration with conditions at least as stringent. The December 17, 1980, submittal contained a number of the required permits without expiration dates and a resolution adopted by the Air Pollution Control Board of the State of Tennessee on December 11, 1980, stating that "The Tennessee Air Pollution Control Board hereby agrees that prior to expiration of the previously issued permits for particulate emission sources in the Kingsport nonattainment area implementation plan, the Board shall issue permits without expiration dates with conditions at least as stringent as those on the permits now in effect." In keeping with this resolution, on August 27, 1981, additional permits without expiration dates were submitted. The submittals described above meet the requirments of the conditional approval given to the Part D revisions for the Kingsport primary particulate nonattainment area.

Kingsport Secondary Particulate

The secondary plan for Kingsport consists of operating permits containing permit conditions representing emission levels that are achieved by reasonably available control technology (RACT) and RACT measures to control fugitive dust emissions. The permit conditions involve particulate matter and visible emission standards, and reasonable limitations on operating hours and capacities. Plans submitted by individual sources were tailored to provide the necessary control of fugitive dust at those sources. Such plans included paving of plant roads, street cleaning, wheel washing, watering or treating unpaved roadways and control of fugitive emissions from outside storage areas. A public hearing concerning the secondary plan was held on April 16, 1980, with adoption of the plan by the Tennessee Air Pollution Control Board on May 1, 1980.

Copperhill Secondary Sulfur Dioxide

After public hearing on July 16, 1980, and adoption by the Tennessee Air Pollution Control Board on August 5, 1980, Tennessee on August 15, 1980, submitted a plan for attainment of the secondary SO_2 NAAQS in Copperhill. This plan contained emission limits which are more restrictive than the original RACT limits set in the primary plan. The secondary plan with these revised RACT limits demonstrates attainment of the secondary SO_2 NAAQS.

These RACT requirements included the following emission limits based on a three-hour average (dry basis, parts per million of sulfur dioxide by volume):

a. Iron Roaster Impingment Scrubbers—50 PPM.
b. Liquid Sulfur Dioxide Plants—375 PPM.
c. Organic Chemical Plants—50 PPM.
d. 1. Copper Smelter—matte launder operation—500 PPM.
2. Copper Smelter—other operations—50 PPM.
e. Sulfuric Acid Plants—500 PPM.

In addition, limits on sulfur content were specified for non-process fuel burning equipment. For No. 1 or No. 2 fuel oil the sulfur weight content is not to exceed 0.50 percent. For No. 4, No. 5, or No. 6 fuel oil the sulfur weight content is not to exceed 1.25 percent.

Action

EPA proposes to remove the conditions on the approvals given to both the Nashville and Kingsport Part D plans for particulate nonattainment areas. The required submittals have been received and are considered sufficient to meet the requirements specified in the notices of conditional approval. EPA also proposes to approve the plans for attainment of the secondary NAAQS for particulates in Kingsport and SO_2 in Copperhill. The secondary plans have been reviewed and meet the requirements for the plans

to be submitted under Part D of Title I of the CAA.

As previously stated, written comments must be received on or before February 4, 1982. A thirty-day comment period is being used because the SIP submission and the issues involved are not so complex as to warrant a longer comment period. At the close of the comment period, EPA will review all comments and publish a notice of final rulemaking.

Under Executive Order 12291, EPA must judge whether a regulation is major and therefore subject to the requirement of a Regulatory Impact Analysis. This regulation is not major because it only approves state actions and imposes no new requirements.

Pursuant to the provisions of 5 U.S.C. section 605(b) the Administrator has certified that SIP approvals under Sections 110 and 172 of the Clean Air Act will not have a significant economic impact on a substantial number of small entities (46 FR 8709, January 27, 1981). The attached rule if promulgated constitutes a SIP approval under Sections 110 and 172 within the terms of the January 27, 1981, certification. This action only approves state actions. It imposes no new requirements.

(Secs. 110, 172, Clean Air Act, as amended (42 U.S.C. 7410 and 7502))

Dated: December 9, 1981.

Charles R. Jeter,

Regional Administrator.

[FR Doc. 82-120 Filed 1-4-82; 8:45 am]

BILLING CODE 6560-38-M

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40 CFR Part 775

[OPTS-62007A; TSH-FRL-1974-5]

Tetrachlorodibenzo-P-Dioxin; Reevaluation of Disposal Prohibition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance Notice of Proposed Rulemaking (ANPR).

SUMMARY: This notice announces EPA's intent to review the rule (40 CFR Part 775) which prohibits Vertac Chemical Company from disposing of specific chemical wastes contaminated with Tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) located at its Jacksonville, Arkansas facility. EPA solicits comments on this notice.

DATE: All comments must be received by March 8, 1982.

ADDRESS: All comments should be sent to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-401, 401 M St. SW., Washington, D.C. 20460.

Comments should include the docket number OPTS 62007A. Comments received on this notice will be available for reviewing and copying from 9:00 a.m. to 4:30 p.m., Monday through Friday, excluding holidays, in room E-107, EPA Headquarters, 401 M St. SW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799), Environmental Protection Agency, Rm. E-511, 401 M St. SW., Washington, D.C. 20460, Toll free: 800-424-9065, in Washington: 554-1404, Outside the USA: (Operator—202-554-1404).

SUPPLEMENTARY INFORMATION: EPA promulgated in the Federal Register of May 19, 1980 (45 FR 32676), a rule under the authority of section 6(a) of the Toxic Substances Control Act (TSCA). The rule prohibited Vertac Chemical Company (Vertac) from disposing of specific chemical wastes contaminated with 2,3,7,8-TCDD located at its Jacksonville, Arkansas facility.

The facility was used by Hercules, Inc., from 1962 to 1972, and Transvaal, Inc., beginning in 1972, to manufacture the pesticides 2,4,5-Trichlorophenoxyacetic acid (2,4,5-T) and silvex. Transvaal, Inc. was reorganized as Vertac in 1978. In response to an administrative order issued by the State of Arkansas on June 15, 1979, Vertac placed wastes with up to 111 parts per million 2,3,7,8-TCDD from the production of these pesticides in approximately 2,700 drums and relocated them to a storage area consisting of a diked concrete slab covered by a fixed metal roof.

Vertac produced additional TCDD-contaminated wastes using 2,4,5-T-contaminated equipment to manufacture 2,4-Dichlorophenoxyacetic acid (2,4-D). These wastes, produced between September 1979, and May 12, 1980, are contained in approximately 3,200 drums and are located on site in a warehouse building and on a concrete loading platform. An unknown number of drums of wastes from 2,4-D production have been generated since May 12, 1980.

A lawsuit was filed by EPA and the State of Arkansas in March, 1980, for an injunction to prohibit discharge of contaminants from the facility and to require proper management of the wastes located at the site.

The Agency recognizes that the rule places a continuing burden on Vertac to store and monitor the TCDD wastes and that it is only a temporary solution. The Agency is reviewing the prohibition against the disposal of these wastes and is seeking information that will aid in determining the most appropriate long-term solution for the TCDD-contaminated wastes stored at Vertac's Jacksonville facility.

EPA invites comments on the key issues pertinent to this case to assist the Agency in reevaluating the facts upon which the May 19, 1980 rule's finding was based. EPA is particularly interested in receiving a proposal from Vertac on how to dispose of the wastes stored at the Jacksonville facility, including: the proposed method of disposal (including destruction); the estimated time needed to accomplish disposal; if disposal is by a destruction method, an estimate of the efficiency of reducing TCDD-contamination and plans for handling any effluents or waste from the destruction process; a plan for preventing exposure to persons handling the wastes; the costs of the contemplated disposal method; and the need for research or development of the method.

In addition, EPA is interested in receiving comments from any person regarding potential methods of disposal of other wastes contaminated with TCDD. Persons intending to dispose of such wastes are currently required to notify the Agency 60 days in advance of their intent to do so. The Agency will review this requirement and consider implementing specific disposal guidelines to replace the need for notifications. Any coments should address the same areas of concern as set forth above for the Vertac wastes.

EPA will evaluate all information supplied in response to the ANPR and consider whether it is sufficient to warrant a change in the rule prohibiting Vertac from disposing of TCDD-contaminated wastes currently stored on site at the Jacksonville facility.

(Sec. 6, Pub. L. 94-469, 90 Stat. 2020 (15 U.S.C. 2605)).

Dated: December 23, 1981.

Anne M. Gorsuch,

Administrator.

[FR Doc. 82-145 Filed 1-4-82; 8:45 am]

BILLING CODE 6560-31-M

NATIONAL SCIENCE FOUNDATION

45 CFR Parts 680, 681, 682, 683, and 684

Proposed Conflict-of-Interests Regulations

AGENCY: National Science Foundation.

ACTION: Proposed regulations.

SUMMARY: These proposed regulations are issued in accordance with E.O. 11222

of May 8, 1965, 3 CFR, 1965 Supplement and Regulations of the Office of Personnel Management, 5 CFR 735.104. They would apply to all employees of the NSF and would consolidate all the conflict-of-interests rules of the NSF into one document. They would replace the current NSF conflict regulations at 45 CFR 600.735.

DATE: Comments must be received on or before: March 8, 1982.

FOR FURTHER INFORMATION CONTACT: General Counsel, National Science Foundation, 1800 G Street NW., Washington, D.C. 20550, Attention: Harriet E. Tucker (202/357–7483).

SUPPLEMENTARY INFORMATION:

Background and Purposes of Proposed Regulations

Federal employees are subject to a variety of conflicts rules from several different sources. There is a series of criminal statutes (18 U.S.C. 201–209) covering several pages in the United States Code. There is the Hatch Act. There is an Executive Order (11222). There are Office of Personnel Management/Office of Government Ethics regulations memoranda interpreting the laws and implementing the Executive Order. There are memoranda from the Attorney General on the effect of the laws. There are two appendices in the Federal Personnel Manual. Every Federal employee is theoretically responsible for knowing about, understanding, and observing the laws and many of the rules that come out of the Executive Order and an implementing regulations.

Many of these sources threat the same or similar subject, but they are nowhere consolidated into a coherent whole, with all the provisions that bear on the same subject brought together. Many of them, particularly the criminal statutes, are drafted in traditional technical legal language that is difficult for employees to understand. Moreover, they are drafted to cover diverse problems that arise all over the Government; the ones that predominate at the NSF are a small and rather unusual subset of those to which the Governmentwide rules are written. At the same time, none of these multitudinous authorities cover some unique problems the NSF repeatedly confronts particularly those that have to do with short-term employees usually known as "rotators."

The NSF has had a number of different conflicts documents of its own, both to implement other laws and regulations and to add a few special rules of its own. The Foundation's formal conflict regulations (45 CFR 600.735) implement the requirements of Executive Order 11222 and the associated OPM regulations. There is a National Science Board resolution, amended by another resolution, on special conflicts problems that arise for National Science Board members. and the Director of the NSF has issued at least four currently effective Staff Memoranda (O/D 74–48, O/D 74–51, O/D 80–5, and O/D 80–27) that concern one or another conflicts problem.

The proposed regulations represent our effort to create a single conflicts document to coherently consolidate all these conflicts rules and replace the multiple documents we have now. They would replace all the existing regulations and internal documents. Moreover, though we cannot relieve employees of legal responsibility for observing the primary external authorities, particularly the criminal statutes, the regulations are designed so that an employee who observes the NSF regulations should by the same token observe the other laws.

Finally, except for Part 681 of the proposed regulations, which provides for review by directorate officials, there is little that is new. Part 680 contains the introduction to the proposed regulations and statutory exemptions. Part 681 contains guidance on handling proposals and awards where a prospective, current, or recent NSF employee may have an actual or a potential conflict of interests. Part 682 covers representational restrictions and involvments with proposals and projects during and after NSF service. Part 683 covers financial disclosure requirements, acts affecting financial interests, outside employment and related matters, and political activiity. And Part 684 states rules for NSF consultants, National Science Board Members, and other "special Government employees."

NSF therefore proposes the following Parts 680–684 be added to Title 45 of the Code of Federal Regulations.

Dated: December 10, 1981.

John B. Slaughter,

Director.

PART 680—NSF CONFLICT-OF-INTERESTS RULES AND STANDARDS OF CONDUCT: INTRODUCTION AND GENERAL PROVISIONS

Subpart A—Introduction to Regulations

Sec.

680.10 Introduction; key terms.
680.11 How to use these regulations; ethics counselors.
680.12 Purposes and principles.
680.13 Summary of conflicts rules.
680.14 Specific responsibilities.
680.15 Special rules for full-time presidential appointees.
680.16 General standards of employee conduct.

Subpart B—Statutory Exemptions

680.20 Necessity and effect of formal exemptions.
680.21 Exemptions under 18 U.S.C. 208(b).
680.22 Certification under 18 U.S.C. 205.

Authority: E.O. 11222 of May 8, 1965, 3 CFR, 1965 Supplement and Regulations of the Office of Personnel Management, 5 CFR 735.104.

Subpart A—Introduction to Regulations

§ 680.10 Introduction; key terms.

(a) Parts 680 through 684 of this title 45 contain the conflict-of-interests rules and standards of conduct for employees and former employees of the National Science Foundation.

(b) "You", the NSF Employee. The principal audience for these regulations is the NSF employee who must comply with and understand them. They are therefore addressed directly to you. Except where provisions plainly indicate othewise, "you" includes every NSF employee. It includes not only permanent civil service employees working at the NSF, but "rotators" and persons working at the NSF under the Intergovernmental Personnel Act. It includes rehired annuitants. It includes part-time employees. It also includes any intermittent employees, temporary consultants, or members of the National Science Board who work or will work for the Government more than 130 days a year. Parts 680–683 state and explain the rules and standards you must observe.

(c) Consultants, Board members, and other "special employees". Most consultants, members of the National Science Board, and other temporary or intermittent employees work for the Government fewer than 130 days a year and are therefore what the law calls "special Government employees". If you are such a "special employee", see Part 684 of these regulations. Part 684 states and explains the rules and standards you must observe. If you are a member of the National Science Board, Part 684 applies to you as to any other "special employee". Subpart B of Part 684 states and explains special rules of the National Science Board that apply only to its members.

(d) *Definitions.* Except where provisions plainly indicate otherwise, certain other terms are used throughout these regulations in standard meanings:

(1) "Award" means any grant, contract, cooperative agreement, loan,

or other arrangement made by the Government.

(2) "Project" means the unit of work that an award supports or helps support.

(3) "Proposal" means an application for an award and includes a bid.

(4) "Other award-related application" means a request for an award amendment, for an increment to a continuing grant, for a no-cost extension, or for an administative approval.

(5) "Institution" means any university, college, business firm, research institute, professional society, or other organization. It includes any university consortium or joint corporation such as AUI, AURA, or JOI, Inc., but not the universities that belong to it. It includes all parts of a university or college, including separate campuses. It does not include other universities or colleges in a multi-institution state or city system, unless you are an employee of the central system offices or an officer, trustee, or equivalent of the system as a whole.

(6) "Directorate" means an NSF directorate, staff office, or other organization that reports immediately to the NSF Director.

(7) "Program Officer" includes assistant and associate program managers.

§ 680.11 How to use these regulations; ethics counselors.

(a) *Conflicts sensitivity.* Section 680.12 outlines the primary sources of conflicts of interests and explains other considerations that underlie the conflicts rules. If you are sensitive to those considerations and identify situations in which someone might at least think that you have a conflict of interests, you will not be likely to violate the conflict-of-interests rules. When you do identify such a situation, of course, you can and should consult these regulations.

(b) *What is expected of you.* You are not expected to be familiar with every section of the regulations. You do have to be thoroughly acquainted with a number of basic conflict-of-interests rules, which are summarized for you in § 680.13. You are also responsible for adhering to general "standards of employee conduct" that are laid out in § 680.16. Full-time Presidential appointees should also be thoroughly acquainted with the special rules in § 680.15. Beyond that the regulations are designed as a reference document and you need not cope with more detail than you find helpful until a problem or question comes up.

(c) *Ethics counselors.* Within the Office of the General Counsel is an attorney who has primary responsibility for conflict-of-interests matters and for liaison with the Office of Government Ethics. This attorney is the "ethics counselor". Working with the ethics counselor are one or more deputy ethics counselors. (Ethics counselors are designated by the General Counsel under authority herey delegated to him.) Whenever you have a conflict-of-interests problem or question and cannot find a clear answer in these regulations, consult an ethics counselor.

§ 680.12 Purposes and principles.

(a) *Effect of conflicts of interests.* There are two principal reasons why you and the NSF should avoid or minimize actual or apparent conflicts of interests.

(1) The success of the NSF in performing its scientific and other functions depends on the effectiveness of its proposal review process in ensuring that the best and most important work is supported. If judgments are warped because of conflicting interests, that effectiveness is compromised. The same is true of other NSF decision processes.

(2) The NSF must earn and retain the confidence of the scientific community, the Congress, and the general public in the integrity, effectiveness, and even-handedness of its proposal-review and other decision processes. It will not do so if the processes are seen to be infected by conflicts of interests.

(b) *What is a conflict of interests?* A conflict of interests is a clash of influences on the actions or judgments of a Federal official between the public interest and private interests or allegiances. There are three primary sources: Personal interests; outside affiliations or relationships; and gifts or favors. The illustrations that follow illustrate the three primary sources. They deliberately present situations that are not clear cut and do not illustrate specific rules you must follow. The pertinent rules appear elsewhere in these regulations.

(1) You might use your government position to further your personal interests, in conflict with the public interest.

Example. If as an NSF program official you recommended a conference of scientists in your field to discuss current issues, then chaired the conference yourself and delivered the principal paper, at least a reasonable suspicion would arise that you had used your Government position to further your own professional prestige or other personal interests.

(2) Outside affiliations or relationships could affect the objectivity of your judgments as a public offical.

Example. A proposal comes to you for handling. You received your degree from the applicant institution and were a professor there until recently. The proposed principal investigator is your cousin. You have potential conflicts of interests arising both from your academic affiliation and your family relationship.

(3) *Gifts or favors* from those interested in agency decisions could affect the objectivity or integrity of your contributions to those decisions.

Example. The chairman of a university department that regularly sends proposals to your unit is in town. After a late afternnon meeting he proposes dinner at a restaurant on his expense account. Acceptance of the dinner would create a potential conflict between your debt of gratitude towards him and your disinterested pursuit of the public interest.

(c) *Inside access and influence.* A special concern that underlies many of the conflicts rules is that your insider's access to other Federal officials and your inside influence with them might allow you to sway their decisions or actions where you or those with whom you have ties are interested.

Example. A personal friend is prinicpal investigator on a proposal pending in another part of your NSF unit. He asks you to check how things are going with that proposal. You talk with the program officer and division director handling the proposal. You not only check the status of the review, but mention what a fine scientist your friend is and how excellent his recent work has been. Your friendship with the investigator may influence your judgment on these points, and your inside influence may affect the actions and judgments of those with whom you talk. This creates a potential conflict between your private allegiance to your friend and the public interest.

(d) *Conflicts that require prohibition or disqualification.* Some of the conflicts of interests would so warp the performance of a Government agency or damage its credibility that they simply cannot be allowed to occur. (If a proposal from a member of your family or from your home institution comes in to your program, for instance, you would clearly have to disqualify yourself from handling it.) Most of the Federal conflict-of-interest laws and a few conflicts rules special to the NSF deal with conflicts or potential conflicts of this sort. They therefore either flatly prohibit you from doing certain things that could give rise to such conflicts or disqualify you from participating in matters where you would have potentially serious conflict.

(e) *Other conflicts.* By no means all conflicts of interests are so serious and clear that flat prohibitions or disqualifications are appropriate. Many,

though real, are subtle, even remote. The seriousness of others so depends on circumstances of the particular case that unvarying rules would be impractical. Most important, there are countervailing considerations. Flat prohibition of activities permitted to others who are not (or have not been) Federal employees can make Federal employment unattractive and so reduce the competence of Government. Disqualification of officials from involvement with particular matters may deprive the agency and the public of the services of those who are best qualified by expertise or experience to make the required judgements or effect the required actions. Therefore the conflicts laws and regulations do not specifically address many potential or actual conflicts that are not serious enough to require flat prohibitions or disqualifications or not easily enough identified by general rule to permit them.

(1) In the handling of proposals and other award-related applications, these regulations require that some such potential conflicts receive special attention from a designated "directorate conflicts official". The conflicts official considers the circumstances of each case and decides whether to require either a disqualification of some form of special handling. See Part 681 of this chapter.

(2) Other actual or potential conflicts may not be covered by any specific rule. You should nonetheless be sensitive to them and do whatever seems wise either to avoid them altogether or to ensure that they affect neither the quality of NSF decisons nor public trust in those decisions.

§ 680.13 Summary of conflicts rules.

(a) This section summarizes the principal conflicts rules that NSF employees (other than "special employees") are expected to observe. Section 680.14 summarizes specific conflicts-related responsibilities assigned to particular organizational units or officials by the regulations. Section 680.15 summarizes special rules for full-time Presidential employees. Rules for consultants, Board members, and other employees who work for the NSF 130 days a year or less are covered in Part 684 of this chapter.

(b) Rules on handling proposals and awards. Part 681 (681.10–681.44).

(1) If you would normally handle a proposal or other application, but possess with respect to it a potentially biasing affiliation or relationship listed in § 681.21, you must bring the matter to the attention of a conflicts official in your directorate or staff office. You must do so whether or not the affiliation or relationship is also designated "normally disqualifying" or "automatically disqualifying". The conflicts official will determine how the matter should be handled and will tell you what further steps to take.

(2) If you become aware that a prospective, current, or recent NSF employee has an involvement or interest in any proposal or other application you are handling, you must bring the matter to the attention of a directorate conflicts official. The conflicts official will decide how the matter should be handled and tell you what further steps to take. If the file reflects that a conflicts official has already been consulted and has decided how the matter should be handled, you may proceed as the conflicts officials has directed, unless something of possible significance has changed.

(3) You must ask each peer reviewer of any proposal you are handling to indicate any possible conflicts of interests the reviewer may have. You should record in the proposal file all interests, affiliations, or relationships revealed by reviewers; determine how, if at all, they ought to affect the use of the review; and describe your determination in the file.

(c) Representational restrictions and involvement with proposals and projects during and after NSF service. Part 682 (§§ 682.10–682.23) of this chapter.

(1) *Current-employee restriction.* During your Federal employment you must not represent anyone (including yourself) in dealings with any Federal official on any proposal, project, or other matter.

(2) *One-year NSF restriction.* For one year after you leave NSF employment you must not represent anyone (including yourself) in dealings with any NSF official on any proposal, project, or other matter.

(3) *"Official responsibility" two-year restriction.* For two years after you leave NSF employment you must not represent anyone else in dealings with any Federal official on any proposal, project, or other matter involving specific parties if the same matter was active under your official responsibility during your last year at the NSF.

(4) *"Personal involvement" permanent restriction.* You must never represent anyone else in dealings with any Federal official on any proposal, project, or other matter involving specific parties if you were personally involved with the same matter as an NSF employee.

General effect. These representational restrictions do not preclude you from being involved as a researcher or educator with proposals submitted to the Government or projects supported by the Government. They do preclude you from negotiating with NSF officials or other Federal officials and from engaging in other representational activities intended to influence their decisions on certain proposals and projects. They do not preclude you from representing yourself before the Government on personal matters, such as audits of your individual tax returns or personnel decisions that affect you.

(d) Financial disclosure. Part 683 Subpart A, §§ 683.10–683.12 of this chapter.

(1) If you are an executive level, SES, or supergrade (GS–16 or equivalent and above) employee, you are a "senior employee" and must file public Financial Disclosure Reports.

(2) Otherwise, if you serve as either a program officer, a directorate administrative official, a grants officer, a contracts officer, an auditor, or a lawyer, you must file confidential Statements of Employment and Financial Interests.

(3) If you fit neither of these categories, no general financial disclosure is required of you.

(4) If you are required to file Financial Disclosure Reports or Statements of Employment and Financial Interests, the Foundation will supply you with the necessary forms. You may ask for them when you need them, but normally they will be sent to you automatically, with instructions.

(e) Acts affecting your financial interests. Part 683, Subpart B (§ 683.20) of this chapter. You must not be personally involved as a Federal employee in the handling of any matter in which you, a member of your immediate family, a business partner, or an organization of which you are or may become a part has a financial interest.

(f) Outside employment, compensation, gifts, etc. Part 683, Subpart C (§§ 683.30–683.36) of this chapter. These rules are too numerous to summarize but they are not difficult to use. Refer to the referenced sections whenever you contemplate any of the following:

(1) Outside employment and income (§ 683.30);

(2) Compensation from private sources (§ 683.31);

(3) Honoraria (§ 683.32);

(4) Reimbursement of expenses or receipt of meals, lodging, or travel tickets from private sources (§ 683.33);

(5) Use of inside Government information in connection with speeches, articles, or other private activities (§ 683.34);

(6) Use of Government property or services for personal or private purposes (§ 683.34);

(7) Participation in an NSF-supported conference or workshop (§ 683.35); or

(8) Receipt of a gift, favor, loan, prize, or award (§ 683.36).

(g) Political activity (Hatch Act). Part 683, Subpart D, (§§ 683.40–683.45) of this chapter.

(1) You may not run for public or party office, except in nonpartisan elections and certain local elections.

(2) You may not participate in election campaigning, except in nonpartisan elections and certain local elections.

(3) You may not take an active part in leading or managing a political party.

(4) You must not use your official authority or influence for political purposes. See § 683.44.

§ 680.14 Specific responsibilities.

Apart from the conflicts rules for all employees summarized in the preceding section, these regulations impose the following additional responsibilities:

(a) *Directorates and staff offices.* Each directorate and staff office is responsible for designating "conflicts officials" and for making sure that all staff who handle proposals and other applications know who the conflicts officials are (§ 681.10(d)).

(b) *Directorate (and staff-office) "conflicts officials".* If your directorate or staff office has designated you as a conflicts official, your responsibilities are described in Part 681, Subpart D, (§§ 681.40–681.44) of this chapter.

(c) *Officials who are recruiting new professional employees.* If those who are recruiting determine that a person has become a "prospective employee", they are responsible for bringing that fact and subsequent developments to the attention of a directorate (or staff-office) conflicts official. Whenever a person currently listed in the NSF principal investigator/project director file seems likely to become an NSF employee, the directorate or office which has recruited that person must inform the Division of Information Systems by memo (so that the principal investigator/project director file can be "flagged" accordingly). It must also send copies of the memo to each NSF division or office that is responsible for an active award or pending proposal involving that person. These and related requirements are further described in Part 681, Subpart C, (§§ 681.30–681.33) of this chapter.

(d) *Directorate for Administration.* The Assistant Director for Administration is responsible for "flagging" the principal investigator/project director file to indicate those who are incoming, current, or recent employees (§681.33(d)).

§ 680.15 Special rules for full-time Presidential appointees.

If you are a Presidential appointee, you are subject to special rules:

(a) You must file a public Financial Disclosure Report within 5 days of your nomination to your position by the President. (§ 683.11)

(b) You must not engage in any other business, vocation, or employment while serving the NSF in a full-time Presidential position. (§ 683.30)

(c) You may not hold office in or act for any institution that has or is seeking NSF awards without the approval of the National Science Board. (§ 683.30)

(d) You may not earn outside income totalling more than 15 percent of your Government salary in any calendar year. (§ 683.30)

(e) You are not subject to the restrictions on political activity, except to those concerning use of official authority or influence for political purposes. (§ 683.40)

§ 680.16 General standards of employee conduct.

(a) *Summary.* This section covers some standards of conduct for Government employees that are not covered elsewhere in the NSF regulations. Most of them are basic standards of integrity, decency, and obedience to law. Violation of any of these standards is grounds for serious disciplinary action.

(b) *Underlying intent.* The intent of these regulations generally is that you should not:

(1) Engage in criminal, infamous, dishonest, immoral, or notoriously disgraceful conduct or in any other conduct prejudicial to the Government or to Government efficiency or economy;

(2) Use your public office for private gain;

(3) Give preferential treatment;

(4) Have direct or indirect financial interests that conflict substantially, or appear to conflict substantially, with your Government duties and responsibilities;

(5) Engage directly or indirectly in financial transactions based on information obtained through your Government employment that is not available to the general public;

(6) Lose your independence or impartiality; or

(7) Make Government decisions outside of the proper official channels.

(c) *Preserving public trust.* You are responsible for helping to earn and maintain the confidence of the public in the integrity of the Government. This requires you to be concerned with appearances as well as actualities.

(d) *Payment of taxes and debts.* You are expected to pay your taxes and your just debts properly and on time. ("Just debts" means those you acknowledge or that have been reduced to final judgment. The Government will not try to determine the validity or amount of any disputed debt.)

(e) *Gambling.* You must not gamble in a Government office or while on duty. This includes participating in a sports pool or a lottery not officially sanctioned by the NSF.

(f) *Familiarity with statutory provisions.* You are legally responsible for acquainting yourself with each statute that relates to your ethical and other conduct as an NSF and Federal employee. Principal among these are the criminal statutes relating to bribery, graft, and conflicts of interests contained in 18 U.S.C. 201–209. these regulations cover the aspects of those statutory provisions that apply to you as an NSF employee. The regulations also cover the provisions of Executive Order 11222, which prescribes standards of ethical conduct for Government officers and employees, and they cover regulations of the Office of Personnel and Management that implement both the criminal statutes and the Executive Order. If you follow the regulations, you should have no trouble with any of those provisions. Not covered in these regulations, however, are the following statutory provisions:

(1) The prohibition against lobbying with appropriated funds (18 U.S.C. 1913).

(2) The prohibitions against disloyalty and striking (5 U.S.C. 7311, 18 U.S.C. 1918).

(3) The prohibitions against disclosure of classified information (18 U.S.C. 798, 50 U.S.C. 783) and disclosure of confidential information (18 U.S.C. 1905).

(4) The provision relating to habitual use of intoxicants to excess (5 U.S.C. 7352).

(5) The prohibition against misuse of a Government vehicle (31 U.S.C. 638a(c)).

(6) The prohibition against misuse of the franking privilege (18 U.S.C. 1719).

(7) The prohibition against use of deceit in an examination or personnel action in connection with Government employment (18 U.S.C. 1917).

(8) The prohibition against fraud or false statements in a Government matter (18 U.S.C. 1001).

(9) The prohibition against mutilating or destroying a public record (18 U.S.C. 2071).

(10) The prohibition against counterfeiting or forging transportation requests (18 U.S.C. 508).

(11) The prohibitions against embezzling Government money or property (18 U.S.C. 641); failing to account for public money (18 U.S.C. 643); and embezzling the money or property of an employee by reason of his employment (18 U.S.C. 654).

(12) The prohibition against unauthorized use of documents relating to claims from or by the Government (18 U.S.C. 285).

(13) The prohibition against acting as the agent of a foreign principal registered under the Foreign Agents Registration Act (18 U.S.C. 219).

Subpart B—Statutory Exemptions

§ 680.20 Necessity and effect of formal exemptions.

The exemptions described in this subpart are provided for by statute, which requires that they be formally promulgated. This subpart provides the formal promulgation and gives notice to the public. If you are an NSF employee, you need not be concerned with them. Anything you need to know that follows from them is either covered elsewhere in these regulations or will be explained if occasion arises by an ethics counselor.

§ 680.21 Exemptions under 18 U.S.C. 208(b).

(a) The Foundation exempts the interests described in the remainder of this section from the operation of section 208(a) and from case-by-case formal determinations under section 208(b)(1) of Title 18, United States Code.

(b) Minor interests. The following financial interests are too inconsequential to affect the integrity of an employee's services to the Government:

(1) Noncorporate bonds;

(2) Shares in a well-diversified money market or mutual fund;

(3) Stocks, bonds, or other securities of a corporation listed on the New York or American Stock Exchange if the aggregate market value of all the securities you hold in that corporation does not exceed $1,000;

(4) Vested pension rights to which no further contributions are being made by your former employer.

(c) Indirect interests. An NSF employee may be a stockholder, partner, employee, officer, or director of an institution, such as a mutual fund, that owns a financial interest in a second institution. If the owning institution's financial interest consists of securities or other evidences of debt of the second institution that amounts to:

(1) Less than 5 percent of the total portfolio of investments of the owning institution,

(2) Less than 5 percent of the total outstanding amounts of the same classes of securities of the second institution, and

(3) Less than would be needed to obtain effective control of the second institution,

then the interest is too remote and inconsequential to affect the integrity of the employee's services to the Government.

(d) Visiting committees. An NSF employee (typically a "special employee") might serve on a visiting committee or similar advisory body at an institution. Any interest that the institution might have in a proposal, project, or other matter that the employee might participate in handling would be too remote to affect the integrity of the employee's services to the Government—unless it involved proposals, projects, or other matters originating from the same department or facility that the visiting committee or similar body advises.

(e) Support services for National Science Board tasks and responsibilities. A member of the National Science Board may need professional, clerical, and administrative services to support the member's personal efforts to carry out Board tasks and responsibilities. With the approval of the Director and the Chairman of the National Science Board and in accordance with other laws and regulations, the NSF may contract with the home institution of the member to provide such services. The institution may receive reimbursement of all allowable costs, but no profit or fee. In such circumstances any financial interests the institution might have are normally too inconsequential to affect the integrity of the services provided by the Board member to the Government.

§ 680.22 Certification under 18 U.S.C. 205.

NSF consultants, members of the National Science Board, and other NSF "special employees" may perform work under NSF awards and their compensation may be charged to such awards, to the extent consistent with these regulations. The Director certifies that the national interest so requires. Other provisions of these regulations ensure that no significant conflict of interests will result.

PART 681.—CONFLICTS OR POTENTIAL CONFLICTS IN HANDLING PROPOSALS AND AWARDS

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681.44 Handling prospective-employee determinations.

Authority: E.O. 11222 of May 8, 1965, 3 CFR, 1965 Supplement and Regulations of the Office of Personnel Management, 5 CFR 735.104.

Subpart A.—Summary

§ 681.10 Summary.

(a) Two types of problems could affect the judgments of program officers and other NSF officials who handle proposals and other applications:

(1) The official might possess outside interests, affiliations, or relationships that could create bias; or

(2) Another NSF employee could have an involvement or interest in the proposal or application.

Whenever either of these problems arises, the official who would normally handle the proposal or other application is asked to bring the problem to the attention of a "directorate conflicts official". This conflicts official examines the case; decides what disqualifications or special handling arrangements, if any, are called for; and places a memo in the file explaining the circumstances and any arrangements made to deal with them. In some cases disqualifications are routine or automatic.

(b) Peer reviewers can also have interests, affiliations, or relationships that might affect their reviews.

Reviewers are asked to reveal any such interests, affiliations, or relationships. Those are then taken into account by NSF officials in making decisions or recommendations based on the reviews.

(c) If you are a program officer or other NSF official who handles proposals and other award-related applications, your responsibilities in these matters are explained in Subpart B (§§ 681.20–681.26).

(d) Each directorate or staff office of the Foundation is responsible for designating "conflicts officials" and for making sure that all staff who handle proposals and other applications know who the conflicts officials are. The directorate conflicts officials need not be in the directorate front office. They could, for example, be division directors.

(e) If you have been designated as a directorate (or staff office) conflicts official, your responsibilities in these matters are explained in Subpart D (§§ 681.40–681.44) of this part, which also provides guidance to help you carry out those responsibilities.

Subpart B.—Guidance for Program Officers and Other Decisionmaking Officials

§ 681.20 Introduction.

(a) If you are a program officer or other NSF official who would normally handle a proposal or other application, but you possess with respect to it a potentially biasing affiliation, listed in § 681.21, that section explains what you should do.

(b) If you become aware that another NSF employee—including a prospective employee or a recent employee (one who has left the NSF within the past year)—has an involvement or interest in a proposal or other application you are handling, § 681.23 explains what you should do.

(c) You must ask each peer reviewer of any proposal or project you are handling to indicate any possible conflicts of interest the reviewer may have. Section 681.25 suggests how you should do that and explains what you should do when a reviewer does have a possible conflict.

(d) Should an employee of another Government agency have an interest in a proposal or other application you receive from anyone other than that agency, do not talk or correspond with him or her at all without first consulting an ethics counselor. He or she could inadvertently be put in technical violation of a criminal statute unless we are careful.

(e) You "handle" a proposal or other application if you recommend a decision on it, make or approve the decision, or otherwise substantially influence the decision. If you are a grants officer, contracts officer, financial official, or lawyer you are affected if you play a significant role in decisions on award budgets or terms. If in doubt, consult an ethics counselor in the Office of the General Counsel.

(f) This part covers only conflicts and potential conflicts in handling proposals and other award-related applications. Conflicts or potential conflicts in handling other matters are covered in § 683.20 of this chapter.

§ 681.21 When you have a potentially biasing affiliation or relationship.

(a) If you would normally handle a proposal or other application, but possess with respect to it a potentially biasing affiliation or relationship listed below, you must bring the matter to the attention of a conflicts official in your directorate or staff office. You must do so whether or not the affiliation or relationship is also designated "normally disqualifyin" or "automatically disqualifying". (Some affiliations or relationships are neither.) The conflicts official will determine how the matter should be handled and will tell you what further steps to take.

(b) Affiliations with an applicant institution:

(1) Current appointment at the institution as professor, adjunct professor, visiting professor, or the like (automatically disqualifying).

(2) Current employment or being under consideration for employment at the institution (automatically disqualifying).

Note.—This may include employment via a consulting or advisory arrangement; check with an ethics counselor.

(3) Any formal or informal reemployment arrangement with the institution (automatically disqualifying).

(4) Current membership on a visiting committee or similar body at the institution (automatically disqualifying, but only for proposals or applications that originate from the department, school, or facility that the visiting committeee or similar body advises).

(5) Ownership of the institution's securities or other evidences of debt (automatically disqualifying).

Note.—Minor or indirect holdings may be exempted; check with an ethics counselor.

(6) Any office, governing board membership, or relevant committee chairmanship in the institution (automatically disqualifying).

Note.—Ordinary membership in a professional society or association is not considered an office.

(7) Current enrollment as a student (normally disqualifying, but only for proposals or applications that originate from the department or school in which one is a student).

(8) Receipt and retention of an honorarium or award from the institution within the last twelve months (automatically disqualifying).

(c) *Relationship with an investigator project director, or other person who has a personal interest in the proposal or other application:*

(1) Blood or marriage relationship (automatically disqualifying if the relationship is with a principal investigator or project director).

(2) Business partnership (automatically disqualifying).

(3) Employment at the same institution within the last 12 months.

(4) Past or present association as thesis advisor or thesis student.

(5) Collaboration on a project or on a book, article, report, or paper within the last 48 months.

(d) Other affiliations or relationships:

(1) Any affiliation or relationship of your spouse, of your minor child, of a blood relative living in your immediate household or of anyone who is legally your partner that you are aware of and that would be covered by paragraph (b) or (c) of this section it it were yours (disqualifying to the same extent as if the affiliation or relationship were yours, except for receipt by your spouse or relative of an honorarium or award, which is not necessarily disqualifying).

(2) Any other relationship, such as close personal friendship, that you think might tend to affect your judgments or be seen as doing so by a reasonable person familiar with the relationship.

§ 681.22 "Automatically disqualifying"; "normally disqualifying".

(a) *"Automatically disqualifying".* If you have an interest, affiliation, or relationship that § 681.21 designates "automatically disqualifying", you should disqualify yourself from handling the affected proposal or other application. You must not participate in handling it under any circumstances. BE CAREFUL: in most cases a violation of this rule would be a Federal crime.

(b) *"Normally disqualifying".* If you have an interest, affiliation, or relationship that § 681.21 designates "normally disqualifying", you should disqualify yourself from handling the affected proposal or other application, unless specifically directed to do otherwise by the conflicts official.

§ 681.23 When a prospective, current, or recent NSF employee has an involvement or interest.

(a) If you become aware that a prospective, current, or recent NSF employee has an involvement or interest in any proposal or other application you are handling, you must bring the matter to the attention of a directorate conflicts official. The conflicts official will decide how the matter should be handled and instruct you accordingly. If the file reflects that a conflicts official has already been consulted and has decided how the matter should be handled, you may proceed as the conflicts official has directed unless something of possible significance has changed.

(b) *What constitutes "an involvement or interest".* A prospective, current, or recent NSF employee "has an involvement or interest" in a proposal or other application if the employee is, was, or will be a member of the research group or project staff involved. If the employee was a member of a research group, but has since severed all relationships with the project and with the group, the employee no longer has an involvement or interest. Unless there has been such a severance, however, appointment of a substitute principal investigator or substitute negotiator would not affect the requirement for consulting a conflicts official.

(c) *Finding out about it.* How do you find out that a person who has an involvement or interest in a proposal or application you are handling is a current, prospective, or recent NSF employee? There are four possibilities:

(1) The proposal or application might say so.

(2) The Foundation's principal investigator/project director file that you routinely check when beginning work on a new proposal will usually indicate that a listed investigator is a current, prospective, or recent NSF employee if that is the case. The mechanism by which this is arranged is explained in § 681.33.

(3) You might receive a copy of a memorandum from another NSF official indicating that an investigator on a proposal already pending or an award already active has become a prospective employee. The circumstances under which such a memorandum will be sent to you are also explained in § 681.33.

(4) You might happen to know or learn of the person's NSF employment or prospective employment through your other activities.

(d) *Your responsibility.* No matter how you find out, once you do, it is your responsibility to bring the matter to the attention of a directorate conflicts official—unless, of course that has already been done. If in doubt, consult the conflicts official or an ethics counselor.

§ 681.24 Directorate conflicts officials.

Your directorate or office is responsible for letting you know who your conflicts officials are. If you do not know, check with the office of the assistant director or office head. Subpart D (§§ 681.40–681.44) explains the responsibilities of the conflicts officials and provides guidance for them.

§ 681.25 Possible conflicts of peer reviewers.

(a) You must ask each peer reviewer of any proposal or similar application you are handling to indicate any possible conflicts of interest the reviewer may have.

(b) In the case of mail review, you may do this by including in the letter requesting the review the following language:

"If you have any relationships with the institution or the persons submitting this proposal, please consider whether they could be construed as creating a conflict of interests for you. Please describe in your own words any relationship that might be so construed. You may use a separate piece of paper and attach it to your review. Regardless of any such relationships, we would like to have your review unless you believe you cannot be objective."

(c) In the case of panel review, you should make an oral request of the panel members, essentially as follows:

"If when we come to consider any particular proposal, you recognize that you have a relationship with the institution or persons submitting the proposal that could be construed as creating a conflict or interests, please let me know. I'll ask you to describe the relationship in your own words and will determine from your description what to do about the situation. You must not participate in reviewing any application in which you or a member of your immediate family or an organization of which you are or may become a part has a financial interest. Otherwise, we'll often just make a note in the file to consider when making final recommendations."

(d) You may use the list in § 681.21 as a guide in responding to reviewer questions about the relationships that should be considered. Section 684.15 explains when a panel reviewer, like any other "special employee", must be excused from review of an application because of a financial interest. Otherwise, no advance disqualification of reviewers is required. There may be other circumstances, though, in which you and the reviewer will conclude that the review would have to be disregarded and would thus be a waste of the reviewer's time.

(e) You should record in the proposal file all interests, affiliations, and relationships revealed by reviewers or otherwise known to you. You should determine how, if at all, those interests, affiliations, or relationships ought to affect the use of the review in assessing the proposal. You should appropriately describe in the file both your determination and the reasoning behind it.

Subpart C—Identifying Prospective, Current, or Recent NSF Employees and Proposals or Awards in Which They Have an Interest

§ 681.30 General.

Sections 681.23 and 681.43 provide for special handling of any proposal or other application in which a prospective, current, or recent NSF employee has an involvement or interest. Section 681.23(c) explains generally how an official who handles a proposal or application might learn that a person who has an involvement or interest is a prospective, current, or recent employee. This Subpart:

(a) Explains more precisely who is a "recent employee", or "prospective employee" (§ 681.31);

(b) Identifies responsibilities of the recruiting directorate or office when a person becomes a "prospective employee" (§ 681.32);

(c) Explains how the recruiting directorate should inform others when it becomes clear that a prospect will become an NSF employee (§ 681.33(a)); and

(d) Requires the Assistant Director for Administration to provide for "flagging" the principal investigator/project director (PI/PD) file to indicate that a person listed there is a prospective, current, or recent NSF employee (§ 681.33(d)).

§ 681.31 "Recent employee"; "prospective employee".

(a) *"Recent employee".* Any former NSF employee who left the NSF within the year before the affected proposal or other application is filed with the NSF should be considered a recent NSF employee.

(b) *"Prospective employee" threshold.* As soon as those recruiting have expressed interest in a particular person in connection with a specific opening and have received some indication of reciprocal interest, that person should be considered a prospective NSF employee—even though no actual offer has been made and even though there is substantial doubt that one would be

accepted if it were made. More specifically:

(1) NSF officials who have an opening on the horizon often discuss it with persons outside the NSF. If the discussion is just a general effort to make members of the appropriate community aware of the opening in the hope that applicants will appear, it makes no one a prospective employee. But if the discussion is with a particular individual whose candidacy is sought, that individual should be considered a prospective employee if (but only if) the candidate expresses some interest. The expression of interest need not be strong. It could amount to no more than a willingness to "think it over" or come in for a talk. After such an expression of interest NSF officials could be influenced in decisions on proposals or other applications by their hopes of getting the candidate to consider the job or to take it.

(2) When a specific vacancy is imminent, the NSF usually solicits and receives applications. Some applications may come from persons in whom there is little or no interest. Others may come from persons the recruiters have never met. Conflicts are unlikely to arise in such cases unless and until the recruiters become sufficiently interested to initiate some direct contact with the applicant, typically by suggesting an interview. At that point the applicant should be considered a "prospective employee". If no direct contact is ever initiated outside the personnel mechanics, the applicant need not be considered a prospective NSF employee.

§ 681.32 What the recruiting directorate or office should do when a person becomes a "prospective NSF employee".

(a) Special attention and special handling of proposals or other applications in which a prospective NSF employee has an involvement or interest are not required automatically. They are required under § 681.23(a) only if an official handling the proposal or application actually becomes aware that a person involved or interested is a prospective employee. Whether to inform other officials that a person is a prospective employee is within the discretion of a conflicts official of the recruiting directorate or office.

(b) If those who are recruiting determine that a person has become a prospective employee under these guidelines, they are responsible for bringing that fact and subsequent developments to the attention of a directorate or office conflicts official. This should be an official who is not directly involved in the recruitment and does not immediately supervise the position for which the prospective employee is being considered.

(c) The conflicts official is responsible for deciding whether, when, and to what extent proposals or other applications involving the prospect require special attention and special handling. See § 681.44.

§ 681.33 Informing others about incoming employees; "flagging".

(a) *When a "prospective employee" becomes an "incoming employee".* Each directorate is responsible for informing the Division of Information Systems by memo whenever a prospective employee listed in the NSF PI/PD (principal investigator/project director) file seems likely in fact to become an NSF employee. The memo should be sent at least as soon as the incoming employee enters into discussions of grade and salary with personnel officials. It might be sent sooner should the responsible conflicts official of the recruiting directorate or office find that appropriate. The memo should identify all active NSF awards and pending NSF proposals with which the prospective employee has an association. This should be checked with the PI/PD file and with the prospective employee.

(b) *Informing other divisions.* The recruiting directorate is also responsible for sending copies of its memo to each NSF division or office that is responsible for such an active award or pending proposal.

(c) *"Signals off".* If the prospect does not become an NSF employee after all, the recruiting directorate is responsible for notifying by memo all those who received its original memo.

(d) *"Flagging".* The Assistant Director for Administration is responsible for "flagging" the PI/PD file to indicate every person listed there who is a current or recent NSF employee or who has been identified in a memo from the recruiting directorate or office as an incoming NSF employee.

Subpart D.—Guidance for Directorate Conflicts Officials

§ 681.40 Summary; responsibilities of conflicts officials.

(a) If your directorate or staff office has designated you as a conflicts official, you have three responsibilities under these regulations:

(1) You determine how to handle a proposal or other application when an official who would normally handle it possesses with respect to it an affiliation or relationship listed in § 681.21. The potential conflicts you should be concerned with in such a case are generlly apparent from the nature of the affiliation or relationship.

(2) You determine how to handle a proposal or other application when a prospective, current, or recent NSF employee has an involvement or interest in it. Section 681.43 describes the potential conflicts you should be concerned with in such a case.

(3) You determine whether, when, and to what extent proposals or other applications involving a prospective NSF employee require special attention and special handling. Section 681.44 offers guidance for such determinations.

(b) Section 681.41 describes the underlying considertions you are called upon to accommodate and balance in making these determinations. Section 681.42 describes the disclosure that is required in all cases that come to you for determination and the forms of special handling you might require in such cases. It also explains what you should do when a particular relationship is considered "automatically disqualifying" or "normally disqualifying".

§ 681.41 Making determinations: Underlying considerations.

When you are called upon to make any of the determinations described in § 681.40, what considerations should influence you in deciding what to do?

(a) The primary purpose of your involvement is to remove or limit the influence of any ties to an applicant institution, investigator, etc. that you think could affect the decisions of an NSF official. Keep in mind that an official may be influenced by such ties without deliberately biasing decisions or even being conscious that his or her judgment is affected. Do not, however, "strain at gnats".

(b) A secondary purpose is to preserve the trust of the scientific community, the Congress, and the general public in the integrity, effectiveness, and even-handedness of the NSF and its award-review processes. This requires you to be concerned with appearances as well as actualities.

(c) An important countervailing consideration is to avoid distorting NSF judgments on proposals and other award actions by disqualifying those who are most competent to make the judgments. So far as possible, you should ensure that those who handle a proposal or other application are competent in the scientific or technical fields involved and are capable of judging the relative standing of a proposal in comparison with other proposals in the same field.

(d) Occasionally, action on a particular proposal or other application raises significant policy questions. As far as possible, you should avoid preventing an official who is responsible for the policy judgments in question from exercising that responsibility.

(e) Finally, you can and should consider the extra paperwork, effort, and expense to the taxpayer required by any special handling you might require.

Except where an interest, affiliation, or relationship is designated "normally disqualifying" or "automatically disqualifying", finding ways to accommodate and balance these competing considerations is left to your ingenuity and judgment.

§ 681.42 Disclosure, disqualification, and other special handling.

(a) *Disclosure.* In every case brought to you as a conflicts official, you should prepare a simple memo for the file. The memo need not be in any particular format and may be handwritten. It should identify the potential conflicts problem involved and should explain what special handling, if any, you have required. Even if you require no additional special handling, the memo will ensure that the Foundation is open about the potential conflict and attentive to it. It will allow those reviewing the recommended action at higher levels to consider any effect the potential conflict might have had and alert them to scrutinize the action more closely. It will allow meaningful audit and oversight and so protect those involved, including you. And it will help preserve public trust in the NSF and in NSF decisions.

(b) *Disqualification.* In some cases disclosure alone will be insufficient to protect against distortion of NSF decisions or undermining of public trust in the NSF and NSF decisions. In some such cases you may decide to require disqualification of the official who possesses the potential conflict. On conflicts considerations alone, of course, this is the best solution. But if the official has unique scientific or technical competence to make the judgments called for, is uniquely qualified to judge the standing of a proposal relative to other proposals against which it must compete, or has responsibility for policy judgments raised in the decision, disqualification of that official would have serious disadvantages. Your judgment should depend heavily on the extent to which someone else will be able to substitute effectively for the official who might be disqualified.

(c) *Other special handling.* You are not confined to relying either on disclosure only or on complete disqualification. Other, intermediate solutions can also go a long way toward removing or minimizing any potential for bias. For example:

(1) Sometimes you might allow a case to be handled normally, but provide for extra peer reviews or extra review within the NSF.

(2) Sometimes you might have an official perform some functions but not others. The official might be able to supply a list of potential reviewers, for example, without running into serious conflicts. Or the official might be consulted by a substitute official on the competitive range in the program where the substitute is competent enough to read reviews and judge the merit of a proposal, but ill-prepared to determine where that places the proposal among those competing for funds within the same program.

(3) In some cases scientists from outside the NSF could be relied on to a greater extent than usual. Suppose a substitute NSF official has less than optimal technical competence or less than optimal sense of the competitive range in the affected program. Such a substitute might nonetheless be able to stand in if aided by an outsider who is more familiar with the scientific subfield or the affected program or both. The outsider might be a former NSF official, a panel member, a scientist from a sister agency, or in an unusual case, a special consultant.

(d) *"Normally disqualifying" or "automatically disqualifying" interests or affiliations.* Although decisions on the kind and degree of special handling that should be required are often left to your discretion, more inflexible disqualification rules do apply in the case of certain interests and affiliations.

(1) If an interest or affiliation is labelled "normally disqualifying" in these regulations, you should routinely disqualify any official who possesses such an interest or affiliation with respect to the proposal or application concerned. If special circumstances require that such an official be allowed to act on the proposal or application, your memo to the file should carefully explain those circumstances and what other precautions you have taken to minimize the potential for bias. Even then, you should not proceed until you have consulted an ethics counselor and the ethics counselor concurs.

(2) If an interest or affiliation is labelled "automatically disqualifying" in § 681.22, you must disqualify any official who possesses such an interest or affiliation with respect to the proposal or application concerned. In most cases, the disqualification is required by criminal law. If you were to allow the official to take any part in the handling of the proposal or application, you would place him or her (and conceivably even yourself) in jeopardy of fine or imprisonment.

(e) *Consolidated handling of related cases.* If you anticipate a number of cases involving the same person and the same general circumstances, you may make a single determination and issue a single memo covering all of the cases. For example, you might issue a memo indicating that a rotator will be disqualified from handling any proposal or application from his or her home institution, and saying who will handle any such proposal or application instead. A copy of this memo should be placed in the file for each affected proposal or award.

§ 681.43 Potential conflicts when an NSF employee has an involvement or interest.

(a) When a prospective, current, or recent NSF employee has an involvement or interest in a pending proposal or other application, you should look for and deal appropriately with the five steps of potential conflicts described in the rest of this section.

(b) Recruiter's conflicts. These are potential conflicts that could arise if an NSF official who is recruiting a prospective employee were simultaneously to handle a proposal or other application in which the prospective employee has an interest. You should identify those actively interested in recruiting the prospective employee and look for ways to limit their involvement in the handling of the proposal or other application. In particular:

(1) The person who would be the immediate supervisor of the prospective employee usually will have an especially active interest in successful recruiting. You should treat that interest as "normally disqualifying".

(2) Those directly involved in discussions with the propective employee will also have an interest in successful recruiting. You should consider their possible conflicts.

(3) Officials at higher echelons who are not directly involved in the particular recruitment may still have an interest in successful recruiting within their organizations. You should consider their possible conflicts.

(c) Superior's conflicts. These are potential conflicts that could arise if an NSF official were to handle a proposal or other application in which one of the official's subordinates has an interest. In particular:

(1) The immediate supervisor of an employee usually will have an

especially active interest in having the employee happy and in maintaining good relations with the employee. You should treat the immediate supervisor's interest as "normally disqualifying" if the interested employee is a prospective or current employee. You need not do so, however, in the case of a recent employee, for the supervisor's interest diminishes when the employment relationship ends.

(2) Persons at higher echelons might also be influenced by an interest in having the employee happy. You should consider whether their involvement in handling the proposal or application can or should be limited.

(d) Subordinate's conflicts. These are potential conflicts that could arise if an NSF official were to handle a proposal or other application in which the official's immediate superior or someone at a higher echelon in the official's "chain of command" has an interest. In particular:

(1) An NSF official would be placed in a particularly difficult position if asked to act on a proposal or other application in which the official's boss has an interest. Thus you should treat the immediate subordinate or a prospective or current employee as having a "normally disqualifying" relationship and only under the most special circumstances allow him or her to have any part in handling the proposal or application. You need not necessarily disqualify one who was the immediate subordinate of a recent employee, however, since the potential conflict would be substantially diminished once the supervisor-subordinate relationship ends.

(2) You may sometimes have to allow less immediate subordinates at lower echelons to play a role if there is not to be serious loss of technical competence and awareness of competitive range in the program affected. But you should take particular care in involving such lower-echelon subordinates. Disqualification would be preferable if it is workable. One possibility if disqualification is not workable may be to allow the official handling the proposal to stay anonymous, dealing with investigators and the grantee institution through another NSF official—perhaps a senior official or a grants officer. Other types of special handling that might be useful in such a case are described in § 681.42(c).

(e) Professional associate's conflicts. These are potential conflicts that could arise if an NSF official were to handle a proposal or other application in which a close professional associate at the NSF have an interest. In particular:

(1) You may have to consider disqualification of a very close associate of the interested employee, particularly where professional association may have led to personal friendship.

(2) When the degree of professional association and personal acquaintance involved is only what normally arises from service within the same organizational unit, little more than disclosure should normally be required.

(f) Reviewer's conflicts. These are potential conflicts that could arise when reviewers are asked to pass upon a proposal involving the interests of a scientist who will later be passing upon their proposals as an NSF program offical. To avoid them:

(1) All files, active and inactive, that involve research or a research group with which the employee was or is associated should be sequestered to protect the anonymity of reviewers.

(2) To the extent possible you may want to provide more protection by selecting as peer reviewers persons who are not supported by any program for which the interested official is responsible.

§ 681.44 Handling prospective-employee determinations.

(a) You may be called upon to determine whether, when, and to what extent proposals or other applications that involve a prospective employee require special attention and special handling. You should be consulted as soon as a person becomes a prospective employee. The procedure for this is described in § 681.32.

(b) *Nature of possible conflicts.* Actual or potential conflicts of interests can arise in such a situation if any of those who would handle a proposal or other application either is trying to recruit the prospective employee or would be a subordinate, supervisor, or close colleague of the potential employee.

(c) *When you should take action.* If there is a significant possibility that such actual or potential conflicts could improperly influence decisions on proposals or other applications or awards, you must institute special handling as described in §§ 681.42 and 681.43. In the case of proposals and awards outside your own directorate or office, you should do that by notifying officials of the other directorate. A conflicts official of that directorate or office will determine what special handling may be necessary there.

(d) *Avoid premature action.* However, you should avoid unnecessarily early disclosure that a person is under consideration for an NSF position, for two reasons:

(1) That a person is considering a change of jobs is often confidential, particularly in earlier stages; and

(2) Knowledge that an interested person is a prospective NSF employee cannot affect an official's judgment on a proposal or other application if the official possesses no such knowledge.

Since an official who works in one NSF organizational unit is less likely to know that a person is under consideration for employment in a different unit, and is also less likely to be influenced by any such knowledge, it normally makes sense to delay notifying officials outside the recruiting until it seems quite likely that the prospect will indeed become an NSF employee.

PART 682—REPRESENTATIONAL RESTRICTIONS AND INVOLVEMENT WITH PROPOSALS AND PROJECTS DURING AND AFTER NSF SERVICE

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682.23 Compensation or reimbursement of expenses from awards.

Authority: E.O. 11222 of May 8, 1965, 3 CFR, 1965 Supplement and Regulations of the Office of Personnel Management, 5 CFR 735.104.

Subpart A.—The Representational Restrictions Generally

§ 682.10 Summary; the four basic representational restrictions.

(a) NSF employees are subject to four basic restrictions on representing private parties in dealings with other Federal officials. The first of these applies while you are employed with the Government. The other three apply for varying periods afterward and are known collectively as the post-employment restrictions.

(1) *Current-employee restriction.* During your Federal employment you must not represent anyone (including yourself) in dealings with any Federal

official on any proposal, project, or other matter.

(2) *One-year NSF restriction.* For one year after you leave NSF employment you must not represent anyone (including yourself) in dealings with any NSF official on any proposal, project, or other matter.

(3) *"Official responsibility" two-year restriction.* For two years after you leave NSF employment you must not represent anyone else in dealings with any Federal official on any proposal, project, or other matter involving specific parties if the same matter was active under your official responsibility during your last year at the NSF.

(4) *"Personal involvement" permanent restriction.* You must never represent anyone else in dealings with any Federal official on any proposal, project, or other matter involving specific parties if you were personally involved with the same matter as an NSF employee.

All four restrictions have to do with representing private parties in dealings with NSF officials or other Federal officials. Here are the distinguishing features:

Current-employee restriction	During Federal employment	Any Federal official	Any matter.
One-year NSF restriction	For one year after NSF employment.	Any NSF official	Any matter.
"Official responsibility" two-year restriction	For two years after NSF employment.	Any Federal official	Any matter involving specific parties that was under your official responsibility.
"Personal involvement" permanent restriction	Forever	Any Federal official	Any matter involving specific parties in which you were personally involved.

(b) Examples. The following examples illustrate the application of these rules.

Example 1. You have been on the Physics faculty at the University of Wyoming and have been principal investigator on grants from the NSF and from the Department of Defense. You come to the NSF for a two-year stint as a section head. While you are away Wyoming names a colleague as principal investigator on both your grants. During your stint at the NSF the Department of Defense grant is about to expire. Your substitute principal investigator files a new proposal with DOD. She asks you to call the DOD program officer, with whom you have great credibility from past dealings, to vouch for her excellence and to urge that he continue to fund the Wyoming work. The current-employee restriction prohibits you from doing so.

Example 2. Same underyling facts as Example 1. After your stint at the NSF you return to Wyoming and want again to become principal investigator on the NSF-supported work. You may do so, but the one-year NSF restriction prohibits you from calling, writing, or visiting NSF officials to represent yourself or your institution on the award.

Example 3. Same facts as Examples 1 and 2. A few months after your return it comes time to file a new proposal for another NSF award so that you can continue the line of investigation you have been pursuing with the NSF support. You may prepare a proposal for your institution and may be listed as principal investigator, but the one-year NSF restriction prohibits you from calling, writing, or visiting NSF officials to represent yourself or your institution on the proposal.

Example 4. Same underlying facts as Example 1. During the last year of your tenure as section head another physics proposal came in from the University of Wyoming. Though the program officer who handled the peer review and submitted a recommendation was in your section, you disqualified yourself from any participation in handling the proposal. A three-year continuing grant was awarded. Within two years after you return to Wyoming a problem comes up with the last increment of the continuing grant. You have meanwhile become department chairman. As department chairman you would normally confer with NSF officials about the problem and try to resolve it. The "official responsibility" two-year restriction prohibits you from doing so. If the problem came up more than two years after you left the NSF, however, you would be free to confer with NSF officials. The "official responsibility" two-year restriction would no longer apply, and the "personal involvement" permanent restriction would not apply because you had no personal involvement in handling the proposal while at the NSF.

Example 5. While you were Director of the Division of Grants and Contracts at the NSF you personally approved the terms of a contract to the Solar Equipment Company for development of solar heating equipment. Subsequently, responsibility for this contract was transferred to the Department of Energy. After you retire from your NSF position, you accept a position with the Solar Equipment Company. A problem comes up under the same contract, and you would normally be responsibile for resolving it in discussions with DOE officials. The "personal involvement" permanent restriction prohibits you from doing so. That you would be dealing with DOE officials, not NSF officials, makes no difference: The restriction applies to dealings with any Federal official.

(c) Proposals and projects. Subpart B (§§ 682.20–682.23) is devoted entirely to the application of the representational restrictions in relation to proposals and projects. In relation to proposals and projects you may rely entirely on the specifics there and use the remainder of this Subpart A solely for background.

(d) Other matters. For most current and former NSF employees the representational restrictions will rarely apply except in relation to proposals and projects. You are nonetheless responsible for making yourself familiar with the restrictions and abiding by them in relation to all covered matters.

(e) Terms and effect. The wording of the restrictions as presented in this section and § 682.20 has been simplified substantially from the wording of the underlying statutes, so that they will be easier to understand. In the process, they have also been deliberately overstated, with exceptions and "escape hatches" left out, so that your initial reaction will be to interpret them conservatively. The next three sections fill in critical concepts: what it means to have "official responsibility" or to be "personally involved" (§ 682.11); what is and is not representation subject to the restriction (§ 682.12), and which are the matters on which representation is restricted (§ 682.13). In the process they explain the exceptions and refinements left out in this section.

(f) Partners. During your Federal service only, there is a further restriction that applies to any partner of a business partnership to which you belong. If you belong to any such business partnership see § 682.14.

(g) Source statutes and penalties for violation. for the most part these restrictions derive from Federal criminal statutes and apply to officials of all Federal agencies. In one respect the NSF rules are stricter. At other agencies the one-year agency restriction applies only to former high-ranking officials; the one year NSF restriction applies to all former NSF employees. Violation of the statutory provisions can lead to criminal prosecution (the penalties are a fine of up to $10,000 or imprisonment for up to two years or both) or to civil debarment from dealings with the NSF (for up to five years). A violation of the NSF's current-employment restriction can lead to disciplinary personnel action against an employee.

(h) Consultation. If still in doubt about any of the rules in this part, consult an ethics counselor in the Office of the General Counsel. You are welcome to consult an ethics counselor for this purpose even after you leave the NSF.

§ 682.11 "Official responsibility"; "personally involved".

(a) The "official responsibility" two-year restriction applies only if you had official responsibility for the matter in question during your last year at the NSF. The "personal involvement" permanent restriction applies only if you were personally involved with the matter in question while at the NSF. This section elaborates the concepts of "official responsibility" and "personal involvement".

(b) Official respsonsibility". You had "official responsibility" for a matter if you had direct authority to approve, disapprove, or otherwise direct Government actions regarding that matter, and it was actually pending during your tenure. It does not matter whether your authority was intermediate or final, whether it was exercisable alone or with others, or whether it was exercisable personally or through subordinates. Specifically:

(1) The scope of your "official responsibility" is ordinarily determined by the areas for which the position you filled or the organization you headed are assigned responsibility by job description, delegation, or other authority.

(2) Any matter under consideration in the NSF is under the "official responsibility" of the Director and of each intermediate supervisor who has responsibility for any employee who actually participates in the matter within the scope of his or her duties.

Example. A proposal under consideration within a particular program is under the "official jurisdiction" of the program officer who actually handles it, of the program director for the program, of the responsible section head, of the responsible division director, of the responsible assistant director, and of the Director of the NSF. Whether it is under the "official responsibility" of any of their deputies depends on the responsibilities assigned to the deputies by the position descriptions, by any formal delegations to them, or by any other legally effective means.

(C) "Personal involvement". Personally involved" is short for the following statutory language:

"Participated personally and substantially as an officer or employee through decision, approval, disapproval, recommendation, the rendering of advice, investigation or otherwise".

In other words:

(1) You may have "participated" and so have been "personally involved" even though you actually made none of the important decisions. You "participated" if you made recommendations, rendered advice, conducted an investigation, or otherwise contributed. Moreover, "approval" is specifically covered. Giving a required approval, however perfunctorily, is covered if the action could not have been taken over your objection.

(2) On the other hand, there is distinction between personal involvement and official responsibility. If you could have intervened in the matter because of your position, but in fact did not, you were not "personally involved".

(3) You must have participated "personally". You participated personally if you gave directions or instructions about the matter to a subordinate who participated directly. If a subordinate participated without any direction or instruction from you about that particular matter, and you did not otherwise participate, you did not participate personally.

(4) You must have participated "substantially". That requires more than knowledge of what was going on, perfunctory involvement, or involvement on an administrative or peripheral issue. Your participation was "substantial" if it was significant to the outcome or would have seemed so to a reasonable outside observer, considering not only the effort you devoted to the matter but the influence of your effort on the outcome. A single act at a critical step, such as an approval, may be substantial. A series of time-consuming peripheral involvements, such as review solely for compliance with administrative or budgetary controls, may be insubstantial.

§ 682.12 Representation covered.

(a) *Representational dealings.* All four of the basic representational restrictions are restrictions on representing private parties in dealings with NSF officials or other Federal officials. The dealings covered are encompassing. They include any formal appearance before an official; any meeting with an official; and any letter, phone call, or other communication with an official.

(b) *Intent to influence and potential controversy required.* Contacts as a representative without intent to influence the officials contacted are not prohibited. Nor are contacts as a representative in connection with a routine request not involving a potential controversy. For example, you may ask a question about the status of a particular matter, as long as there is no implicit attempt to influence the outcome. You may request publicly available documents. You may communicate with an official as long as the communication has no connection with an adversary proceeding, to impart purely factual information.

Example. While an NSF employee you helped write the current contract for the Kitt Peak National Observatory, with which you are now a staff scientist. You are asked to make a scientific presentation to NSF officials at the annual review of the Kitt Peak program. You may do so. You may not, however, participate in or support any appeal for more funds for Kitt Peak during the review. Indeed, it would be better for you not to be present at all when funding and other contractual subjects are discussed. If you were not a staff scientist at Kitt Peak, but only a user, that would not change things for this purpose.

(c) *Assisting without appearing or communicating with officials.* You are not prohibited from helping those who are representing a private party with Federal officials, as long as you do not yourself make an appearance or otherwise communicate with the officials. You may advise officials or representatives of the party, may make suggestions about whom they should contact and what they should say, and may even draft documents and letters, as long as you do not personally sign or transmit them. CAUTION: What is permitted under Federal law may be prohibited by rules of professional ethics, particularly if you are a lawyer.

(d) *Assisting by personal presence at an appearance or meeting.* A former high-ranking employee (SES, GS–17, or above) who had official responsibility for a matter or was personally involved while a Federal employee may violate the criminal statutes by being present to assist others at a meeting with Federal officials or an appearance before them, even though the former employee never speaks with the Federal officials. The NSF goes further and asks that (whether high-ranking or not) if you would be barred from directly representing anyone in connection with any matter, you refrain from being personally present while others are meeting with NSF officials. In rare cases where there are special circumstances the General Counsel or the Director may waive this restriction to the extent consistent with the Government-wide law and regulations.

(e) *Dealings with officials of the legislative branch not covered.* Where the basic representational restrictions refer to dealings with "Federal officials", that covers officials of a Federal Executive-branch or administrative agency and officials of Federal courts or administrative tribunals. It does not, however, encompass Members of Congress, their staffs, or other officials of the legislative branch.

(f) *Representing the United States.* During you Government service, you

may naturally represent your office, the NSF, or the Government (or anyone else, for that matter) with other Federal officials if the representation is part of your official duties. After your Government service, moreover, you may represent an office or agency of the Government itself in dealings with officials of another office or agency any time you are asked to do so.

(g) *Representing yourself.* The "official responsibility" two-year restriction and the "personal involvement" permanent restriction do not apply if you represent only yourself. They would apply, however, if you were to represent yourself and another person, such as an institution or organization with which you are employed or affiliated. The current-employee representational restriction and the one-year NSF restriction do apply even if you were to represent only yourself. Even they, however, do not apply to:

(1) Any expression of your views on policy issues, where the circumstances make obvious that you are only speaking as an informed and interested citizen, not representing any financial or other interests of your own or of any other person or institution with whom you are associated;

(2) Any appearance or communication concerning matters of a personal and individual nature, such as your income taxes; your salary, benefits, or rights as a Federal employee; or the application of conflict-of-interests rules to something you propose to do; or

(3) Any appearance on your own behalf in any litigation or administrative proceeding.

They do apply, however, to contacts seeking grants or business, except for discussions about employment with an agency as a consultant or otherwise and scientific or technical proposals, presentations, or communications. See § 682.20.

§ 682.13 "Matters" covered.

(a) *Matters involving specific parties.* The "official responsibility" two-year restriction and the "personal involvement" permanent restriction both cover only a "matter involving specific parties". Generally, such a matter is a specific proceeding affecting the legal rights of the parties to the proceeding or an isolatable transaction or related set of transactions between identifiable parties. A "party" may be either a person or an institution, and one such party other than the Government is enough.

(1) In the context of the NSF a "matter involving specific parties" will usually consist of a proposal or bid, the award-or-declination decision process with respect to it, any award that results, and any subsequent administrative action related to the project. Such "matters" are covered in Subpart B of this part.

(2) Otherwise, typical "matters involving specific parties" include other kinds of contracts or agreements; applications for permits, licenses, or the like; requests for rulings or similar official determinations; claims; investigations or audits; charges or accusations against individuals or firms; adjudicatory hearings; and court cases. These are relatively uncommon at the NSF, but when current or former NSF employees have been officially responsible for such matters or personally involved in them, the representational restrictions may apply. If in doubt consult an ethics counselor in the Office of the General Counsel.

(b) *Same or different matter.* The "official responsibility" two-year restriction and the "personal involvement" permanent restriction cover such a matter only if during your NSF service the same matter was under your official responsibility or you were personally involved in it. Except where guidance is provided in Subpart B of this part, you should not decide for yourself whether a "matter involving specific parties" is the same as one for which you had "official responsibility" or with which you were "personally involved" while at the NSF. Consult an ethics counselor in the Office of the General Counsel.

(c) *Other "matters".* The current-employee restriction and the one-year NSF restriction both cover matters that do not *not* "involve specific parties" as well as those that do. Such broader "matters" include:

(1) Determinations to establish or disestablish a particular program or set its budget level for a particular fiscal year;

(2) Decisions to undertake or terminate a particular project;

(3) Decisions to open or not open a contract to competitive bidding;

(4) Decisions on particular NSF rules or formal policy, such as adoption or amendment of a resolution by the National Science Board, promulgation or amendment of an NSF regulation or circular, amendment of standard grant or contract terms, or changes to such NSF policy documents as "Grants for Scientific Research and the Grants Policy Manual"; and

(5) Agency positions on particular legislative or regulatory proposals.

On the other hand, the statutory term is really not just "matter", but "particular matter". The word "particular" is intended to exclude broad technical areas, policy issues, and conceptual work done before a program has become particularized into one or more specific projects. You should not, however, rely on this hazy distinction alone to take you out from under either of the representational restrictions that cover matters not involving specific parties without checking with an ethics counselor in the Office of the General Counsel.

(d) *Boundaries of matters not involving specific parties.* In connection with the current-employee restriction and the one-year NSF restriction, you need not consider whether a "matter" is the same as or separate from any other matter. Those two restrictions cover any "matter", whether or not you have previously had any responsibility for or involvement with it.

§ 682.14 Restriction on your partners.

While you are a Federal official no person who is legally your partner in a business of professional partnership may act as agent or attorney for anyone in dealings with any other Federal official on any matter under your official responsibility or with which you are or have been personally involved as a Federal official. A partner who violates this rule commits a Federal crime punishable by a fine of up to $5000 or imprisonment for up to one year or both. In general, your partners may safely steer clear of this restriction by using the definitions and guidance in the earlier sections of this Subpart A, treating "act as agent or attorney" as equivalent to "represent" (it may actually be slightly less encompassing). They may consult on this restriction with attorneys in the Office of the NSF General Counsel. If they prefer to consult other counsel, they should refer to 18 U.S.C. 207(g).

Subpart B—Involvement With Proposals and Projects During and After NSF Service

§ 682.20 General; restricted representational activities vs. permitted research or educational activities.

(a) *Basic representational restrictions.* The same four representational restrictions described in Subpart A of this part apply to representational activities involving proposals or projects.

(1) *Current-employee restriction.* During your Federal employment you must not represent anyone (including yourself) in dealings with any Federal official on any proposal or project.

(2) *One-year NSF restriction.* For one year after you leave NSF employment

you must not represent anyone (including yourself) in dealings with any NSF official on any proposal or project.

(3) *"Official responsibility" two-year restriction.* For two years after you leave NSF employment you must not represent anyone else in dealings with any Federal official on any proposal or project if the same proposal or project was active under your official responsibility during your last year at the NSF.

(4) *"Personal involvement" permanent restriction.* You must never represent anyone else in dealings with any Federal official on any proposal or project if you were personally involved with the same proposal or project as an NSF employee.

(b) *Examples.* Examples 1 through 4 in § 682.10(b) illustrate the application of these restrictions.

(c) *General effect.* These representational restrictions do not preclude you from being involved as a researcher or educator with proposals submitted to the Government or projects supported by the Government. They do preclude you from negotiating with NSF officials or other Federal officials and from engaging in other representational activities intended to influence their decisions on certain proposals and projects.

(d) *Restricted representational dealings.* If you write, call, visit, or otherwise communicate with an official you have "dealt" with the official. Those dealings are representational if you try to influence the official to suggest, recommend, or approve:

(1) An award;

(2) An award amount, a budget, or particular budget items;

(3) Particular award terms or conditions;

(4) An award amendment, increase, or extension;

(5) An administrative approval; or

(6) Any other action affecting a proposal or project.

(e) *Permitted research and educational activities.* You do not engage in representational dealings, and so you violate none of the representational restrictions, by:

(1) Participating in research or other work supported under an award from the NSF or another Federal agency;

(2) Being listed as an investigator in a proposal or award;

(3) Preparing a proposal that will be submitted to the NSF or another Federal agency (but if you prepare it during your NSF tenure, you must do so entirely on your own time);

(4) Making a scientific or technical presentation to officials of the NSF or another Federal agency (at a site visit, for example) or otherwise communicating scientific or technical information to them on the work being proposed or conducted; or

(5) Communicating with officials of the NSF or another Federal agency, with no intent to influence them, to request routinely available and noncontroversial information, such as the status of the decision process on a proposal.

Be very careful with these last two activities particularly; it would be easy to fall into trying to influence actions of the officials involved. If you can, let someone else make the presentation or request. If in any doubt, consult an ethics counselor in the Office of the General Counsel.

(f) *Specifics on proposals.* You may prepare a proposal for submission to the NSF or another Federal agency even though you would be precluded by one of the three post-employment restrictions from any representational dealings with agency officials about it. You may sign the cover sheet to signify your agreement to assume responsibility if an award is made for the scientific and technical direction of the project and for the preparation of required technical reports. You may not, however, sign any cover letter submitting the proposal for the University. Nor may you call, write, or visit the agency program officer who is handling the proposal to urge an award, haggle over budgets, or the like. You may respond to requests from the program officer or another NSF official for scientific and technical information relating to the proposal, such as might be needed to respond to reviewer comments. You must not, however, couple the information you supply with any attempt to influence the decision on the proposal other than what inheres in the provision of the information itself. At the NSF the proposal will receive special scrutiny and may require special handling to avoid conflict of interests, but you have no special responsibility in that connection.

(g) *Other issues related to represenation.* Section 682.12 covers a number of other issues related to representation. Among these are assisting in representation without appearing or communicating with officials (generally permitted); assisting by personal presence at an appearance or meeting (generally prohibited); representing the Government (generally permitted); and representing yoursef alone (depends). The rules and explanations given there apply to proposals or projects just as to other matters. If any confusion persists after you read them, consult an ethics counselor in the Office of the General Counsel.

§ 682.21 Proposals and projects over which you had official responsibility or with which you were personally involved.

(a) The "official responsibility" two-year restriction applies only if you had official responsibility for the proposal or project in question during your last year at the NSF. The "personal involvement" permanent restriction applies only if you were personally involved with the proposal or project while at the NSF. You will therefore need to need to know: (1) When a project is the same as one proposed or active while you were at the NSF, and (2) whether you had official responsibility for the project or were personally involved with it.

(b) *When is a project the same project?* All usual aspects of the handling of a particular proposal and of any award made onthe proposal relate to the same "project". This includes:

(1) The initial peer review and award-or-declination decision process;

(2) Review and approvals of an award recommendation;

(3) Negotiation of budget and award terms;

(4) Negotiation of award amendments;

(5) Consideration of continuing-grant increments; and

(6) Consideration of any extensions or administrative approvals.

(c) *Exceptions.* (1) A negotiation or determination on disposition of rights in any invention or publication that arises out of an award normally is a separate matter from the processing and monitoring of the award, but not from discussions or negotiations about disposition of rights that took place before the invention was made or the publication written.

(2) Separate task orders under a continuing order agreement or the like constitute separate "matters" if the tasks and the negotiations are actually separate.

(3) An ethics counselor may determine that other matters arising from a particular proposal or award constitute separate "matters" if the circumstances warrant.

(d) *Renewals.* An application that involves a continuation or outgrowth of work that the investigators have been doing under a previous NSF award is part of the same "project" as the original proposal and project unless:

(1) A complete new proposal and a new budget are submitted;

(2) They are subjected to a complete new competitive peer review or evaluation; and

(3) The review or evaluation involves a new group or reviewers, a substantial fraction of whom did not review the earlier proposal.

(e) *"Official responsibility".* You had "official responsibility" for a proposal or project if you were personally responsible for handling it or if you headed a directorate, division, section, or program that was responsible for handling it. (The Director has "official responsibility" for every proposal or project active at the NSF during his or her tenure.) You will find further elaboration of "official responsibility" in § 682.12(b).

(f) *"Personal involvement".* You were "personally involved" with a proposal or project if you handled the peer review of the proposal; if you made any formal recommendation or decision on it, including any approval of an award recommendation or other action; if you reviewed the proposal or made a site visit; or if you otherwise made a substantial contribution to the handling of the proposal or project. You will find further elaboration of "personally involved" in § 682.12(c).

§ 682.22 When you are or would be principal investigator.

(a) *Retention of ties to research, etc. permitted.* Many scientists and educators interrupt active research and teaching careers to spend a year or two at the NSF as "rotators" and then return to research and teaching, usually at the same institution from which they came. Many such rotators (and a few permanent employees) who have been principal investigators under NSF awards before coming to the NSF, retain some interest or association with the work. If you have been the principal investigator under an NSF award, you are not precluded from retaining ties to the work under the award after you become an NSF employee. Subject to the restrictions on outside employment explained in Part 683 of the NSF conflict-of-interests regulations, you may stay in contact with those who are continuing the work in your laboratory or on your project. You may continue to supervise graduate students. And you may visit and work in the laboratory on your own time for these purposes.

(b) *Substitute principal investigator.* Before you come to the NSF, however, the NSF requires that you and your institution designate, subject to NSF approval, a substitute principal investigator—*i.e.*, another scientist who will be responsible for the work and equipment and will represent the project and the institution in any dealings with NSF officials while you are at the NSF.

(c) *Suspension of work on an NSF award.* Appointment of a substitute principal investigator is unnecessary if all work under an award is to be completely suspended while you are at the NSF. If the work is to be suspended, you and your institution should so inform the NSF by letter before your NSF employment begins. Work under the award may be resumed when you complete your NSF employment, and its term may be extended to account for the time lost during your NSF employment.

(d) *Substitute negotiator.* As soon as you leave the NSF, you may again be principal investigator on an NSF project, may be listed as principal investigator in any proposal or award, and may sign a proposal as principal investigator. However, the NSF asks that you and your institution formally designate (subject to NSF approval) a "substitute negotiator" who, though not principally responsible for the work, will represent the project and the institution in dealings with NSF officials from which you would be restricted. In the typical case, the one-year NSF restriction will require that a substitute negotiator continue to serve that function for one year after you leave the NSF. In the rarer case of a proposal or project for which you had official responsibility or with which you were personally involved, there should be a substitute negotiator for as long as the "official responsibility" two-year restriction or the "personal involvement" permanent restriction bar you from such representational dealings.

(e) *Renewal proposals submitted during your NSF service.* During your NSF service a proposal may be submitted for continuation or extension of work on which you were principal investigator before coming to the NSF and to which you intend to return. The role you will play in the work proposed should be clearly spelled out in the proposal, and the proposal should prominently indicate that you are currently an NSF employee. If work under a resulting award would begin before you leave the NSF, a substitute principal investigator must be named. If the work would not begin until after you leave the NSF, you may be named as principal investigator, but a substitute negotiator must be named.

(f) *Your involvement or interest in project to be open.* The appointment of a substitute principal investigator or a substitute negotiator is not intended to conceal or obscure your continued involvement or interest in the project. Just the opposite: your involvement or interest should be made unmistakably plain. This will ensure that any proposal or other award-related application will be given the special attention and special handling called for under Part 681 of this chapter.

(g) *Purposes of "substitute" requirements.* The appointment of a "substitute principal investigator" or "substitute negotiator" ensures against unthinking violation of the restrictions on dealings with NSF officials. It serves this purpose by flagging proposals or awards affected by the restrictions and by identifying someone else with whom NSF officials can properly discuss them or negotiate over them. Designation of a substitute principal investigator while you are at the NSF has two additional functions: it identifies another person to be responsible for the work and equipment, and it reminds all concerned that during your NSF service your primary attentions must be on your NSF duties.

(h) *Proposals and awards of other agencies.* The "substitute principal investigator" and "substitute negotiator" requirements described in this section are specific to the NSF. If you are or would be a principal investigator under a project proposed to or supported by another Federal agency, however, you should carefully observe the representational restrictions as they apply to dealings with officials of other Federal agencies. The current-employee restriction is particularly likely to apply.

§ 682.23 Compensation or reimbursement of expenses from NSF awards.

(a) *Compensation from NSF awards.* While you are an NSF employee, you may not receive any salary, consulting fee, honorarium or other form of compensation for your services from an NSF award, or any other Federal award either directly or indirectly. In other words, you may not receive money for your services in connection with a project, a conference, or other work that was supported in whole or in part by funds provided from an NSF award. After you cease to be an NSF employee, you may again receive compensation from an NSF award.

(b) *Expenses from an NSF award.* While an NSF employee you may not receive any reimbursement of expenses from an NSF award.

PART 683—OTHER CONFLICTS RULES

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Sec.

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Authority: E.O. 11222 of May 8, 1965, 3 CFR, 1965 Supplement and Regulations of the Office of Personnel Management, 5 CFR 735.104.

Subpart A—Financial Disclosure

§ 683.10 Who must make general financial disclosure.

(a) If you are an executive level, SES, or supergrade employee, you are a "senior employee" and must file public Financial Diclosure Reports. See § 683.11.

(b) If you are not a "senior employee" but serve as either a program officer, a directorate administrative official, a grants and contracts officer, an auditor, or a lawyer, you must file confidential Statements of Employment and Financial Interests. See § 683.12.

(c) If you are in neither of these categories, no general financial disclosure is required of you. You may ignore the rest of this subpart.

(d) If you are required to file Financial Disclosure Reports or Statements of Employment and Financial Interests, the foundation will supply you with the necessary forms. You may ask for them when you need them, but normally they will be sent to you automatically, with instructions.

§ 683.11 Financial disclosure requirements for senior employees.

(a) If you are a "senior employee" you must file an initial Financial Disclosure Report within 30 days after you first come to the Foundation or are promoted into a senior-employee position. You must thereafter file a Financial Disclosure Report by May 15 of each year. And you must file a termination Financial Disclosure Report within 30 days after you leave the Government.

(b) File your Reports with an ethics counselor. The ethics counselor will help with problems or questions that arise in completing the forms, and is required by law to review your Report after you file it. The ethics counselor may contact you about any errors you make in filling out the form or about questions that are raised by what you report.

(c) The law requires the NSF to make each Report you file available to the public within 15 days after you file it.

(d) Any person who wants to see or copy your Report must make a written request. A copy of any such request will be sent to you.

(e) If you are nominated by the President to an NSF position and must be confirmed by the Senate, your initial Report must be filed with the NSF within five days after your nomination.

(f) If you fail to file a required Report, fail to file information required to be reported, or file false information, you are subject to disciplinary action. If you do any of those things willfully, the law requires the Director of the Foundation to report to the Attorney General, who has authority to enforce the disclosure requirements against any knowing or willful violation by suits seeking civil penalties of up to $5,000.

§ 683.12 Financial disclosure requirements for program officers, grants and contracts officers, auditors, and lawyers.

(a) If § 683.10(b) indicates that you are one of those who must file Statements of Employment and Financial Interests, you must file an initial Statement within 30 days after you are first appointed to a covered position either by promotion or as a new NSF employee. You must thereafter file a Statement each year by July 31.

(b) File your Statements with the Personnel Office.

(c) Your Statements will be held in the strictest confidence allowed by law. The Personnel Office will keep them in a locked file and will release them or allow disclosure of information from them only with your written approval or that of the General Counsel. Before any release or disclosure on the authority of the General Counsel you will be notified and will have an opportunity to comment, except when information is requested for an official investigation of a possible criminal violation.

(d) If you fail to file a required Statement, fail to file information required to be reported, or file false information, you are subject to disciplinary action.

Subpart B—Acts Affecting Financial Interests

§ 683.20 Acts affecting your financial interests.

(a) *No acting as a Federal employee where you have a financial interest.* You must not be personally involved as a Federal employee in the handling of any proposal, award, or other matter in which you, a member of your immediate family, a business partner, or an organization of which you are or may become a part has a financial interest. BE CAREFUL: Violation of this rule may also result in a violation of a criminal statute for which the penalties are a fine of up to $10,000, imprisonment for up to two years, or both.

(b) *Proposals and awards.* You will not violate this restriction in handling proposals and awards as long as you abide by the requirements on handling proposals and awards described in Part 681 of these regulations.

(c) *"Personally involved".* The term "personally involved" has exactly the same meaning here as in connection with the represention restrictions described in Part 682 of this chapter. It is elaborated in § 682.12(b) of this chapter. In general, you can be "personally involved" in the handling of a matter even though you actually make none of the critical decisions, if you contribute by recommendations, advice, approval, or the like, and your contribution is substantial.

(d) *"Matter".* The term "matter" also has the same meaning here as in connection with the representational restrictions described in Part 682 of this chapter. It is elaborated in § 682.13 of this chapter. Note that here specific parties need not be involved.

(e) *Immediate family.* Only your spouse and minor children are considered members of your "immediate family" under this rule. Be careful though; other relatives are covered by rules described elsewhere in these regulations.

(f) *"Organization of which you are or may become a part".* You are a part of an organization if you are an officer, director, trustee, partner, or employee. You "may become" part of an organization if you are negotiating with it or have an arrangement with it concerning prospective employment.

(g) *Waiver.* This provision may be waived where the interest is so insubstantial as to be likely to affect the integrity of your services to the Government. If yo think such a waiver is called for, consult an ethics counselor in the Office of the General Counsel. The ethics counselor will advise you and

will make a recommendation to the official who would have to approve such a waiver.

Subpart C.—Outside Employment, Compensation, Income, Gifts, Etc.

§ 683.30 Outside employment ("moonlighting") and income.

(a) *Permitted within limits; duty first.* While not on official duty, you may work for private firms or organizations either for pay or as a volunteer, within limits established by the rest of this subpart. Be sure that you understand all of those limits before undertaking any such outside work. Those that do not relate to compensation apply whether or not you work for pay. A basic limit, of course, is that duty comes first. You should not engage in any outside activity that impairs your health, exhausts your energies, or otherwise prevents you from doing your NSF job.

(b) *Policymaking or administrative work for certain organizations.* You may not participate as a policymaking officer for any research or educational institution, any scientific society, or any professional association without the written approval of an ethics counselor. Whenever a major policy question is presented by a request for such approval, you or the ethics counselor may raise the matter with the General Counsel and, if appropriate, with the Director of the Foundation.

(c) *Special rules for full-time Presidential appointees.* If you are a Presidential appointee:

(1) You must not engage in any other business, vocation, or employment while serving in the Presidential position.

(2) You may not hold office in or act for any institution that has or is seeking NSF awards without the approval of the National Science Board.

(3) You may not earn outside income totalling more than 15 percent of your Government salary in any calendar year. Earned outside income includes salaries, honoraria, and other forms of compensation for services. It does not include investment income (dividends, interest, or the like). It does not include reimbursement for meals, lodging, travel, or other expenses. And it does not include prizes or awards, even if an award carries an obligation to give lectures.

§ 683.31 Compensation.

(a) *Basic restrictions on outside compensation.* Three basic rules restrict compensation (not including reimbursement of expenses) you can accept from sources other than your Federal salary:

(1) *No extra compensation for official duties.* You must not seek or accept any contribution or supplement to your Government salary for doing any part of your NSF job.

(2) *No compensation in connection with any matter involving the Government.* You must not seek or accept any compensation for services by you or anyone else in connection with any proposal, project, or other matter in which the United States is a party or has a direct interest.

(3) *No compensation out of any Federal award.* You must not seek or accept any compensation out of funds that come wholly or partly from an NSF award.

BE CAREFUL: A violation of any of these rules would be a Federal crime.

(b) *Pensions and other employee benefits.* These rules do not preclude you from continuing to participate in a bona fide pension or other employee benefit plan maintained by a former employer.

(c) *Wording and terms.* The wording of these restrictions has been simplified here substantialy from the wording of the underlying statutes, so that they will be easier to understand. Interpret them conservatively, and if in any doubt about the meaning of terms consult an ethics counselor in the Office of the General Counsel.

§ 683.32 Honoraria.

(a) *Honoraria on official duty.* You must not accept any honoraria for speeches, papers, lectures, or the like delivered in the course of your official duties. However, if declining an honorarium would appear embarrassing or insulting to the offeror, particularly one from another country, you may accept the honorarium on behalf of the Foundation and deposit it into a special trust fund account or into the Treasury. Under no circumstances may you accept an honorarium for yourself for acts performed in your official capacity.

(b) *Honoraria—while not on official duty.* You may accept honoraria for speeches, papers, or lectures delivered while you are not on official duty, subject to general limits on outside employment described in § 683.30, general restrictions on receipt of compensation described in § 683.31, and prohibitions against misuse of inside information described in § 683.34. You will be disqualified for one year from handling proposals and other award-related applications that involve the interests of the person or institution from which you received any honorarium. See § 681.21 of this chapter. Moreover, the law restricts the amounts of honorarium you may accept:

(1) You must not accept an honorarium of more than $2,000 for any speech, paper, lecture, or the like (excluding reimbursements for meals, lodging, and travel).

(2) You may not receive more than $25,000 in honoraria in any calendar year.

(3) If you are a Presidential employee, honoraria count toward the fifteen-percent limit on your outside income. See § 683.30(d)(3).

§ 683.33 Reimbursements and services in kind.

(a) *For official travel.* You may not accept money from private sources to reimburse you for expenses incurred during travel on official NSF business, though private sources may reimburse the NSF for your expenses. You may accept meals, lodging, or travel tickets (not money) from private sources when you are traveling on official NSF business, but not if they would be paid for out of funds that come wholly or partly from an NSF award. There is one exception to the reservation about funds that come from an NSF award: if you are attending a conference, symposium, or other meeting funded by the NSF, you may accept meals and lodging (but NOT travel tickets) if they are offered to everyone attending the meeting and alternate arrangements for meals and lodging are unavailable or would cause an unusual inconvenience. If you do accept meals or lodging while on official travel, your per diem must be reduced accordingly.

(b) *Travel, etc. when not on duty.* If you are on leave, not representing the Foundation, and not expected primarily to discuss NSF policy or procedures, these restrictions do not apply. However, you may not accept services in kind or reimbursement for travel expenses if the sources would be funds that come wholly or partly from an NSF award.

§ 683.34 Misuse of inside information or Government Property.

(a) *No misuse of inside information.* If your Government job gives you access to information not generally available to the public, you must not use that information for your private benefit or make it available for the private benefit of any other person or institution.

(b) *Consulting, lecturing, etc. about the NSF.* You must not receive anything of monetary value for consulting, lecturing, writing, or public discussion that concerns the responsibilities, the programs, or the operations of the NSF or that draws on official information or

ideas not generally available to the public.

(c) *Waivers.* The Director, the Deputy Director, or an assistant director may waiver application of these rules and authorize use of non-public information in the public interest. Any such authorization must be in writing. Consult an ethics counselor in the Office of the General Counsel.

(d) *Private use of public property or services.* You must not use Government property or services for your private benefit or for the private benefit of others, except as your normal public duties benefit particular members of the public in intended ways.

§ 683.35 Participation in NSF-supported conferences and workshops.

You may participate in a conference, workshop, or similar event supported by NSF funds, provided you do not receive any compensation, honorarium, or the like for your participation. You may not serve as an organizer or director of such an NSF-supported event, unless its purpose is to plan, assess, or publicize NSF programs. You may discuss arrangements with the organizers or directors as long as you do not use the influence that derives from your NSF position to pressure them.

§ 683.36 Gifts, favors, loans, prizes, and awards.

(a) *Gifts and favors generally.* You may not directly or indirectly solicit or accept a gift, a favor, or a loan from any person or organization:

(a) That has or is seeking NSF awards;

(2) That has interests potentially affected by what you do in your NSF job; or

(3) That may be trying to affect your official actions.

(You may, however, accept promotional things of trivial value such as pens, pencils, note pads, and calendars.)

(b) *Meals or entertainment.* By extension, you should ordinarily avoid accepting meals or entertainment from such persons or organizations if you can avoid doing so within the reasonable bounds of politeness. You may, however, occasionally accept a modest meal offered as a courtesy or convenience during a site visit or a luncheon or dinner meeting.

(c) *Prizes and awards.* The restrictions in paragraph (a) of this section do not prevent you from accepting a prize or award for scientific or other public achievement given by a university, scientific society, or other organization. However, you may accept anything of value that accompanies the prize or award only if it is not paid for out of funds that come wholly or partly from an NSF award. You will be disqualified for one year from handing proposals and other award-related applications that involve the interests of the person or institution from which you received any such prize or award. See § 682.21 of this chapter.

(d) *From foreign governments.* You may not accept a gift or decoration from a foreign government in accordance with the Foreign Relations Authorization Act of 1978. Essentially, you may accept a gift of "minimal value". Minimal value means retail value in the United States at the time of acceptance of $100 or less. If the gift is of more than minimal value you should not accept it unless doing so would likely cause offense or embarrassment. Acceptance of any gift of more than minimal value is deemed to have been accepted on behalf of the United States and, upon acceptance, shall become the property of the United States. Consult an ethics counselor for assistance in depositing the gift with the United States.

Subpart D—Political Activity

§ 682.40 Introduction; who's covered.

(a) *Hatch Act.* In order to ensure that day-to-day government actions (such as award of grants) are not affected by political motives and in order to preserve a nonpolitical civil service that is selected on merit, not on political considerations, the law restricts the involvement of Federal civil service employees with partisan politics. These restrictions derive from a law popularly known as "the Hatch Act".

(b) *Summary of Hatch Act restrictions.*

(1) The Hatch Act restrictions do not affect your basis political rights. See § 682.41.

(2) You may not run for public or party office, except in nonpartisan elections and certain local elections. See § 682.41(a).

(3) You may not participate in election campaigning, except in nonpartisan elections and certain local elections. See § 682.42(c).

(4) You may not take an active part in leading or managing a political party. See § 682.43.

(5) You must not use your official authority or influence for political purposes. See § 682.44.

(c) *Presidential appointees.* You are subject to these restrictions if you are an NSF employee, unless you are a Presidential appointee whose appointment was subject to Senate confirmation. If you are such a Presidental appointee, you are subject only to the restrictions described in § 682.44. You need not be concerned with the rest of this subpart except as it affects your colleagues and subordinates.

(d) *Employee coverage.* If you are subject to the "Hatch Act" restrictions, they apply even while you are on leave or while you are on detail or assignment to a non-Federal post. They apply even if you work for the Government only part-time. If you work for the Government as a temporary employee, the restrictions apply as long as your temporary employment lasts. If you work for the Government as an intermittent employee, the restrictions apply only while you are in an active-duty status, but that includes the entire 24 hours of any day on which you work for the Government at all. (If in doubt about the employment category to which you belong, check with Personnel.)

(e) *Political party.* Any political party or political club, national or state, is a "political party" under this Subpart, except where provisions specifically refer to a "national political party".

§ 683.41 Basic political rights unaffected.

The Hatch Act restrictions do not affect your basic political rights. Specifically:

(a) You may register and vote as you choose in any election.

(b) You may contribute to a political party or candidate, though you may not be pressured to do so because of your Federal employment.

(c) You may be a member of a political party or other political organization. You may attend party meetings and vote on issues. You may not, however, be involved in managing or leading the organization. See § 683.43.

(d) You may write, call, or visit any Federal, state, or local political official (including, for example, your Congressman) to express your views on any political issue and on how the official should vote or act on the issue.

(e) You may sign political petitions, including nominating petitions, but you may not circulate such petitions for others to sign. See § 683.42(d)(2).

§ 683.42 Candidacy and campaigns.

(a) *Running for office.* You may not run for nomination or election to public office. There are two exceptions:

(1) You may run in an election in which no candidate runs as representing any national political party. (Currently, this means the Democratic or Republican party, but if another party wins electoral votes in a Presidential election, that could change.)

(2) Your may run for office in most of the local political jurisdictions in the Washington, D.C. area if you run as an

independent not representing any political party, national or otherwise. (To be sure that your jurisdiction is among those in which this is permitted, check with an Ethics Counselor in the Office of the General Counsel.)

(b) *No partisan campaigning.* You may not campaign for or against a political party or candidate in an election for public office or in an election for party office. Essentially the same two exceptions apply:

(1) You may campaign for a candiate in an election in which no candidate runs as representing any national political party.

(2) If you could be an independent candidate in a local election described in paragraph (a)(2) of this section, you may campaign for an independent candidate in such an election.

You may not campaign for any side of a question or issue that is specifically identifed with a political party.

(c) *What constitutes campaigning.* You "campaign" when you:

(1) Actively participate in management of a campaign;

(2) Initiate nominating petitons or canvass for signatures on nominating petitions;

(3) Endorse or oppose a candidate or a position through political advertisements, broadcasts, campaign literature, or the like;

(4) Speak at rallies, candidate nights, party caucuses, or other political gatherings;

(5) Solicit campaign contributions, promote political dinners or similar events, sell tickets for such events, or otherwise participate in campaign fundraising;

(6) Help to handle campaign finances;

(7) Distribute campaign material;

(8) Host a coffee, cocktail party, or buffet for a candidate or a candidate's surrogate;

(9) Drive voters to the polls;

(10) Work at the polls as a checker, challenger, pollwatcher, or the like, or

(11) Do any other work on behalf of a candidate.

(d) *Nonpartisan election duties.* In connection with an election, you may perform nonpartisan duties provided for by law as an election clerk, judge, or the like.

(e) *Appointment to nonelective office.* You may accept appointment to nonelective public office, subject to the same limits that apply to any other outside employment. See Subpart C, §§ 683.30–683.36.

§ 683.43. Party activities.

You may not take an active part in leading or managing a political party. You do that when you:

(a) Participate in organizing or reorganizing it;

(b) Serve as a party officer or as a member of a national, state, or local party committee or stand as a candidate for such a position);

(c) Participate in party fundraising or in handling party finances.

(d) Serve as a delegate, alternate, or proxy to a party convention (though you may attend such a convention); or

(e) Take an active part in conducting or running a meeting, rally, fund-raising function, convention, or other party gathering (though you may attend such a gathering).

§ 683.44. Political use of official authority or influence.

You must not use your official authority or influence for political purposes. Thus:

(a) You must not use your official position or authority to interfere with an election or to affect the result of an election.

(b) You must not solicit political contributions from other Federal employees, allow your name to appear on any fundraising appeal likely to be sent to Federal employees, or allow anyone to solicit or receive political contributions in a building where Federal employees work.

(c) You must not discriminate against any other employee because of his or her political opinions or affiliations. This is a "prohibited personnel practice". See regulations of the Merit Systems Protection Board at 5 CFR 1250.3(b)(3).

PART 684—RULES FOR CONSULTANTS, BOARD MEMBERS, AND OTHER "SPECIAL EMPLOYEES"

Subpart A—General Rules for Consultants, Board Members, and Other "Special Employees"

Sec.

684.10 "Special employees".
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Subpart B—Special Rules of the National Science Board for Board Members

Sec.

684.20 Summary.
684.21 Participation in Board deliberations.
684.22 Participation in NSF-Supported Projects.

Authority.—E.O. 11222 of May 8, 1965, 3 CFR, 1965 Supplement and Regulations of the Office of Personnel Management, 5 CFR 735.104.

Subpart A—General Rules for Consultants, Board Members, and Other "Special Employees"

§ 684.10 "Special employees".

(a) *"Special employees".* Any NSF consultant, National Science Board member, or other temporary or intermittent employee (including a rehired annuitant) who works or is expected to work for the NSF not more than 130 days a year is a "special Government employee." The rules in this Subpart apply to you only if you are such a "special employee". Other employees should see Parts 680 through 683 of the NSF conflict-of-interests regulations.

(b) *Days worked.* If you have any uncertainty about how many days you work or are expected to work for the NSF, consult an ethics counselor in the Office of the General Counsel. There are specific rules for counting the days, and the rules that apply while you are still employed differ somewhat from those that apply afterward.

§ 684.11 Summary of rules for "special employees".

(a) This section summarizes the principal conflicts requirements that you are expected to observe as an NSF "special employee". It references the subsequent provisions of this subpart in which these requirements are elaborated. You are encouraged as well to read the introductory sections (§§ 680.10–680.12) of the general NSF conflict-of-interests regulations. Members of the National Science Board are committed to observe besides the requirements summarized here and detailed in the remainder of this Subpart, the special rules of the Board for its members. See Subpart B, §§ 684.20–684.22.

(b) NSF work on proposals and awards of others.

(1) If you serve on a panel that reviews proposals or otherwise serve as a peer reviewer, you will be given instructions designed to deal with any conflict of interests you may have.

(2) If you participate in action on proposals and awards as a National Science Board member, see § 684.21.

(3) If you should otherwise become involved with the handling of a proposal or other award-related application you should follow the same rules and procedures on conflicts or potential conflicts in handling proposals and awards as regular NSF employees. They are set out in Part 681 of the NSF conflicts regulations, §§ 681.20–681.26.

(c) Financial disclosure (§ 684.12).

(1) If you are compensated at a rate at or above the lowest rate for a GS–16 regular employee and plan to work or actually do work more than sixty days in any calendar year, you must file public Financial Disclosure Reports.

(2) If you are not required to file public Financial Disclosure Reports, you must file a confidential Statement of Financial Interests at the time of your appointment (or reappointment).

(3) You may ask for forms if you need them. Normally, however, they will be provided to you automatically, with instructions.

(d) Political activity (Hatch Act) (§ 684.13). The Hatch Act prohibits you from being involved in an election campaign or in political-party activity on any day when you work for the Government.

(e) Representational restrictions and involvement with proposals and awards during and after NSF service (§ 684.14).

(1) you must never represent anyone in dealings with any Federal official on any proposal, project, or other matter involving specific parties if you have been personally involved with that matter at or for the NSF.

(2) If you have been employed with the NSF more than sixty days a year, you must not represent anyone in dealings with any NSF official during your NSF service and for one year thereafter on any proposal, project, or other matter involving specific parties.

General effect: These restrictions do not preclude you from preparing a proposal for your institution, from serving as principal investigator under an NSF proposal or award, from otherwise working under an NSF award, or from receiving compensation or expenses out of an NSF award. If you are a member of the National Science Board, however, see § 684.22.

(f) Compensation (§ 684.15).

(1) While you are an NSF "special employee" you must not seek or accept (except from the Government) any compensation for services by you or anyone else in relation to any matter involving specific parties if you have been personally involved for the Government.

(2) If you have been employed with the NSF for more than sixty days in the last 365, you must not seek or accept (except from the Government) any compensation for services by you or anyone else in relation to any matter involving specific parties that is pending in the NSF.

(g) Acts affecting your financial interests (§ 684.16). You must not be personally involved as a Federal employee in the handling of any proposal, award, or other matter in which you, a member of your immediate family, a business partner, or an organization of which you are or may become a part has a financial interest. You will not violate this restriction with respect to proposals and awards as long as you follow the instructions provided in paragraph (b) of this section.

(h) Use of inside information (§ 684.17). If your work for the Government gives you access to information not generally available to the public, you must not use that information for your private benefit or make it available for the private benefit of any other person or organization.

(i) *Effect of simplified wording.* The wording of the requirements as presented in these regulations has been simplified substantially from the wording of underlying statutes and other authorities, so that they will be easier to understand. Your initial interpretation should be conservative. If in doubt on the meaning of terms or otherwise troubled, consult an ethics counselor in the Office of the General Counsel.

(j) *General standards of conduct.* You are also responsible for being familiar with general standards of conduct described in § 680.18 of this chapter and for observing them.

§ 684.12 Financial disclosure.

(a) Unless you are required under paragraph (b) of this section to file public Financial Disclosure Reports, you must file a confidential Statement of Employment and Financial Interests at the time of your appointment (and of any reappointment). The Personnel Office automatically supplies you with the necessary forms, and you file the Statement there.

(b) High-ranking "special employees" who work more than sixty days a year. If you are compensated as a "special employee" at a rate at or above the lowest rate for a GS–16 regular employee, you are a "senior employee". Regular senior employees are required to file public Financial Disclosure Reports. You are required to do so, however, only if you plan to work or actually do work more than sixty days in any calendar year. Specifically:

(1) If at the time of your appointment you are expected to serve more than sixty days in any calendar year, you must file such a Report then and again within thirty days after your appointment ends.

(2) If you did not file at the time of your appointment, but do in fact serve more than sixty days in any calendar year, you must file such a Report within fifteen days of your sixty-first day of work and again within thirty days after your appointment ends.

(3) In either case, if you in fact serve more than sixty days in any calendar year, you must also file such a Report before May 15 of the next year.

A person who is under consideration for nomination to the National Science Board may be asked to file a Financial Disclosure Report with the White House or the Senate through the Office of Government Ethics as part of the clearance process even if not expected to serve more than sixty days a year. Such a Report will not be made public by the NSF.

(c) Filing of financial disclosure reports. If you are required to file Financial Disclosure Reports, the necessary forms ordinarily will be sent to you automatically, with instructions. You should inquire, however, if you think you may go over the sixty-day limit, and you may ask for forms from the Office of the General Counsel whenever you need them. File your Reports with an ethics counselor in the Office of the General Counsel. The ethics counselors will help with problems or questions that arise in completing the forms. The law also requires them to review your Report after you file it. They may contact you about any errors you make in filling out the form and about any questions that are raised by what you report. The law requires them to make each Report you file available to the public within fifteen days after receiving it. A copy of any request for your Report will be sent to you.

§ 684.13 Political activity (Hatch Act).

The Hatch Act and other laws restrict the involvement of Federal civil service employees with partisan politics. The restrictions apply to you for all of any day during which you work for the Government. If you have any plan or intention of being involved in any election campaign or political-party activity on any such day, consult an ethics counselor in the Office of the General Counsel before doing so. Members of the National Science Board, as Presidential appointees, are not subject to these rules. They are subject only to a restriction on using official authority or influence for political purposes. Part 683, Subpart D, §§ 683.40—683.44 on this chapter, cover the Hatch Act restrictions in greater detail.

§ 684.14 Representing private interests before the NSF or other Federal agencies.

(a) *"Personal involvement" permanent restriction.* All NSF "special

employees" are subject to the following basic restriction:

You must never represent anyone in dealings with any Federal official on any proposal, project, or other matter involving specific parties if you have been personally involved with that matter at or for the NSF.

(b) *NSF restriction.* If you have been employed with the NSF more than sixty days a year, you are subject to one other restriction:

During your NSF service and for one year thereafter you must not represent anyone in dealings with any NSF official on any proposal, project, or other matter involving specific parties.

BE CAREFUL: Violation of either of these restrictions may also be a Federal crime.

(c) *Effect on involvement with proposals and projects.* These representational restrictions do not preclude you from being involved as a researcher or educator with proposals submitted to the NSF or other Government agencies or with projects supported by the NSF or by other Government agencies. They may preclude you from being the one to write, call, visit, or otherwise communicate with a Federal official about a proposal or project.

(d) *"Personally involved".* You can be "personally involved" even though you actually make none of the critical decisions if you contribute to them by recommendations, advice, approval, or the like, but your involvement must have been substantial. If you are a member of the National Science Board, you have definitely been "personally involved" with a matter if you have participated in any Board or Board-committee action on the matter or have taken part in a Board or committee discussion immediately preceding such an action.

§ 684.15 Compensation.

(a) *Compensation where you have been involved for the Government.* All "special Government employees" are subject to the following restriction:

While you are an NSF "special employee" you must not seek or accept (except from the Government) any compensation for services by you or anyone else in relation to any matter involving specific parties if you have been personally involved with that matter for the Government.

(b) *Compensation in relation to NSF matters.* If you have been employed with the NSF for more than sixty days in the last 365 and still are, you are subject to one other restriction:

You must not seek or accept any compensation for services by you or anyone else in relation to any matter involving specific parties pending in the NSF.

BE CAREFUL: Violation of either of these rules may also be a Federal crime.

(c) *NSF awards.* You may, however, perform work under an NSF award and may receive compensation charged to the award for the work.

(d) *"Personally involved".* You can be "personally involved" even though you actually make none of the critical decisions if you contribute to them by recommendations, advice, approval, or the like, but your involvement must have been substantial. If you are a member of the National Science Board, you have definitely been "personally involved" with a matter if you have participated in any Board or Board committee action on the matter or have taken part in a Board or committee discussion immediately preceding such an action.

§ 684.16 Acts affecting your financial interests.

(a) *No acting as a Federal employee where you have a financial interest.* You must not be personally involved as a Federal employee in the handling of any proposal, award, or other matter in which you, a member of your immediate family, or an organization of which you are or may become a part has a financial interest. BE CAREFUL: violation of this rule may also be a Federal crime.

(b) *Proposals and awards.* You will not violate this restriction with respect to proposals and awards as long as you follow the instructions provided in § 684.11(b).

(c) *"Personally involved".* The term "personally involved" has exactly the same meaning here as in connection with the representational restrictions described in § 684.14. See § 684.14(d).

(d) *"Matter".* The word "matter" has a somewhat broader meaning here than the phrase "matter involving specific parties" used in § 684.14. If in doubt, consult an ethics counselor in the Office of the General Counsel. National Science Board members should consult the Chairman of the Board.

(e) *Immediate family.* Only your spouse and minor children are considered members of your "immediate family" under this rule.

(f) *"Organization of which you are or may become a part".* You are a part of an organization if you are an officer, director, trustee, partner, or employee. You "may become" a part of an organization if you are negotiating with it or have an arrangement with it concerning prospective employment.

(g) *Waiver.* This provision may be waived where the financial interest involved is so insubstantial that it is unlikely to affect the integrity of your services to the Government. If you think such a waiver is called for, consult an ethics counselor in the Office of the General Counsel. The ethics counselor will advise you and will make a recommendation to the official who would have to approve such a waiver. National Science Board members should consult with the Chairman of the Board.

§ 684.17 Inside information.

(a) If your Government job gives you access to information not generally available to the public, you must not use that information for your private benefit or make it available for the private benefit of any other person or organization.

(b) You must not receive anything of monetary value for consulting, lecturing, writing, or public discussion that primarily concerns the responsibilities, programs, or operations of the Foundation or that draws significantly on official information or ideas not generally available to the public.

(c) The Director, the Deputy Director, an assistant director, or (in the case of Board members) the Chairman of the National Science Board may waive application of these rules and authorize use of non-public information in the public interest. Any such authorization must be obtained in writing. Consult an ethics counselor in the Office of the General Counsel. National Science Board members should consult with the Chairman.

§ 684.18 General standards of conduct for "special employees".

(a) *Use of Government employment for private gain.* You must not use your Government employment for a purpose that is (or gives the appearance of being) motivated by desire for private gain for yourself or anyone else, particularly anyone with whom you have family, business, or financial ties.

(b) *Use of Government employment for extortion.* You must not use your Government employment to coerce (or appear to coerce) anyone to provide financial benefit to yourself or anyone else, particularly anyone with whom you have family, business, or financial ties.

(c) *Gifts and favors.* On days when you are working at or for the NSF or in connection with NSF employment you must not seek or accept from anyone who has business with the NSF any gift, tip, loan, entertainment, or favor for yourself or anyone else, particularly anyone with whom you have family, business, or financial ties. This does not include promotional items of trivial value or a modest meal offered as a courtesy when there is no apparent connection with NSF business.

(d) *Misuse of Government property.* You must not use Government property or services for your private benefit or for the private benefit of others, except as you public duties benefit particular members of the public in intended ways.

(e) *Familiarity with statutory provisions.* You are legally responsible for acquainting yourself with each statute that relates to your ethical and other conduct as an NSF and Federal employee. Principal among these are the criminal statutes relating to bribery, graft, and conflicts of interests contained in 18 U.S.C. 201–209. The aspects of those statutory provisions that apply to you as an NSF "special employee" are covered by these regulations. These regulations also cover the provisions of Executive Order 11222, which prescribes standards of ethical conduct for Government officers and employees, and regulations of the Office of Personnel and Management that implement both the statutory provisions and the Executive Order. If you follow the regulations, you should have no trouble with any of those provisions. The regulations do not cover a number of other statutes that you must obey as a Federal employee:

(1) The prohibition against lobbying with appropriated funds (18 U.S.C. 1913).

(2) The prohibitions against disloyalty and striking (5 U.S.C. 7311, 18 U.S.C. 1918).

(3) The prohibitions against disclosure of classified information (18 U.S.C. 798, 50 U.S.C. 783) and disclosure of confidential information (18 U.S.C. 1905).

(4) The provision on habitual use of intoxicants to excess (5 U.S.C. 7352).

(5) The prohibition against misuse of a Government vehicle (31 U.S.C. 638a(c)).

(6) The prohibition against misuse of the franking privilege (18 U.S.C. 1719).

(7) The prohibition against use of deceit in an examination or personnel action in connection with Government employment (18 U.S.C. 1917).

(8) The prohibition against fraud or false statements in a Government matter (18 U.S.C. 1001).

(9) The prohibition against multilating or destroying a public record (18 U.S.C. 2071).

(10) The prohibition against counterfeiting and forging transportation requests (18 U.S.C. 508).

(11) The prohibitions against embezzlement of Government money or property (18 U.S.C. 641), failing to account for public money (18 U.S.C. 643), and embezzlement of the money or property of an employee by reason of his employment (18 U.S.C. 654).

(12) The prohibition against unauthorized use of documents relating to claims from or by the Government (18 U.S.C. 285).

(13) The prohibition against an employee acting as the agent of a foreign principal registered under the Foreign Agents Registration Act (18 U.S.C. 219).

Subpart B—Special Rules of the National Science Board for Board Members

§ 684.20 Summary.

(a) As a member of the National Science Board you are covered by rules for "special employees" described in Subpart A of this Part 684. This Subpart B contains specific rules of the Board that apply only to its members. If there is doubt about the interpretation or application of these requirements, consult the Chairman of the Board.

§ 684.21 Participation in Board deliberations.

(a) *Recusal.* You are asked to excuse yourself from deliberations and votes of the Board or any of its committees on any action that would affect:

(1) The interests of an institution with which you, your spouse, a minor child, a blood relative who lives with you, or anyone who is legally your partner has any of the affiliations listed in paragraph (b) of this section, or

(2) The interests of an individual with whom you, your spouse, a minor child, a blood relative who lives with you, or anyone who is legally your partner has any of the relationships listed in paragraph (c) of this section.

(b) *Affiliations with affected institutions.* (1) Ownership of the institution's stocks, bonds, notes, or other evidences of debt (other than through mutual funds).

Note.—Minor or indirect holdings may be exempted; check with an ethics counselor. National Science Board members should check with the Chairman.

(2) Current employment.

(3) Any formal or informal arrangement for future employment.

(4) Current appointment as professor, adjunct professor, visiting professor, or the like Governing board membership.

(5) Chairmanship of any committee of the institution that has an interest in the Board's action.

(6) Any other office (not including ordinary membership in a professional society or association).

(7) Current membership on a visiting committee or similar body if the department or other part of the institution advised will be directly affected by the Board's action.

(8) Current enrollment as a student in a department or school that has an interest in the Board's action.

(9) Any other affiliation with the institution that you think would destroy your objectivity or be seen as doing so by a reasonable person familiar with the affiliation.

(c) *Relationships with affected individuals.* (1) Blood or marriage relationship with a principal investigator.

(2) Any other relationship, such as close personal friendship, that you think might tend to destroy your objectivity or be seen as doing so by a reasonable person familiar with the relationship.

§ 684.22 Participation in NSF-supported projects.

(a) *Proposals and new awards.* You must not be listed as an investigator on any proposal submitted to the NSF or on any award made by the NSF while you are on the Board. (Proposals pending when you are nominated will be handled case-by-case by the General Counsel.) Nor should you receive any compensation under an award made by the NSF while you are on the Board. You may, however, do work on a project supported by such an award and may be reimbursed for expenses you incur in doing so.

(b) *Existing awards.* If you are already an investigator or consultant under an NSF award when you become a Board member, you may continue work under the award in the same capacity and may be compensated under the award to the extent established before your nomination. If you have been principal investigator before you become a Board member, you and your institution should select a substitute negotiator. The substitute negotiator need not be responsible for the work, but should represent the project and the institution in dealings with NSF officials on whom you might have undue influence because of your Board position.

[FR Doc. 82-174 Filed 1-4-82; 8:45 am]
BILLING CODE 7555-01-M

FEDERAL MARITIME COMMISSION

46 CFR Part 510

[General Order 4, Rev.; Docket No. 80-13]

Licensing of Independent Ocean Freight Forwarders

AGENCY: Federal Maritime Commission.

ACTION: Notice of Further Proposed Rulemaking.

SUMMARY: The Commission's proposed final rules in this proceeding would have

amended 46 CFR 510.32(j) to prohibit the waiver or reduction of forwarding fees, which had previously been allowed under certain circumstances. Prior to the effective date of 46 CFR 510.32(j), the Commission determined to consider further the proper treatment of such fees when applied to shipments for relief agencies or charitable organizations, concurrently staying the prohibition as it pertained to such organizations pending final resolution of the matter. The Commission hereby serves notice of further proposed rulemaking to amend 46 CFR 510.32(j) in order to continue to allow ocean freight forwarders to provide forwarding services to relief agencies or charitable organizations free of charge or at reduced fees.

DATE: Comments on or before February 4, 1982.

ADDRESS: Inquiries and comments (original and 15 copies) to: Francis C. Hurney, Secretary, Federal Maritime Commission, 1100 L Street, NW., Washington, D.C. 20573, (202) 523–5725.

SUPPLEMENTARY INFORMATION: The Commission instituted this proposed rulemaking on March 17, 1980 (45 FR 17029) to revise General Order 4 (46 CFR Part 510), which governs the licensing and operations of independent ocean freight forwarders (forwarders). One of the proposed changes was the deletion from original § 510.24(b) of General Order 4 of the provision which allows forwarders to provide forwarding services free of charge or at a reduced rate when the shipments involved are made by recognized relief agencies or charitable organizations. Because designation of various entities as charitable organizations for purposes of this section is generally made by ocean carriers on a discretionary basis and is subject to no clear guidelines, the Commission viewed this provision as vulnerable to misuse and thus sought to delete it as part of the agency's efforts to combat illegal rebating and prevent discrimination among shippers.

Notice of the proposed revisions to General Order 4 generated numerous comments from all sectors of the maritime industry, and two entities provided the Commission with comments directly addressing the proposed prohibition of reduced forwarding fees embodied in proposed § 501.32(j).[1] The American Council of Voluntary Agencies for Foreign Service, Inc., objected to the proposed change and requested that the rule which existed in § 510.24(b) at the time of the comment period be retained. The National Customs Brokers and Forwarders Association of America, Inc., on the other hand, agreed with the new provision and the Commission's rationale for instituting it.

The Commission published final rules in this proceeding on may 1, 1981, (46 FR 24565) with a scheduled effective date of October 1, 1981. As part of the final rules, the Commission adopted without modification the proposed § 510.32(j) and stated that "in order to avoid discrimination between shippers (the Commission) deleted the exceptions contained in current § 510.24(b), which allowed a forwarder to perform forwarding services for relief or charitable agencies free of charge or at a reduced rate". (46 FR 24567).

Prior to the October 1, 1981 effective date of those rules, the Commission stayed that portion of § 510.32(j)[2] which affected shipments by relief agencies and charitable organizations.

Since the Commission stayed the implementation of its total ban on reduced forwarding fees, it has reviewed its original rule allowing exceptions for relief agencies and charitable organizations. In the course of this review, the Commission weighed the potential for misuse of this exception against its humanitarian intent, and the Commission is now considering reverting to its former practice of allowing the waiver or reduction of forwarding fees on relief and charitable shipments. Given the noncommercial nature of such shipments and the humanitarian intent of the sponsoring organizations, the waiver or reduction of forwarding fees on these types of shipments would not appear to create discrimination of a type or degree which would undermine the purposes of sections 14, 16 and 17 of the Shipping Act, 1916, or be detrimental to the foreign commerce of the United States. Moreover, the Commission has no specific evidence of past abuses under its old rules.

That portion of § 510.32(j) which affects shipments of relief agencies or charitable organizations will continue to be stayed pending the adoption of a final rule in this further rulemaking.

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Commission certifies that the revision proposed herein would not, if promulgated, have a significant economic impact in a substantial number of small entities. The proposal would merely reinstate the previous rule which had been in effect for a number of years, and no additional reports or records are required by the instant proposal.

PART 510—LICENSING OF INDEPENDENT OCEAN FREIGHT FORWARDERS

§ 510.32 [Amended]

Therefore, pursuant to sections 21, 43 and 44 of the Shipping Act, 1916 (46 U.S.C. 820, 841a, and 841b), and section 4 of the Administrative Procedure Act (5 U.S.C. 553), the Commission proposes to revise § 510.32(j) of its General Order 4 (46 CFR Part 510) to read as follows:

* * * * *

(j) *Reduced forwarding fees.* No licensee shall render, or offer to render, any freight forwarding service free of charge or at a reduced fee in consideration of receiving compensation from an oceangoing common carrier or for any other reason. Exception: A licensee may perform freight forwarding services for recognized relief agencies or charitable organizations, which are designated as such in the tariff of the oceangoing common carrier, free of charge or at reduced fees.

By the Commission.

Francis C. Hurney,

Secretary.

[FR Doc. 82–256 Filed 1–4–82; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[General Docket No. 81–786; RM–3832; RM–3126; FCC 81–525]

Auditory Training Devices

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes to amend its rules regarding the use of auditory training devices (Part 15, Subpart G). Presently the rules restrict the operation of these low power devices to institutional education programs for auricular instruction of persons with speech or hearing impairments. Removal of this restriction will enhance auditory assistance services to the handicapped. Continuation of the applicable technical standards will insure a low interference potential to licensed services.

[1] Section 510.32(j) reads: (j) *Reduced forwarding fees.* Except as otherwise provided in this part, no licensee shall render, or offer to render, any forwarding service free of charge or at a reduced fee in consideration of receiving compensation from oceangoing common carriers on the relevant shipment or for any other reason.

[2] Notice of the Stay appeared September 14, 1981 at 46 FR 45612, as clarified by a further notice which appeared October 1, 1981 at 46 FR 48199.

DATE: Comments are due by January 15, 1982 and replies by February 1, 1982.

ADDRESS: Federal Communications Commission, 1919 M Street NW., Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: L. Art Wall, Office of Science and Technology, Federal Communications Commission, Washington, D.C. 20554 (202) 653–8247, Room 8302.

SUPPLEMENTARY INFORMATION:

Adopted: November 12, 1981.
Released: December 14, 1981.

In the matter of amendment of Subpart G of Part 15 of the Commission's Rules and Regulations regarding Auditory Training Devices; General Docket No. 81–786, RM–3832, RM–3126.

1. The Commission is herein considering the following petitions to amend Subpart G of Part 15 of the Rules relating to Auditory Training Devices:

(a) Petition for Rulemaking (RM–3126) filed by Williams Sound Corporation (Williams) on May 1, 1978 requesting (i) the redefining of the scope of the subject Subpart, (ii) the provision of the 530 kHz and 1610 kHz frequencies for use by auditory support systems, and (iii) the adoption of appropriate technical parameters that would permit proper operation.

(b) Petition for Rulemaking (RM–3832) filed by Phonic Ear, Inc. (Phonic Ear) on January 12, 1981, requesting the removal of any restriction on the places or locations where auditory training devices [1] may be used.

These petitions have in common the request to modify § 15.331 of the rules and both would amend the definition of auditory training devices to expand the environment in which such devices can operate. No comments were filed within the 30 day pleading period after public notice of these petitions; subsequently, several letters relating to Phonic Ears' petition were received by the Commission. These letters have been treated as comments.

Background

2. By Notice of Proposed Rulemaking and Memorandum and Order released March 30, 1971, the Commission instituted Docket No. 19185 concerning the provision for the licensing of auditory training devices for persons with hearing-impairments. The Commission, on July 6, 1972, adopted a new Subpart G of the rules [2] which established provisions whereby an auditory training system could be operated without individual license in institutional education programs for auricular instruction of persons having speech or hearing handicaps. These provisions primarily covered the operation of such systems in the band 72–76 MHz [3] and set forth specific technical standards. Under these standards and other requirements in Part 16 of the rules, the Commission found that the operation of systems consisting of low power transmitters for short distance communications for the intended purposes would be appropriate.

Place-of-Use Restriction

3. The present rules state that auditory training systems may be operated "in institutional educational programs for auricular instruction of persons having speech or hearing handicaps." (See § 15.331) Phonic Ear points out that there is no discussion in Docket No. 19185 which details the origination of this language. Phonic Ear further asserts that such language is both an unnecessary restriction and an artificial limitation on the benefits which may be derived from the use of auditory training devices.

4. We agree that the history behind the limitation on the use of auditory training devices in instructional program is vague. In part the reasons relate to the concept of low power devices. Briefly, our low power rules are based on the concept that devices which operate at low power, which radiate a limited field strength, and which therefore would have a small likelihood of causing harmful interference to licensed services can be authorized without issuing individual licenses. The determination as to the possibility of interference involves an analysis, among other things, of the environment in which a particular device will be operating. All information, studies and statements leading to the current rules were based on the use of auditory training devices in institutional educational programs; so it is understandable how this limitation was derived. The statements and requests of the petitioners have prompted us to review these rules.

5. The petitioners' requests as to the place-of-use restriction appear reasonable. Phonic Ear has provided some analysis of the interference potential of auditory devices in the 72–76 MHz band assuming no changes in the technical parameters. We also have considered the effect of an expanded evironment for auditory devices on the interference situation and foresee no serious problems. We therefore agree that liberalization of the rules appears warranted. Several waivers to the subject rules have been granted authorizing the use of these devices outside the environment of institutional education programs. To our knowledge, the use of these devices has not caused any adverse reactions or interference and, in fact, has generated favorable responses from users.[4] In the absence of a significant threat of interference and because we recognize the service these devices provide, we are proposing to remove the restriction on the place(s) at which auditory devices may be used.

6. Even though we are proposing to permit the use of these devices at any location we recognize that the technical specifications contained in the existing rules for the 72–76 MHz band (e.g., transmitter power, field strength, frequency tolerance), not a subject of this Notice, may make operation at some sites unsatisfactory or impractical. For example the power permitted may not be adequate to cover a large auditorium. Nevertheless it is these same technical specifications which we believe make it feasible to propose broad expansion of the use of auditory training devices. We believe that on balance our proposed action greatly extends the potenial benefits of auditory training devices even given the technical/operation limitations inherent in any device subject to low power regulations. It should be noted that the Commission is not making a finding as to the need for 72–76 MHz auditory devices in certain places that are not well suited for that type of operation. To enable these devices to effectively serve the needs of the handicapped in all settings might require a change in the applicable technical standards. We note that if higher signal strength is required for minimally acceptable operation, such operation may be outside the regulatory purview of Part 15 of the rules.[5] In other words, licensed operation may be required.

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[1] As currently defined in § 15.4(1) an auditory training devices is a transmitter or receiver used for auricular instruction of persons having speech or hearing handicaps.

[2] Report and Order released July 11, 1972 (FCC 72–606) 35 F.C.C. 2d 677. These rules were subsequently modified by Memorandum Opinion and Order released March 8, 1973, (FCC 73–234) 39 F.C.C. 2d 983.

[3] Other provisions permit operation of auditory devices on other frequencies, but with more restrictive technical parameters.

[4] See letter of March 30, 1979 to the Buffalo Philharmonic Orchestra and letter of April 30, 1981 to Arena Stage.

[5] It is possible of course to investigate the question of whether the technical standards applied to auditory devices might be raised somewhat without representing a significant interference concern. In conjunction with the proposed liberalization, however, such an investigation would prove more complicated and certainly more time-consuming.

7. As mentioned above, it is the nature of low power devices that technical specifications must be imposed. Our primary concern is to prevent harmful interference to licensed services and we believe in this case this concern is protected. Nevertheless, we request that commenters address the need for, and the ways to provide, additional safeguards to licensed users. One such safeguard might be permitting the operation of these devices only in enclosed structures, where the attenuation of the radiated signal due to the structure's walls would reduce the possibility of interference.

8. While limiting operation of these devices to enclosed structures would reduce their interference potential, such a restriction would, in effect, preclude use of portable devices. A portable system that provides communications between a parent and a deaf child is an example of a system that would not be compatible with any restriction on the location of the transmitter. We are not herein proposing such a restriction but should one be found necessary to alleviate interference concerns, we inquire as to how necessary mobile operations could be accommodated while maintaining a low interference potential.

Operation on 530 kHz and 1610 kHz Frequencies

9. In addition to the proposal discussed above, Williams petitions that provisions be made for the use of the 530 kHz and 1610 kHz frequencies by auditory devices.[6] Williams suggests that operation of an auditory support system using these frequencies could provide valuable service to hearing impaired persons. Such system would consist of a low power AM radio transmitter and standard, readily-available AM pocket radios equipped with earphones. To assure proper operation, Williams suggests certain technical parameters be permitted and incorporated in the rules.[7]

10. Williams argues that there is "no suitable means . . . for providing auditory support to hearing impaired persons in large auditorium-type gatherings and that the use of the requested frequencies and the associated use of readily available AM radio receivers is particularly significant in reducing the costs of this service—a feature that is of considerable importance to senior citizens." However, our proposal to remove restrictions on the places of operation of auditory devices in the 72–76 MHz band will provide the desired service to persons having hearing impairments.[8] Granted, these systems have different characteristics and are competitive; but we believe the statement that "no means exist" is no longer accurate.

11. While one of the Commission's objectives is to create an unregulated, competitive marketplace environment for the development of telecommunications, there are many other issues that must be considered—especially as they relate to unlicensed low power devices. With regard to Williams' request for less restrictive technical parameters for auditory devices operating on the 530 and 1610 kHz frequencies, the Commission has several unanswered misgivings. First Williams has provided no study as to the interference potential of its proposal to AM broadcasting, or to the Travelers Information Service. This of particular concern since Williams is proposing to operate with a power far in excess of what the Commission now permits under its low power rules in an area of heavily used spectrum particularly susceptible to interference.[9] Second Williams' reliance on standard AM radio receivers as an important feature in its proposal may be more of a deterrent than an advantage, because there is a distinct possibility that the easy availability of AM receivers would increase the likelihood of Williams' system being employed for purposes contrary to Commission policy. This also is of particular concern since these devices would operate without a license from the Commission. Third, Williams has not adequately described the need for dual types of systems, each using different parts of the spectrum, to accomplish the same purpose. Therefore we are not now proposing the technical parameters associated with the use of the 530 and 1610 kHz frequencies as requested by Williams. That part of Williams petition to expand the sphere of use of auditory devices is being proposed as discussed above.

12. Despite our apprehensions, we recognize that Williams proposal, if implemented, could be of some benefit to hearing impaired persons. It is not our intention in this proceeding to foreclose alternatives such as Williams' proposal if the benefits outweigh the disadvantages. We therefore solicit comments on the use of 530 and 1610 kHz with the technical parameters proposed by Williams. Particular attention should be made to our concerns expressed in paragraph 11. If comments are persuasive that the benefits of Williams' petition could be greater than the disadvantages, we may pursue Williams' proposal in a further notice. Therefore, action on Williams' proposal, to the extent not being contained herein, is deferred.

Ancillary Issues

13. *Use of Auditory Devices.* It has come to the Commission's attention that the devices involved in this proceeding for the benefit of the hearing impaired can provide a service to visually impaired persons as well.[10] While the use of these devices is different, the operation is described as practically identical—the exceptions being operation on a separate channel (to prevent interference between separate transmissions) and relaying of stage events through commentary rather than reproduction and amplification of the actual sound. These differences do not materially alter the basic service provided, i.e., assistance to the handicapped to increase the level of their enjoyment and participation in performances and other group activities. The only adverse aspect to the use of these devices is the expansion of the operational environment accompanied with the potential interference to license services. As mentioned earlier, the extent to which these devices will operate and the environment in which they will operate are major factors in determining the interference situation. We do not see the extension in the use of these devices for visually impaired persons to signficantly alter the conclusions regarding the interference potential of such devices.

14. At the time of adoption, the rules governing auditory assistance devices included the requirement that transmitters used in the system receive type approval from the Commission.[11]

[6] The 530 kHz and 1610 kHz frequencies are allocated to the Travelers Information Service (See Table of Frequency Allocations in Part 2 of the Commission's rules.)

[7] I.e., maximum input power—250 mw (equivalent to a field strength of approximately 2000 μV at 30 meters on 530 kHz); emission suppression —20dB; antenna length—3 meters power line feedback—200 μV; frequency tolerance—± .01%.

[8] Alternative systems and technologies include induction field and infrared transmissions. Additionally, the 1979 World Administrative Radio Conference adopted the proposal to urge countries to use frequencies in the 3–4 MHz band to provide a common worldwide channel for low power wireless hearing devices. (See Final Acts, 1979 WARC, Note 3406A/506).

[9] The 535–1605 kHz frequency band is allocated to the AM Broadcasting Service (See Table of Allocations in Part 2 of the Commission's rules).

[10] See June 30, 1981 letter on behalf of the Washington Ear, Inc. requesting use of auditory devices at certain Washington area theaters by vusually impaired persons.

[11] *See* Part 2, Subpart J—Type approval is an equipment authorization issued by the Commission

Continued

This type of authorization was believed necessary to closely monitor the progress of these new devices. Experience with these devices has provided valuable data to both the Commission and the manufacturers as to their operation. On this basis we believe that the equipment authorization requirement can be relaxed from type approval to certification. Because of marketplace incentives to increase the power and range of Part 15 transmitters, and the corresponding potential for interference, we feel that certification is the minimal regulation necessary to protect against radio interference. Accordingly, we also propose in this Notice to require certification of auditory devices in place of the more stringent type approval authorization.

Summary

15. We believe that the proposals contained in this Notice will be of substantial benefit to aurally and visually impaired persons. We recognize certain limitations to the proposed operations that are a result of the technical provisions. However, because such operations will be unlicensed, we believe these limitations can not be avoided.

16. Accordingly, we propose to amend Subpart G of Part 15 of the Commission's rules and regulations as set forth in the Appendix. Authority for the actions taken herein is contained in sections 4, 302 and 303 of the Communications Act of 1934, as amended.

17. Pursuant to section 605 of the Regulatory Flexibility Act of 1980 the Commission certifies that the action proposed herein will not have a significant economic impact on a substantial number of small entities. The rules, if adopted, would allow the operation of the subject devices regardless of location for the provision of auditory assistance to the handicapped. Moreover, very few businesses are involved in the production of these devices.

18. Pursuant to applicable procedures set forth in § 1.415 of the Commission's rules, interested parties may file comments on or before January 15, 1982, and reply comments on or before February 1, 1982. All relevant and timely-filed comments will be considered by the Commission before final action is taken in this proceeding. In reaching its decision, the Commission may take into consideration information and ideas not contained in the comments, provided that such information, or a writing indicating the nature and source of such information, is placed in the public file, and provided that the fact of the Commission's reliance on such information is noted in the Report and Order.

19. For purposes of this non-restricted notice and comment rulemaking proceeding, members of the public are advised that *ex parte* contacts are permitted from the time the Commission adopts a notice of proposed rulemaking until the time a public notice is issued stating that a substantive disposition of the matter is to be considered at a forthcoming meeting or until a final order disposing of the matter is adopted by the Commission, whichever is earlier. In general, an *ex parte* presentation is any written or oral communication (other than formal written comments/pleadings and formal oral arguments) between a person outside the Commission and a Commissioner or a member of the Commission's staff who addresses the merits of the proceeding. Any person who submits a written *ex parte* presentation must serve a copy of that presentation on the Commission's Secretary for inclusion in the public file. Any person who makes an oral *ex parte* presentation addressing matters not fully covered in any previously-filed written comments for the proceeding must prepare a written summary of that presentation; on the day of oral presentation, that written summary must be served on the Commission's Secretary for inclusion in the public file, with a copy to the Commission official receiving the oral presentation. Each *ex parte* presentation described above must state on its face that the Secretary has been served, and must also state by docket number the proceeding to which it relates. See generally, § 1.1231 of the Commission's rules, 47 CFR § 1.1231.

20. It is ordered that a copy of this notice shall be sent to the Chief Counsel for Advocacy of the Small Business Administration.

21. It is ordered that delegated authority be given to the Chief Scientist to act, during the pendency of this rulemaking, on waiver requests consistent with the rules proposed herein.

22. In accordance with the provisions of § 1.419 of the Commission's rules, an original and five copies of all statements, briefs or comments filed shall be furnished the Commission. Responses will be available for public inspection during business hours in the Commission's Public Reference Room in its headquarters in Washington, D.C.

23. For further information concerning this proceeding contact F. Ronald Netro, Office of Science and Technology (202) 653–8100. A summary of the Commission's procedures governing *ex parte* contacts in informal rulemakings is available from the Commission's Consumer Assistance Office, F.C.C., Washington, D.C., 20554, (202) 632–7000.

(Secs. 4, 303, 307, 48 Stat., as amended, 1066, 1082, 1083; 47 U.S.C. 154, 303, 307)

Federal Communications Commission.

William J. Tricarico,

Secretary.

Appendix

PART 15—RADIO FREQUENCY DEVICES

It is proposed that 47 CFR Part 15 of the Commission's Rules and Regulations be amended as follows:

Subpart G—Auditory Assistance Devices

1. The title of Subpart G—Auditory Training Devices be changed to read "Auditory Assistance Devices."

2. Section 15.331—Scope of this subpart, be revised to read:

§ 15.33 Scope of this subpart.

This subpart provides rules under which a restricted radiation device may be operated without individual license as an auditory assistance device for handicapped persons. Such devices may be for auricular training in educational institutions and for auditory assistance at places of public gatherings, such as theaters, auditoriums and churches. The provisions herein are in addition to the general provisions for low power communications devices in Subpart D of this Part.

3. Replace the term "auditory training" with the term "auditory assistance" in the following sections:

§ 15.332
§ 15.333 (a) and (b)
§ 15.337 (a) and (b)
§ 15.341 (a) and (b)
§ 15.345
§ 15.347 (b) and (c)
§ 15.351 (a), (b), and (c)
§ 15.353
§ 15.355(a)
§ 15.361
§ 15.363

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based on examination and measurement of one or more sample units by the Commission at its laboratory. Certification is an equipment authorization issued by the Commission on the basis of a review of a test report and other documents submitted by the manufacturer.

§ 15.365
§ 15.367
§ 15.375 (a) and (b)
§ 15.377

4. Section 15.335—Operation in the band 88–108 MHz, be revised to read:

§ 15.335 Operation in the band 88–108 MHz.

An auditory assistance system may be operated in the band 88–108 MHz provided the transmitter meets the technical specifications in Subpart E of this part and the receiver has been certificated pursuant to § 15.345.

5. Section 15.347(a)—Equipment authorization for transmitter, be revised to read:

§ 15.347 Equipment authorization for transmitter.

(a) A transmitter operating in the band 72–76 MHz or the 88–108 MHz as part of an auditory assistance system shall be certificated pursuant to subpart B of this Part.

* * * * *

6. Section 15.4(1)—definition of auditory training device be amended to read:

§ 15.4 General definitions.

* * * * *

(l) *Auditory assistance device*—A transmitter or receiver used for the provision of auditory assistance to the handicapped. Such devices may be used for auricular training in educational institutions and for auditory assistance at places of public gatherings, such as, churches, theaters and auditoriums.

* * * * *

Concurring Statement of FCC Commissioners James H. Quello, Anne P. Jones and Mimi Weyforth Dawson

In re: Notice of Proposed Rule Making to amend Part 15 of the Commission's Rules concerning the use of low power radio devices for providing communciations services for handicapped persons.

While we generally support the proposal to reduce restrictions on the use of auditory training devices, we do have some concerns about the use of specific frequencies immediately adjacent to the AM broadcast band with increased power levels. The potential for interference to AM broadcasting through widespread use of those frequencies and power levels would seem to be significant. Thus, the burden to be borne by those advocating such usage, in our views, will be significant.

Therefore, we concur.

[FR Doc. 82–147 Filed 1–4–82; 8:45 am]

BILLING CODE 6712–01–M

INTERSTATE COMMERCE COMMISSION

49 CFR Parts 1039 and 1300

[Ex Parte No. 230 (Sub-No. 5)]

Improvement of Trailer-on-Flatcar (TOFC) and Container-on-Flatcar (COFC) (Service Regulation)

AGENCY: Interstate Commerce Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: In response to court action, we are reopening this proceeding to reconsider the exemption for the Alaska Railroad (ARR) and propose to amend the rules to clarify that the exemption is limited to trailer-on-flatcar (TOFC) and container-on-flatcar (COFC) service performed by rail carriers. We would also make other minor technical corrections to the rules.

DATE: Comments are due February 19, 1982.

ADDRESS: An original and 10 copies of comments should be sent to: Room 5340, Interstate Commerce Commission, Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT: Jane F. Mackall, (202) 275–7656.

SUPPLEMENTARY INFORMATION: Effective March 23, 1981, this Commission exempted from Interstate Commerce Commission regulation[1] "railroad and truck transportation provided by a rail carrier as part of a continuous intermodal movement." On September 21, 1981, the United States affirmed all but one aspect of our decision. *American Trucking Associations* v. *I.C.C.*, Nos. 81–4046 and 81–4080 (U.S.C.A., 5th Cir. September 21, 1981). The Court reversed that portion of our decision exempting service performed by the Alaska Railroad. The Court also urged us to rephrase the rule itself to leave no doubt that the exemption applies only to TOFC/COFC, and not all continuous intermodal movements. This notice is issued in response to the Court's order.

Alaska Railroad. The Court held that this exemption was arbitrary and capricious due to the existence of Federal subsidies, antitrust immunity, and the apparent absence of the usual forms of market competition. We did not discuss in detail the particular situation of the ARR in our decision. We, instead, stated that we would review the matter if problems arose, citing H.R. Rep. No. 96–1430, 96th Cong. 2d. Sess. 105 (1980).

After re-examining the record and our earlier decision, we are proposing to eliminate the ARR as a party to the exemption. This does not, however, mean that we are prohibited from concluding, based on additional evidence and analysis, that the ARR exemption is warranted. However, if we are to do so, we must be able persuasively to resolve the matters raised by the court. For this reason, we are seeking comments on this subject. Parties wishing to retain the ARR exemption should present evidence and argument addressing the issues raised by the court. Concurrently, parties supporting the proposal to withdraw the exemption as to the ARR should also submit evidence and argument. On the basis of these further submissions and our own analysis, we will re-evaluate this portion of the exemption.

Technical Amendments. In response to the court's suggestion, we propose to amend 49 CFR 1039.13 to include a specific reference to TOFC/COFC service. After we modified 49 CFR 1300.0(a)(i) and 1300.67(b)(1) in this proceeding, we finalized other changes to these rules. Ex Parte No. 261 (Sub-No. 1), *In the Matter of Tariffs Containing Joint Rates and Through Routes—Freight Forwarders and Nonvessel Operating Common Carriers by Water (NVO)*, 365 I.C.C. 136 (1981) (46 FR 35516). Section 1300.0(a)(1) now is clearly inapplicable to exempt service by the use of the phrase "their *regulated* joint rates and through routes" (emphasis added.) We see no need for further clarifying language. A comparable addition to § 1300.67(b)(1) is proposed here.

The proposed rules are contained in the appendix.

It does not appear that this action will significantly affect either the quality of the human environment or conservation of energy resources. However, comments are invited.

The Commission certifies that this action will not have a significant effect on a substantial number of small entities. The only substantive change affects the Alaska Railroad, a Federally-subsidized rail carrier.

Decided: December 17, 1981.

By the Commission, Chairman Taylor, Vice Chairman Clapp, Commissioners Gresham and Gilliam.

Agatha L. Mergenovich,

Secretary.

Appendix

Chapter X title 49 of the Code of Federal Regulations is proposed to be amended as follows:

[1] Except for accounting and reporting requirements.

PART 1039—CONTRACTS AND EXEMPTIONS

1. Section 1039.13 would be revised to read as follows:

§ 1039.13 Rail intermodal transportation exemption.

Railroad and truck trailer-on-flatcar (TOFC) and container-on-flatcar (COFC) transportation provided by a rail carrier as part of a continuous intermodal movement is exempt from the provisions of Subtitle IV of Title 49 with certain exceptions. TOFC/COFC movements performed by the Alaska Railroad are not included in the exemption. Carriers must continue to comply with Commission accounting and reporting requirements. All railroad tariffs pertaining to the transportation of intermodal freight in TOFC/COFC service will no longer apply except to the extent adopted by carriers' quotations. Nothing in this exemption shall be construed to affect our jurisdiction under section 10505 or our ability to enforce this decision or any subsequent decision made under authority of this exemption section. This exemption shall remain in effect, unless modified or revoked by a subsequent order of this Commission.

(49 U.S.C. 10321(a) and 10505)

PART 1300—FREIGHT TARIFFS; RAILROADS, WATER CARRIERS, AND PIPELINE COMPANIES SUBJECT TO SECTION 6 OF THE INTERSTATE COMMERCE ACT AND CARRIERS JOINTLY THEREWITH

§ 1300.67 [Amended]

2. Section 1300.67 would be amended as follows:

Section 1300.67(b)(1) would be amended by inserting in the first sentence the phrase "on its regulated traffic" following "may establish a through route and joint rate."

(49 U.S.C. 10762)

[FR Doc. 82-185 Filed 1-4-82; 8:45 am]
BILLING CODE 7035-01-M

Notices

Federal Register
Vol. 47, No. 2
Tuesday, January 5, 1982

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

COMMISSION ON CIVIL RIGHTS

Massachusetts Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Massachusetts Advisory Committee to the Commission will convene at 4:00 p.m., and will end at 6:00 p.m., on January 28, 1982, at the New England Regional Office, 55 Summer Street, 8th Floor, Boston, Massachusetts, 02110. The purpose of this meeting is to plan for the study of affirmative action in the private sector.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Bradford E. Brown, 17 Roberta Jean Circle, P.O. Box 95, East Falmouth, Massachusetts, 02536, (617) 548–5123 or contact the New England Regional Office, 55 Summer Street, 8th Floor, Boston, Massachusetts, 02110, (617) 223–4671.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., December 30, 1981.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82–114 Filed 1–4–82; 8:45 am]

BILLING CODE 6335–01–M

Massachusetts Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Massachusetts Advisory Committee to the Commission will convene at 4 p.m., and will end at 6 p.m., on February 9, 1982, at the New England Regional Office, 55 Summer Street, 8th Floor, Boston, Massachusetts, 02110. The purpose of this meeting is to discuss affirmative action in the private sector; civil rights developments in Massachusets in 1981; and fair housing in Boston.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Bradford E. Brown, 17 Roberta Jean Circle, P.O. Box 95, East Falmouth, Massachusetts, 02536, (617) 548–5123 or the New England Regional Office, 55 Summer Street, 8th Floor, Boston, Massachusetts, 02110, (617) 223–4671.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., December 30, 1981.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82–113 Filed 1–4–82; 8:45 am]

BILLING CODE 6335–01–M

New Jersey Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the New Jersey Advisory Committee to the Commission will convene at 6:30 p.m., and will end at 8:30 p.m., on January 27, 1982, at the Norris McGaughlan, 1081 Route 22, Sommerville, New Jersey. The purpose of this meeting is to discuss program plans for fiscal year 82.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Clyde C. Allen, 620 Sheridan Avenue, Plainfield, New Jersey, 07060, (212) 572–7577 or the Eastern Regional Office, Jacob K. Javits Building, 26 Federal Plaza, Room 1639, New York, New York, 10278, (212) 264–0400.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., December 30, 1981.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82–115 Filed 1–4–82; 8:45 am]

BILLING CODE 6335–01–M

South Carolina Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S Commission on Civil Rights, that a meeting of the South Carolina Advisory Committee to the Commission will convene at 1:00 p.m., and will end at 3:30 p.m., on January 27, 1982, at the Gressette Senate Office Building, Room 507, State Capitol Complex, Columbia, South Carolina, 29201. The purpose of this meeting is to orientate the new members; review draft SAC report on Voting Rights Act; and discuss program plans for fiscal year 82.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Oscar P. Butler, P.O. Box 1702, South Carolina State College, Orangeburg, South Carolina, 29117, (803) 536–7040 or the Southern Regional Office, Citizens Trust Bank Building, 74 Piedmont Avenue, N.E., Room 362, Atlanta, Georgia, 30303, (404) 221–4391.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission

Dated at Washington, D.C., December 30, 1981.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82–112 Filed 1–4–82; 8:45 am]

BILLING CODE 6335–01–M

CIVIL RIGHTS COMMISSION

South Dakota Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the South Dakota Advisory Committee to the Commission will convene at 9:00 a.m., and will end at 4:00 p.m., on January 22, 1982, at the Kings Inn Motel, in the Tower Room, 220 South Pierre, Pierre, South Dakota, 57501. The purpose of this meeting is to orientate new members, and to review the status of current Committee activities.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Marvin Amiotte, Oglala Sioux Tribe, Box 1053, Pine Ridge, South Dakota, 57770, (605) 867–5140 or the

Rocky Mountain Regional Office, Brook Towers, 1020 Fifteenth Street, Suite 2235, Denver, Colorado, 80202, (303) 837–2211.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82–148 Filed 1–4–82; 8:45 am]

BILLING CODE 6335–01–M

DEPARTMENT OF COMMERCE

Office of the Secretary

National Voluntary Laboratory Accreditation Program; Acoustical Testing Services; Public Workshops

AGENCY: Assistant Secretary of Commerce for Productivity, Technology, and Innovation, Commerce.

ACTION: Notice of public workshops to develop the technical requirements of a laboratory accreditation program for acoustical testing services.

SUMMARY: The Department of Commerce hereby announces that it will hold two informal public workshops to provide interested parties an opportunity to participate in the development of technical requirements of a laboratory accreditation program (LAP) for acoustical testing services (Acoustics LAP) under the Procedures of the National Voluntary Laboratory Accreditation Program (NVLAP), 15 CFR Part 7a, as amended (46 FR 37029 (July 17, 1981)).

The first workshop will consider test methods which deal primarily with the measurement of the properties of acoustical materials and the precision measurement of sound power and sound pressure levels. The second workshop will consider test methods covering the measurement of noise producing products and the engineering measurement of sound power and sound pressure levels.

DATES: *Workshop A* will start February 23, 1982 at 9:30 a.m. and end on February 24, 1982 at 5:00 p.m. *Workshop B* will start March 10, 1982 at 9:30 a.m. and end on March 11, 1982 at 5:00 p.m.

ADDRESS: Both workshops will be held in Lecture Room A, Administration Building, at the National Bureau of Standards, Gaithersburg, Maryland.

FOR FURTHER INFORMATION CONTACT: Dr. Gerald A. Berman, Room B06, TECH Bldg., National Bureau of Standards, Washington, D.C. 20234, phone: 301–921–2427. Persons who wish to attend either or both workshops should contact Dr. Berman not later than January 22, 1982, in order to allow enough time for mail delivery of preparatory documents for the workshop.

SUPPLEMENTARY INFORMATION: On October 19, 1981, the U.S. Department of Commerce (DOC) published in the **Federal Register** (46 FR 51267) a final finding of need to accredit laboratories that provide acoustical testing services.

The final finding of need listed test methods which will be included in the Acoustics LAP, methods which will be considered for inclusion, and methods which were excluded for the reasons stated. Because of the number and diversity of the test methods to be included or considered for the Acoustics LAP, two workshops have been planned. *Workshop A* will consider test methods which deal primarily with the measurement of the properties of acoustical materials and the precision measurement of sound power and sound pressure levels. *Workshop B* will consider test methods covering the measurement of noise producing products and the engineering measurement of sound power and sound pressure levels. The specific test methods are:

Workshop A: ANSI/ASTM C367; ANSI/ASTM C384; ANSI/ASTM C423; ASTM C522; ASTM C523; ANSI/ASTM E90; ANSI/ASTM E336; ASTM E477; ANSI/ASTM E492; ANSI/ASTM E596; ASTM E756; ANSI S1.13; ANSI S1.31; ANSI S1.32; ANSI S1.35; ISO 3741; ISO 3742; and ISO 3745.

Workshop B: ANSI B71.1; ANSI S1.29; ANSI S1.33; ANSI S1.34; ANSI S3.17; ANSI S3.19; ANSI S5.1; ISO 3743; ISO 3744; ISO 6080; MIL–STD–740B; MIL–STD–1474B; SAE–J 192a; SAE–J 1161; Title 40 CFR, Chapter I, Part 204; Title 40, CFR, Chapter I, Part 205; AMCA Test Code 300; ADC 1062; ARI 270; and ARI 350.

Before DOC can formally establish this LAP, the technical requirements for accrediting laboratories that provide acoustical testing services must be developed. Information needed and issues to be discussed at the workshop include:

1. Precision and accuracy expectations for the test methods;

2. Possible approaches to proficiency testing including the identification of those test methods for which proficiency testing should be developed and the type of proficiency test to be used in each case;

3. Necessary materials and protocols for assessing a laboratory's performance, including appropriate documentation;

4. The portions of the test methods which represent accreditable functions.

5. Supplemental information which will tailor the criteria (referenced in § 7a.19 of 15 CFR Part 7a, NVLAP Procedures) to the test methods in this LAP (such supplemental information could include requirements for dimensions and geometry of test installation and specific auxiliary measurement apparatus such as read-out instrumentation for each test).

6. Sources of assessors for this LAP and credentials or qualifications which assessors should possess.

The following procedures are established for the workshops:

1. *Purpose.* The purpose of the workshops is to provide all interested persons with an opportunity to participate in the development of the technical requirements of the Acoustics LAP and to enable DOC to secure valuable expert advice to develop these requirements.

2. *Conduct of Workshops.* These workshops will be informal non-adversary meetings. The presiding officer shall have the right to allocate the time available for discussion of each issue on the workshop agendas and to exercise such authority as may be necessary to insure the equitable and efficient conduct of the workshops and to maintain order.

3. *General Provisions.* The informal workshops will be open to the public. Summary minutes of the workshops will be prepared. A copy of those minutes will be available for inspection and copying in the Central Reference and Records Inspection Facility, Room 5317, Main Commerce Building, 14th Street between E Street and Constitution Avenue, NW., Washington, D.C. 20230.

Dated: December 30, 1981.

Robert B. Ellert,

Acting Assistant Secretary for Productivity, Technology, and Innovation.

[FR Doc. 82–138 Filed 1–4–82; 8:45 am]

BILLING CODE 3510–17–M

COMMODITY FUTURES TRADING COMMISSION

Exchange Proposals to Trade Commodity Options

Correction

In FR Doc. 81–37049, appearing on page 62893 in the issue of Tuesday, December 29, 1981, make the following correction:

In the second column, the fourth line should have read: "the following boards of trade: Chicago Board of Trade to trade options on U.S. long-term Treasury bonds futures contracts; Chicago Mercantile Exchange to trade."

BILLING CODE 1505–01–M

DEPARTMENT OF DEFENSE

Department of the Army

Military Traffic Management Command; Military Personal Property Symposium; Open Meeting

Announcement is made of a meeting of the Military Personal Property Symposium. This meeting will be held on 21 January 1982 at the Quality Inn, Pentagon City, 300 Army Navy Drive, Arlington, Virginia and will convene at 0900 hours and adjourn at approximately 1500 hours.

Proposed Agenda: The purpose of the Symposium is to provide an open discussion and free exchange of ideas with the public on procedural changes to the Personal Property Traffic Management Regulation (DOD 4500.34–R), and the handling of other matters of mutual interest relating to the movement and/or storage of household goods and unaccompanied baggage, as well as proposed changes and innovations in the Department of Defense Personal Property Movement and Storage Program.

All interested persons desiring to submit topics to be discussed should submit them in writing to the Commander, Military Traffic Management Command, ATTN: MT–PPM. Topics to be discussed should be received on or before 8 January 1982.

Dated: December 23, 1981.

Robert F. Waldman,

Deputy Director, Directorate of Personal Property.

[FR Doc. 82–207 Filed 1–4–82; 8:45 am]

BILLING CODE 3710–08–M

Department of the Navy

Chief of Naval Operations Executive Panel Advisory Committee; Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. I), notice is hereby given that the Chief of Naval Operations (CNO) Executive Panel Advisory Committee will meet on January 20–21, 1982, from 9:00 a.m. to 5:00 p.m. each day, at 2000 North Beauregard Street, Alexandria, Virginia. All sessions will be closed to the public.

The entire agenda for the meeting will consist of discussions of the Navy's net assessment, research and development programs and warfare appraisals and related intelligence. These matters constitute classified information that is specifically authorized by Executive order to be kept secret in the interest of national defense and is, in fact, properly classified pursuant to such Executive order. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 552b(c)(1) of title 5, United States Code.

For further information concerning this meeting, contact: Lieutenant Kathleen M. Cummings, Executive Secretary, CNO Executive Panel Advisory Committee, 2000 North Beauregard Street, Room 392, Alexandria, VA 22311, Telephone (703) 756–1205.

Dated: December 29, 1981.

P. B. Walker,

Captain, JAGC, U.S. Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 82–105 Filed 1–4–82; 8:45 am]

BILLING CODE 3810–AE–M

Office of the Secretary

DOD Advisory Group on Electron Devices; Meeting

Working Group D (Mainly Laser Devices) of the DoD Advisory Group on Electronic Devices (AGED) will meet in closed session 8 and 10 February 1982 at the Naval Postgraduate School, Monterey, California.

The mission of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group D meeting will be limited to review of research and development programs which the military propose to initiate with industry, universities or in their laboratories. The laser area includes programs on developments and research related to low energy lasers for such applications as battlefield surveillance, target designation, ranging, communications, weapon guidance and data transmission. The review will include classified program details throughout.

In accordance with 5 U.S.C. App 1, 10(d) (1976), it has been determined that ths Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1976), and that accordingly, this meeting will be closed to the public.

Sheila Levine,

Acting OSD Federal Register Liaison Officer, Department of Defense.

December 30, 1981.

[FR Doc. 82–177 Filed 1–4–82; 8:45 am]

BILLING CODE 3810–01–M

DOD Advisory Group on Electron Devices; Meeting

Working Group B (Mainly Low Power Devices) of the DoD Advisory Group on Electron Devices (AGED) will meet in closed session 24 March 1982 at the AGED at 1925 N. Lynn Street, Arlington, Virginia 22209.

The mission of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group B meeting will be limited to review of research and development programs which the military propose to initiate with industry, universities or in their laboratories. The low power device area includes such programs as integrated circuits, charge coupled devices and memories. The review will include classified program details throughout.

In accordance with 5 U.S.C. App 1, 10(d) (1976), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552(c)(1) (1976), and that accordingly, this meeting will be closed to the public.

Sheila Levine,

Acting OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 82–176 Filed 1–4–82; 8:45 am]

BILLING CODE 3810–01–M

DEPARTMENT OF EDUCATION

Office of Elementary and Secondary Education

Grants to State Educational Agencies to Improve Interstate and Intrastate Coordination of Migrant Education Activities

AGENCY: Department of Education.

ACTION: Notice of Closing for Transmittal of Applications for Fiscal Year 1981 (Program Year 1982).

Applications are invited for new grants under the Migrant Education Interstate and Intrastate Coordination

Program to improve the coordination of activities conducted under the Title I, Elementary and Secondary Education Act (ESEA), Migrant Education Basic State Formula Grant Program.

The authority for this special coordination program is contained in section 143 of Title I, ESEA, as amended by Pub. L. 95–561. Funds are appropriated through a reservation from the total Title I, ESEA, Migrant Education Program appropriation. (20 U.S.C. 2763)

The only eligible applicants are State educational agencies (SEAs).

The purpose of this program is to provide grants to SEAs, that may apply individually or cooperatively (i.e., as a group or consortium), to plan and implement special projects designed to improve the interstate and intrastate coordination of migrant education activities.

Closing Date for Transmittal of Applications: An applicant SEA must mail or hand deliver its application for a grant to the U.S. Department of Education by March 9, 1982.

Applications Delivered by Mail: An applicant SEA that sends its application by mail must address its application to the U.S. Department of Education, Application Control Center, Attention: 84.144, Washington, D.C. 20202.

An applicant SEA must show proof of mailing consisting of one of the following:

(1) A legibly-dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of Education.

If an applicant SEA sends its application through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing:

(1) A private metered postmarked.

(2) A mail receipt that is not dated by the U.S. Postal Service.

An applicant SEA should note that the U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant SEA should check with its local post office.

The Secretary encourages an applicant SEA to use registered or, at least, first class mail. The Secretary notifies a late applicant SEA that its application will not be considered.

Applications Delivered by Hand: An applicant SEA that hand delivers its application must take the application to the U.S. Department of Education, Application Control Center, Regional Office Building 3, Room 5673, Seventh and D Streets SW., Washington, D.C.

The Application Control Center accepts a hand-delivered application between 8 a.m. and 4:30 p.m. (Washington, D.C. time) daily, except Saturdays, Sundays, and Federal holidays.

The Application Control Center does not accept an application that is hand delivered after 4:30 p.m. on the closing date.

Program Information: The Secretary awards grants under this program to SEAs to support special projects designed to promote and enhance the interstate and intrastate coordination of migrant education activities conducted under the Migrant Education Basic State Formula Grant Program. The basic program provides instructional and supporting services to meet the special educational needs of migratory children.

The Secretary published proposed regulations for this special coordination program on October 22, 1981 (at 46 FR 51879). The proposed regulations include a non-exhaustive listing of the types of projects that the Secretary may fund under this program. These project areas were identified in consultation with SEAs as addressing areas of significant national need in interstate and intrastate coordination of migrant education activities. The Secretary is identifying the nine project areas described in the proposed regulations as the funding priorities for FY 1982.

An applicant SEA should refer to the proposed regulations for this program for some additional guidance on the types of projects and activities contemplated under these project areas.

As described in the proposed regulations for this program, one of the selection criteria for evaluating project applications is "Annual Priorities" which reflects an assessment of the extent to which an application addresses one of the identified priority areas for funding in the relevant fiscal year.

Available Funds: The Secretary estimates that there will be $3,104,190 available for FY 1982 grants. The Secretary estimates that these funds will support 20 projects with most grants funded between $50,000 and $300,000. These estimates, however, do not bind the U.S. Department of Education to a specific number of grants nor to the amount of any grant unless that amount is otherwise specified by statute or regulations.

An applicant SEA may propose a project of from one to three years. However, the continued funding for projects approved for more than one year is subject to the availability and amount of a Congressional appropriation.

Application Forms: The U.S. Department of Education's Migrant Education Programs office will mail application forms and instructions to all eligible SEAs. An applicant SEA may obtain additional forms and instructions by writing to Migrant Education Programs, Office of Elementary and Secondary Education, U.S. Department of Education, 400 Maryland Avenue, S.W. (ROB–3, Room 3608), Washington, D.C. 20202.

An applicant SEA must prepare and submit its application in accordance with the regulations, instructions, and forms included in the grant application package.

The Secretary strongly urges that the narrative portion of an application not exceed 30 pages. The Secretary also urges that an applicant not submit information that is not requested.

Applicable Regulations: The regulations that apply to this program include the following:

(a) The proposed Migrant Education Interstate and Intrastate Coordination Program Regulations (34 CFR Part 205), which were published as a notice of proposed rulemaking (NPRM) in the **Federal Register** on October 22, 1981. An applicant SEA should base its application on the NPRM. If material changes are made in the final regulations, the Secretary may extend the closing date to permit applicant SEAs to amend their applications.

(b) The Migrant Education Basic State Formula Grant Program Regulations (34 CFR Part 204), where applicable.

(c) The Education Department General Administrative Regulations (EDGAR)(34 CFR parts 75 and 77).

Further Information: For further information, contact Mr. Ken Frye, Acting Director, Division of Program Operations, Migrant Education Programs, Office of Elementary and Secondary Education, 400 Maryland Avenue, S.W. (ROB–3, Room 3608), Washington, D.C. 20202. Telephone (202) 472–6100

(20 U.S.C. 2763)

(Catalog of Federal Domestic Assistance No. 84.144; Migrant Education/Interstate and Intrastate Coordination Program)

Dated: December 29, 1981.

[FR Doc. 82–111 Filed 1–4–82; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

[Docket No. ERA-R-79-43 B]

Electric and Gas Utilities Covered in 1982 by Titles I and III of the Public Utility Regulatory Policies Act of 1978 and Titles II and VII of the National Energy Conservation Policy Act of 1978 and Requirements for State Regulatory Authorities to Notify the Department of Energy

AGENCY: Economic Regulatory Administration, Energy.

ACTION: Notice.

SUMMARY: Sections 102(c) and 301(d) of the Public Utility Regulatory Policies Act of 1978 (PURPA) and section 211(b) of the National Energy Conservation Policy Act (NECPA) require the Secretary of Energy to publish a list, before the beginning of each calendar year, identifying each electric utility and gas utility to which Titles I and III of PURPA and Titles II and VII of NECPA apply during such calendar year. This Notice contains the list for 1982. The list is published here as two separate tabulations, Appendices A and B. Appendix A lists the covered utilities by State, and Appendix B lists them alphabetically. These two tabulations are referred to hereinafter as "the lists".

Each State regulatory authority is required, pursuant to sections 102(c) and 301(d) of PURPA and section 211(b) of NECPA, to notify the Secretary of Energy of each electric utility and gas utility on the list for which such State regulatory authority has ratemaking authority. In addition, written comments are requested on the accuracy of the list of electric utilities and gas utilities.

DATE: Notifications by State regulatory authorities and written comments must be received by no later than 4:30 p.m. of February 4, 1982.

ADDRESS: Notifications and written comments should be forwarded to: Department of Energy, Division of Fuels Conversion, 2000 M Street, NW. (Room 6114), Docket No. ERA-R-79-43B, Washington, D.C. 20461.

FOR FURTHER INFORMATION CONTACT: Ronald D. White, Fuels Conversion Division, Economic Regulatory Administration, Department of Energy, 2000 M Street, Room 6128, Washington, D.C. 20461, 202/653-3459.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to sections 102(c) and 301(d) of the Public Utility Regulatory Policies Act of 1978 (PURPA), Pub. L. 95-617, 92 Stat. 3117 *et seq.* (16 U.S.C. 2601 *et seq.*), and section 211(b) of the National Energy Conservation Policy Act (NECPA), Pub. L. 95-619, 92 Stat. 3206 *et seq.*, (42 U.S.C. 8211 *et seq.*), hereinafter referred to as the "Acts", the Department of Energy (DOE) is required to publish a list of utilities to which Titles I and III of PURPA and Titles II and VII of NECPA apply in 1982. State regulatory authorities are required by the above cited Acts to notify the Secretary of Energy as to their ratemaking authority over the listed utilities. The inclusion or exclusion of any utility on or from the list does not affect the legal obligations of such utility or the responsible State regulatory authority under the Acts.

The term "State regulatory authority" means any State, including the District of Columbia and Puerto Rico, political subdivision thereof, and any agency or instrumentality of either which has authority to fix, modify, approve, or disapprove rates with respect to the sale of electric energy or natural gas by any utility (other than such State agency), and in the case of a utility for which the Tennessee Valley Authority (TVA) has ratemaking authority, the term "State regulatory authority" means the TVA.

Title I of PURPA sets forth ratemaking and regulatory policy standards with respect to electric utilities. Section 102(c) requires the Secretary of Energy to publish a list, before the beginning of each calendar year, identifying each electric utility to which Title I applies during such calendar year. An electric utility is defined as any person, State agency or Federal agency, which sells electric energy. An electric utility is covered by Title I for any calendar year if the electric utility had total sales of electric energy for purposes other than resale in excess of 500 million kilowatt-hours during any calendar year beginning after December 31, 1975, and before the immediately preceding calendar year. An electric utility is covered in 1982 if it exceeded the threshold in 1976, 1977, 1978, 1979 or 1980.

Title III of PURPA addresses ratemaking and other regulatory policy standards with respect to natural gas utilities. Section 301(d) of Title III requires the Secretary of Energy to publish a list, before the beginning of each calendar year, identifying each gas utility to which Title III applies during such calendar year. A gas utility is defined as any person, State agency or Federal agency, engaged in the local distribution of natural gas, and the sale of natural gas to any ultimate consumer of natural gas. A gas utility is covered by Title III for any calendar year if the gas utility had total sales of natural gas for purposes other than resale in excess of 10 billion cubic feet during any calendar year beginning after December 31, 1975, and before the immediately preceding calendar year. A gas utility is covered in 1982 if it exceeded the threshold in 1976, 1977, 1978, 1979, or 1980. Title II, Part 1, of NECPA addresses residential conservation programs, and Title VII of NECPA, recently enacted as part of the Energy Security Act, Pub. L. 96-294, 94 Stat. 611 *et seq.* (42 U.S.C. 8701 *et seq.*), addresses commercial building and multi-family dwelling conservation programs. Section 211(b) contains a requirement, similar to that of PURPA, that the Secretary of Energy publish a list of electric and gas utilities to which Titles II and VII apply. The NECPA requirements for coverage of electric utilities and gas utilities differ from the PURPA requirements in only three respects:

(1) The threshold for electric utilities is 750 million kilowatt-hours for purposes other than resale;

(2) A utility is covered for any calendar year if it exceeded the threshold during the second preceding calendar year. A utility is covered in 1982 if it exceeded the threshold in 1980; and

(3) Only utilities which have residential sales are covered by Title II and only utilities which have sales to commercial buildings or multi-family dwellings are covered by Title VII.

In previous years, the process of publishing the statutorily required PURPA/NECPA list has been carried out by compilation and publication, first, of a proposed list, and then, on the basis of comments which were received on the proposed list, publication of a final list. DOE has decided this year to proceed directly to a final list because it believes, on the basis of its past experience in preparing and publishing PURPA/NECPA lists, that this will be more efficient, and can, at the same time, produce a list which is as useful as that produced by the previously used process.

In compiling the list published today, DOE began with the 1981 list (45 FR 85386, December 24, 1980). DOE then revised the 1981 list, upon the assumption that all entities included on the 1981 list are properly included on the 1982 list unless DOE has information to the contrary. In doing this, DOE took into account information which was received from the American Public Power Association, the Rural Electrification Agency, or included in public documents, regarding entities which exceeded the PURPA and NECPA thresholds for the first time in 1980. DOE

believes that it will become aware of any errors or omissions in the list published today by means of the comment process called for by this notice. DOE will, after consideration of any comment and other information available to DOE, provide notice of any further additions or deletions to the list.

II. Notification and Comment Procedures

No later than 4:30 p.m. of (the 30th day after the date of publication), each State regulatory authority must notify the Department of Energy in writing of each utility on the list over which it has ratemaking authority. Fifteen copies of such notification should be submitted to the address indicated in the "ADDRESS" section of this Notice and should be identified on the outisde of the envelope and on the document with the designation "Docket No. ERA–R–79–43B". Such notification should include:

(1) A complete list of electric utilities and gas utilities over which the State regulatory authority has ratemaking authority,

(2) Legal citations pertaining to the ratemaking authority of the State regulatory authority, and

(3) For any listed utility known to be subject to other ratemaking authorities within the State for portions of its service area, a precise description of the portion to which such notification applies.

All interested persons, including State regulatory authorities, are invited to comment in writing on any errors or omissions with respect to the list. Five copies of such comments should be sent to the address indicated in the "ADDRESS" section of this Notice and should be identified on the outside of the envelope and on the document with the designation "Docket No. ERA–R–79–43B". Written comments should include the commenter's name, address and telephone number.

All notifications and comments received by DOE will be available for public inspection in the ERA Reading Room, Room 7120, Federal Building, 12th & Pennsylvania Avenue, NW., Washington, D.C. 20461, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday.

III. List of Electric Utilities and Gas Utilities

DOE is publishing, in Appendix A and Appendix B, two different tabulations of the list of utilities which meet both PURPA and NECPA coverage requirements. In both appendices, the listed utilities not covered by NECPA are noted. As stated above, the inclusion or exclusion of any utility on or from the list does not affect its legal obligation or that of the responsible State regulatory authority under PURPA and NECPA.

Appendix A is a tabulation of utilities which separately identifies, by State, each State regulatory authority, the covered utilities it regulates, and other covered utilities in the State not regulated by the State regulatory authority. This tabulation, including explanatory notes, is based on information provided to DOE by State regulatory authorities in response to the October 10, 1980 **Federal Register** Notice (45 FR 67552) requiring State regulatory authorities to notify DOE of each utility on the list over which it has ratemaking authority, comments rescinded with respect to that notice, and subsequent information available to DOE.

The utilities classified in Appendix A as not regulated by the State regulatory authority may in fact be regulated by local municipal authorities. These municipal authorities would be State agencies as defined by PURPA, and thus have responsibilities under PURPA identical to those of the State regulatory authority. Therefore, each such municipality is to notify DOE of each utility on the list over which it has ratemaking authority.

In Appendix B, the utilities are listed alphabetically, subdivided into electric utilities and gas utilities, and further subdivided by type of ownership: investor-owned utilities, publicly owned utilities, and rural cooperatives.

The changes to the 1981 list of electric and gas utilities are as follows:

Additions:

Cobb Electric Membership Corporation
Cotton Electric Cooperative
Dixie Electric Membership Corporation
Rappahannock Electric Cooperative
Trico Electric Cooperative, Inc.
Virginia Electric and Power Company

Deletions:

Public Service Company of New Hampshire (ME)

Modifications:

CHANGE—Delmarva Power and Light Company of Virginia
TO—Delmarva Power and Light Company

(Public Utility Regulatory Policies Act of 1978, Pub. L. 95–617, 92 Stat. 3117 *et seq.* (16 U.S.C. 2601 *et seq.*); National Energy Conservation Act, Pub. L. 95–619, 92 Stat. 3206 *et seq.*) (42 U.S.C. 8211 *et seq.*))

Issued in Washington, D.C., on December 24th, 1981.

Rayburn Hanzlik,

Administrator, Economic Regulatory Administration.

All gas utilities listed below had natural gas sales, for purposes other than resale, in excess of 10 billion cubic feet in 1976, 1977, 1978, 1979 or 1980 and are covered by PURPA Title III and NECPA Titles II and VII. Utilities marked (*) do not have residential or commercial sales, and therefore, are not covered by NECPA Titles II and VII.

All electric utilities listed below had electric energy sales, for purposes other than resale, in excess of 500 million kilowatt-hours in 1976, 1977, 1978, 1979 or 1980. All, except those marked (*), are covered by PURPA Title I and NECPA Titles II and VII. Utilities marked (*) either do not exceed the NECPA threshold of 750 million kilowatt-hours in 1980 for purposes other than resale, or do not have residential or commercial sales, and therefore, are not covered by NECPA Title II or VII.

State: Alabama

Regulatory Authority: Alabama Public Service Commission.

Gas Utilities

Investor-Owned:
Alabama Gas Corporation
Mobile Gas Service Corporation

Electric Utilities

Investor-Owned:
Alabama Power Company:

The following covered utilities within the State of Alabama are not regulated by the Alabama Public Service Commission:

Electric Utilities

Publicly-Owned:
Decatur Electric Department
*Dothan Electric Department
*Florence Electricity Department
Huntsville Electric System

State: Alaska

Regulatory Authority: Alaska Public Utilities Commission.

Gas Utilities

Investor-Owned:
Alaska Gas and Service Company

Electric Utilities

Rural Electric Cooperatives:
Chugach Electric Association
Publicly-Owned:
Anchorage Municipal Light & Power Department

State: Arizona

Regulatory Authority: Arizona Corporation Commission.

Gas Utilities

Investor-Owned:
Arizona Public Service Company
Southern Union Gas Company
Southwest Gas Corporation

Electric Utilities

Investor-Owned:
Arizona Public Service Company
Tuscon Electric Power Company

The following covered utility within the State of Arizona is not regulated by the Arizona Corporation Commission:

Electric Utilities

Publicly-Owned:
Salt River Project Agricultural Improvement and Power District
*Trico Electric Cooperative, Inc.

State: Arkansas

Regulatory Authority: Arkansas Public Service Commission.

Gas Utilities

Investor-Owned:
Arkansas-Louisiana Gas Company
Arkansas-Oklahoma Gas Corporation
Arkansas Western Gas Company
Associated Natural Gas Company

Electric Utilities

Investor-Owned:
Arkansas-Missouri Power Company
Arkansas Power and Light Company
Empire District Electric Company
Oklahoma Gas and Electric Company
Southwestern Electric and Power Company
Rural Electric Cooperatives:
*First Electric Cooperative Corporation

The following covered utility within the State of Arkansas is not regulated by the Arkansas Public Service Commission:

Publicly-Owned:
*North Little Rock Electric Department

State: California

Regulatory Authority: California Public Utilities Commission.

Gas Utilities

Investor-Owned:
Pacific Gas and Electric Company
San Diego Gas and Electric Company
Southern California Gas Company
Southwest Gas Corporation

Electric Utilities

Investor-Owned:
Pacific Gas and Electric Company
Pacific Power and Light Company
San Diego Gas and Electric Company
Sierra Pacific Power Company
Southern California Edison Company

The following covered utilities within the State of California are not regulated by the California Public Utilities Commission:

Electric Utilities

Publicly-Owned:
Anaheim Electric Division
Burbank Public Service Department
*Glendale Public Service Department
Imperial Irrigation District
Los Angeles Department of Water and Power
Modesto Irrigation District
Palo Alto Electric Utility
Pasadena Water and Power Department
Riverside Public Utilities
Sacramento Municipal Utility District
Santa Clara Electric Department
*Turlock Irrigation District
Vernon Municipal Light Department

Gas Utilities

Publicly-Owned:
Long Beach Gas Department

State: Colorado

Regulatory Authority: Colorado Public Utilities Commission.

Gas Utilities

Investor-Owned:
Greeley Gas Company
Iowa Electric Light and Power Company
Kansas-Nebraska Natural Gas Company
Peoples Natural Gas Company, Division of Internorth, Inc.
Public Service Company of Colorado
Publicly-Owned:
Colorado Springs Department of Public Utilities (jurisdiction only outside city limits)

Electric Utilities

Investor-Owned:
Central Telephone and Utilities Corporation
Public Service Company of Colorado
Publicly-Owned:
Colorado Springs Department of Public Utilities (jurisdiction only outside city limits)

The following covered utilities within the State of Colorado are not regulated by the Colorado Public Utilities Commission:

Gas Utilities

Publicly-Owned:
Colorado Springs Department of Public Utilities (within city limits)

Electric Utilities

Publicly-Owned:
Colorado Springs Department of Public Utilities (within city limits)

State: Connecticut

Regulatory Authority: Connecticut Division of Public Utility Control.

Gas Utilities

Investor-Owned:
Connecticut Light and Power Company
Connecticut Natural Gas Corporation
Southern Connecticut Gas Company

Electric Utilities

Investor-Owned:
Connecticut Light and Power Company
Hartford Electric Light Company
United Illuminating Company

State: Delaware

Regulatory Authority: Delaware Public Service Commission.

Gas Utilities

Investor-Owned:
Delmarva Power and Light Company

Electric Utilities

Investor-Owned:
Delmarva Power and Light Company

State: District of Columbia

Regulatory Authority: Public Service Commission of the District of Columbia.

Gas Utilities

Investor-Owned:
Washington Gas Light Company

Electric Utilities

Investor-Owned:
Potomac Electric Power Company

State: Florida

Regulatory Authority: Florida Public Service Commission.

Gas Utilities

Investor-Owned:
City Gas Company of Florida
Peoples Gas System

Electric Utilities

Investor-Owned:
Florida Power Corporation
Florida Power and Light Company
Gulf Power Company
Tampa Electric Company
Publicly-Owned: The Florida Public Service Commission has rate structure jurisdiciton over the following utilities—
*Gainesville Regional Utilities
Jacksonville Electric Authority
Lakeland Department of Electricity and Water
Orlando Utilities Commission
Tallahassee, City of
Rural Electric Cooperatives: The Florida Public Service Commission has rate structure jurisdiction over the following utilities—
Clay Electric Cooperative
Lee County Electric Cooperative
*Withlachoochee River Electric Cooperative

State: Georgia

Regulatory Authority: Georgia Public Service Commission.

Gas Utilities

Investor-Owned:
Atlanta Gas Light Company
Chattanooga Gas Company
Gas Light Company of Columbus

Electric Utilities

Investor-Owned:
Georgia Power Company
Savannah Electric and Power Company

The following utilities within the State of Georgia are not regulated by the Georgia Public Service Commission:

Electric Utilities

Publicly-Owned:
*Albany Water, Gas & Light Commission
Rural Electric Cooperatives:
*Cobb Electric Membership Corporation
*Flint Electrical Membership Corporation
*Jackson Electric Membership Corporation
North Georgia Electric Membership Corporation

State: Hawaii

Regulatory Authority: Hawaii Public Utilities Commission

Gas Utilities

None.

Electric Utilities

Investor-Owned:
Hawaiian Electric Company, Inc.

State: Idaho

Regulatory Authority: Idaho Public Utilities Commission.

Gas Utilities

Investor-Owned:
Intermountain Gas Company
Washington Water Power Company

Electric Utilities

Investor-Owned:
Idaho Power Company
Pacific Power and Light Company
Utah Power and Light Company
Washington Water Power Company

State: Illinois

Regulatory Authority: Illinois Commerce Commission

Gas Utilities

Investor-Owned:
Central Illinois Light Company
Central Illinois Public Service Company
Illinois Power Company
Interstate Power Company
Iowa-Illinois Gas and Electric Company
North Shore Gas Company
Northern Illinois Gas Company
Panhandle Eastern Pipeline Company
Peoples Gas, Light and Coke Company

Electric Utilities

Investor-Owned:
Central Illinois Light Company
Central Illinois Public Service Company
Commonwealth Edison Company
Illinois Power Company
Interstate Power Company
Iowa-Illinois Gas and Electric Company
Union Electric Company

The following covered utility within the State of Illinois is not regulated by the Illinois Commerce Commission:

Electric Utilities

Publicly-Owned:
Springfield Water, Light and Power Department

State: Indiana

Regulatory Authority: Indiana Public Service Commission.

Gas Utilities

Investor-Owned:
Indiana Gas Company
Kokomo Gas and Fuel Company
Northern Indiana Public Service Company
Southern Indiana Gas and Electric Company
Terre Haute Gas Corporation
*Publicly-Owned:
Citizens Gas and Coke Utility

Electric Utilities

Investor-Owned:
Indiana and Michigan Electric Company
Indianapolis Power and Light Company
Northern Indiana Public Service Company
Public Service Company of Indiana
Southern Indiana Gas and Electric Company
Publicly-Owned:
Richmond Power and Light

State: Iowa

Regulatory Authority: Iowa Commerce Commission.

Gas Utilities

Investor-Owned:
Interstate Power Company
Iowa Electric Light and Power Company
Iowa-Illinois Gas and electric Company
Iowa Power and Light Company
Iowa Public Service Company
Iowa Southern Utilities Company
Minnesota Gas Company
North Central Public Service Company
Peoples Natural Gas Company, Division of Internorth, Inc.

Electric Utilities

Investor-Owned:
Interstate Power Company
Iowa Electric Light and Power Company
Iowa-Illinois Gas and Electric Company
Iowa Power and Light Company
Iowa Public Service Company
Iowa Southern Utilities Company
Union Electric Company
Publicly-Owned: The Iowa Commerce Commission has service and safety regulation over the following utilities—
*Muscatine Power and Water Omaha Public Power District

State: Kansas

Regulatory Authority: Kansas State Corporation Commission.

Gas Utilities

Investor-Owned:
Anadarko Production Company
Arkansas-Louisiana Gas Company
Gas Service Company
Greeley Gas Company
Kansas-Nebraska Natural Gas Company
Kansas Power and Light Company
Northern Natural Gas Company
Panhandle Eastern Pipeline Company
Peoples Natural Gas Company, Division of Internorth, Inc.
Union Gas System Inc.

Electric Utilities

Investor-Owned:
Central Kansas Power Company
Empire District Electric Company
Kansas City Power and Light Company
Kansas Gas and Electric Company
Kansas Power and Light Company
Southerwestern Public Service Company
Western Power Division Central Telephone and Utilities Corporation

The following covered utility within the State of Kansas is not regulated by the Kansas State Corporation Commission:

Electric Utilities

Public-Owned:
Kansas City Board of Public Utilities

State: Kentucky

Regulatory Authority: Kentucky Energy Regulatory Commission.

Gas Utilities

Investor-Owned:
Columbia Gas of Kentucky, Inc.
Inland Gas Company
Louisville Gas and Electric Company
Union Light, Heat and Power Company
Western Kentucky Gas Company

Electric Utilities

Investor-Owned:
Kentucky Power Company
Kentucky Utilities Company
Louisville Gas and Electric Company
Union Light, Heat and Power Company
Rural Electric Cooperatives:
Green River Electric Corporation
Henderson-Union Rural Electric Cooperative Corporation

The following covered utilities within the State of Kentucky are not regulated by the Kentucky Energy Regulatory Commission:
*Owensboro Municipal Utilities
*Pennyrile Rural Electric Cooperative Corporation
*Warren Rural Electric Cooperative Corporation
*West Kentucky Rural Electric Cooperative Corporation

State: Louisiana

Regulatory Authority: Louisiana Public Service Commission.

Gas Utilities

Investor-Owned:
Arkansas-Louisiana Gas Company
Entex, Inc.
Gulf States Utilities Company
Louisiana Gas Service Company

Electric Utilities

Investor-Owned:
Arkansas Power and Light
Central Louisiana Electric Company
Gulf States Utilities Company
Louisiana Power and Light Company (jurisdiction only outside of the Parish of Orleans)
Southwestern Electric Power Company

The following covered utilities within the State of Louisiana are not regulated by the Louisiana Public Service Commission:

Gas Utilities

Investor-Owned:
New Orleans Public Service, Inc.

Electric Utilities

Investor-Owned:
New Orleans Public Services, Inc.
Louisiana Power and Light Company (within the Parish of Orleans)
Publicly-Owned:
Lafayette Utilities System
Rural Electric Cooperatives:
*Dixie Electric Membership Corporation
Southwest Louisiana Electric Membership Corporation

State: Maine

Regulatory Authority: Maine Public Utilities Commission.

Gas Utilities

None.

Electric Utilities

Investor-Owned:
Bangor Hydro-Electric Company
Central Maine Power Company

State: Maryland

Regulatory Authority: Maryland Public Service Commission.

Gas Utilities

Investor-Owned:
Baltimore Gas and Electric Company
Washington Gas Light Company

Electric Utilities

Investor-Owned:
Baltimore Gas and Electric Company
Delmarva Power and Light Company of Maryland
Potomac Edison Company
Potomac Electric Power Company
Rural Electric Cooperatives:
Southern Maryland Electric Cooperative, Inc.

State: Massachusetts

Regulatory Authority: Massachusetts Department of Public Utilities.

Gas Utilities

Investor-Owned:
Bay State Gas Company
Boston Gas Company
Commonwealth Gas Company
Lowell Gas Company
New Bedford Gas and Edison Light Company

Electric Utilities

Investor-Owned:
Boston Edison Company
Cambridge Electric Light Company
Eastern Edison Company
Massachusetts Electric Company
New Bedford Gas and Edison Light Company
Western Massachusetts Electric Company

State: Michigan

Regulatory Authority: Michigan Public Service Commission.

Gas Utilities

Investor-Owned:
Consumers Power Company
Michigan Consolidated Gas Company
Michigan Gas Utilities Company
Michigan Power Company
Southeastern Michigan Gas Company
Wisconsin Public Service Corporation

Electric Utilities

Investor-Owned:
Consumers Power Company
Detroit Edison Company
Indiana and Michigan Electric Company
*Lake Superior District Power Company
*Michigan Power Company
Upper Peninsula Power Company
Wisconsin Electric Power Company
Wisconsin Public Service Company

The following covered utilities within the State of Michigan are not regulated by the Michigan Public Service Commission:

Electric Utilities

Publicly-Owned:
Lansing Board of Water and Light

State: Minnesota

Regulatory Authority: Minnesota Public Utility Commission.

Gas Utilities

Investor-Owned:
Greeley Gas Company
Inter City Gas Company
Interstate Power Company
Iowa Electric Light and Power Company
Minnesota Gas Company
Montana-Dakota Utilities Company
North Central Public Service Company
Northern States Power Company
Peoples Natural Gas Company, Division of Internorth, Inc.

Electric Utilities

Investor-Owned:
Interstate Power Company
Minnesota Power and Light Company
Northern States Power Company
Otter Tail Power Company

The following covered utility within the State of Minnesota is not regulated by the Minnesota Public Service Commission:

Electric Utilities

Rural Electric Cooperatives:
*Anoka Electric Cooperative

State: Mississippi

Regulatory Authority: Mississippi Public Service Commission.

Gas Utilities

Investor-Owned:
Entex, Inc.
Mississippi Valley Gas Company

Electric Utilities

Investor-Owned:
Mississippi Power and Light Company
Mississippi Power Company

The following covered utilities within the State of Mississippi are not regulated by the Mississippi Public Service Commission:

Electric Utilities

Rural Electric Cooperatives:
*4-County Electric Power Association
*Singing River Electric Power Association
*Southern Pine Electric Power Association

State: Missouri

Regulatory Authority: Missouri Public Service Commission.

Gas Utilities

Investor-Owned:
Associated Natural Gas Company
Gas Service Company
Laclede Gas Company Consolidated
Missouri Public Service Company
Peoples Natural Gas Company, Division of Internorth, Inc.

Electric Utilities

Investor-Owned:
Arkansas-Missouri Power Company
Empire District Electric Company
Kansas City Power and Light Company
Missouri Edison Company
Missouri Power and Light Company
Missouri Public Service Company
Missouri Utilities Company
St. Joseph Light and Power Company
Union Electric Company

The following covered utilities within the State of Missouri are not regulated by the Missouri Public Service Commission:

Gas Utilities

Investor-Owned:
Cities Service Gas Company
Publicly-Owned:
Springfield City Utilities

Electric Utilities

Publicly-Owned:
*Independence Power and Light Department
Springfield City Utilities

State: Montana

Regulatory Authority: Montana Public Service Commission.

Gas Utilities

Investor-Owned:
Montana-Dakota Utilities Company
Montana Power Company

Electric Utilities

Investor-Owned:
Black Hills Power and Light Company
Montana-Dakota Utilities Company
Montana Power Company
Pacific Power and Light Company
Washington Water Power Company

State: Nebraska

Regulatory Authority: Nebraska Public Service Commission.

The Commission does not regulate the rates and services of the gas and electric utilities of the State of Nebraska.

The following covered utilities within the State of Nebraska are not regulated by the Nebraska Public Service Commission:

Electric Utilities

Publicly-Owned:
Lincoln Electric System
Nebraska Public Power District
Omaha Public Power District

Gas Utilities

Investor-Owned:
Gas Service Company
Iowa Electric Light and Power Company
Iowa Public Service Company
Kansas-Nebraska Natural Gas Company
Minnesota Gas Company
Northern Natural Gas Company
Northwestern Public Service Company
Peoples Natural Gas Company, Division of Internorth, Inc.

The governing body of each Nebraska municipality exercises ratemaking jurisdiction over gas utility rates, operations and services provided by a gas utility within its city or town limits. These municipal authorities would be State agences as defined by PURPA, and thus have responsibilities under PURPA identical to those of the State regulatory authority.

Publicly-Owned:
Metropolitan Utilities District of Omaha

State: Nevada

Regulatory Authority: Nevada Public Service Commission.

Gas Utilities

Investor-Owned:
Southwest Gas Corporation

Electric Utilities

Investor-Owned:
Idaho Power Company
Nevada Power Company
Sierra Pacific Power Company

State: New Hampshire

Regulatory Authority: New Hampshire Public Utilities Commission.

Gas Utilities

None.

Electric Utilities

Investor-Owned:
Public Service Company of New Hampshire

State: New Jersey

Regulatory Authority: New Jersey Department of Energy, Board of Public Utilities.

Gas Utilities

Investor-Owned:
Elizabethtown Gas Company
New Jersey Natural Gas Company
Public Service Electric and Gas Company
South Jersey Gas Company

Electric Utilities

Investor-Owned:
Atlantic City Electric Company
Jersey Central Power and Light Company
Public Service Electric and Gas Company
Rockland Electric Company

State: New Mexico

Regulatory Authority: New Mexico Public Service Commission.

Gas Utilities

Gas Company of New Mexico

Electric Utilities

Investor-Owned:
Community Public Service Company
El Paso Electric Company
*New Mexico Electric Service Company
Public Service Company of New Mexico
Southwestern Public Service Company

State: New York

Regulatory Authority: New York Public Service Commission.

Gas Utilities

Investor-Owned:
Brooklyn Union Gas Company
Columbia Gas of New York, Inc.
Consolidated Edison Company of New York, Inc.
Long Island Lighting Company
National Fuel Gas Distribution Corporation
New York State Electric and Gas Corporation
Niagara Mohawk Power Corporation
Orange and Rockland Utilities
Rochester Gas and Electric Corporation

Electric Utilities

Investor-Owned:
Central Hudson Gas and Electric Corporation
Consolidated Edison Company of New York
Long Island Lighting Company
New York State Electric and Gas Corporation
Niagara Mohawk Power Corporation
Orange and Rockland Utilities
Rochester Gas and Electric Corporation

The following covered utility within the State of New York is not regulated by the New York Public Service Commission:

Electric Utilities

Publicly-Owned:
*Power Authority of New York

State: North Carolina

Regulatory Authority: North Carolina Utilities Commission.

Gas Utilities

Investor-Owned:
North Carolina Natural Gas Corporation
Piedmont Natural Gas Company
Public Service Company, Inc. of North Carolina

Electric Utilities

Investor-Owned:
Carolina Power and Light Company
Duke Power Company
Virginia Electric and Power Company

The following covered utilities within the State of North Carolina are not regulated by the North Carolina Utilities Commission:

Electric Utilities

Publicly-Owned:
Fayetteville Public Works Commission
*Greenville Utilities Commission
*Rocky Mount Public Utilities
*Wilson Utilities Department

State: North Dakota

Regulatory Authority: North Dakota Public Service Commission.

Gas Utilities

Investor-Owned:
Montana-Dakota Utilities Company
Northern States Power Company

Electric Utilities

Investor-Owned:
Montana-Dakota Utilities Company
Northern States Power Company
Otter Tail Power Company

State: Ohio

Regulatory Authority: Ohio Public Utilities Commission.

Gas Utilities

Investor-Owned:
Cincinnati Gas and Electric Company
Columbia Gas of Ohio, Inc.
Dayton Power and Light Company
East Ohio Gas Company
National Gas and Oil Company
West Ohio Gas Company

Electric Utilities

Investor-Owned:
Cincinnati Gas and Electric Company
Cleveland Electric Illuminating Company
Columbus and Southern Ohio Electric Company
Dayton Power and Light Company
Monongahela Power Company
Ohio Edison Company
Ohio Power Company
Toledo Edison Company

The following covered utilities within the State of Ohio are not regulated by the Ohio Public Utilities Commission:

Electric Utilities

Publicly-Owned:
*Cleveland Division of Light and Power
Rural Electric Cooperatives:
*South Central Power Company

State: Oklahoma

Regulatory Authority: Oklahoma Corporation Commission.

Gas Utilities

Investor-Owned:
Arkansas-Louisiana Gas Company
Arkansas-Oklahoma Gas Corporation
Gas Service Company
Lone Star Gas Company
Oklahoma Natural Gas Company
Southern Union Gas Company
Union Gas System Inc.

Electric Utilities

Investor-Owned:
Empire District Electric Company
Oklahoma Gas and Electric Company
Public Service Company of Oklahoma
Southwestern Public Service Company

The following covered utility within the State of Oklahoma is not regulated by the Oklahoma Corporation Commission.
* Cotton Electric Cooperative

Gas Utilities

Investor-Owned:
Cities Service Gas Company

State: Oregon

Regulatory Authority: Public Utility Commissioner of Oregon.

Gas Utilities

Investor-Owned:
Cascade Natural Gas Corporation
Northwest Natural Gas Company

Electric Utilities

Investor-Owned:
Idaho Power Company
Pacific Power and Light Company
Portland General Electric Company

The following covered utilities within the State of Oregon are not regulated by the Public Utility Commissioner of Oregon:

Electric Utilities

Publicly-Owned:
Central Lincoln People's Utility District
* Clatskanie People's Utility District
Eugene Water and Electric Board
* Springfield Utilities Board
Rural Electric Cooperatives:
* Umatilla Electric Cooperative Association

State: Pennsylvania

Regulatory Authority: Pennsylvania Public Utility Commission.

Gas Utilities

Investor-Owned:
Carnegie Natural Gas Company

Columbia Gas of Pennsylvania, Inc.
Equitable Gas Company
National Fuel Gas Distrbution Corporation
North Penn Gas Company
Pennsylvania Gas and Water Company
Peoples Natural Gas Company
Philadelphia Electric Company
T. W. Phillips Gas and Oil Company
UGI Corporation

Electric Utilities

Investor-Owned:
Duquesene Light Company
Metropolitan Edison Company
Pennsylvania Electric Company
Pennsylvania Power Company
Pennsylvania Power and Light Company
Philadelphia Electric Company
* UGI—Luzerne Electric Division
West Penn Power Company

The following covered utility within the State of Pennsylvania is not regulated by the Pennsylvania Public Commission:

Gas Utilities

Publicly-Owned:
Philadelphia Gas Works

State: Puerto Rico

Regulatory Authority: Puerto Rico Public Service Commission.

Gas Utilities

None.

Electric Utilities

None.

The following covered utility within Puerto Rico is not regulated by the Puerto Rico Public Service Commission:

Electric Utilities

Publicly-Owned:
Puerto Rico Electric Power Authority

State: Rhode Island

Regulatory Authority: Rhode Island Public Utilities Commission.

Gas Utilities

Investor-Owned:
Providence Gas Company

Electric Utilities

Investor-Owned:
Blackstone Valley Electric Company
Narragansett Electric Company

State: South Carolina

Regulatory Authority: South Carolina Public Service Commission.

Gas Utilities

Investor-Owned:
* Carolina Pipeline Company
Piedmont Natural Gas Company
South Carolina Electric and Gas Company

Electric Utilities

Investor-Owned:
Carolina Power and Light Company
Duke Power Company
South Carolina Electric and Gas Company

The following covered utility within the State of South Carolina is not regulated by the South Carolina Public Service Commission:

Electric Utilities

Publicly-Owned:
South Carolina Public Service Authority

State: South Dakota

Regulatory Authority: South Dakota Public Utilities Commission.

Gas Utilities

Investor-Owned:
Iowa Public Service Company
Minnesota Gas Company
Montana-Dakota Utilities Company
Northwestern Public Service Company

Electric Utilities

Investor-Owned:
Black Hills Power and Light Company
Iowa Public Service Company
Montana-Dakota Utilities Company
Northern States Power Company
*Northwestern Public Service Company
Otter Tail Power Company

The following covered utility within the State of South Dakota is not regulated by the South Dakota Public Service Commission:

Electric Utilities

Publicly-Owned:
Nebraska Public Power District

State: Tennessee

Regulatory Authority: Tennessee Public Service Commission.

Gas Utilities

Investor-Owned:
Chattanooga Gas Company
Nashville Gas Company

Electric Utilities

Investor-Owned:
Arkansas Power and Light Company
Kentucky Utilities Company
Kingsport Power Company

The following covered utilities within the State of Tennessee are not regulated by the Tennessee Public Service Commission:

Electric Utilities

Publicly-Owned:
*Bristol Tennessee Electric System
Chattanooga Electric Power Board
*Clarksville Department of Electricity
*Cleveland Utilities
*Greeneville Light and Power System
*Jackson Utility Division—Electric Department
Johnson City Power Board
Knoxville Utilities Board
*Lenoir City Utilities Board
Memphis Light, Gas and Water Division
*Nashville Electric Services
Rural Electric Cooperatives:
*Appalachian Electric Cooperative
Cumberland Electric Membership Corporation
*Duck River Electric Membership Corporation
*Gibson County Electric Membership Corporation
*Meriwether Lewis Electric Cooprative
Middle Tennessee Electric Membership Corporation
*Southwest Tennessee Electric Membership Corporation
*Tri-County Electric Membership Corporation
*Upper Cumberland Electric Membership Corporation
Volunteer Electric Cooperative

Gas Utilities

Publicy-Owned:
Memphis Light, Gas and Water Division

State: Tennessee

Regulatory Authority: Tennessee Valley Authority.

Gas Utilities

None.

Electric Utilities

Publicly-Owned:
*Bristol Tennessee Electric System
Chattanooga Electric Power Board
*Clarksville Department of Electricity
*Cleveland Utilities
Decatur Electric Department
*Florence Electricity Department
*Greeneville Light and Power System
Huntsville Electric System
Jackson Utility Division—Electric Department
Johnson City Power Board
Knoxville Utilities Board
*Lenoir City Utilities Board
Memphis Light, Gas and Water Division
Nashville Electric Service
Rural Electric Cooperatives:
*Appalachian Electric Cooperative
Cumberland Electric Membership Corporation
*Duck River Electric Membership Corporation
*Four-County Electric Power Association
*Gibson County Electric Membership Corporation
*Meriwether Lewis Electric Cooperative
Middle Tennessee Electric Membership Corporation
North Georgia Electric Membership Corporation
*Pennyrile Rural Electric Cooperative Corporation
*Southwest Tennessee Electric Membership Corporation
*Tri-County Electric Membership Corporation
*Upper Cumberland Electric Membership Corporation
Volunteer Electric Cooperative
*Warren Rural Electric Cooperative Corporation
*West Kentucky Rural Electric Cooperative Corporation

State: Texas

Regulatory Authority: Texas Public Utility Commission.

Gas Utilities

Investor-Owned:
None.

Electric Utilities

Investor-Owned:
Central Power and Light Company
Community Public Service Company
Dallas Power and Light Company
El Paso Electric Company

Gulf States Utilities
Houston Lighting and Power Company
Southwestern Electric Power Company
*Southwestern Electric Service Company
Southwestern Public Service Company
Texas Electric Service Company
Texas Power and Light Company
West Texas Utilities Company
Publicly-Owned:
*Lower Colorado River Authority
Rural Electric Cooperatives:
*Pedernales Electric Cooperative

The governing body of each Texas municipality excercises exclusive original jurisdiction over electric utility rates, operations and services provided by an electric utility (whether privately owned or publicly owned) within its city or town limits, unless the municipality has surrendered this jurisdiction to the Texas Public Utility Commission. The Commission hears *de novo* appeals from the decisions of such municipalities. These municipal authorities would be State agencies as defined by PURPA, and thus have responsibilities under PURPA identical to those of a State regulatory authority.

The municipally-owned electric utilities listed below are not under the commission's original ratemaking jurisdiction.

Electric Utilities

Publicly-Owned:
Austin Electric Department
Garland Electric Department
*Lubbock Power and Light
San Antonio City Public Service Board

State: Texas

Regulatory Authority: Railroad Commission of Texas.

Gas Utilities

Investor-Owned:
Arkansas-Louisiana Gas Company
Entex, Inc.
Lone Star Gas Company
Peoples Natural Gas Division of Northern Natural Gas Company
Pioneer Natural Gas Company
Southern Union Gas Company

The Railroad Commission of Texas has special appellate jurisdiction over ratemaking decisions of the governing body of any municipality which affect the rates of a municipally-owned gas utility as provided by State statute. The governing body of each Texas municipality exercises exclusive original ratemaking jurisdiction over gas utility rates, operations, and services provided by a gas utility within its city or town limits. These municipal authorities would be State agencies as defined by PURPA, and thus have responsiblities under PURPA identical to those of a State regulatory authority.

The following covered utilities within the State of Texas are not regulated by the Railroad Commission of Texas:

Gas Utilities

Investor-Owned:
City Service Gas Company
Publicly-Owned:
City Public Service Board (San Antonio)

State: Utah

Regulatory Authority: Utah Public Service Commission.

Gas Utilities

Investor-Owned:
Mountain Fuel Supply Company

Electric Utilities

Investor-Owned:
Utah Power and Light Company
Rural Electric Cooperatives:
*Moon Lake Electric Association

State: Vermont

Regulatory Authority: Vermont Public Service Board.

Gas Utilities

None.

Electric Utilities

Investor-Owned:
Central Vermont Public Service Corporation
Green Mountain Power Corporation
Public Service Company of New Hampshire

State: Virginia

Regulatory Authority: Virginia State Corporation Commission.

Gas Utilities

Investor-Owned:
Columbia Gas of Virginia, Inc.,
Virginia Electric and Power Company
Washington Gas Light Company

Electric Utilities

Investor-Owned:
Appalachian Power Company
Delmarva Power and Light Company
* Old Dominion Power Company
Potomac Edison Company
Potomac Electric and Power Company
Virginia Electric and Power Company

Rural Electric Cooperatives:

* Prince William Electric Cooperative
* Rappahannock Electric Cooperative

The State covered utility within the State of Virginia is not regulated by the Virginia State Corporation Commission.

Gas Utilities

Publicly-Owned:
City of Richmond, Virginia, Department of Public Utilities

State: Washington

Regulatory Authority: Washington Utilities and Transportation Commission.

Gas Utilities

Investor-Owned:
Cascade Natural Gas Corporation
Northwest Natural Gas Company
Washington Natural Gas Company
Washington Water Power Company

Electric Utilities

Investor-Owned:
Pacific Power and Light Company
Puget Sound Power and Light Company
Washington Water Power Company

The State covered utility within the State of Washington are not regulated by the Washington Utilities and Transportation Commission.

Electric Utilities

Publicly-Owned:
* Port Angeles Light and Water Department
Public Utility District No. 1 of Benton County
Public Utility District No. 1 of Chelan County
Public Utility District No. 1 of Clark County
Public Utility District No. 1 of Cowlitz County
* Public Utility District No. 1 of Douglas County
* Public Utility District No. 1 of Franklin County
Public Utility District of Grant County
Public Utility District No. 1 of of Grays Harbor County
* Public Utility District No. 1 of Lewis County
Public Utility District 1 of Snohomish County
* Richland Energy Services Department
Seattle City Light Department
Tacoma Public Utilities—Light Division

State: West Virginia

Regulatory Authority: West Virginia Public Service Commission.

Gas Utilities

Investor-Owned:
Columbia Gas of West Virginia, Inc.
Consolidated Gas Supply Corporation
Equitable Gas Company

Electric Utilities

Investor-Owned:
Appalachian Power Company
Monogahela Power Company
Potomac Edision Company
Virginia Electric and Power Company
Wheeling Electric Company

State: Wisconsin

Regulatory Authority: Wisconsin Public Service Commission.

Gas Utilities

Investor-Owned:
Madision Gas and Electric Company
Northern States Power Company
Wisconsin Fuel and Light Company
Wisconsin Gas Company
Wisconsin Natural Gas Company
Wisconsin Power and Light Company
Wisconsin Public Service Corporation

Electric Utilities

Investor-Owned:
* Lake Superior District Power Company
Madison Gas and Electric Company
Northern State Power Company
Wisconsin Electric Power Company
Wisconsin Power and Light Company
Wisconsin Public Service Corporation

State: Wyoming

Regulatory Authority: Wyoming Public Service Commission

Gas Utilities

Investor-Owned:
Cheyenne Light, Fuel and Power Company

Kansas-Nebraska Natural Gas Company
Montana-Dakota Utilities Company
Mountain Fuel Supply Company

Electric Utilities

Investor-Owned:
Black Hills Power and Light Company
Montana-Dakota Utilities Company
Pacific Power and Light Company
Utah Power and Light Company
Rural Electric Cooperative:
* Tri-County Electric Association, Inc.

Appendix B

Electric Utilities

All utilities listed below had electric energy sales, for purposes other than resale, in excess of 500 million kilowatt hours in 1976, 1977, 1978, 1979 or 1980. All except those marked (*), are covered by PURPA Title I and NECPA Title II and VII. Utilities marked (*) either did not exceed the NECPA threshold of 750 million kilowatt-hour in 1980, for purposes other than resale, or do not have residential or commerical sales and, therefore, are not covered by NECPA Titles II and VII. The utilities listed more than once have sales in more than one State, and those States are indicated by abbreviations in parentheses.

Investor-Owned:
Alabama Power Company
Appalachian Power Company (VA)
Appalachian Power Company (WV)
Arizona Public Service Company
Arkansas-Missouri Power Company (AR)
Arkansas-Missouri Power Company (MO)
Arkansas Power & Light Company (AR)
Arkansas Power & Light Company (LA)
Arkansas Power & Light Company (TN)
Alantic City Electric Company
Baltimore Gas & Electric Company
Bangor Hydro-Electric Company
Black Hills Power & Light Company (MT)
Black Hills Power & Light Company (SD)
Black Hills Power & Light Company (WY)
Blackstone Valley Electric Company
Boston Edison Company
Cambridge Electric Light Company
Carolina Power & Light Company (NC)
Carolina Power & Light Company (SC)
Central Hudson Gas & Electric Corporation
Cental Illinois Light Company
Cental Illinois Public Service Company
* Central Kansas Power Company
Central Louisiana Electric Company
Central Maine Power Company
Central Power & Light Company
Central Vermon Public Serice Corporation
Cincinnati Gas & Electic Company
Cleveland Electric Illuminating Company
Columbus and Southern Ohio Electric Company
Commonweath Edision Company
Community Public Service Company (NM)
Community Public Service Company (TX)
Connecticut Light & Power Company
Consolidated Edision Company of New York
Consumers Power Company
Dallas Power & Light Company
Dayton Power & Light Company
Delmarva Power & Light Company (DE)
Delmarva Power & Light Company of Maryland
Delmarva Power & Light Company of Virginia
Detroit Edison Company
Duke Power Company (NC)
Duke Power Company (SC)
Duquesne Light Company
Eastern Edison Company
El Paso Electric Company (NM)
El Paso Electric Company (TX)
Empire District Electric Company (AR)
Empire District Electric Company (KS)
Empire District Electric Company (MO)
Empire District Electric Company (OK)
Florida Power Corporation
Florida Power & Light Company
Georgia Power Company
Green Mountain Power Corporation
Gulf Power Company
Gulf States Utilities Company (LA)
Gulf States Utilities Company (TX)
Hartford Electric Light Company
Hawaiian Electric Company Inc.
Houston Lighting & Power Company
Idaho Power Company (ID)
Idaho Power Company (NV)
Idaho Power Company (OR)
Illinois Power Company
Indiana & Michigan Electric Company (IN)
Indiana & Michigan Ellectric Company (MI)
Indianapolis Power & Light Company
Interstate Power Company (IA)
Interstate Power Company (IL)
Interstate Power Company (MN)
Iowa Electric Light & Power Company
Iowa-Illinois Gas & Electric Company (IA)
Iowa-Illinois Gas & Electric Company (IL)
Iowa Power & Light Company
Iowa Public Service Company (IA)
Iowa Public Service Company (SD)
Iowa Southern Utilities Company
Jersey Central Power & Light Company
Kansas City Power & Light Company (KS)
Kansas City Power & Light Company (MO)
Kansas Gas & Electric Company
Kansas Power & Light Company
Kentucky Power Company
Kentucky Utilities Company (KY)
Kentucky Utilities Company (TN)
Kingsport Power Company
*Lake Superior District Power Company (MI)
*Lake Superior District Power Company (WI)
Long Island Lighting Company
Louisiana Power & Light Company
Louisville Gas & Electric Company
Madison Gas & Electric Company
Massachusetts Electric Company
Metropolitan Edison Company
*Michigan Power Company
Minnesota Power & Light Company
Mississippi Power Company
Mississippi Power & Light Company
Missouri Edison Company
Missouri Power & Light Company
Missouri Public Service Company
Missouri Utilities Company
Monongahela Power Company (OH)
Monongahela Power Company (WV)
Montana-Dakota Utilities Company (MT)
Montana-Dakota Utilities Company (ND)
Montana-Dakota Utilities Company (SD)
Montana-Dakota Utilities Company (WY)
Montana Power Company
Narragansett Electric Company
Nevada Power Company
New Bedford Gas & Edison Light Company
*New Mexico Electric Service Company
New Orleans Public Service, Inc.
New York State Electric & Gas Corporation
Niagara Mohawk Power Corporation
Northern Indiana Public Service Company
Northern States Power Company (MN)
Northern States Power Company (ND)
Northern States Power Company (SD)
Northern States Power Company (WI)
*Northweastern Public Service Company
Ohio Edison Company
Ohio Power Company
Oklahoma Gas & Electric Company (AR)
Oklahoma Gas & Electric Company (OK)
*Old Dominion Power Company
Orange & Rockland Utilities
Otter Tail Power Company (MN)
Otter Tail Power Company (ND)
Otter Tail Power Company (SD)
Pacific Power Light Company (CA)
Pacific Power Light Company (ID)
Pacific Power Light Company (MT)
Pacific Power Light Company (OR)
Pacific Power Light Company (WA)
Pacific Power Light Company (WY)
Pennsylvania Electric Company (PA)
Pennsylvania Power & Light Company
Pennsylvania Power Company
Philadelphia Electric Company
Portland General Electric Company
Potomac Edison Company (MD)
Potomac Edison Company (VA)
Potomac Edison Company (WV)
Potomac Electric Power Company (DC)
Potomac Electric Power Company (MD)
Potomac Electric Power Company (VA)
Public Service Company of Colorado
Public Service Company of Indiana
Public Service Company of New Hampshire (NH)
Public Service Company of New Hampshire (VT)
Public Service Company of New Mexico
Public Service Company of Oklahoma
Public Service Electric and Gas Company
Puget Sound Power & Light Company
Rochester Gas & Electric Corporation
Rockland Electric Company
St. Joseph Light & Power Company
San Diego Gas & Electric Company
Savannah Electric & Power Company
Sierra Pacific Power Company (CA)
Sierra Pacific Power Company (NV)
South Carolina Electric & Gas Company
Southern California Edison Company
Southern Indiana Gas & Electric Company
Southwestern Electric Power Company (AR)
Southwestern Electric Power Company (LA)
Southwestern Electric Power Company (TX)
*Southwestern Electric Service Company
Southwestern Public Service Company (KS)
Southwestern Public Service Company (NM)
Southwestern Public Service Company (OK)
Southwestern Public Service Company (TX)
Tampa Electric Company
Texas Electric Service Company
Texas Power & Light Company
Toledo Edison Company
Tucson Electric Power Company
*UGI-Luzerne Electric Division

Union Electric Company (IA)
Union Electric Company (IL)
Union Electric Company (MO)
Union Light, Heat & Power Company
United Illuminating Company
*Upper Peninsula Power Company
Utah Power & Light Company (ID)
Utah Power & Light Company (UT)
Utah Power & Light Company (WY)
Virginia Electric & Power Company (NC)
Virginia Electric & Power Company (VA)
Virginia Electric & Power Company (WV)
Washington Water Power Company (ID)
Washington Water Power Company (MT)
Washington Water Power Company (WA)
West Penn Power Company
West Texas Utilities Company
Western Massachusetts Electric Company
Western Power Division of Central Telephone & Utilities Corporation (CO)
Western Power Division of Central Telephone & Utilities Corporation (KS)
Wheeling Electric Company
Wisconsin Electric Power Company (MI)
Wisconsin Electric Power Company (WI)
Wisconsin Power & Light Company
Wisconsin Public Service Corporation (MI)
Wisconsin Public Service Corporation (WI)

Publicly-Owned:
*Albany Water, Gas & Light Commission (GA)
Anaheim—Electric Division (CA)
*Anchorage Municipal Light & Power Department (AK)
Austin Electric Department (TX)
*Bristol Tennessee Electric System (TN)
*Burbank Public Service Department (CA)
Central Lincoln People's Utility District (OR)
Chattanooga Electric Power Board (TN)
*Clarksville Department of Electricity (TN)
*Clatskanie People's Utility District (OR)
*Cleveland Division of Light & Power (OH)
*Cleveland Utilities (TN)
Colorado Springs Department of Public Utilities (CO)
Decatur Electric Department (AL)
*Dothan Electric Department (AL)
Eugene Water & Electric Board (OR)
Fayetteville Public Works Commission (NC)
*Florence Electricty Department (AL)
*Gainesville Regional Utilities (FL)
Garland Electric Department (TX)
*Glendale Public Service Department (CA)
*Greeneville Light & Power System (TN)
*Greenville Utilities Commission (NC)
Huntsville Electric System (AL)
Imperial Irrigation District (CA)
*Independence Power & Light Department (MO)
Jackson Utility Division—Electric Department (TN)
Jacksonville Electric Authority (FL)
Johnson City Power Board (TN)
Kansas City Board of Public Utilities (KS)
Knoxville Utilities Board (TN)
Lafayette Utilities System (LA)
Lakeland Department of Electricity and Water (FL)
Lansing Board of Water & Light (MI)
*Lenoir City Utilities Board (TN)
Lincoln Electric System (NE)
Los Angeles Department of Water and Power (CA)
*Lower Colorado River Authority (TX)
*Lubbock Power & Light (TX)
Memphis Light, Gas & Water Division (TN)
Modesto Irrigation District (CA)
*Muscatine Power & Water (IA)
Nashville Electric Service (TN)
Nebraska Public Power District (NE)
Nebraska Public Power District (SD)
*North Little Rock Electric Department (AR)
Omaha Public Power District (IA)
Omaha Public Power District (NE)
Orlando Utilities Commission (FL)
*Owensboro Municipal Utilities (KY)
Palo Alto Electric Utility (CA)
Pasadena Water & Power Department (CA)
*Power Authority of New York (NY)
*Port Angeles Light & Water Department (WA)
Public Utility District No. 1 of Benton County (WA)
Public Utility District No. 1 of Chelan County (WA)
Public Utility District No. 1 of Clark County (WA)
Public Utility District No. 1 of Cowlitz County (WA)
*Public Utility District No. 1 of Douglas County (WA)
*Public Utility District No. 1 of Franklin County (WA)
Public Utility District of Grant County (WA)
Public Utility District No. 1 of Grays Harbor County (WA)
*Public Utility District No. 1 of Lewis County (WA)
Public Utility District No. 1 of Snohomish County (WA)
Puerto Rico Electric Power Authority
*Richland Energy Services Department (WA)
Richmond Power & Light (IN)
Riverside Public Utilities (CA)
*Rocky Mount Public Utilities (NC)
Sacramento Municipal Utility District (CA)
Salt River Project Agricultural Improvement and Power District (AZ)
San Antonio City Public Service Board (TX)
Santa Clara Electric Department (CA)
Seattle City Light Department (WA)
South Carolina Public Service Authority
Springfield City Utilities (MO)
*Springfield Utilities Board (OR)
Springfield Water, Light & Power Department (IL)
Tacoma Public Utilities—Light Division (WA)
Tallahassee, City of (FL)
*Turlock Irrigation District (CA)
Vernon Municipal Light Department (CA)
*Wilson Utilities Department (NC)

Rural Electric Cooperatives

*Anoka Electric Cooperative (MN)
*Appalachian Electric Cooperative (TN)
Chugah Electric Association (AK)
Clay Electric Cooperative (FL)
*Cobb Electric Membership Corporation (GA)
*Cotton Electric Cooperative (OK)
Cumberland Electric Membership Corporation (TN)
*Duck River Electric Membership Corporation (TN)
*Dixie Electric Membership Corporation (LA)
*First Electric Cooperative Corporation (AR)
*Flint Electrical Membership Corporation (GA)
*Four County Electric Power Association (MS)
*Gibson County Electric Membership Corporation (TN)
Green River Electric Corporation (KY)
Henderson-Union Rural Electric Cooperative Corporation (KY)
*Jackson Electric Membership Corporation (GA)
Lee County Electric Cooperative (FL)
*Meriwether Lewis Electric Cooperative (TN)
Middle Tennessee Electric Membership Corporation (TN)
* Moon Lake Electric Association (UT)
North Georgia Electric Membership Corporation (GA)
* Pedernales Electric Cooperative (TX)
* Pennyrile Rural Electric Cooperative Corporation (KY)
* Prince William Electric Cooperative (VA)
* Rappahannock Electric Cooperative (VA)
* Singing River Electric Power Association (MS)
* South Central Power Company (OH)
Southern Maryland Electric Cooperative, Inc. (MD)
* Southern Pine Electric Power Association (MS)
Southwest Louisiana Electric Membership Corporation (LA)
* Southwest Tennessee Electric Membership Corporation (TN)
* Trico Electric Cooperative, Inc. (AZ)
* Tri-County Electric Membership Corporation (TN)
* Tri-County Electric Association, Inc. (WY)
* Umatilla Electric Cooperative Association (OR)
* Upper Cumberland Electric Membership Corporation (TN)
Volunteer Electric Cooperative (TN)
* Warren Rural Electric Cooperative Corporation (KY)
* West Kentucky Rural Electric Cooperative Corporation (KY)
* Withlacoochee River Electric Cooperative (FL)

Federal Agencies

* Bonneville Power Administration (OR)
* Tennessee Valley Authority (TN)
* Western Area Power Administration (CO)

Gas Utilities

All gas utilities listed below had natural gas sales, for purposes other than resale, in excess of 10 billion cubic feet in 1976, 1977, 1978, 1979 or 1980 and are covered by PURPA Title III and NECPA Titles II and VII. Utilities marked (*) do not have residential or commercial sales, and therefore, are not covered by NECPA Title II or VII. The utilities listed more than once have sales in more than one State and those States are indicated by abbreviations in parentheses.

Investor-Owned

Alabama Gas Corporation
Alaska Gas & Service Company
Anadarko Production Company
Arizona Public Service Company
Arkansas-Louisiana Gas Company (AR)
Arkansas-Louisiana Gas Company (KS)
Arkansas-Louisiana Gas Company (LA)
Arkansas-Louisiana Gas Company (OK)
Arkansas-Louisiana Gas Company (TX)
Arkansas-Oklahoma Gas Corporation (AR)
Arkansas-Oklahoma Gas Corporation (OK)
Arkansas Western Gas Company
Associated Natural Gas Company (AR)
Associated Natural Gas Company (MO)
Atlanta Gas Light Company
Baltimore Gas & Electric Company
Bay State Gas Company
Boston Gas Company
Brooklyn Gas Union Company
Carnegie Natural Gas Company
* Carolina Pipeline Company
Cascade Natural Gas Corporation (OR)
Cascade Natural Gas Corporation (WA)
Central Illinois Light Company
Central Illinois Public Service Company
Chattanooga Gas Company (GA)
Chattanooga Gas Company (TN)
Cheyenne Light, Fuel and Power Company
Cincinnati Gas and Electric Company
Cities Service Gas Company (covered by NECPA only)
City Gas Company of Florida
Columbia Gas of Kentucky, Inc.
Columbia Gas of New York, Inc.
Columbia Gas of Ohio, Inc.
Columbia Gas of Pennsylvania, Inc.
Columbia Gas of Virginia, Inc.
Columbia Gas of West Virginia, Inc.
Commonwealth Gas Company
Connecticut Light & Power Company
Connecticut Natural Gas Corporation
Consolidated Edison Company of New York, Inc.
Consolidated Gas Supply Corporation
Consumers Power Company
Dayton Power & Light Company
Delmarva Power & Light Company (DE)
East Ohio Gas Company
Elizabethtown Gas Company
Entex Inc. (LA)
Entex Inc. (MS)
Entex Inc. (TX)
Equitable Gas Company (PA)
Equitable Gas Company (WV)
Gas Company of New Mexico
Gas Light Company of Columbus
Gas Service Company (KS)
Gas Service Company (MO)
Gas Service Company (NE)
Gas Service Company (OK)
Greeley Company (CO)
Greeley Gas Company (KS)
Greeley Gas Company (MN)
Gulf States Utilities Company
Illinois Power Company
Indiana Gas Company
Inland Gas Company
Inter City Gas Company
Intermountain Gas Company
Interstate Power Company (IA)
Interstate Power Company (IL)
Interstate Power Company (MN)
Iowa Electric Light & Power Company (CO)
Iowa Electric Light & Power Company (IA)
Iowa Electric Light & Power Company (MN)
Iowa Electric Light & Power Company (NE)
Iowa-Illinois Gas & Electric Company (ILA)
Iowa-Illinois Gas & Electric Company (IL)
Iowa Power & Light Company
Iowa Public Service Company (IA)
Iowa Public Service Company (NE)
Iowa Public Service Company (SD)
Iowa Southern Utilities Company
Kansas-Nebraska Natural Gas Company (CO)
Kansas-Nebraska Natural Gas Company (KS)
Kansas-Nebraska Natural Gas Company (NE)
Kansas-Nebraska Natural Gas Company (WY)
Kansas Power & Light Company
Kokomo Gas & Fuel Company
Laclede Gas Company Consolidated
Lone Star Gas Company (OK)
Lone Star Gas Company (TX)
Long Island Lighting Company
Louisiana Gas Service Company
Louisville Gas & Electric Company
Lowell Gas Company
Madison Gas & Electric Company
Michigan Consolidated Gas Company
Michigan Gas Utilities Company
Michigan Power Company
Minnesota Gas Company (IA)
Minnesota Gas Company (MN)
Minnesota Gas Company (NE)
Minnesota Gas Company (SD)
Mississippi Valley Gas Company
Missouri Public Service Company
Mobile Gas Service Corporation
Montana-Dakota Utilities Company (MN)
Montana-Dakota Utilities Company (MT)
Montana-Dakota Utilities Company (ND)
Montana-Dakota Utilities Company (SD)
Montana-Dakota Utilities Company (WY)
Montana Power Company
Mountain Fuel Supply Company (UT)
Mountain Fuel Supply Company (WY)
Nashville Gas Company
National Fuel Gas Distribution Corporation (NY)
National Fuel Gas Distribution Corporation (PA)
National Gas and Oil Company
New Bedford Gas and Edison Light Company
New Jersey Natural Gas Company
New Orleans Public Service, Inc.
New York State Electric & Gas Corporation
Niagara Mohawk Power Company
North Carolina Natural Gas Corporation
North Central Public Service Company (IA)
North Central Public Service Company (MN)
North Shore Gas Company
Northern Illinois Gas Company
Northern Indian Public Service Company
Northern Natural Gas Company (KS)
Northern Natural Gas Company (NE)
Northern States Power Company (MN)
Northern States Power Company (ND)
Northern States Power Company (WI)
North Penn Gas Company
Northwest Natural Gas Company (OR)
Northwest Natural Gas Company (WA)
Northwestern Public Service Company (NE)
Northwestern Public Service Company (SD)
Oklahoma Natural Gas Company
Orange & Rockland Utilities
Pacific Gas & Electric Company
Panhandle Eastern Pipeline Company (IL)
Panhandle Eastern Pipeline Company (KS)
Pennsylvania Gas & Water Company
Peoples Gas, Light and Coke Company
Peoples Gas System
Peoples Natural Gas Company
Peoples Natural Gas Company, Division of Internorth, Inc. (CO)
Peoples Natural Gas Company, Division of Internorth, Inc. (IA)
Peoples Natural Gas Company, Division of Internorth, Inc. (KS)
Peoples Natural Gas Company, Division of Internorth, Inc. (MI)
Peoples Natural Gas Company, Division of Internorth, Inc. (MN)
Peoples Natural Gas Company, Division of Internorth, Inc. (MO)
Peoples Natural Gas Company, Division of Internorth, Inc. (NE)
Peoples Natural Gas Company, Division of Internorth, Inc. (TX)
Philadelphia Electric Company
Piedmont Natural Gas Company (NC)
Piedmont Natural Gas Company (SC)
Providence Gas Company
Public Service Company of Colorado
Public Service Company, Inc. of North Carolina
Public Service Electric and Gas Company
Rochester Gas & Electric Corporation
Northern Indiana Public Service Company
Northern Natural Gas Company (KS)
Northern Natural Gas Company (NE)
Northern States Power Company (MN)
Northern States Power Company (ND)
Northern States Power Company (WI)
North Penn Gas Company
Northwest Natural Gas Company (OR)
Northwest Natural Gas Company (WA)
Northwestern Public Service Company (NE)
Northwestern Public Service Company (SD)
Oklahoma Natural Gas Company
Orange & Rockland Utilities
Pacific Gas & Electric Company
Panhandle Eastern Pipeline Company (IL)
Panhandle Eastern Pipeline Company (KS)
Pennsylvania Gas & Water Company
Peoples Gas, Light and Coke Company
Peoples Gas System
Peoples Natural Gas Company
Peoples Natural Gas
Peoples Natural Gas
Peoples Natural Gas
Peoples Natural Gas
Peoples Natural Gas
Peoples Natural Gas
Peoples Natural Gas
Peoples Natural Gas
Philadelphia Electric Company
Piedmont Natural Gas Company (NC)
Piedmont Natural Gas Company (SC)
Pioneer Natural Gas Company
Providence Gas Company
Public Service Company of Colorado
Public Service Company, Inc. of North Carolina
Public Service Electric and Gas Company
Rochester Gas & Electric Corporation
San Diego Gas & Electric Company
South Carolina Gas & Electric Company

South Jersey Gas Company
Southeastern Michigan Gas Company
Southern California Gas Company
Southern Conneticut Gas Company
Southern Indiana Gas & Electric Company
Southern Union Gas Company (AZ)
Southern Union Gas Company (OK)
Southern Union Gas Company (TX)
Southwest Gas Corporation (AZ)
Southwest Gas Corporation (CA)
Southwest Gas Corporation (NV)
Terre Haute Gas Corporation
T.W. Phillips Gas and Oil Company
UGI Corporation
Union Gas System, Inc. (KS)
Union Gas System, Inc. (OK)
Union Light, Heat & Power Company (KY)
Virginia Electric & Power Company
Washington Gas Light Company (DC)
Washington Gas Light Company (MD)
Washington Gas Light Company (VA)
Washington Natural Gas Company
Washington Water Power Company (ID)
Washington Water Power Company (WA)
West Ohio Gas Company
Western Kentucky Gas Company
Wisconsin Fuel & Light Company
Wisconsin Gas Company
Wisconsin Natural Gas Company
Wisconsin Power & Light Company
Wisconsin Public Service Corporation (MI)
Wisconsin Public Service Corporation (WI)

Public-Owned

Citizens Gas & Coke Utility (IN)
City of Richmond, Virginia, Department of Public Utilities (VA)
City Public Service Board (San Antonio) (TX)
Colorado Springs, Department of Public Utilities (CO)
Long Beach Gas Department (CA)
Memphis Light, Gas & Water Division (TN)
Metropolitan Utilities District of Omaha (NE)
Philadelphia Gas Works (PA)
Springfield City Utilities (MO)

[FR Doc 82-213 Filed 1-4-82; 8:45 am]
BILLING CODE 6450-01-M

[Docket No. ERA-FC-81-019; ERA Case No. 51518-0672-21-22]

City of Kissimmee, Florida; Modification of Exemption Order

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Modification of order granting exemption from the prohibitions of the Powerplant and Industrial Fuel Use Act of 1978.

The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives notice of its approval of a request by the City of Kissimmee, Florida (Kissimmee) for a modification of ERA's Decision and Order issued December 14, 1981 (46 FR 61915). The Order granted a permanent peakload powerplant exemption to Kissimmee from the prohibitions against (1) the use of petroleum or natural gas as a primary energy source by new powerplants and (2) the construction of new powerplants without the capability to use an alternate fuel as a primary energy source, which are contained in Title II of the Powerplant and Industrial Fuel Use Act of 1978 (42 U.S.C. 8301 et. seq. (FUA or the Act)).

Kissimmee is adding a waste heat boiler and steam turbine to the simple cycle combustion turbine for which the peakload exemption was granted. This addition will increase the capacity of the facility from 29,000 to 49,000 kilowatts and will improve operating efficiency since the waste heat from the combustion turbine will be used to generate additional kilowatt hours. No additional natural gas or oil will be used as primary energy in the combined cycle unit.

ERA hereby modifies its Order to limit the operation of Kissimmee's combined cycle unit, Roy Hansel Unit No. 21, to 1500 hours of operation per year and total electrical production to 73,500,000 KWH per year.

Issued in Washington, D.C., on December 29, 1981.

Robert L. Davies,

Director, Fuels Conversion Division, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 82-175 Filed 1-4-82; 8:45 am]
BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket Nos. ER80-592, et al.]

Alleghany Power System, et al.; Compliance Filing

January 4, 1982.

The filing Company submits the following:

Take notice that on December 14, 1981, Central Illinois Public Service Company (CIPS) tendered for filing Rate Schedule, Third Party Purchase and Resale Transactions, FERC Order 84. Such filing is made pursuant to the Commission's order, issued December 18, 1981, which approved CIPS' offer of settlement.

The rates set forth in the above mentioned rate schedule pertain to Docket Nos. ER80-603-001, ER80-606-001, ER80-646-001, ER80-661-001, ER80-747-001, ER80-748-001, ER80-749-001, ER80-754-001 and ER80-779-001.

Any person desiring to be heard or to protest this filing should file comments with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, on or before January 22, 1982. Comments will be considered by the Commission in determining the appropriate action to be taken. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-157 Filed 1-4-82; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. ER82-163-000]

Appalachian Power Co.; Filing

December 29, 1981.

The filing Company submits the following:

Take notice that American Electric Power Service Corporation (AEP) on behalf of its affiliate, Appalachian Power Company (APCo) tendered for filing on December 18, 1981, a change of rate schedule, Modification No. 16 to the Interconnection Agreement between APCo and Virginia Electric and Power Company (VEPCO). This Modification provides for an extension of the present System Unit Power sale by APCo of 600 MW to VEPCO from January 1, 1982 to December 31, 1982.

The demand charge for said service will be $6.25/KW-month.

AEP requests that the Commission accept the Modification for filing on or before January 1, 1982 as it intends to continue the sale of System Unit Power to VEPCO as of that date.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 15, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-87 Filed 1-4-82; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. ER82-180-000]

Arkansas Power & Light Co.; Filing

January 4, 1982.

The filing Company submits the following:

Take notice that Arkansas Power & Light Company (AP&L) on December 23, 1981, tendered for filing a proposed change in its rates and charges to seven municipalities, two rural electric cooperatives, and a privately owned utility system. The proposed change would increase revenues from jurisdictional sales and services to these customers by $59,543, based on billing determinants for the 12-month period ending October 31, 1981.

AP&L states that the proposed increased rates are required by the annual redetermination of the decommissioning surcharge rate for AP&L's nuclear generation units. The redetermination is mandated by the currently approved Rate Schedules WM3 and WC3. AP&L states that the proposed change in rates for service to the municipal and cooperative customers have been prepared in accordance with the provisions of the August 8, 1980, Settlement Agreement between the Company and those customers. AP&L requests waiver of the Commission's regulations to permit effective dates of November 1, 1981, for service under Rate Schedule W81S, and January 30, 1982, for service under Rate Schedule W81.

Copies of the proposed rate schedules and statements comparing the sales and revenues therefrom were served on AP&L's jurisdictional customers affected by the filing. Copies were also served on the Arkansas Public Service Commission, and the Missouri Public Service Commission.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 22, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-158 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ID-1990-000]

Jonathan W. Booraem; Application

December 30, 1981.

The filing individual submits the following:

Take notice that on December 21, 1981, Jonathan W. Booraem filed an application pursuant to Section 305(b) of the Federal Power Act to hold the following positions:

Director of Financial Studies—Central Vermont Public Service Corporation
Secretary—Central Vermont Public Service Corporation—Bradford Hydroelectric, Inc.
Secretary—Central Vermont Public Service Corporation—East Barnet Hydoelectric, Inc.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8 and 1.10). All such petitions or protests should be filed on or before January 22, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-47 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 4448-000]

CHASM Hydro, Inc.; Application for Preliminary Permit

December 30, 1981.

Take notice that CHASM Hydro, Inc. (Applicant) filed on April 1, 1981, an application for preliminary permit (pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)) for Project No. 4448 to be known as the Forge Dam Project located on the Chateaugay River in Franklin and Clinton, Counties, New York. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. John H. Dowd, Box 319, Chateaugay, New York 12920.

Project Description—The proposed project would utilize the existing facilities consisting of: (1) A 155-foot long and 20-foot high concrete reinforced masonry buttress-type dam with a 90-foot long wingwall at the right (east) side and a 77.5-foot long wingwall at the left (west) side; (2) two screened and steel-gated 6-foot square intake structures at the dam's left side; (3) a reservoir (Chateaugay Lake) having a surface area of 3,000 acres and a storage capacity of 82,500 acre-feet at norml maximum pool elevation 1,310 m.s.l.; (4) an 8-foot diameter 6-foot long steel penstock; and (5) appurtenant facilities.

Applicant proposes to construct: (1) An 8-foot diameter 400-foot long penstock along the left bank; (2) a reinforced concrete powerhouse containing a generating unit having a rated capacity of 350-kW; (3) a 600-foot long transmission line; and (4) appurtenant facilities. The Applicant estimates that the average annual energy output would be 2,150,000 kWh. Applicant would sell the project energy to New York State Electric & Gas Corporation.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant seeks issuance of a preliminary permit for a period of 18 months, during which time it would evaluate the existing facilities, determine the engineering, economic and environmental feasibility, perform studies, and prepare an application for a FERC license. Applicant estimates the cost of the work under the permit to be $20,000.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before March 1, 1982, the competing application itself, or a notice of intent to file such an application (see: 18 CFR 4.30 et seq. (1981)).

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before March 1, 1982, and should specify the type of application forthcoming. Any application for license or exemption from licensing must be filed in accordance with the Commission's regulations (see: 18 CFR 4.30 et seq. or 4.101 et seq. (1981), as appropriate).

Submission of a timely notice of intent to file an application for preliminary permit, allows an interested person to file an acceptable competing application for preliminary permit no later than April 30, 1982.

Agency Comments—Federal, State, and local agencies are invited to submit

comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1,.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 1, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS," NOTICE OF INTENT TO FILE COMPETING APPLICATION," "COMPETING APPLICATION," "PROTEST," or "PETITION TO INTERVENE," as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-70 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-173-000]

Cincinnati Gas & Electric Co.; Proposed Tariff Change

December 30, 1981.

The filing Company submits the following:

Take notice that The Cincinnati Gas & Electric Company (Cincinnati) tendered for filing on December 21, 1981, a proposed change in the optional fixed rate for emergency energy transactions between Cincinnati and the Tennessee Valley Authority (Authority). The proposed change increases the optional fixed rate for emergency energy transactions from 5 mills per kilowatthour to 40 mills per kilowatthour effective 65 days after the filing.

Cincinnati states that the reason for the increase is to establish an equitable rate for emergency transactions between Cincinnati and the Authority.

Copies of the filing were served upon the Authority and the Public Utilities Commission of Ohio.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 18, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-61 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER78-194]

Cleveland Electric Illuminating Co.; Compliance Filing

December 30, 1981.

The filing Company submits the following:

Take notice that on December 15, 1981, the Cleveland Electric Illuminating Company (CEI) filed a Second Revised Sheet No. 3 to CEI's FERC Electric Tariff, Original Volume No. 1. Such filing was made pursuant to the Commission's letter of order November 16, 1981.

Any person desiring to be heard or to protest this filing should file comments with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, on or before January 18, 1982. Comments will be considered by the Commission in determining the appropriate action to be taken. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-62 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. EL-82-2-000]

Connecticut Light and Power Co.; Petition for Declaratory Order

January 4, 1982.

Take notice that on November 25, 1981, the Connecticut Light and Power Company (Petitioner) filed a petition pursuant to 18 CFR 1.7(c) (1978) requesting that the Commission issue an order determining its jurisdiction over the Petitioner's existing operating hydroelectic generating site. The project is located on the Bantam River in Litchfield County, Connecticut. Correspondence concerning the petition should be addressed to: Mr. W. G. Counsil, Northeast Utilities Service Company, P.O. Box 270, Hartford, Connecticut 06101.

Power generated at the project is utilized by Petitioner for sale to its customers.

As described in the petition, the project consists of an existing 20-foot high, 87-foot long, concrete dam and a powerhouse with a single turbine generator with a total rated capacity of 320 kW.

Anyone desiring to be heard or to make any protest about this application should file a petition to intervene or a protest with the Federal Energy Regulatory Commission, in accordance with the requirements of the Commission's Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1979). Comments not in the nature of a protest may also be submitted by conforming to the procedures specified in § 1.10 for protests. In determining the appropriate acton to take, the Commission will consider all protests or other comments filed, but a person who merely files a protest or comments does not become a party to the proceeding. To become a party or to participate in any hearing, a person must file a petition to intervene in accordance with the Commission's Rules. Any comments, protest or petition to intervene must be filed on or before February 22, 1982. The Commission's address is: 825 North Capitol Street NE., Washington, D.C. 20426 The application is on file with the Commission and is available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-159 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-181-000]

Consumers Power Co.; Filing

January 4, 1982.

The filing Company submits the following:

Take notice that Consumers Power Company on December 24, 1981, tendered for filing a Coordinated Operating Agreement dated September 1, 1981, between Consumers Power Company and Northern Michigan Electric Cooperative, Inc., Wolverine Electric Cooperative, Inc., City of Grand Haven, Michigan, City of Traverse City, Michigan and City of Zeeland, Michigan (hereinafter collectively referred to as the "MCP members"); the Alba Interconnection Facilities Agreement between Consumers Power Company and Northern Michigan Electric Cooperative, Inc.; the Redwood Interconnection Facilities Agreement between Consumers Power Company and Wolverine Electric Cooperative, Inc.; the Hersey Interconnection Facilities Agreement between Consumers Power Company and Wolverine Electric Cooperative, Inc.; the Livingston Interconnection Facilities Agreement between Consumers Power Company and Northern Michigan Electric Cooperative, Inc.; the Blendon Interconnection Facilities Agreement between Consumers Power Company and Wolverine Electric Cooperative, Inc.; and the Grand Traverse Interconnection Facilities Agreement between Consumers Power Company, Northern Michigan Electric Cooperative, Inc., and City of Traverse City, Michigan; and Supplemental Agreement No. 1, dated September 1, 1981, to each of the above agreements.

Consumers Power Company states that copies of the filing were served on the MCP members and on the Michigan Public Service Commission.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 22, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding.

Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-160 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5573-000]

Cook Electric, Inc.; Application for Exemption for Small Hydroelectric Power Project Under 5 MW Capacity

January 4, 1982.

Take notice than on October 28, 1981, Cook Electric, Inc. (Applicant) filed an application, under Section 408 of the Energy Security Act of 1980 (Act) (16 U.S.C. 2705, and 2708 *as amended*), for exemption of a proposed hydroelectric project from licensing under Part I of the Federal Power Act. The proposed small hydroelectric project, Project No. 5573 would be located on Big Sheep and Little Creeks, within Wallowa-Whitman National Forest near Joseph in Wallowa County, Oregon. Correspondence with the Applicant should be directed to: Mr. Dale Hatch, Cook Electric, Inc., P.O. Box 1071, Twin Falls, Idaho 83301.

Project Description—The proposed project would consist of: (1) A 7-foot high diversion structure diverting water from the existing Wallowa Valley Irrigation District Canal into a power canal; (2) an 18,000-foot long power canal; (3) a 7.5-foot high diversion structure diverting the waters of Little Sheep Creek into the Power Canal; (4) a 45-inch diameter steel penstock; (5) a powerhouse with a total installed capacity of 4,250 kW; and (6) an 8-mile long, 13.8-kV transmission line interconnecting with an existing 13.8-kV transmission line owned by Pacific Power and Light Company.

The Applicant estimates that the average annual energy output would be 14.843 million kWh.

Purpose of Exemption—An exemption, if issued, gives the Exemptee priority of control, development, and operation of the project under the terms of the exemption from licensing, and protects the Exemptee from permit or license applicants that would seek to take or develop the project.

Agency Comments—The U.S. Fish and Wildlife Service, The National Marine Fisheries Service, and the Oregon Department of Fish and Wildlife are requested, for the purposes set forth in Section 408 of the Act, to submit within 60 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 60 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Competing Applications—Any qualified license applicant desiring to file a competing application must submit to the Commission, on or before February 22, 1982 either the competing license application that proposes to develop at least 7.5 megawatts in that project, or a notice of intent to file such a license application. Submission of a timely notice of intent allows an interested person to file the competing license application no later than 120 days from the date that comments, protests, etc. are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33 (b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33 (a) and (d) (1980).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before February 22, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the

Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-161 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5639-000]

Danielson Fence Co.; Application For Exemption for Small Hydroelectric Power Project Under 5 MW Capacity

December 29, 1981.

Take notice that on November 9, 1981, Danielson Fence Company (Applicant) filed an application under Section 408 of the Energy Security Act of 1980 (Act) (16 U.S.C. §§ 2705 and 2708 *as amended*), for exemption of a proposed hydroelectric project from licensing under Part I of the Federal Power Act. The proposed small hydroelectric project (Project No. 5639) would be located on the Five Mile River in the Town of Killingly, Windham County, Connecticut. Correspondence with the Applicant should be directed to: Mr. Gary Halliwell, Halliwell Associates, Inc., 865 Waterman Avenue, East Providence, Rhode Island 02914.

Project Description—The proposed project would consist of: (1) an old stone block gravity dam, 16 feet high and 115 feet long; (2) an impoundment covering 12 acres with negligible storage; (3) an existing stone and concrete headrace, 25 feet wide and 460 feet long; (4) an existing powerhouse approximately 15 by 25 feet housing a new 325-kW turbine/generator unit operating under a head of 24 feet; (5) a new 30-foot long, 2.3-kV transmission line between the powerhouse and the existing utility powerhouse; and (6) appurtenant facilities. The entire electrical generation of 1.73 million kWh would be sold to the Connecticut Light and Power Company.

Purpose of Exemption—An exemption, if issued, gives the Exemptee priority of control, development, and operation of the project under the terms of the exemption from licensing, and protects the Exemptee from permit or license applicants that would seek to take or develop the project.

Agency Comments—The U.S. Fish and Wildlife Service, The National Marine Fisheries Service, and the Connecticut Fish and Wildlife Unit are requested, for the purposes set forth in Section 408 of the Act, to submit within 60 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 60 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Competing Application—Any qualified license applicant desiring to file a competing application must submit to the Commission, on or before February 10, 1982, either the competing license application that proposes to develop at least 7.5 megawatts in that project, or notice of intent to file such a license application. Submission of a timely notice of intent allows an interested person to file the competing license application no later than 120 days from the date that comments, protests, etc, are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33 (b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33 (a) and (d) (1980).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must received on or before February 10, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-88 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-171-000]

Duke Power Co.; Filing

December 30, 1981.

The filing Company submits the following:

Take notice that Duke Power Company (Duke Power) tendered for filing on December 21, 1981 a supplement to the Company's Electric Power Contract with the City of Monroe. Duke Power states that this contract is on file with the Commission and has been designated Duke Power Company Rate Schedule FERC No. 238.

Duke Power further states that the Company's contract supplement, made at the request of the customer and with agreement obtained from the customer, provides for the following increase in contract demand: Delivery Point No. 3 from 55,000 KW to 70,000 KW.

Duke Power indicates that this supplement also includes an estimate of sales and revenue for twelve months immediately preceding and for the twelve months immediately succeeding the effective date. Duke Power proposes an effective date of February 17, 1982.

According to Duke Power copies of this filing were mailed to the City of Monroe and the North Carolina Utilities Commission.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 18, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-63 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-170-000]

Duke Power Co.; Filing

December 29, 1981.

The filing Company submits the following:

Take notice that Duke Power Company (Duke Power) tendered for filing on December 21, 1981 a supplement to the Company's Electric Power Contract with Crescent Electric Membership Corporation. Duke Power states that this contract is on file with the Commission and has been designated Duke Power Company Rate Schedule FERC No. 248.

Duke Power further states that the Company's contract supplement, made at the request of the customer and with agreement obtained from the customer, provides for the following increases in designated demand: Delivery Point No. 1 from 5,500 KW to 6,200 KW, Delivery Point No. 2 from 6,300 KW to 7,200 KW, Delivery Point No. 3 from 2,600 KW to 3,000 KW, Delivery Point No. 4 from 5,600 KW to 7,000 KW, Delivery Point No. 6 from 2,500 KW to 3,600 KW, Delivery Point No. 8 from 10,000 KW to 13,700 KW, Delivery Point No. 9 from 5,500 KW to 8,400 KW, Delivery Point No. 10 from 5,300 KW to 6,500 KW, Delivery Point No. 11 from 5,400 KW to 7,900 KW, Delivery Point No. 12 from 3,100 KW to 3,700 KW, Delivery Point No. 15 from 1,400 KW to 1,800 KW, and Delivery Point No. 17 from 5,000 KW to 5,600 KW.

Duke Power indicates that this supplement also includes an estimate of sales and revenue for twelve months immediately preceding and for the twelve months immediately succeeding the effective date. Duke Power proposes an effective date of February 17, 1982.

According to Duke Power copies of this filing were mailed to Crescent Electric Membership Corporation and the North Carolina Utilities Commission.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 15, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-89 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 4437-001]

Glacier Energy Co.; Application for Exemption for Small Hydroelectric Power Project Under 5 MW Capacity

December 30, 1981.

Take notice that on October 29, 1981, Glacier Energy Company (Applicant) filed an application, under Section 408 of the Energy Security Act of 1980 (Act) (16 U.S.C. 2705, and 2708 as amended), for exemption of a proposed hydroelectric project from licensing under Part I of the Federal Power Act. The proposed small hydroelectric project, Project No. 4437 would be located on Diobsud Creek in the Mount Baker/Snoqualime National Forest, Skagit County, Washington. Correspondence with the Applicant should be directed to: Mr. William Devine, Glacier Energy Company, P.O. Box 68, Maple Falls, Washington 98226.

Project Description—The proposed project would consist of: (1) A 4-foot high, 100-foot long diversion weir on Diobsud Creek at elevation 1,000 feet; (2) an 8,000-foot long, 36-inch diameter steel pipeline and penstock; (3) a powerhouse at elevation 450 feet containing a single 5,000 kW generating unit; (4) a switchyard adjacent to the powerhouse; (5) up to 5,000 feet of transmission line; and (6) approximately 3 miles of access roads. Applicant estimates that the project would have an average annual energy output of 29,600 MWh.

Purpose of Exemption—An exemption, if issued, gives the Exemptee priority of control, development, and operation of the project under the terms of the exemption from licensing, and protects the Exemptee from permit or license applicants that would seek to take or develop the project.

Agency Comments—The U.S. Fish and Wildlife Service, The National Marine Fisheries Service, and the Washington Departments of Fisheries and Game are requested, for the purposes set forth in Section 408 of the Act, to submit within 60 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 60 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Competing Applications—Any qualified license applicant desiring to file a competing application must submit to the Commission, on or before February 11, 1982, either the competing license application that proposes to develop at least 7.5 megawatts in that project, or a notice of intent to file such a license application. Submission of a timely notice of intent allows an interested person to file the competing license application no later than 120 days from the date that comments, protests, etc. are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33(b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33(a) and (d) (1980).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before February 11, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-71 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 3511-001]

David Goodman and George R. Oliger; Application for Minor License

December 29, 1981.

Take notice that David Goodman and George R. Oliger (Applicant) filed on November 12, 1981, an application for license [pursuant to the Federal Power Act, 16 U.S.C. 791(a)—825(r)] for construction and operation of a water power project to be known as Groveville Power Project No. 3511. The project would be located on Fishkill Creek in Dutchess County, New York. This application for license was filed during the term of Applicant's Preliminary permit for the Groveville Power Project No. 3511 issued March 11, 1981. Correspondence with the Applicant should be directed to: David Goodman & George R. Oliger, 80 Eighth Avenue, Suite 1306, New York, New York 10011.

Project Description—The proposed project would be run-of-the-river and would consist of: (1) An existing gravity dam constructed of cut rock and capped with concrete forming an ogee spillway approximately 150 feet long and 40 feet high; (2) a reservoir having minimal pondage; (3) a rehabilitated intake structure with repaired gates and new trashracks; (4) an existing riveted steel penstock, 9 feet in diameter and approximately 160 feet long, leading to (5) an existing powerhouse to be renovated and equipped with two new 369-kW turbine-generator units having a total rated capacity of 737 kW; (6) a restored tailrace; (7) a modified substation connecting to an existing 13.2-kV transmission line; and (8) appurtenant facilities. The Applicant estimates that the average annual energy output would be 3,100,000 kWh.

Purpose of Project—Project energy would be sold to the Central Hudson Gas and Electric Company.

Agency Comments—Federal, State, and local agencies that receive this notice through direct mailing from the Commission are requested to provide comments pursuant to the Federal Power Act, the Fish and Wildlife Coordination Act, the Endangered Species Act, the National Historic Preservation Act, the Historical and Archeological Preservation Act, the National Environmental Policy Act, Pub. L. No. 88-29, and other applicable statutes. No other formal requests for comments will be made.

Comments should be confined to substantive issues relevant to the issuance of a license. A copy of the application may be obtained directly from the Applicant. If an agency does not file comments within the time set below, it will be presumed to have no comments.

Competing Applications—Anyone desiring to file a competing application must submit to the Commission, on or before February 10, 1982, either the competing application itself [See 18 CFR 4.33 (a) and (d)] or a notice of intent [see 18 CFR 4.33 (b) and (c)] to file a competing application. Submission of a timely notice of intent allows an interested person to file an acceptable competing application no later than the time specified in § 4.33(c) or § 4.101 et. seq. (1981).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before February 10, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-82 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5472-000]

Gordon Falls Hydro Associates; Application for Preliminary Permit

December 29, 1981.

Take notice that Gordon Falls Hydro Associates (Applicant) filed on October 6, 1981, an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a)—825(r)] for Project No. 5472 to be known as the Gordon Falls Project located on the Mattawamkeag River in the town of Matawamkeag, Penobscot and Aroostook Counties, Maine. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Peter F. O'Connell, President, O.B.C., Inc., One Heritage Drive, North Quincy, Massachusetts 02171.

Project Description.—The proposed project, an entirely new facility, would consist of: (1) A 55-foot high, 750-foot long concrete gravity dam; (2) an 8 mile

long, 1,100-acre reservoir with no usable storage capacity at elevation 300 feet m.s.l.; (3) an intake structure located at the dam; (4) a .6-mile long, 17-foot diameter penstock; (5) a powerhouse containing two turbine-generator units with a total rated capacity of 20 MW discharging at a tailwater elevation of 250 feet m.s.l.; (6) a transmission line of undertermined length; and (7) appurtenant facilities. A market for the energy produced at the project would be determined during the term of permit.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. The work proposed under this preliminary permit would include economic evaluation, geotechnical boring and seismic refraction tests along the axis of the proposed dam, engineering plans, and an environmental assessment. Any disturbed areas will be restored after completion of geological investigations. Based on results of these studies, Applicant would decide whether to proceed with more detailed studies and the preparation of an application for license to construct and operate the project. Applicant estimates that the work to be performed under this preliminary permit would cost $700,000.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before April 2, 1982, the competing application itself, or a notice of intent to file such an application [see: 18 CFR 4.30 et. seq. (1981); and Docket No. RM81-15, issued October 29, 1981, 46 FR 55245, November 9, 1981.]

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before March 2, 1982, and should specify the type of application forthcoming. Any application for license or exemption from licensing must be filed in accordance with the Commission's regulations [see: 18 CFR 4.30 et seq. or 4.101 et seq. (1981), as appropriate].

Submission of a timely notice of intent to file an application for preliminary permit, allows an interested person to file an acceptable competing application for preliminary permit no later than May 3, 1982.

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 2, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-83 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ID-1676-001]

James E. Griffin; Application

December 30, 1981.

The filing individual submits the following:

Take notice that on December 21, 1981, James E. Griffin filed an application pursuant to Section 305(b) of the Federal Power Act to hold the following positions:

President, Chief Executive Officer, and Director—Central Vermont Public Service Corporation
President, Chief Executive Officer, and Director—Connecticut Valley Electric Company, Inc.
Chairman, Chief Executive Officer and Director—Vermont Electric Power Company, Inc.
Chairman, Chief Executive Officer, and Director—Vermont Yankee Nuclear Power Corporation
Director—Yankee Atomic Electric Company
Director—Connecticut Yankee Atomic Power Company
Director—Maine Yankee Atomic Power Company
President and Director—Central Vermont Public Service Corporation—Bradford Hydroelectric, Inc.
President and Director—Central Vermont Public Service Corporation—East Barnet Hydroelectric, Inc.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 22, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-49 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5729-000]

Hollingsworth & Vose Co.; Application for Exemption

December 29, 1981.

Take notice that Hollingsworth & Vose Company (Applicant), on December 7, 1981, filed an Application for Exemption for its Clarks Mills Lower Dam development, Project No. 5729, located on the Batten Kill River in Washington County, New York, for all or part of Part I of the Federal Water Power Act, pursuant to 18 C.F.R. Part 4, Subpart K (1980), implementing in part Section 408 of the Energy Security Act of 1980 (Public Law No. 96-294, 94 Stat. 611), and Sections 405 and 408 of the Public Utility Regulatory Policies Act of 1978 Law No. 95-617, Title IV, 16 U.S.C. §§ 2705 and 2708. The Application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. William J. Kenny, Esquire, Perito, Duerk, Carlson & Pinco, P.C., 1140 Connecticut Avenue NW., Suite 400, Washington, D.C. 20036.

Project Description—The proposed run-of-the-river development which is

the subject of this Application for Exemption is the lower development in a two-development project. The upper development is the subject of an exemption application filed September 14, 1981, as FERC No. 4667–001. The development would consist of: (1) the existing lower Dam, a reinforced concrete structure approximately 250 feet long and 20 feet high; (2) the existing 300-acre foot reservoir at elevation 109.0 feet (U.S.G.S.); (3) the existing inlet gate; (4) a concrete flume leading to; (5) an existing powerhouse containing four new generators connected to existing turbines to be reconditioned with a total rated capacity of 1,250 kW; disharging into (6) an existing tailrace; and (7) appurtenant works. The Applicant estimates average annual energy generaged at the lower development to be 6,100,000 kWh.

Purpose of Project—Project energy would be utilized by the Applicant to serve the power needs of its existing paper mill operated at the project site, with surplus power sold to a local utility.

Purpose of Exemption—An exemption, if issuéd, gives the Exemptee priority of control, development, and operation of the project under the terms of the exemption from licensing, and protects the Exemptee from permit or license applicants that would seek to take or develop the project.

Competing Application—Any qualified license applicant desiring to file a competing application must submit to the Commission, on or before February 16, 1982 either the competing license application that proposes to develop at least 7.5 megawatts in that project, or notice of intent to file such a license application. Submission of a timely notice of intent allows an interested person to file the competing license application no later than 120 days from the date that comments, protests, etc. are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33(b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33(a) and (d) (1980).

Agency Comments—The U.S. Fish and Wildlife Service and the New York State Department of Environmental Conservation are requested, for the purposes set forth in Section 408 of the Act, to submit appropriate terms and conditions to protect any fish and wildlife resources. Other Federal, State, and local agencies that receive this notice through direct mailing from the Commission are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 60 days from the issuance of this notice, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone desiring to be heard or to make any protests about this application should file a petition to intervene or a protest with the Commission, in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR § 1.8 or § 1.10 (1980). Comments not in the nature of a protest may also be submitted by conforming to the procedures specified in § 1.10 for protests. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but a person who merely files a protest or comments does not become a party to the proceeding. To become a party or to participate in any hearing, a person must file a petition to intervene in accordance with the Commission's Rules. Any comments, protests, or petitions to intervene must be received on or before Febraury 16, 1982. The Commission's address is: 825 North Capitol Street NE., Washington, D.C. 20426. The application is on file with the Commission and is available for public inspection.

Filing and Service of Responsible Documents—Any filings must bear in all capital letters the title "COMMENTS", "PROTEST", or "PETITION TO INTERVENE", as applicable and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–90 Filed 1–4–82; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 5659–000]

Hydro Management, Inc.; Application for Preliminary Permit

December 30, 1981.

Take notice that Hydro Management, Incorporated (Applicant) filed on November 16, 1981, an application for preliminary permit (pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)) for Project No. 5659 to be known as the Williams Creek Power Project located on Williams Creek, in Lincoln County, Montana. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. W. H. Edelman III, President, Hydro Management, Incorporated, Route 1, Box 169, Ronan, Montana 59864.

Project Description—The proposed project would consist of: (1) A 24-foot long, 3-foot high diversion structure on Williams Creek; (2) a 21,000-foot long, 16-inch diameter penstock; (3) a powerhouse with an installed capacity of 1500 kW; and (4) an 11,000-foot long, 14.4-kV transmission line from the powerhouse to an existing 14.4-kV transmission line owned by the Lincoln Electric Cooperative Inc. The Applicant estimates that the average annual energy production would be 9.072 million kWh. The proposed project is entirely located on U.S. Federal Lands owned by Kootenai National Forest.

Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The Applicant seeks issuance of a preliminary permit for a period of 36 months during which it would conduct technical, environmental and economic studies, and also prepare an FERC license application. No new roads would be needed for conducting these studies. The Applicant estimates that the cost of undertaking these studies would be $13,000.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before March 3, 1982, the competing application itself, or a notice of intent to file such an application (see: 18 CFR 4.30 et seq. (1981), and Docket No. RM81–15, issued October 29, 1981, 46 FR 55245, November 9, 1981).

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before March 3, 1982, and should

specify the type of application forthcoming. Any application for license or exemption from licensing must be filed in accordance with the Commission's regulations (see: 18 CFR 4.30 et seq. or 4.101 et seq. (1981), as appropriate).

Submission of a timely notice of intent to file an application for preliminary permit, allows an interested person to file an acceptable competing application for preliminary permit no later than May 3, 1982.

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions to Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 3, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-72 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5662-000]

Hydro Management, Inc.; Application for Preliminary Permit

January 4, 1982.

Take notice that Hydro Management, Inc. (Applicant) filed on November 16, 1981, an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a)—825(r)] for Project No. 5662 to be known as the Grave Creek Power Project located on Grave Creek in Lincoln County, Montana. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. W. H. Edelman, III, President, Hydro Management, Incorporated, Route 1, Box 169, Ronan, Montana 59864.

Project Description.—The proposed project would consist of: (1) A 24-foot long, 3-foot high diversion structure on Grave Creek; (2) a 21,200-foot long, 20-inch diameter penstock; (3) a powerhouse with a total installed capacity of 600 kW; and (4) a 300-foot long, 14.4-kV transmission line from the powerhouse to the Stahl Creek Power Project transmission line. The Applicant estimates that the average annual energy production would be 3.629 million kWh. the proposed project is entirely located on Federal lands owned by Kootenai National Forest.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant seeks issuance of a preliminary permit for a period of 36 months during which it would conduct technical, environmental and economic studies, and also prepare an FERC license application. The Applicant estimates that the cost of undertaking these studies would be $6,000.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before February 11, 1982, the competing application itself, or a notice of intent to file such an application [see: 18 CFR 4.30 et. seq. (1981); and Docket No. RM1-15, issued October 29, 1981, 46 FR 55245, November 9, 1981.]

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before February 11, 1982, and should specify the type of application forthcoming. Any application for license or exemption from licensing must be filed in accordance with the Commission's regulations [see: 18 CFR 4.30 et seq. or 4.101 et seq. (1981), as appropriate].

Submission on a timely notice of intent to file an application for preliminary permit, allows an interested person to file an acceptable competing application for preliminary permit no later than April 9, 1982.

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before February 11, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-162 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5663-000]

Hydro Management, Inc.; Application for Preliminary Permit

January 4, 1982.

Take notice that Hydro Management, Inc. (Applicant) filed on November 16, 1981, an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)] for Project No. 5663 to be known as the Foundation Creek Power Project located on Foundation Creek in Lincoln County, Montana. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. W. H. Edelman, III, President, Hydro Management, Incorporated, Route 1, Box 169, Ronan, Montana 59864.

Project Description—The proposed project would consist of: (1) A 18-foot long, 3-foot high diversion structure; (2) a 8,000-foot long, 14-inch diameter penstock; (3) a powerhouse with a total installed capacity of 350 kW; and (4) a 21,2000-foot long, 14.4-kV transmission line from the powerhouse to the Blue Sky Creek Power Project transmission line. The Applicant estimates that the average annual energy production would be 2.117 million kWh. The proposed project is entirely located on Federal lands owned by Kootenai National Forest.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant seeks issuance of a preliminary permit for a period of 36 months during which it would conduct technical, environmental and economic studies, and also prepare an FERC license application. The Applicant estimates that the cost of undertaking these studies would be $3,500.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before February 11, 1982, the competing application itself, or a notice of intent to file such an application [see: 18 CFR 4.30 et. seq. (1981); and Docket No. RM81–15, issued October 29, 1981, 46 FR 55245, November 9, 1981.]

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before February 11, 1982, and should specify the type of application forthcoming. Any application for license or exemption from licensing must be filed in accordance with the Commission's regulations [see: 18 CFR 4.30 et. seq. or 4.101 et. seq. (1981), as appropriate].

Submission of a timely notice of intent to file an application for preliminary permit, allows an interested person to file an acceptable competing application for preliminary permit no later than April 9, 1982.

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests or petitions to intervene must be received on or before February 11, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–163 Filed 1–4–82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5680-000]

Hydro Resource Co.; Application for Preliminary Permit

December 30, 1981.

Take notice that Hydro Resource Company (Applicant) filed on November 24, 1981, an application for preliminary permit (pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)) for Project No. 5680 to be known as the Kilborn Creek Project located on Kilborn Creek in Lewis County, Washington. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. Jerry L. Johnson, Agent, P.O. Box 485, Lynden, Washington 98264.

Project Description—The proposed project would consist of: (1) A 50-foot long, 8-foot high diversion structure; (2) a 6,500-foot long, 30-inch diameter diversion conduit; (3) a 2,000-foot long, 30-inch diameter penstock; (4) a powerhouse with a total rated capacity of 3,200 kW; and (5) a 2,600-foot long, 69-kV transmission line from the powerhouse to an existing 69-kV transmission line. The Applicant estimates that the average annual energy production would be 28 million kWh. The project is located within the boundaries of Gifford Pinchot National Forest.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. The Applicant seeks issuance of a preliminary permit for a period of 24 months during which it would conduct technical, environmental and economic studies, and also prepare an FERC license application. The Applicant estimates that the cost of undertaking these studies would be $150,000.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before March 1, 1982, the competing application itself, or a notice of intent to file such an application (see: 18 CFR 4.30 et seq. (1981); and Docket No. RM81–15, issued October 29, 1981, 46 FR 55245, November 9, 1981.)

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before March 1, 1982, and should specify the type of application forthcoming. Any application for license

or exemption from licensing must be filed in accordance with the Commission's regulations (see: 18 CFR 4.30 et seq. or 4.101 et seq. (1981), as appropriate).

Submission of a timely notice of intent to file an application for preliminary permit, allows an interested person to file an acceptable competing application for preliminary permit no later than April 30, 1982.

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 1, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS"," NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-73 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER77-531]

Illinois Power Co.; Compliance Filing

December 30, 1981.

The filing Company submits the following:

Take notice that on December 21, 1981, Illinois Power Company filed a refund report in compliance with the Commission's April 10, 1981 order.

Any person desiring to be heard or to protest this filing should file comments with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D. C. 20426, on or before January 18, 1982. comments will be considered by the Commission in determining the appropriate action to be taken. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb.

Secretary.

[FR Doc. 82-50 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER 78-380]

Indiana & Michigan Electric Co.; Compliance Filing

December 30, 1981.

The filing Company submits the following:

Take notice that on April 23, 1981, Indiana & Michigan Electric Company filed a refund report pursuant to the Commission's March 20, 1981 letter order.

Any person desiring to be heard or to protest this filing should file comments with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, on or before January 18, 1982. Comments will be considered by the Commission in determining the appropriate action to be taken. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-51 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5608-000]

Ben Johnson; Application for Exemption for Small Hydroelectric Power Project Under 5 MW Capacity

December 30, 1981.

Take notice that on November 2, 1981, Ben Johnson (Applicant) filed an application under Section 408 of the Energy Security Act of 1980 (Act) (16 U.S.C. 2705 and 2708 as amended), for exemption of a proposed hydroelectric project from licensing under Part I of the Federal Power Act. The proposed small hydroelectric project (Project No. 5608) would be located on McCully Creek in Wallowa County, Oregon. Correspondence with the Applicant should be directed to: Gerald Sandlin, Ranch Foreman, Rt. 1, Box 170, Joseph, Oregon 97846.

Project Description—The proposed project would consist of a powerhouse containing a single 200-kW generating unit on the bank of McCully Creek at elevation 4,581 feet. The project would use water from an existing irrigation system and would have an average annual generation of 732 MWh.

Purpose of Project—Project power would be sold to the Pacific Power and Light Company.

Agency Comments—The U.S. Fish and Wildlife Service, The National Marine Fisheries Service, and the Oregon Department of Fish and Wildlife are requested, for the purposes set forth in section 408 of the Act, to submit within 60 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 60 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Competing Application—Any qualified license applicant desiring to file a competing application must submit to the Commission, on or before February 16, 1982 either the competing license application that proposes to develop at least 7.5 megawatts in that project, or notice of intent to file such a license application. Submission of a timely notice of intent allows an interested person to file the competing license application no later than 120 days from the date that comments,

protests, etc. are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33 (b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33 (a) and (d) (1980).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of its Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before February 16, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB, 825 North Capitol Street NE., Washington, D.C. 20426. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-74 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP75-142-001, et al.]

Jupiter Energy Corp.; Petition To Amend

December 29, 1981.

Take notice that on December 11, 1981, Jupiter Energy Corporation (Jupiter Energy), 400 E. Randolph Street, Chicago, Illinois 60601, filed in Docket Nos. CP75-142, G-12583 and CS76-501 [1] a petition to amend the orders issued in the instant dockets pursuant to section 7(c) of the Natural Gas Act so as to authorize continuation of service previously rendered by Jupiter Energy's predecessor, The Jupiter Corporation (Jupiter), all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

It is stated that under the terms of a June 30, 1981, assignment all the properties involved in the jurisdictional transactions in which Jupiter was engaged have been transferred to Jupiter's wholly-owned subsidiary, Jupiter Energy, which acquired and succeeded to all rights of Jupiter and assumed all its obligations. Jupiter Energy proposes herein to continue service previously rendered by Jupiter in the instant dockets.

Jupiter Energy further requests the Commission redesignate all Jupiter Gas Rate Schedules as Jupiter Energy's Gas Rate Schedules effective as of June 30, 1981.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before January 21, 1982, file with the Federal Energy Regulatory 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.

Kennth F. Plumb,

Secretary.

[FR Doc. 82-75 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5616-000]

City of Leavenworth, Wash.; Application for Preliminary Permit

December 29, 1981.

Take notice that City of Leavenworth, Washington (Applicant) filed on November 6, 1981, an application for preliminary permit (pursuant to the Federal Power Act, 16 U.S.C. 791(a)—825(r)) for Project No. 5616 to be known as the Icicle Creek on lands within Snoqualmie National Forest in Chelan County, Washington. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: E. Lorene Young, Mayor, 815 Front Street, P.O. Box 287, Leavenworth, Washington 98826.

Project Description—The proposed project would consist of: (1) A 15-foot high, 50-foot long diversion dam; (2) a reservoir with a storage capacity of 4 acre feet; (3) two intake structures, one each on 8-mile Creek and Rat Creek; (4) a 5-mile long penstock; (5) a powerhouse containing a single generating unit with an installed capacity of 80MW, and (6) a .5-mile long 115-kV transmission line interconnecting with Chelan County's existing substation at Leavenworth. Applicant estimates that the average annual energy output would be 300 million kWh.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant has requested a 36-month permit to prepare a definitive project report including preliminary designs and geological, environmental and economic feasibility studies. The cost of the above activities, along with obtaining agreements with the U.S. Forest Service and other Federal, State and local agencies conducting final field surveys would be $205,000.

Competing Applications—This application was filed as a competing application to Capital Development Company's application for Project No. 4465-000 filed on April 2, 1981. Public notice of the filing of the initial application, which has already been given, established the due date for filing competing applications or notices of intent. In accordance with the Commission's regulations, no competing application for preliminary permit or notices of intent to file an application for preliminary permit or license will be accepted for filing in response to this notice. Any application for license or exemption from licensing, or notice of intent to file an exemption application, must be filed in accordance with the Commission's regulations (See: 18 CFR 4.30 et. seq. or 4.101 et. seq. (1981), as appropriate).

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

[1] These proceedings were commenced before the FPC. By joint regulation of October 1, 1977 (10 CFR 1000.1), they were transferred to the Commission.

Comments, Protests, or Petitions to Intervene—Anyone may submit comments, a protest, or a petition To intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before February 12, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS" "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Room 208 RB at the above address. A copy of any petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-81 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-158-000]

Maine Electric Power Co.; Filing

December 29, 1981.

The filing Company submits the following:

Take notice that on December 9, 1981, Maine Electric Power Company (MEPCO) tendered for filing a transmission contract between MEPCO and the Massachusetts Municipal Wholesale Electric Company (MMWEC) for the delivery of 100 MW of Point LePreau power under MEPCO's Rate Schedule No. 1 Supplement No. 5.

The term of the proposed contract shall begin on the first day of the month following the commercial operation date of Point LePreau Unit No. 1 and shall end on October 31, 1987, with MMWEC having the right of three (3) consecutive annual extensions provided a 24 months' notice is given for each extension. MEPCO may terminate any extension of the proposed agreement beyond October 31, 1987 upon 26 months' notice.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 11, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-92 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ID-1965-001]

Richard W. Mallary; Application

December 30, 1981.

The filing individual submits the following:

Take notice that on December 21, 1981, Richard W. Mallary filed an application pursuant to Section 305(b) of the Federal Power Act to hold the following positions:

Executive Vice President, Central Vermont Public Service Corporation.
Executive Vice President, Connecticut Valley Electric Company, Inc.
Director, Central Vermont Public Service Corporation—Bradford Hydroelectric, Inc.
Director, Central Vermont Public Service Corporation—East Barnet Hydroelectric, Inc.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 22, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-52 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-169-000]

Mid-Continent Area Power Pool Agreement; Filing

December 29, 1981.

The filing Company submits the following:

Take notice that on December 21, 1981, the MAPP Coordination Center, as filing agent for the Mid-Continent Area Reliability Coordination Council, filed an Agreement to Terminate the Mid-Continent Area Reliability Coordination Agreement (MARCA) in that all of the functions performed and services rendered under MARCA are duplicated in the Mid-Continent Area Power Pool Agreement (MAPP).

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 15, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-91 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-168-000]

Mid-Continent Area Power Pool Agreement; Filing

December 29, 1981.

The filing Company submits the following:

Take notice that on December 21, 1981, the MAPP Coordination Center, (MAPP) filed an amendment to the Mid-Continent Area Power Pool Agreement which would add a Design Review Committee to the MAPP Agreement.

MAPP requests an effective date of December 31, 1981.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 15, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-53 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ID-1663-000]

Theodore W. Millspaugh, Jr.; Application

December 30, 1981.

The filing individual submits the following:

Take notice that on December 21, 1981, Theodore W. Millspaugh, Jr. filed an application pursuant to section 305(b) of the Federal Power Act to hold the following positions:

Treasurer, Central Vermont Public Service Corporation.
Treasurer, Connecticut Valley Electric Company, Inc.
Treasurer, Central Vermont Public Service Corporation—Bradford Hydroelectric, Inc.
Treasurer, Central Vermont Public Service Corporation—East Barnet Hydroelectric, Inc.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 22, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-53 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-175-000]

Mississippi Power & Light Co.; Filing

December 30, 1981.

The filing Company submits the following:

Take Notice that on December 21, 1981, Mississippi Power & Light Company (MP&L) tendered for filing an Assignment and Operating Agreement between it and Delta Electric Power Association (Delta) dated as of June 1, 1981. This Assignment served to release MP&L from its obligations under MP&L Agreements for Purchase of Power at each separate Delta delivery point and assigned those certain Agreements for Purchase of Power to South Mississippi Electric Power Association (SMEPA). With this transfer of power supply responsibility from MP&L to SMEPA, MP&L commenced providing SMEPA with transmission service under MP&L Rate Schedule FERC No. 251 with supplements as accepted for filing by the Commission in Docket No. ER79-259 (now terminated).

Consistent with the rearrangement of rights and obligations agreed to in the Assignment, MP&L proposes that its Agreements for Purchase of Power (designated as MP&L Rate Schedules, FERC Numbers 173, 174, 175, 176, 177, 178, 179, 181, 208, 209, 214, 219, 220, 223, 225, 231, 233, 253) be cancelled as of June 1, 1981. Accordingly, MP&L with the concurrence of SMEPA and Delta, requests waiver of the Commission's notice requirements to permit an effective cancellation date of June 1, 1981.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with §§1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8 and 1.10). All such petitions or protests should be filed on or before January 18, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-54 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-174-000]

Mississippi Power & Light Co.; Notice of Filing

December 30, 1981.

The filing Company submits the following:

Take Notice that on December 21, 1981, Mississippi Power & Light Company (MP&L) tendered for filing an Assignment and Operating Agreement between it and Yazoo Valley Electric Power Association (Yazoo Valley) dated as of June 1, 1981. This Assignment served to release MP&L from its obligations under MP&L's Agreements for Purchase of Power at each separate Yazoo Valley delivery point and assigned those certain Agreements for Purchase of Power to South Mississippi Electric Power Association (SMEPA). With this transfer of power supply responsibility from MP&L to SMEPA, MP&L commenced providing SMEPA with transmission service under MP&L Rate Schedule FERC No. 251 with supplements as accepted for filing by the Commission in Docket No. ER79-259 (now terminated).

Consistent with the rearrangement of rights and obligations agreed to in the Assignment, MP&L proposes that its Agreements for Purchase of Power (designated as MP&L Rate Schedules, FERC Numbers 202, 203, 204, 206) be cancelled as of June 1, 1981. Accordingly, MP&L with the concurrence of SMEPA and Yazoo Valley, requests waiver of the Commission's notice requirements to permit an effective cancellation date of June 1, 1981.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol, Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 18, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file

with the Commission and are available for public inspection.

Kennth F. Plumb,

Secretary.

[FR Doc. 82-65 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-176-000]

Mississippi Power & Light Co.; Notice of Filing

December 30, 1981.

The filing Company submits the following:

Take Notice that on December 21, 1981, Mississippi Power & Light Company (MP&L) tendered for filing an Assignment and Operating Agreement between it and Twin County Electric Power Association (Twin County) dated as of June 1, 1981. This Assignment served to release MP&L from its obligations under MP&L's Agreements for Purchase of Power at each separate Twin County delivery point and assigned those certain Agreements for Purchase of Power to South Mississippi Electric Power Association (SMEPA). With this transfer of power supply responsibility from MP&L to SMEPA, MP&L commenced providing SMEPA with transmission service under MP&L Rate Schedule FERC No. 251 with supplements as accepted for filing by the Commission in Docket No. ER79-259 (now terminated).

Consistent with the rearrangement of rights and obligations agreed to in the Assignment, MP&L proposed that its Agreements for Purchase of Power (designated as MP&L Rate Schedules, FERC Numbers 196, 197, 198, 199, 200, 201, 242) be cancelled as of June 1, 1981. Accordingly, MP&L with the concurrence of SMEPA and Twin County, requests waiver of the Commission's notice requirements to permit an effective cancellation date of June 1, 1981.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 18, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-66 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 4860-001]

Modesto Irrigation District; Application for Preliminary permit

January 4, 1982.

Take notice that Modesto Irrigation District (Applicant) filed on August 5, 1981, an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a)-825(r)] for Project No. 4860-001 to be known as the Slate Creek Yuba Project located on Slate Creek on land within the Plumas National Forest in Yuba County, California. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. A. Lee DeLano, P.O. Box 4060, Modesto, California 95350.

Project Description—The proposed project would consist of: (1) A 6-foot high 120-foot long diversion structure; (2) a 60-inch diameter, 3,500-foot long conduit, (3) a 48-inch diameter, 500-foot long penstock; (4) a powerhouse to containing a single generating unit with a capacity of 4100 kW, and (5) a 2.5-mile long, 12-kV transmission line interconnecting with an existing Pacific Gas and Electric transmission line. Applicant estimated that the annual energy production is 35.8 million kWh.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant had requested a 24-month permit to prepare definitive project report including results of geological, environmental, and economic feasibility studies. The cost of above activities along with preparing of an environmental impact report, obtaining agreements with the U.S. Forest Service and other Federal, State and local agencies, preparing a license application and conducting final field surveys is estimated by the Applicant to be $45,000.

Competing Applications—This application was filed as a competing application to Consolidated Hydroelectric, Inc.'s application for Project No. 4263-000 filed on February 26, 1981. Public notice of the filing of the initial application, which has already been given, established the due date for filing competing application or notices of intent. In accordance with the Commission's regulations, no completing application for preliminary permit, or notices of intent to file an application for preliminary permit or license will be accepted for filing in response to this notice. Any application for license or exemption from licensing, or notice of intent to file an exemption application, must be filed in accordance with the Commission's regulations [see: 18 CFR 4.30 et. seq. or 4.101 et. seq. (1981), as appropriate].

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) if an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests or petitions to intervene must be received on or before February 2, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "PROTESTS", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secreatry, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Room 208 RB at the above address. A copy of any petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-164 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 4840-001]

Modesto Irrigation District; Application for Preliminary Permit

January 4, 1982.

Take notice that Modesto Irrigation District (Applicant) filed on August 5, 1981 an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)] for Project No. 4840–001 to be known as the Soctish Creek Humboldt Power located on Soctish Creek on land under the management of the U.S. Bureau of Indian Affairs. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. A. Lee DeLano, P.O. Box 4060, Modesto, California 95350.

Project Description—The proposed project would consist of: (1) A 5-foot high, 80-foot long diversion structure; (2) a 48-inch diameter, 4000-foot long conduit; (3) a 36-inch diameter, 800-foot long penstock; (4) a powerhouse containing a single generating unit with a capacity of 1600 kW, and (5) a 0.5 mile long, 12-kV transmission line interconnecting with an existing transmission line of Pacific Gas and Electric Company. Applicant estimates that the annual average energy production would be 15.8 million kWh.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant has requested a 24-month permit to prepare a definitive project report including results of geological, environmental, and economic feasibility studies. The cost of the above activities along with preparation of an environmental impact report, obtaining agreements with the U.S. Bureau of Indian Affairs and other Federal, State and local agencies, preparing a license application and conducting final field surveys is estimated by the Applicant to be $45,000.

Competing Applications—This application was filed as a competing application to Consolidated Hydroelectric, Inc.'s application for Project No. 4262–000 filed on February 26, 1981. Public notice of the filing of the initial application, which has already been given, established the due date for filing competing applications or notices of intent. In accordance with the Commission's regulations, no competing application for preliminary permit, or notices of intent to file an application for preliminary permit or license will be accepted for filing in response to this notice. Any application for license or exemption from licensing, or notice of intent to file an exemption application, must be filed in accordance with the Commission's regulations [see: 18 CFR 4.30 et. seq. or 4.101 et. seq. (1981), as appropriate].

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, To Petitions to Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions, to intervene must be received on or before February 2, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS," "PROTEST," or "PETITION TO INTERVENE," as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Room 208 RB at the above address. A copy of any petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-165 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER32-161.000]

New England Power Co; Filing

December 29, 1981.

The filing Company submits the following:

Take notice that on December 18, 1981 New England Power Company ("NEP") filed an amendment to its presently effective FERC Electric Tariff, Original Volume Number 3 to provide an additional type of non-PTF transmission service at the distribution primary level on a cost of service basis.

NEP requests that the Commission allow the new rate to become effective on January 11, 1982, subject to refund and waiver of the Commission's Regulations.

Any person desiring to be heard or to make any protest with reference to this filing should submit to the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, on or before January 15, 1982, petitions to intervene or protest according to the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests will be considered by the Commission in determining the appropriate action to be taken, but protests will not serve to make protestants parties to the proceeding. A person wishing to become a party must file a petition to intervene. Copies of the application and supporting documents are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-94 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-177-000]

New England Power Pool; Notice of Filing

December 30, 1981.

The filing Company submits the following:

Take notice that on December 22, 1981, the New England Power Pool (NEPOOL) filed an Agreement Amending NEPOOL Power Pool Agreement (Amendment), dated as of September 1, 1981, which modifies the provisions of the New England Power Pool Agreement, dated as of September 1, 1971.

NEPOOL indicates that the Amendment (1) provides for revision of section 12.6 of the NEPOOL Agreement to redefine the circumstances under which a generating unit, which is out of service on a scheduled or unscheduled basis, may provide its owner with the right to obtain Scheduled Outage Service or Unscheduled Outage Service pricing for energy or operating reserve service that the Participant obtains through the pool during the period that the unit is unavailable; and (2) adds a new section 12.13 which changes pool dispatch and billing rules during an energy shortage period following a determination by the pool's Management Committee of the existence of an energy shortage which adversely

affects the bulk power supply of the New England region and any adjoining areas served by pool participants. NEPOOL has filed with the Amendment a copy of the special pool rules to be applicable during an energy shortage period, entitled Dispatch And Billing Rules During Energy Shortages.

NEPOOL proposes that the Amendment become effective as of December 1, 1981, and has requested waiver of the Commission's customary notice rules to permit the Amendment to become effective as of that date.

Any person desiring to be heard or to make any protest with reference to the Amendment should on or before January 18, 1982, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, petitions to intervene or protests in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). Persons wishing to become parties to a proceeding or to participate as a party in any hearing related thereto must file petitions to intervene in accordance with the Commission's Rules. 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. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-67 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-182-000]

Niagara Mohawk Power Corp.; Filing

January 4, 1982.

The filing Company submits the following:

Take notice that Niagara Mohawk Power Corporation (Niagara), on December 24, 1981, tendered for filing as a rate schedule, an agreement between Niagara and the Central Vermont Public Service Corporation (Central Vermont) dated December 1, 1981.

The agreement provides for the purchase for resale to Central Vermont Public Service Corporation of short term power and associated energy from Ontario Hydro and to provide transmission service for the delivery of said short term power and associated energy. Niagara is requesting an effective date as of December 1, 1981.

Copies of the filing were served upon the following:

Central Vermont Public Service Corporation, 77 Grove Street, Rutland, VT 05701

Public Service Commission, State of New York, Three Rockefeller State Plaza, Albany, NY 12223

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions shall be filed on or before January 22, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-166 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-154-000]

Northern States Power Co.; Filing

(December 29, 1981.)

The filing Company submits the following:

Take notice that Northern States Power Company (NSP) on December 15, 1981, tendered for filing the Shared Transmission Agreement with Southern Minnesota Municipal Power Agency.

The Agreement, dated November 18, 1981, avoids the construction of duplicating facilities, coordinates the development of transmission facilities and provides for the delivery of power and energy to NSP customers and Southern Minnesota members in NSP area. An effective date of November 18, 1981, is requested.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 11, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-95 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP82-110-000]

Orange and Rockland Utilities, Inc.; Application

December 30, 1981.

Take notice that on December 9, 1981, Orange and Rockland Utilities, Inc. (Applicant), One Blue Hill Plaza, Pearl River, New York 10965, filed in Docket No. CP81-110-000 an application pursuant to Section 1(c) of the Natural Gas Act for exemption from the provisions of the Natural Gas Act and the Regulations of the Commission thereunder for the sale of natural gas for resale to New York State Electric & Gas Corporation (NYSEG), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant states that it received authorization from the Commission for the sale of natural gas for resale to NYSEG on April 16, 1956, in Docket No. G-9439. Applicant wishes to increase sales to NYSEG from 2,900 Mcf per day to 3,300 Mcf per day. Although Applicant has requested such increase in its application filed in Docket No. CP81-21 on October 17, 1980, Applicant herein requests exemption in lieu of the authorization to increase sales to NYSEG.

Applicant asserts that all gas sold to NYSEG at Goshen, New York, is ultimately consumed within New York. It is further explained that The Public Service Commission of the State of New York would exercise jurisdiction over Applicant's sales for resale to NYSEG.

Any person desiring to be heard or to make any protest with reference to said application should on or before January 18, 1982, file with the Federal Energy Regulatory 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-54 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5637-000]

Pancheri, Inc.; Application for Exemption for Small Hydroelectric Power Project Under 5 mW Capacity

December 30, 1981.

Take notice that on November 9, 1981, Pancheri, Inc. (Applicant) filed an application under Section 408 of the Energy Security Act of 1980 (Act) (16 U.S.C. 2705 and 2708 as amended), for exemption of a proposed hydroelectric project from licensing under Part I of the Federal Power Act. The proposed small hydroelectric project (Project No. 5637) would be located on the Telford Pipeline in Butte County, Idaho. Correspondence with the Applicant should be directed to: Mr. G. L. Smith, Appropriate Technologies, Inc., P.O. Box 1016, Idaho Falls, Idaho 83402.

Project Description—The proposed project would consist of: (1) A 300-foot long, 10-inch diameter extension of the Telford Pipeline; (2) a powerhouse containing a single 150-kW generating unit; and (3) a 7,000-foot long, 25-kV transmission line. The project would have an average annual generation of 1,048 MWh.

Purpose of Project—Project power would be sold to the Utah Power and Light Company.

Agency Comments—The U.S. Fish and Wildlife Service, the National Marine Fisheries Service, and the Idaho Department of Fish and Game are requested, for the purposes set forth in Section 408 of the Act, to submit within 60 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 60 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Competing Application—Any qualified license applicant desiring to file a competing application must submit to the Commission, on or before February 16, 1982 either the competing license application that proposes to develop at least 7.5 megawatts in that project, or notice of intent to file such a license application. Submission of a timely notice of intent allows an interested person to file the competing license application no later than 120 days from the date that comments, protests, etc. are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33 (b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33 (a) and (d) (1980).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of its Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before February 16, 1982.

Filing and Service of Responsive Documents—Any filings, must bear in all capital letters the title "COMMENTS," "NOTICE OF INTENT TO FILE COMPETING APPLICATIONS," "COMPETING APPLICATION," "PROTEST," or "PETITION TO INTERVENE," as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB, 825 North Capitol Street NE., Washington, D.C. 20426. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-76 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ID-1851-001]

John W. Powers; Application

January 4, 1982.

The filing individual submits the following:

Take notice that on December 24, 1981, John W. Powers filed an application pursuant to Section 305(b) of the Federal Power Act to hold the following positions:

Treasurer: Niagara Mohawk Power Corporation
Treasurer: St. Lawrence Power Company
Director: Beebee Island Corporation
Treasurer: Beebee Island Corporation
Director: HYDRA-CO Enterprises, Inc.
Treasurer: Moreau Manufacturing Corporation
Assistant Treasurer: NM Uranium, Inc.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 26, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-167 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-162-000]

Public Service Co. New Hampshire; Filing

December 29, 1981.

The filing Company submits the following:

Take notice that Public Service Company of New Hampshire (PSNH) on December 18, 1981, tendered for filing an initial rate for firm transmission service to be provided to Central Maine Power Company. PSNH states that on a 1980

test year basis the revenues for this transaction would equal $328,368.

PSNH requests waiver of the Commission's notice requirements to allow for an effective date of December 15, 1981.

According to PSNH copies of the filing were served upon Central Maine Power Company and the public service commissions of Maine and New Hampshire.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All such petitions or protests should be filed on or before January 15, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-96 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5295-000]

Public Utilities Commission, City and County of San Francisco, Calif.; Application for Exemption for Small Hydroelectric Power Project Under 5 MW Capacity

December 29, 1981.

Take notice that on August 28, 1981, The Public Utilities Commission of the City and County of San Francisco, California (Applicant) filed an application under Section 408 of the Energy Security Act of 1980 (Act) (16 U.S.C. 2705 and 2708 *as amended,* for exemption of a proposed hydroelectric project from licensing under Part I of the Federal Power Act. The proposed small hydroelectric project (FERC Project No. 5295) would be located on Lower Moccasin Creek, Tuolumne County, California. Correspondence with the Applicant should be directed to: Mr. D. W. Coffey, 693 Vermont Street, San Francisco, California 94107.

Project Description—The proposed project would consist of: (1) a 2,500-foot long, 10-foot diameter penstock; (2) a powerhouse containing one generating unit with a rated capacity of 2,400 kW; and (3) a 300-foot long transmission line from the powerhouse to an existing transmission line. The Applicant estimates that the average annual energy production would be 10 million kWh.

Purpose of Exemption—An exemption, if issued, gives the Exemptee priority of control, development, and operation of the project under the terms of the exemption from licensing, and protects the Exemptee from permit or license applicants that would seek to take or develop the project.

Agency Comments—The U.S. Fish and Wildlife Service, The National Marine Fisheries Service, and the California Department of Fish and Game are requested, for the purposes set forth in Section 408 of the Act, to submit within 60 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 60 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Competing Applications.—Any qualified license applicant desiring to file a competing application must submit to the Commission on or before February 10, 1982 either the competing license application that proposes to develop at least 7.5 megawatts in that project, or notice of intent to file such a license application. Submission of a timely notice of intent allows an interested person to file the competing license application no later than 120 days from the date that comments, protests, etc. are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33(b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33 (a) and (d) (1980).

Comments, Protests, or Petitions To Intervene.—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of its Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before February 10, 1982.

Filing and Service of Responsive Documents.—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION," "COMPETING APPLICATION," "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB, 825 North Capitol Street, NE., Washington, D.C. 20426. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-84 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[GP82-12-000]

Natural Gas Well Category Determination; Railroad Commission of Texas

December 30, 1981.

In the matter of Railroad Commission of Texas; Section 102 and 103 NGPA Determination, R.L. Burns Corporation, Baker '1160' Well #2, RRC Docket No. F-7C-031892, FERC JD-81-32977; reopening and request for withdrawal of final well category determination.

On October 2, 1981, the Railroad Commission of Texas (Texas) filed with the Federal Energy Regulatory Commission (Commission) a letter advising the Commission that Texas had, on the basis of new information, reconsidered a final well category determination that the R.L. Burns

Corporation (Burns) Baker '1106' Well #2 qualified as a well producing from a new onshore reservior and as a new onshore production well pursuant to sections 102(c)(1)(C) and 103(c) of the Natural Gas Policy Act of 1978 (NGPA), 15 U.S.C. 3301–3432 (Supp. II 1978). That determination became final pursuant to § 275.202(a) of the Commission's regulations on July 12, 1981.

On May 22, 1981, Burns informed Texas that the subject well was not producing from the Cal(Canyon-Gas) field, a new onshore reservior, but rather from the Cal(Canyon) field, an oil reservoir that does not qualify as a new onshore reservoir. Burns requested withdrawal of the section 102(c)(1)(C) determination and asked that Texas continue the well's qualification, but only as a new onshore production well under section 103(c) of the NGPA.

Upon reconsideration of Burns' application, Texas concluded that the subject well qualifies under section 103 of the NGPA as a new onshore production well. The well was spudded on June 23, 1980, after the February 19, 1977 date set by section 103(c)(1). It satisfies the State well-spacing requirements as required by section 103(c)(2) and the proration unit requirements of section 103(c)(3). Texas amended its determination, withdrawing the section 102 determination and leaving the well qualified under section 103.

Because the well category determination has become final, the Commission must reopen the determination, pursuant to § 275.205(a) of the regulations, if "(1) in making the determination the Commission or the jurisdictional agency relied on any untrue statement of material fact; or (2) there was omitted a statement of material fact necessary in order to make the statements made not misleading, in light of the circumstances under which they were made. . . ."

With respect to the question of refunds arising out of this request for withdrawal the subject well category determination, notice is hereby given that the question of whether refunds, plus interest as computed under § 154.102(d) of the Commission's regulations, will be required is a matter subject to review and final determination of the Commission.

Any person desiring to be heard or to make any protest to the requested withdrawal should, by February 4, 1982, file with the Federal Energy Regulatory Commission, 825 North Capitol St., NE., Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of §§ 1.8 or 1.10 of the Rules of Practice and Procedure. All protests filed will be considered in determing the appropriate action to be taken, but will not make protestants' parties to the proceeding. Any person wishing to become a party must file a petition to intervene in accordance with the Commission's rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–48 Filed 1–4–82; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ID–1703–000]

Donald L. Rushford; Application

December 30, 1981.

The filing individual submits the following:

Take notice that on December 21, 1981, Donald L. Rushford filed an application pursuant to Section 305(b) of the Federal Power Act to hold the following positions:

Vice President and General Counsel Central Vermont Public Service Corporation
General Counsel, Connecuticut Valley Electric Company, Inc.
Vice President and General Counsel and Director, Central Vermont Public Service Corporation—Bradford Hydroelectric, Inc.
Vice President and General Counsel and Director, Central Vermont Public Service Corporation—East Barnet Hydroelectric, Inc.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 22, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–55 Filed 1–4–82; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER82–167–000]

San Diego Gas & Electric Co.; Filing

December 29, 1981.

The filing Company submits the following:

Take notice that San Diego Gas & Electric Company (SDG&E), on December 21, 1981, tendered for filing one Service Agreement under Volume 1 of its F.E.R.C. Electric Tariff under which SDG&E will sell and deliver nonfirm energy to any electric utility for resale in accordance with SDG&E's Service Schedule, SDG&E–1. SDG&E requests waiver of the Commission's notice requirements to allow for an effective date of July 1, 1981.

According to SDG&E copies of the filing were served on all parties to the Service Agreement, and the state Regulatory Commissions of California, New Mexico and Arizona.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 15, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–97 Filed 1–4–82; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ID–1668–000]

Robert E. Schill; Application

December 30, 1981.

The filing individual submits the following:

Take notice that on December 21, 1981, Robert E. Schill filed an application pursuant to Section 305(b) of the Federal Power Act to hold the following positions:

Vice President—Finance and Corporate Planning, Central Vermont Public Service Corporation.
Vice President, Connecticut Valley Electric Company, Inc.
Vice President and Director, Central Vermont Public Service Corporation—Bradford Hydroelectric, Inc.
Vice President and Director, Central Vermont Public Service Corporation—East Barnet Hydroelectric, Inc.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance

with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 22, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-57 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. QF81-8-001]

Sea World; Application for Commission Certification of Qualifying Status for a Modification to Qualifying Cogeneration Facility

December 30, 1981.

On November 13, 1981, Sea World (Applicant) of San Diego, California, filed with the Federal Energy Regulatory Commission (Commission) an application for certification of a modification to a qualifying cogeneration facility pursuant to § 292.207 of the Commission's rules. The original application filed by Sea World on December 18, 1980 under Docket No. QF81-8-000 requesting certification of qualifying status of a cogeneration facility, was granted in a Delegation Order issued on September 4, 1981.

The facility is being modified by the addition of a new natural gas fired, reciprocating engine with waste heat recovery equipment and absorption chillers and by the addition of an absorption chiller to the existing system. Electric capacity of the facility will increase from 1260 kilowatts to 1950 kilowatts and useful steam output will increase from 6.89 million Btu's/hour to 8.23 million Btu's/hour. Installation of the modification will begin in February 1982.

Any person desiring to be heard or objecting to the granting of qualifying status to the modified facility should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and procedure. All such petitions or protests must be filed by February 4, 1982 and must be served on the applicant. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-56 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP82-101-000]

Southern Natural Gas Co.; Application

December 30, 1981.

Take notice that on December 2, 1981, Southern Natural Gas Company (Applicant) P.O. Box 2563, Birmingham, Alabama 35202, filed in Docket No. CP82-101-000 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 for Peoples Natural Gas Company, Division of InterNorth, Inc. (Peoples), and the construction and operation of facilities necessary therefor, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Pursuant to a transportation agreement dated November 23, 1981, Applicant proposes to transport up to 50 billion Btu of natural gas per day or such greater quantity as Applicant may accept from time to time on an interruptible basis for Peoples. It is stated that Peoples would purchase the gas from Northern Natural Gas Company, Division on InterNorth, Inc. (Northern) for reasale to Allied Chemical, operating company of Allied Corporation (Allied), at Allied's plant near Geismar, Louisiana. It is asserted that Northern would deliver certain volumes of gas to Applicant at the interconnection of the jointly-owned pipeline that extends from the producer's platform in Mississippi Canyon Block 194 and Applicant's 14-inch Romere Pass pipeline, Plaquemines Parish, Louisiana (Romere Pass Point). It is further anticipated that Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee) would transport on behalf of Northern additional volumes of gas to Applicant which would be received by Applicant at the interconnection between the pipeline facilities of Applicant and Tennessee in Lowndes County, Mississippi (Pugh Point), and at the interconnection between the jointly-owned facilities of Applicant and Tennessee and the facilities of Tennessee in Clarke County, Mississippi (Rose Hill Point).

Applicant states that it would transport People's gas from these delivery points to a redelivery point at the proposed interconnection of a fuel line to be contructed from Allied's Geismar plant and Applicant's Duck Lake-Franklinton Line in Iberville Parish, Louisiana. Applicant proposes the construction and operation of a new pipeline tap, meter station, and appurtenant facilities to be installed as the interconnecting facilities at the proposed redeliviery point. Such facilities are estimated to cost $54,400 which would be reimbursed by Peoples.

Peoples, it is stated, would compensate Applicant for the proposed service at 24.0 cents per million Btu for all gas received at the Romere Pass Point and 12.0 cents per million Btu for all gas received at the Pugh Point and the Rose Hill Point. Applicant would retain 1.0 percent of the quantity of gas received at the Romere Pass Point for company use and lost or unaccounted for gas.

It is stated that the proposed transportation service would be beneficial in that it would provide Peoples with a means of delivering gas to Allied without having to construct additional duplicative facilities.

Any person desiring to be heard or to make any protest with reference to said application should on or before January 18, 1982, file with the Federal Energy Regulatory 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 jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no 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. 82-58 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP82-116-000]

Southwest Gas Corp.; Application

December 29, 1981.

Take notice that on December 14, 1981, Southwest Gas Corporation (Applicant), P.O. Box 15015, Las Vegas, Nevada 89114, filed in Docket No. CP82-116-000 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 four new tap facilities, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant proposes to construct and operate the Robison tap and the Wilder tap on its Elko Lateral and the Moore tap and Sauer tap on its Gabbs Lateral in order to deliver gas to residential customers in Humboldt and Churchill Counties, Nevada. Applicant states that the annual usage for the Robison and Wilder taps would be 99 Mcf and 88 Mcf for the Moore tap and 389 Mcf for the Sauer tap. Sales of gas would be made pursuant to Applicant's existing authorization from the Public Service Commission of Nevada, it is asserted.

It is stated that the cost of the Elko Lateral facilities would be aproximately $900 each and the cost of the Gabbs Lateral facilities would be approximately $1,640 each. Such cost, it is asserted, would be financed by an advance made to Applicant by the customers.

Any person desiring to be heard or to make any protest with reference to said application should on or before January 21, 1982, file with the Federal Energy Regulatory 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 jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, an hearing will be held without further notice before the Commission or its designee 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. 82-77 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. Project No. 5219-000]

Spring River Power Developers and the City of Searcy, Arkansas; Application for Preliminary Permit

December 29, 1981.

Take notice that Spring River Power Developers and the City of Searcy, Arkansas (Applicants) filed on August 11, 1981, an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a)-825(r) for Project No. 5219 to be known as the Dam No. 3 Project located on the Spring River near Mammoth Spring in Fulton County, Arkansas. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicants should be directed to: Mr. Glenn N. Sink, P.O. Box 1052, Searcy, Arkansas 72143.

Project Description.—The proposed project would consist of: (1) an existing concrete dam owned by the Arkansas Power & Light Company, 150 feet long and 30 feet high; (2) an impoundment with a storage of approximately 350 acre-feet at an elevation of 240 msl; (3) new trash racks and inlet works; (4) an rehabilitated wood frame powerhouse, 20 by 30 feet, containing two turbine/generating units with a total capacity of 350 kW; (5) a rehabilitated switchyard at the east end of the dam; and (6) an existing 33-kV transmission line 200 yards long. The average annual generation of 1.5 million kWh would probably be sold to the Arkansas-Missouri Power Corporation.

Proposed Scope of Studies Under Permit.—A preliminary permit, if issued, does not authorize construction. Applicants seek issuance of a preliminary permit for a period of three years, during which time it would perform surveys and geological investigations, determine the economic feasiblility of the project, reach final agreement on sale of project power, secure financing commitments, consult with Federal, State, and local government agencies concerning the potential environmental effects of the project, and prepare an application for FERC license, including an environmental report. Applicants estimate the cost of the studies under the permit would be $19,000.

Competing Applications.—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before April 5, 1982, the competing application itself, or a notice of intent to file such an application [see: 18 CFR 4.30 et seq. (1981)].

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before March 5, 1982, and should specify the type of application forthcoming. Any application for license or exemption from licensing must be filed in accordance with the Commission's regulations [see: 18 CFR 4.30 et seq. or 4.101 et seq. (1981), as appropriate].

Submission of a timely notice of intent to file an application for preliminary permit, allows an interested person to file an acceptable competing application for preliminary permit no later than May 5, 1982.

Agency Comments.—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene.—Anyone may submit

comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 5, 1982.

Filing and Service of Responsive Documents.—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-98 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 4283-001]

Fred N. Sutter, Jr.; Application for Exemption for Small Hydroelectric Power Project Under 5 MW Capacity

December 30, 1981.

Take notice that on November 2, 1981, Fred N. Sutter, Jr., (Applicant) filed an application under section 408 of the Energy Security Act of 1980 (Act) (16 U.S.C. 2705 and 2708 as amended), for exemption of a proposed hydroelectric project from licensing under Part I of the Federal Power Act. The proposed small hydroelectric project (FERC Project No. 4283-001 would be located on Millseat Creek near Shingletown in Shasta County, California. Correspondence with the Applicant should be directed to: Mr. Fred N. Sutter, Jr., P.O. Box 137, Shingletown, California 96088.

Project Description.—The proposed project would consist of:

(1) A 4-foot high, 30-foot long rock fill diversion structure;

(2) A 2,000-foot long, 30-inch diameter steel penstock;

(3) A powerhouse with a total installed capacity of 100 kW; and

(4) A 300-foot long, 12.5-kv transmission line interconnecting with an existing Pacific Gas and Electric Company transmission line.

The Applicant estimates that average annual production would be 0.722 million kWh.

Purpose of Exemption.—An exemption, if issued, gives the Exemptee priority of control, development, and operation of the project under the terms of the exemption from licensing, and protects the Exemptee from permit or license applicants that would seek to take or develop the project.

Agency Comments.—The U.S. Fish and Wildlife Service, The National Marine Fisheries Service, and the California Department of Fish and Game are requested, for the purposes set forth in Section 408 of the Act, to submit within 60 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies that receive this notice through direct mailing from the Commission are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 60 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Competing Applications.—Any qualified license applicant desiring to file a competing application must submit to the Commission, on or before February 11, 1982 either the competing application that proposes to develop at least 7.5 megawatts in that projects, or a notice of intent to file such a license application no later than 120 days from the date that comments, protests, etc. are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33 (b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33 (a) and (d) (1980).

Comments, Protests, or Petitions To Intervene.—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests or petitions to intervene must be received on or before February 11, 1982.

Filing and Service of Responsive Documents.—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-78 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5677-000]

Swanson Mining Corp. and Walter M. Gleason; Application for Exemption for Small Hydroelectric Power Project Under 5 MW Capacity

January 4, 1982.

Take notice that on November 24, 1981, Swanson Mining Corporation and Walter M. Gleason (Applicant) filed an application, under Section 408 of the Energy Security Act of 1980 (Act) (16 U.S.C. 2705, and 2708 *as amended*), for exemption of a proposed hydroelectric

project from licensing under Part I of the Federal Power Act. The proposed small hydroelectric project, Project No. 5677 would be located on Madden Creek, near Willow Creek, in Humboldt County, California. Correspondence with the Applicant should be directed to: Walter M. Gleason, Hearst Building, Suite 1200, Third and Market Streets, San Francisco, California 94103.

Project Description.—The proposed project would consist of: (1) An existing 7-foot high, 32-foot long concrete and steel diversion dam; (2) a short 42-inch diameter pipe; (3) an existing 1,065-foot long earthen canal; (4) an 800-foot long steel syphon; (5) an existing 7,200-foot long canal; (6) a 5,400-foot long penstock; (7) a powerhouse containing one generating unit rated at 2,000 kW; and (8) a 1,000-foot long transmission line. The average annual energy generation is 7.9 million kWh.

Purpose of Exemption.—An exemption, if issued, gives the Exemptee priority of control, development, and operation of the project under the terms of the exemption from licensing, and protects the exemptee from permit or license applicants that would seek to take or develop the project.

Purpose of Project.—The power output from the project would be sold to the Pacific Gas and Electric Company.

Agency Comments.—The U.S. Fish and Wildlife Service, The National Marine Fisheries Service, and the California Department of Fish and Game are requested, for the purposes set forth in Section 408 of the Act, to submit within 60 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to a granting of an exemption. If an agency does not file comments within 60 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Competing Applications.—Any qualified license applicant desiring to file a competing application must submit to the Commission, on or before February 19, 1982 either the competing license application that proposes to develop at least 7.5 megawatts in that project, or a notice of intent to file such a license application. Submission of a timely notice of intent allows an interested person to file the competing license application no later than 120 days from the date that comments, protests, etc. are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33 (b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33 (a) and (d) (1980).

Comments, Protests, or Petitions To Intervene.—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before February 19, 1982.

Filing and Service of Responsive Documents.—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-168 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP80-65-009]

Tennessee Gas Pipeline Co.; Petition To Amend

December 30, 1981.

Take notice that on December 3, 1981, Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Petitioner), P.O. Box 2511, Houston, Texas 77001, filed in Docket No. CP80-65-009 a petition to amend Opinion No. 121 and Order Approving Settlement Agreement issued in said docket on May 20, 1981, so as to authorize the construction and operation of approximately 660 feet of 10¾-inch pipeline, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

It is stated that by Opinion No. 121, the Commission authorized, *inter alia*, the firm transportation of storage gas on behalf of a number of Petitioner's customers including Orange and Rockland Utilities, Inc. (Orange and Rockland) in connection with a storage service to be rendered for Orange and Rockland, among others, by Penn-York Energy Corporation and for the construction and operation of facilities by Petitioner in connection with such transportation. The receipt and delivery points for the gas to be received and delivered by petitioner for Orange and Rockland are to be at the present point of interconnection between the facilities of Petitioner and Orange and Rockland at the Pearl River sales meter station, it is stated. It is submitted that such deliveries are to be made to Orange and Rockland through the existing 6-inch Orange and Rockland delivery line No. 329B-100 located in Bergen County, New Jersey, and Rockland County, New York.

Petitioner has recently determined that the existing 6-inch Orange and Rockland delivery line would not enable the delivery of the transportation volumes to Orange and Rockland at the required pressure. Petitioner, therefore, proposes to replace the existing 6-inch pipeline with approximately 660 feet of 10¾-inch pipeline. The estimated cost of such replacement is $125,500 which would be reimbursed by Orange and Rockland.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before January 18, 1982, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with

the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-59 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP82-12-000]

Tennessee Gas Pipeline Co.; Order Accepting for Filing and Suspending Tariff Sheets Subject to Refund and Conditions, Rejecting Tariff Sheets, Consolidating Proceedings, Initiating Hearing and Establishing Procedures

December 30, 1981.

On November 30, 1981, Tennessee Gas Pipeline Company, a Division of Tenneco, Inc. (Tennessee) tendered for filing pursuant to Section 4 of the Natural Gas Act proposed changes in its FERC Gas Tariff, Original Volume Nos. 1 and 2[1] to become effective January 1, 1982. The proposed tariff sheets reflect a general rate increase which would increase revenues from jurisdictional sales and service by approximately $122.3 million annually. The proposed tariff sheets also include a Transportation Cost Rate Adjustment which would allow Tennessee to track increases and decreases in costs paid for transmission and compression of gas by others.

Tennessee states that the principal reasons for the proposed rate changes are: (1) An increase in the overall rate of return to 15.72%, plus an additional allowance of 1% to reflect the further risk which Tennessee experiences in a period of ever increasing costs; (2) a major increase in gas plant of approximately $249 million and related expenses; (3) an increase in the cost of materials, supplies, wages, and services required to operate and maintain Tennessee's pipeline; (4) a substantial increase in prepayments to Tennessee's producer-suppliers; and (5) a significant increase in the cost of transportation and storage of gas by others.

The cost of service underlying the rates filed herein reflects costs associated with certain facilities that have not been certificated. The rates also reflect Tennessee's adoption of a dekatherm billing basis and a three part rate for its jurisdictional sales as set forth in its filings of April 30, 1981, in Docket Nos. RP81-56 and RP81-54.

Tennessee requests waiver of § 154.38(d)(3) of the Commission's Regulations to accept for filing First Revised Sheet No. 225 and Original Sheet No. 226 reflecting the Transportation Cost Rate Adjustment provision. The Commission rejected Tennessee's last request for such a provision by order issued May 29, 1981, in Docket No. RP81-54, 15 FERC ¶61,194. that rejection is still pending before the Commission on rehearing, and the issues raised in connection with that rejection will be addressed in the Commission's order on rehearing in that docket. Accordingly, First Revised Sheet No. 225 and Original Sheet No. 226 shall be rejected for the same reasons stated in the order issued in Docket No. RP81-54, *et al.* The rejection is without prejudice to the proposal contained in such tariff sheets being considered as an issue in this proceeding and without prejudice to such tariff sheets being retendered should such approval be granted on rehearing in Docket No. RP81-54, *et al.*

Notice of Tennessee's filing was issued on December 8, 1981, with petitions to intervene due by December 17, 1981. Petitions to intervene were filed by the petitioners listed in Appendix B. The Commission finds that all petitioners have demonstrated an interest in this proceeding warranting their participation. Accordingly, their petitions will be granted.

A late petition to intervene was filed by Equitable Gas Company (Equitable) on December 23, 1981. Equitable states that notice of said tariff filing was published in the Federal Register of December 14, 1981, and was not received by Equitable in its Pittsburgh office until December 18, 1981. Equitable states further that the Commission's notice requires that petitions or protests be filed by December 17, 1981. Equitable submits that the time allowed for filing petitions to intervene is unreasonably short. For good cause shown, we shall grant Equitable's late petition to intervene.

Based upon a review of Tennessee's filing, the Commission finds that the proposed rate increase and tariff modifications have not been shown to be just and reasonable and may be unjust, unreasonable and unduly discriminatory or otherwise unlawful. Accordingly, the Commission shall accept for filing Tennessee's revised tariff sheets as listed in Appendix A, with the exception of those tariff sheets expressly rejected, and suspend their effectiveness for five months until June 1, 1982, when they shall be permitted to become effective subject to refund and to the conditions set forth below.

In a number of suspension orders, the Commission has addressed the considerations underlying the Commission's policy regarding rate suspensions.[2] For the reasons given there, we conclude that rate filings should generally be suspended for the maximum period permitted by statute where preliminary study leads the Commission to believe that the filing may be unjust and unreasonable or in violation of other statutory standards. We have acknowledged, however, that shorter suspension may be warranted in circumstances where suspension for the maximum period may lead to harsh and inequitable results. No such circumstances have been presented here.

Tennessee's cost of service includes certain facilities which have not been certificated and placed in service. The Commission normally accepts proposed rates that reflect the costs of facilities not placed in service conditioned upon the filing of revised tariff sheets to reflect elimination of such facilities before the proposed rates go into effect. In this respect, Tennessee should be permitted to include these items conditioned upon the filing of revised tariff sheets reflecting the elimination of costs associated with any facilities not in service on or before June 1, 1982. Also, this waiver will be granted upon the condition that Tennessee shall not be permitted to make offsetting adjustments other than those made pursuant to Commission approved tracking provisions, those adjustments required by this order, and those required by other Commission orders. Acceptance of Tennessee's filed tariff sheets is further conditioned upon Tennessee's filing revised tariff sheets and supporting data at the end of the test period to reflect the actual balance of advance payments in Account 166 as of September 30, 1981. The inclusion of a higher advance payment balance, however, will not be permitted to increase this level of the original suspended rates.

For purposes of this filing, Tennessee has used the *Atlantic Seaboard* method[3] of cost classification, cost allocation and rate design in determining rates. The Commission has been placing companies on notice that the use of the *Atlantic Seaboard* method

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[1] A list of proposed tariff sheets is set forth in Appendix A to this order.

[2] *E.g., Valley Gas Transmission, Inc.*, Docket No. RP80-98 (August 22, 1980) (one day suspension); *Great Lakes Gas Transmission Company*, Docket No. RP80-134 (September 24, 1980) (five month suspension).

[3] *Atlantic Seaboard Corporation*, 11 FPC 43 (1952).

may be inadequate and contrary to the public interest.[4] Consequently, Tennessee should be placed on notice that to the extent that the rates found just and reasonable for Tennessee after hearing and decision departs from the *Atlantic Seaboard* methodology by assigning additional fixed costs to the commodity component of its rates, Tennessee may be subject to undercollections.

Tennessee's proposed rate increase filed in Docket Nos. RP81–54 is still pending. In view of the commonality of issues, Docket Nos. RP82–12 and RP81–54, *et al.*, shall be consolidated for purposes of hearing and decision.

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 the revised rates proposed by Tennessee in Docket No. RP82–12.

(B) Tennessee's tendered First Revised Sheet No. 225 and Original Sheet No. 226 to its FERC Gas Tariff, Original Volume No. 1 in Docket No. RP82–12 comprising its Transportation Cost Rate Adjustment provision is rejected without prejudice to the proposal contained therein being considered as an issue in this proceeding and without prejudice to the tariff sheets being retendered should such approval be granted on rehearing in Docket No. RP81–54.

(C) Pending hearing and decision, and subject to the conditions of the ordering paragraph below and those described in the body of this order, Tennessee's tendered tariff sheets listed in Appendix A, and not rejected above, shall be accepted for filing and suspended for the full statutory period of five months until June 1, 1982, when they shall be permitted to become effective, subject to refund.

(D) Tennessee shall file on or before June 1, 1982, revised tariff sheets to reflect:

(1) Elimination of costs associated with facilities not in service on or before June 1, 1982, *Provided, however,* Tennessee shall not be permitted to make offsetting adjustments other than those made pursuant to Commission approved tracking provisions, those adjustments required by this order, and those required by other Commission orders.

(2) The actual balance of advance payments in Account No. 166 as of June 1, 1982, *Provided, however,* that the inclusion of a higher advance payment balance will not be permitted to increase the level of the original suspended rates.

(E) Docket Nos. RP81–54, *et al.*, is consolidated for purposes of hearing and decision.

(F) Staff shall be required to serve top sheets on or before April 7, 1982.

(G) A Presiding Administrative Law Judge to be designated by the Chief Administrative Law Judge for that purpose (18 CFR 3.5(d)), shall convene a prehearing conference in this proceeding to be held within ten days after the service of top sheets in a hearing room of the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426. The Presiding Administrative Law Judge is authorized to establish such further procedural dates as may be necessary and to conduct further proceedings in accordance with this order and the Rules of Practice and Procedure.

(H) The petitioners identified in Appendix B to this order are permitted to intervene in this proceeding subject to the rules and regulations of the Commission; *Provided, however,* that the participation of the intervenors shall be limited to matters affecting asserted rights and interests set forth in their petition to intervene and *Provided, further,* that the admission of such intervenors shall not be construed as recognition that they might be aggrieved by any order entered in this proceeding.

By the Commission.

Kenneth F. Plumb,

Secretary.

Appendix A—Tennessee Gas Pipeline Company, Docket No. RP82–12–000

Original Volume No. 1

First Revised Sheet No. 226
Second Revised Sheet No. 225
Substitute Third Revised Sheet No. 21
Substitute Fourth Revised Sheets Nos. 20 and 22
A Sheet Reserving Original Sheet Nos. 227 through 325 for Future Use

Original Volume 2

First Revised Sheet Nos. 299QQ4, 299QQ5, and 299RR5; Second Revised Sheet Nos. 267L, 277B, 286E, 297D, 297E, 299V6, 299W5, 299X6, 299EE6, 286E, 299FF5, 299GG7, 299MM5, 299NN4, 299OO5, and 322D; Third Revised Nos. 266J, 267K, 268C, 287E, 288D, 289E, 290E, 291E, 292E, 299L9, 299M6, 299N5, 299Q5, 299R5, 299S9, and 299S10; Fourth Revised Nos. Nos. 266I, and 274E; Sixth Revised Sheet No. 141A; Seventh Revised 249H, and 249I; Eighth Revised Sheet No. 245D; Ninth Revised Sheet Nos. 76, and 215; Tenth Revised Sheet Nos. 53, 54, and 77; Eleventh Revised Sheet No. 141; Thirteenth Revised Sheet Nos. 11, and 12.

Appendix B—List of Intervenors

Alabama-Tennessee Natural Gas Company
Brooklyn Union Gas Company
The Cities of Springfield, Clarksville & Portland, Tennessee
Columbia Gas Transmission Corporation
Consolidated Edison Company of New York, Inc.
Consolidated Gas Supply Corporation
Elizabethtown Gas Company
Equitable Gas Company (Late petition granted for good cause shown)
National Fuel Gas Supply Corporation
The New England Customer Group
New York State Electric & Gas Corporation
Niagara Mohawk Power Corporation
Northern Illinois Gas Company
Orange & Rockland Utilities Company
The Public Service Commission of the State of New York
Public Service Electric & Gas Company
Texaco, Inc.
Texas Gas Transmission Corporation
Western Kentucky Gas Company

[FR Doc. 82–169 Filed 1–4–82; 8:45 am]
BILLING CODE 6717–01–M

[4] *See, Natural Gas Pipeline Company of America,* order issued April 30, 1981, in Docket No. RP81–49–000, 15 FERC ¶ 61,112.

[Docket No. ER82–172–000]

Union Electric Co.; Filing

December 30, 1981.

The filing Company submits the following:

Take notice that on December 21, 1981, Union Electric Company (Union) tendered for filing a Fifth Amendment and Fourth Revised Service Schedules C and D to the Interchange Agreement dated July 2, 1976 between Union and Kentucky Utilities Company.

Union indicates that said agreements provide for revisions in certain rates under said Interchange Agreement.

Union proposes an effective date of January 1, 1982, and therefore requests waiver of the Commission's notice requirements.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 18, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file

with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-68 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-166-000]

Union Electric Co.; Filing

December 29, 1981.

The filing Company submits the following:

Take notice that on December 21, 1981, Union Electric Company (Union) tendered for filing a Boundary Line Agreement dated October 19, 1981, between the City of Farmington, Missouri and Union. Said Agreement provides a basis for supplying electric service to customers in one service area more economically by line extension made across the boundary lines from the adjacent utility.

Union requests an effective date of January 1, 1982, and therefore requests waiver of the Commission's notice requirements.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 15, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-99 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-165-000]

Union Electric Co.; Filing

December 29, 1981.

The filing Company submits the following:

Take notice that on December 21, 1981, Union Electric Company (Union) tendered for filing a Boundary Line Agreement dated October 26, 1981, between the Missouri Power & Light Company and Union. Said Agreement provides basis for supplying electric service to customers in one service area more economically by line extension made across the boundary lines from the adjacent utility.

Union proposes an effective date of January 1, 1982, and therefore requests waiver of the Commission's notice requirements.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 15, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-100 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER82-164-000]

Union Electric Co.; Filing

December 29, 1981.

The filing Company submits the following:

Take notice that on December 18, 1981 Union Electric Company (UE) tendered for filing First Revised Schedules G and H to the Interchange Agreement dated September 22, 1971 between UE, Associated Electric Cooperative, Inc., Kansas Gas & Electric Company, and Public Service Company of Oklahoma.

Said agreements provide for revisions in reservation charges for Short-term Firm Power and System Participation Power under said Interchange Agreement.

UE requests an effective date of February 1, 1982 for the revised Schedules.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 15, 1982. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-101 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP82-111-000]

United Gas Pipe Line Co.; Application

December 29, 1981.

Take notice that on December 10, 1981, United Gas Pipe Line Company (Applicant), P.O. Box 1478, Houston, Texas 77001, filed in Docket No. CP82-111-000 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 to serve, through Entex, Inc. (Entex), the Foster-Goldsby Estate, a right-of-way grantor located in Lafayette Parish, Louisiana, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant proposes herein to construct and operate a farm tap on its 10-inch Iowa-Franklin line in Lafayette Parish, Louisiana, in order to provide service to the Foster-Goldsby Estate. The proposed farm tap is estimated to cost $1,226 to be financed from funds on hand. It is stated that Entex would provide service to this right-of-way grantor from its existing allocation purchased from Applicant under Applicant's Rate Schedule DG-S.

Any person desiring to be heard or to make any protest with reference to said application should on or before January 21, 1928, file with the Federal Energy Regulatory 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 continued in and subject to jurisidiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act

and the Commission's Rules and Practice and Procedure, a hearing will be held without further notice before the Commission or its designee 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 uncessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-79 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5077-001]

Roberta B. Weil; Application for Exemption for Small Hydroelectric Power Project Under 5 MW Capacity.

December 29, 1981.

Take notice that on July 21, 1981, Roberta B. Weil (Applicant) filed an application under Section 408 of the Energy Security Act of 1980 (Act) (16 U.S.C. §§ 2705 and 2708 *as amended,* for exemption of a proposed hydroelectric project from licensing under Part I of the Federal Power Act. The proposed small hydroelectric project (Project No. 5077) would be located on the Quinebaug River in the Town of Brooklyn, Windham County, Connecticut. Correspondence with the Applicant should be directed to: Ms. Roberta B. Weil, 2462 Arizona Avenue, Apartment #1, Santa Monica, California 90404.

Project Description—The proposed project would consist of: (1) An existing dam, 14 feet high and 250 feet long; (2) existing intake works comprising low level outlets and wooden slide gates with trashracks and a log boom to be added; (3) a small impoundment of negligible storage; (4) a new, 100-foot long steel penstock from the existing canal to the new powerhouse; (5) the new powerhouse, 30 by 70 feet, with one 2000-kV and possibly another 500-kW unit; (6) a new, 600-foot long tailrace; (7) a new transmission line one mile long; and (8) appurtenant facilities. The 8 million kWh of electrical energy generated would be sold to the Connecticut Light and Power Company.

Purpose of Exemption—An exemption, if issued, gives the Exemptee priority of control, development, and operation of the project under the terms of the exemption from licensing, and protects the Exemptee from permit or license applicants that would seek to take or develop the project.

Agency Comments—The U.S. Fish and Wildlife Service, The National Marine Fisheries Service, and the Connecticut Fish and Waterlife Unit are requested, for the purposes set forth in Section 408 of the Act, to submit within 60 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 60 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Competing Applications—Any qualified license applicant desiring to file a competing application must submit to the Commission, on or before March 8, 1982 either the competing license application that proposees to develop at least 7.5 megawatts in that project, or notice of intent to file such a license application. Submission of a timely notice of intent allows an interested person to file the competing license application no later than 120 days from the date that comments, protests, etc. are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33 (b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33(a) and (d) (1980).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before February 8, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB, 825 North Capitol Street NE., Washington, D.C. 20426. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-85 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5243-000]

Western Hydro Electric Inc.; Application for (Minor) License

December 29, 1981.

Take notice that Western Hydro Incorporated (Applicant) filed on August 18, 1981, an appplication for license [pursuant to the Federal Power Act, 16 U.S.C. 791(a)-825(r)] for construction and operation of a water power project to be known as the Lost Creek Hydro Project No. 5243. The project would be located on Lost Creek, Weber River, in Morgan County, Utah. Correspondence with the Applicant should be directed to: Mr. J. Kirk Rector, Attorney at Law, 4832 Colony Circle, Salt Lake City, Utah 84117.

Project Description—The proposed project would utilize the existing Bureau of Reclamation's Lost Creek Dam and Reservoir, operated and maintained by the Weber Basin Water Conservancy District, and would consist of: (1) A new 36-inch diameter siphon penstock, approximately 750 feet long, leading to (2) a new powerhouse, near the right

dam abutment outlet works, containing two generating units having a rated capacity of 200 kW and 450 kW, respectively, for a total rated capacity of 650 kW; (3) a tailrace; (4) a new transmission line, approximately 600 feet long, connecting to an existing 46-kV transmission line; (5) a switchyard; and (6) appurtenant facilities. The Applicant estimates that the average annual energy output would be 2,771,496 kWh.

Purpose of Project—Project energy would be sold to the Utah Power and Light Company.

Agency Comments—Federal, State, and local agencies that receive this notice through direct mailing from the Commission are requested to provide comments pursuant to the Federal Power Act, the Fish and Wildlife Coordination Act, the Endangered Species Act, the National Historic Preservation Act, the Historical and Archeological Preservation Act, the National Environmental Policy Act, Pub. L. No. 88-29, and other applicable statutes. No other formal requests for comments will be made.

Comments should be confined to substantive issues relevant to the issuance of a license. A copy of the application may be obtained directly from the Applicant. If an agency does not file comments within the time set below, it will be presumed to have no comments.

Competing Applications—Anyone desiring to file a competing application must submit to the Commission, on or before February 16, 1982, either the competing application itself [See 18 CFR 4.33 (a) and (d)] or a notice of intent [See 18 CFR 4.33 (b) and (c)] to file a competing application. Submission of a timely notice of intent allows an interested person to file an acceptable competing application no later than the time specified in § 4.33(c) or § 4.101 et seq. (1981).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before February 16, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or 'PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-86 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5605-000]

Woodbridge Irrigation District; Application for Preliminary Permit

December 30, 1981.

Take notice that Woodbridge Irrigation District (Applicant) filed on November 4, 1981, an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a)—825(r)] for Project No. 5605 to be known as the Woodbridge Hydroelectric Project located on the Mokelumne River in San Joaquin County, California. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. James C. Hanson, 921 Eleventh Street, Suite 400, Sacramento, California 95814.

Project Description—The proposed project would consist of: (1) The existing 25-foot high Woodbridge Diversion Dam and 475-acre Lodi Lake; (2) a powerhouse at the dam containing 2 to 4 generating units with a total rated capacity of 600 kW; (3) a switchyard adjacent to the powerhouse; and (4) a 560-foot long, 12-kV transmission line. The project would have an average annual energy output of 2 million kWh.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant has requested a 36-month permit to prepare a definitive project report, including geological, environmental and economic feasibility studies. The cost of the above activities, along with preparation of an environmental impact report, obtaining agreements with Federal, State and local agencies, conducting final field surveys, and preparing designs and a license application is estimated by the Applicant to be between $30,000 and $45,000.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before March 1, 1982, the competing application itself (see: 18 CFR 4.30 et. seq. (1981)). A notice of intent to file a competing application for preliminary permit will not be accepted for filing.

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before April 30, 1981, and should specify the type of application forthcoming. Applications for licensing or exemption from licensing must be filed in accordance with the Commission's regulations (see: 18 CFR 4.30 et. seq. or 4.101 et seq. (1981), as appropriate.

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 1, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documetns must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb,

Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-80 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

JD NO	JA DET	JDI NO	D SEC CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
TEXAS RAILROAD COMMISSION							
-ADDISON ENERGY INC				RECEIVED: 11/30/81 JA: TX			
8208499	F-78-042456	4204932319	102-4	BRANDT TRUMAN F #3	(WEENEDA)	37.0	ODESSA NATURAL CO
-AMERICAN QUASAR PETROLEUM CO				RECEIVED: 11/30/81 JA: TX			
8208428	F-8A-039809	4244530934	103	BEVERS 1-U	BROWNFIELD S (FUSSELMAN)	0.0	
-AMOCO PRODUCTION CO				RECEIVED: 11/30/81 JA: TX			
8208477	F-08-041857	4200332623	103	BLOCK 9 FUHRMAN MASCHO UNIT #132	FUHRMAN-MASCHO	11.3	PHILLIPS PETROLEU
8208447	F-10-040471	4239330799	103	LIPS RANCH A #12	LIPS-MISSISSIPPIAN	966.0	NATURAL GAS PIPEL
-ARCO OIL AND GAS COMPANY				RECEIVED: 11/30/81 JA: TX			
8208435	F-10-039992	4229530812	102-4	BECHTOLD #1	BECHTOLD (SQUAWBELLY)	73.0	PHILLIPS PETROLEU
8208524	F-08-042640	4237133397	103	CORDZ #1	PAYTON (YATES)	29.9	PERRY GAS PROCESS
8208530	F-08-042646	4237133389	103	CORTZ #2	PAYTON (YATES)	32.1	PERRY GAS PROCESS
8208529	F-08-042645	4237133441	103	CORTZ #3	PAYTON (YATES)	45.3	PERRY GAS PROCESS
8208528	F-08-042644	4237133436	103	CORTZ #4	PAYTON (YATES)	0.7	PERRY GAS PROCESS
8208527	F-08-042643	4237133460	103	CORTZ #5	PAYTON (YATES)	21.5	PERRY GAS PROCESS
8208526	F-08-042642	4237133459	103	CORTZ #6	PAYTON (YATES)	0.7	PERRY GAS PROCESS
8208531	F-7C-042652	4223531790	103	KETCHUM MOUNTAIN (CLFK) UNIT 54-4	KETCHUM MT (CLEARFORK)	14.4	J L DAVIS
8208444	F-10-040350	4217900000	108	WORLEY-REYNOLDS #6	PANHANDLE GRAY COUNTY	9.1	PHILLIPS PETROLEU
-CA-TEX PETROLEUM INC				RECEIVED: 11/30/81 JA: TX			
8208479	F-09-041935	4200935369	102-2	C K GARVEY H #2	ARCHER COUNTY REGULAR	0.0	MID STATES GAS CO
-CANYON CO				RECEIVED: 11/30/81 JA: TX			
8208537	F-7C-042669	4210533528	103	SUE HOOVER EST #2-2	AMERICAN (SPRABERRY B)	60.0	EL PASO NATURAL G
-CARTER EXPLORATION CO				RECEIVED: 11/30/81 JA: TX			
8208434	F-02-039959	4246900000	102-4	E J SPIEGELHAUER #1	VICTORIA NE (2400)	400.0	DELHI GAS PIPELIN
-CHAMPLIN EXPLORATION INC				RECEIVED: 11/30/81 JA: TX			
8208517	F-03-042617	4205131304	103	A M BARNETT #1 (RRC#14183)	GIDDINGS (AUSTIN CHALK-3	120.0	CLAJON GAS CO
-CHAMPLIN PETROLEUM COMPANY				RECEIVED: 11/30/81 JA: TX			
8208385	F-03-034547	4205100000	102-2	W F NOWAK #1	GIDDINGS	0.0	FERGUSON CROSSING
8208385	F-03-034547	4205100000	103	W F NOWAK #1	GIDDINGS	0.0	FERGUSON CROSSING
-CLAYTON W WILLIAMS JR				RECEIVED: 11/30/81 JA: TX			
8208419	F-03-038735	4205100000	102-2	BENTON-KAZMIR UNIT #1	GIDDINGS	0.0	VALERO TRANSMISSI
8208445	F-03-040372	4205100000	102-2	BENTON-KAZMIR UNIT #2	GIDDINGS (AUSTIN CHALK 3	0.0	VALERO TRANSMISSI
8208437	F-03-040013	4205100000	102-2	JOHN POLANSKY #1	GIDDINGS (AUSTIN CHALK-3	0.0	VALERO TRANSMISSI
-CONOCO INC				RECEIVED: 11/30/81 JA: TX			
8208470	F-09-041721	4221531096	107-TF	A A MCALLEN #68	MCALLEN RANCH (VICKSBURG	200.0	VALERO INTERSTATE
8208509	F-7B-042544	4243330919	103	I S MCMILLIN-A-#3 ID #15152	FRANKIRK (ELLENBURGER)	71.9	CITIES SERVICE CO
8208496	F-04-042421	4213100000	108	ROBERT DRISCOLL #363	CONOCO-DRISCOLL (COLE M)	2.5	TRANSCONTINENTAL
8208497	F-04-042422	4213100000	108	ROBERT DRISCOLL #383	CONOCO-DRISCOLL (DRISCOL	0.3	TRANSCONTINENTAL
-CPC EXPLORATION INC				RECEIVED: 11/30/81 JA: TX			
8208539	F-03-042689	4214930577	102-2	L PETERS UNIT LEASE #13580	GIDDINGS (BUDA)	100.0	PHILLIPS PETROLEU
-CRB OIL & GAS INC				RECEIVED: 11/30/81 JA: TX			
8208399	F-03-035525	4205131171	102-2	MALDONADO #1	GIDDINGS (AUSTIN CHALK)	45.0	CLAJON GAS CO

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME
8208387	F-03-034935	4214933925			102-2	MUENSTER UNIT #1
						RECEIVED: 11/30/81 JA: TX
-CROWN CENTRAL PETROLEUM CORP						
8208453	F-01-041079	4217730637			102-3	R J KLEIMANN #1
						RECEIVED: 11/30/81 JA: TX
-D L WHITAKER OIL CO						
8208476	F-7B-041846	4242932854			103	WESLEY #1
						RECEIVED: 11/30/81 JA: TX
-DELTA OIL & GAS CO						
8208511	F-09-042580	4250333851			103	DONNELL ESTATE A
						RECEIVED: 11/30/81 JA: TX
-DIAMOND SHAMROCK CORPORATION						
*8208510	F-10-042550	4234100000			108	ROBERTSON D #1
8208461	F-10-041475	4229530937			103	WALLACE HAMKER B #2-590
						RECEIVED: 11/30/81 JA: TX
-DILLA PIPE & SUPPLY INC						
8208508	F-01-042540	4232531348			103	LOUISE POERNER #1 (07327)
						RECEIVED: 11/30/81 JA: TX
-DISCOVERY OPERATING INC						
*8208386	F-7C-034818	4241330935			103	HENDERSON #1
						RECEIVED: 11/30/81 JA: TX
-EL PASO EXPLORATION CO						
8208372	F-7C-016988	4210532338			102-4	ODESSA #4-2
						RECEIVED: 11/30/81 JA: TX
-ESENJAY PETROLEUM CORP						
8208454	F-02-041170	4217531481			102-4	VINCENT E HEARD #1
8208454	F-02-041170	4217531481			103	VINCENT E HEARD #1
						RECEIVED: 11/30/81 JA: TX
-EXXON CORPORATION						
*8208487	F-08-042081	4200332782			103	FULLERTON CLEARFORK UNIT #1719
8208457	F-04-041383	4242700000			108	KELSEY 19-BS UNIT #303 (05143)
8208417	F-04-038253	4200730647			103	NINE MILE POINT CONSOL UNIT #11
8208416	F-04-038252	4200730684			103	NINE MILE POINT CONSOL UNIT #13
						RECEIVED: 11/30/81 JA: TX
-FRAC INC						
8208538	F-08-042677	4200332750			103	THORNBERRY 7 #1 #26664
						RECEIVED: 11/30/81 JA: TX
-GLEN COVE OPERATING CO						
8208502	F-7B-042524	4208300000			103	A W GULLEY #1 (76419)
8208503	F-7B-042525	4208330736			103	L P WHITTINGTON #1 (72860)
						RECEIVED: 11/30/81 JA: TX
-GREAT WEST OPERATING CO INC						
8208462	F-7B-041585	4213332783			102-4	SCHREINER #1
						RECEIVED: 11/30/81 JA: TX
-GULF OIL CORPORATION						
8208536	F-04-042664	4247932964			107-TF	BRUNI MINERAL TRUST A #15
8208525	F-04-042641	4247932645			107-TF	BRUNI MINERAL TRUST A NO 14
8208494	F-06-042410	4236531043			107-TF	CARTHAGE UNIT 110 WELL NO 2
8208506	F-08-042537	4247501226			108	ESTES E W #161
8208514	F-08-042599	4247502490			108	HUTCHINGS STOCK ASSN #487
8208516	F-08-04260	4247502497			108	HUTCHINGS STOCK ASSN #494
8208515	F-08-042600	4247511140			108	HUTCHINGS STOCK ASSN #758
8208507	F-08-042538	4210931369			108	TXL-CX-/NCT-B/#9
						RECEIVED: 11/30/81 JA: TX
-GUY A SWARTZ						
8208460	F-7C-041465	4208130747			103	HARRIS EST #1
						RECEIVED: 11/30/81 JA: TX
-H V RISIEN						
8208481	F-04-042023	4224931236			103	HRANICKY #2
						RECEIVED: 11/30/81 JA: TX
-HARRISON INTERESTS LTD						
8208400	F-7C-035532	4210500000			103	JOE F BEAN C #4
8208400	F-7C-035532	4210500000			107-TF	JOE F BEAN C #4
						RECEIVED: 11/30/81 JA: TX
-HEXAGON OIL & GAS INC						
8208450	F-7B-040963	4214330679			102-4	PANHILL #1
						RECEIVED: 11/30/81 JA: TX
-HNG OIL COMPANY						
8208486	F-04-042052	4250531375			102-2	ANTONIO VELA #1
8208486	F-04-042052	4250531375			103	ANTONIO VELA #1
8208486	F-04-042052	4250531375			107-TF	ANTONIO VELA #1

FIELD NAME	PROD	PURCHASER
GIDDINGS (AUSTIN CHALK-3	80.0	PHILLIPS PETROLEU
PEACH CREEK (AUSTIN CHAL	91.0	SOUTH CEN-TEX GAS
STEPHENS COUNTY REGULAR	0.0	LONE STAR GAS
YOUNG COUNTY REGULAR	0.0	LONE STAR GAS CO
PANHANDLE WEST	3.0	NORTHERN NATURAL
NORTHRUP	600.0	
FAIRFIELD	25.5	VALERO TRANSMISSI
DISCOVERY (CANYON)	54.0	CRA INC
INGHAM QUEEN	24.0	EL PASO NATURAL G
SARCO CREEK W (4850)	300.0	TRUNKLINE GAS CO
SARCO CREEK W (4850)	300.0	TRUNKLINE GAS CO
FULLERTON	15.0	PHILLIPS PETROLEU
KELSEY SOUTH (ZONE 19-B/	1.2	TRUNKLINE GAS CO
NINE MILE POINT	395.0	NATURAL GAS PIPEL
NINE MILE POINT	365.0	NATURAL GAS PIPEL
FUHRMAN-MASCHO	9.5	PHILLIPS PETROLEU
GULLEY (SERRATT)	115.0	UNION TEXAS PETRO
GLEN COVE EAST (JENNINGS	330.0	UNION TEXAS PETRO
SHOAF MERGNER	100.0	ODESSA NATURAL GA
JUANITA (LOBO)	365.0	TENNESSEE GAS PIP
JUANITA (LOBO)	1825.0	TENNESSEE GAS PIP
CARTHAGE (COTTON VALLEY)	150.0	UNITED GAS PIPE L
WARD-ESTES NORTH	1.0	CABOT CORP
WARD-ESTES NORTH	1.0	CABOT CORP
WARD-ESTES NORTH	1.0	CABOT CORP
WARD-ESTES NORTH	1.0	CABOT CORP
GERALDINE (FORD)	1.0	CONTINENTAL OIL &
LYGAY	40.0	SUN OIL CO
WADE CITY (2800' 3RD MET	128.0	VALERO TRANSMISSI
PIKES PEAK DRAW (CANYON)	300.0	INTRATEX GAS CO
PIKES PEAK DRAW (CANYON)	300.0	INTRATEX GAS CO
X-RAY S (MARBLE FALLS LO	110.0	VALERO TRANSMISSI
ROLETA (8150)	376.0	HOUSTON PIPE LINE
ROLETA (8150)	376.0	HOUSTON PIPE LINE
ROLETA (8150)	376.0	HOUSTON PIPE LINE

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JD NO	JA INST	API NO	D SEC CAT	WELL NAME
-HOUSTON OIL & MINERALS CORPORATION			RECEIVED: 11/30/81 JA: TX	
8208471	F-7C-041723	4245130655	102-4	HOBLIT-JACOBS #6
-INDEPENDENT EXPLORATION CO			RECEIVED: 11/30/81 JA: TX	
8208458	F-8A-041397	4210130278	102-4	SHOTTS #1 94839
-INDIAN WELLS OIL CO			RECEIVED: 11/30/81 JA: TX	
8208522	F-7C-042632	4223531706	103	PHILLIPS #4-5
-J B PRODUCTION CO			RECEIVED: 11/30/81 JA: TX	
8208410	F-7C-037088	4239931663	103	ROBERTS #1
-J CLEO THOMPSON & JAMES CLEO THOMPS			RECEIVED: 11/30/81 JA: TX	
8208463	F-7C-041651	4210533444	102-4	UNIVERSITY 29-31W #2
8208464	F7C041652	4210533441	102-4	UNIVERSITY 29-33E #2
-JENNINGS EXPLORATION CO			RECEIVED: 11/30/81 JA: TX	
8208448	F-01-040752	4250700000	102-4	H&F PROPERTIES C #2 93414
-KA-HUGH INTERNATIONAL INC			RECEIVED: 11/30/81 JA: TX	
8208436	F-02-039994	4223900000	103	LIONEL PASTOR #1
-KEITH D GRAHAM			RECEIVED: 11/30/81 JA: TX	
8208408	F-03-036854	4205131201	102-2	HOUSTON #1
8208407	F-03-036853	4205131350	102-2	STEELY UNIT #1
-KILROY CO OF TEXAS			RECEIVED: 11/30/81 JA: TX	
8208451	F-03-040982	4220131106	102-4	BUSHNELL R L UNIT #1
-L M YOUNG			RECEIVED: 11/30/81 JA: TX	
8208504	F-7B-042528	4204900000	102-4	W R CHAMBERS #E-1
-LA ACEITE ENERGY INC			RECEIVED: 11/30/81 JA: TX	
8208473	F-7B-041733	4205933146	102-4	DR DONALD W WARREN #3
-LA SALLE ENERGY CORP			RECEIVED: 11/30/81 JA: TX	
8208415	F-01-038135	4217700000	102-2	GONZALES #1
-M J BRANNON			RECEIVED: 11/30/81 JA: TX	
8208520	F-7B-042624	4208332226	102-4	SAM HUNTER 90383
-MARTIN OIL & GAS CO			RECEIVED: 11/30/81 JA: TX	
8208411	F-03-037344	4205130840	102-2	THOMPSON-SEBESTA UNIT #1
-MAVERICK PETROLEUM INC			RECEIVED: 11/30/81 JA: TX	
8208381	F-01-030049	4232300000	103	HOFFMAN #1
-MCMORAN PRODUCTION CO			RECEIVED: 11/30/81 JA: TX	
8208421	F-04-039230	4270030041	102-4	STATE TRACT 1064-L #A-6AU
8208420	F-04-039229	4270030034	102-4	STATE TRACT 1064-L B-3 U
8208429	F-04-039935	4270030028	102-4	STATE TRACT 1064-L N/2 #A-3
8208430	F-04-039936	4270030036	102-4	STATE TRACT 1064-L N/2 #A-5
8208432	F-04-039938	4270030033	102-4	STATE TRACT 1064-L N/2 #A-7L
8208431	F-04-039937	4270030035	102-4	STATE TRACT 1064-L N/2 #A-7U
8208433	F-04-039939	4270030032	102-4	STATE TRACT 1064-L N/2 #A-8L
8208422	F-04-039231	4270030027	102-4	STATE TRACT 1064-L SW/4 #B-2U
-MECCA ENERGY INC			RECEIVED: 11/30/81 JA: TX	
8208488	F-7B-042134	4242932880	103	CURRY UNIT #1
-MHM OIL CO INC			RECEIVED: 11/30/81 JA: TX	
8208489	F-7B-042137	4213533200	102-4	TALLEY #1
-MIDWAY OIL CORP			RECEIVED: 11/30/81 JA: TX	
8208480	F-03-042013	4205131619	102-4	HIGGASON MCGHEE #1
-MITCHELL ENERGY CORPORATION			RECEIVED: 11/30/81 JA: TX	
8208483	F-09-042030	4250333683	102-4	C A MCMURTRY #1 20138
8208482	F-09-042029	4250334034	102-4	C A MCMURTRY #3-T 20967
8208484	F-09-042031	4250334039	102-4	C A MCMURTRY #3C 20991
8208485	F-09-042032	4250334304	102-4	C A MCMURTRY #4 20138
8208373	F-03-017950	4249700000	108	D J WILSON #2 28853

FIELD NAME	PROD	PURCHASER
ALLEN HILL (STRAWN)	36.5	
INDEPENDENT BEND CONGLOM	396.0	PALO DURO PIPELIN
IRION W (CANYON)	11.0	NORTHERN NATURAL
URBAN (MILES)	0.0	ODESSA NATURAL CO
UNIVERSITY 29 (STRAWN DE	240.0	
UNIVERSITY 29 (STRAWN DE	250.0	
ALLIGATOR SLOUGH (BRACER	128.0	VALERO TRANSMISSI
LAWARD NORTH (5700-B-)	100.0	UNITED GAS PIPELI
GIDDINGS (AUSTIN CHALK A	1046.8	FERGUSON CROSSING
GIDDINGS (AUSTIN CHALK -	270.8	FALCON GAS CO
FAIRBANKS S (GOODYKOONTZ	819.0	UNITED TEXAS TRAN
DALE (CADDO)	50.0	ODESSA NATURAL CO
HAPPY JACK (LAKE)	120.0	LONE STAR GAS CO
CHRISTIAN (6800*)	0.0	TIPPERARY GATHERI
BURKETT S (DUFFER)	31.0	SOUTHWESTERN GAS
CALDWELL (AUSTIN CHALK)	0.0	CLAJON GAS CO
WILDCAT-SPILLMAN (1300*	36.0	VALERO TRANSMISSI
BLOCK 1064-L	1825.0	VALLEY PIPE LINE
BLOCK 1064-L	1825.0	VALLEY PIPE LINE
BLOCK 1064-L	1825.0	VALLEY PIPE LINE
BLOCK 1064-L	1825.0	VALLEY PIPE LINE
BLOCK 1064-L	1825.0	VALLEY PIPE LINE
BLOCK 1064-L	1095.0	VALLEY PIPE LINE
BLOCK 1064-L	1825.0	VALLEY PIPE LINE
BLOCK 1064-L	912.0	VALLEY PIPE LINE
STEPHENS COUNTY REGULAR	4.0	WARREN PETROLEUM
SHOAF-MERGNER (MISS)	90.0	ODESSA NATURAL CO
CALDWELL (AUSTIN CHALK)	108.0	CLAJON GAS CO
JERMYN WEST (CADDO)	310.0	SOUTHWESTERN GAS
JERMYN WEST (MARBLE FALL	60.0	SOUTHWESTERN GAS
JERMYN WEST (LOWER CADDO	220.0	SOUTHWESTERN GAS
JERMYN WEST (CADDO)	65.0	SOUTHWESTERN GAS
BOONSVILLE (BEND CONGL)	15.0	NATURAL GAS PIPEL

JD NO	JA DKT	FED NO	D SEC CA	FILL NAME
8208414	F-03-037743	4228700000	103	WENKE #1
			RECEIVED: 11/30/81 JA: TX	
-MOBIL PRDG TEXAS & NEW MEXICO INC				
8208449	F-04-040797	4235531779	102-4	O L CARDWELL UNIT #1
			RECEIVED: 11/30/81 JA: TX	
-MONTERREY PETROLEUM CORP				
8208498	F-03-042453	4247330340	102-4	HARPER WOOD #1
			RECEIVED: 11/30/81 JA: TX	
-MORMAC ENERGY CORP				
8208495	F-02-042412	4229732634	102-4	L A REAGAN #1
8208404	F-01-036457	4228330743	103	SOUTH TEXAS SYNDICATE A #7-42
			RECEIVED: 11/30/81 JA: TX	
-NATURAL GAS ANADARKO INC				
8208384	F-10-034249	4235700000	102-4	DICKENSON #1-307T
			RECEIVED: 11/30/81 JA: TX	
-NORTH CENTRAL OIL CORPORATION				
8208398	F-09-035293	4249700000	102-4	C W POUNDS UNIT #2-C
			RECEIVED: 11/30/81 JA: TX	
-PEGGY ANN INC				
8208472	F-7B-041730	4209330881	102-4	EDDIE LINDLEY #3
8208467	F-7B-041681	4209330882	102-4	EDDIE LINDLEY #4
8208468	F-7B-041682	4209330869	102-4	EDDIE LINDLEY #5
			RECEIVED: 11/30/81 JA: TX	
-PENNZOIL PRODUCING COMPANY				
8208442	F-04-040268	4247932985	102-4	BMT-ALICE B HALL GU NO 38-1
			RECEIVED: 11/30/81 JA: TX	
-PETRO-LEWIS CORPORATION				
8208377	F-06-029737	4240100000	103	JOE PEARSON #1
8208377	F-06-029737	4240100000	107-TF	JOE PEARSON #1
			RECEIVED: 11/30/81 JA: TX	
-PEYTON MCKNIGHT JR				
8208418	F-06-038511	4240100000	103	J L BURTON EST #3
8208418	F-06-038511	4240100000	107-TF	J L BURTON EST #3
			RECEIVED: 11/30/81 JA: TX	
-PHILLIPS PETROLEUM COMPANY				
8208397	F-10-035103	4217900000	108	JOHNSON AA #1
8208391	F-10-035055	4217900000	108	JOHNSON AA #10
8208392	F-10-035056	4217900000	108	JOHNSON AA #11
8208393	F-10-035057	4217900000	108	JOHNSON AA #13
8208394	F-10-035060	4217900000	108	JOHNSON AA #15
8208396	F-10-035102	4217900000	108	JOHNSON AA #2
8208395	F-10-035101	4217900000	108	JOHNSON AA #4
8208390	F-10-035053	4217900000	108	JOHNSON AA #6
8208389	F-10-035052	4217900000	108	JOHNSON AA #8
8208388	F-10-035051	4217900000	108	JOHNSON AA #9
8208466	F-08-041676	4249503466	108	MCCABE #290 (21555)
			RECEIVED: 11/30/81 JA: TX	
-R L BURNS CORP				
8208492	F-01-042290	4217730809	103	J VLASAK #1
			RECEIVED: 11/30/81 JA: TX	
-R M HILL				
8208401	F-08-035757	4250334416	103	DENNY HEIRS #1
			RECEIVED: 11/30/81 JA: TX	
-RALPH L WAY INC				
8208542	F-7C-042718	4238332045	103	UNIVERSITY 10 #3
			RECEIVED: 11/30/81 JA: TX	
-RANGER PETROLEUM				
8208513	F-10-042593	4206530902	103	BURNETT #1087
8208512	F-10-042592	4206530901	103	BURNETT #2087
			RECEIVED: 11/30/81 JA: TX	
-RAY HERRING				
8208541	F-7B-042696	4236332472	102-4	WILLINGHAM #7
8208540	F-7B-042695	4236303232	102-4	WILLINGHAM A-1
			RECEIVED: 11/30/81 JA: TX	
-ROCKWOOD RESOURCES INC				
8208409	F-03-037015	4248132091	103	COLLINS #1
			RECEIVED: 11/30/81 JA: TX	
-RODMAN PETROLEUM CORP				
8208535	F-7B-042665	4213333010	103	TALLEY #1
			RECEIVED: 11/30/81 JA: TX	
-SEARCH DRILLING CO				

F	NAME	PROD	PURCHASER
	GIDDINGS (AUSTIN CHALK)	0.0	
	WILDCAT	137.8	
	CHAPMAN (WILCOX 9890)	27.3	PRODUCER'S GAS CO
	OAKVILLE (WILCOX 7930)	365.0	TRANSCONTINENTAL
	WASHBURN EAST (4600)	110.0	L F & G GAS GATHE
	PARNELL (MORROW UPPER 90	270.0	TRANSWESTERN PIPE
	WILDCAT (PROPOSED: BOONE	365.0	NATURAL GAS PIPEL
	DELEON N (STRAWN)	90.0	SOUTHWESTERN GAS
	DE LEON N (STRAWN)	140.0	SOUTHWESTERN GAS
	DE LEON N (STRAWN)	140.0	SOUTHWESTERN GAS
	AVIATORS N (12000*)	913.0	
	OAK HILL (COTTON VALLEY)	386.9	HYDROCARBON TRANS
	OAK HILL (COTTON VALLEY)	386.9	HYDROCARBON TRANS
	OAK HILL (COTTON VALLEY)	360.0	LONE STAR GAS CO
	OAK HILL (COTTON VALLEY)	360.0	LONE STAR GAS CO
	PANHANDLE GRAY	0.0	
	PANHANDLE GRAY	0.0	
	PANHANDLE GRAY	0.0	
	PANHANDLE GRAY	0.0	
	PANHANDLE GRAY	0.0	
	PANHANDLE GRAY	0.0	
	PANHANDLE GRAY	0.0	
	PANHANDLE GRAY	0.0	
	PANHANDLE GRAY	0.0	
	PANHANDLE GRAY	0.0	
	EMPEROR (DEVONIAN)	16.7	EL PASO NATURAL G
	CHRISTIAN (6800)	8.0	VALERO TRANSMISSI
	EDMONDS E MARBLE FALLS C	36.0	LONE STAR GAS CO
	FARMER (SAN ANDRES)	19.4	NORTHERN NATURAL
	PANHANDLE - CARSON COUNT	0.0	PANHANDLE EASTERN
	PANHANDLE - CARSON COUNT	0.0	PANHANDLE EASTERN
	RYAN (CONGL 4365)	80.0	SOUTHWESTERN GAS
	RYAN	25.0	SOUTHWESTERN GAS
	GRESHMAN (4400)	0.0	
	EASTLAND COUNTY REGULAR	12.0	LONE STAR GAS CO

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8208523	F-10-042636	4229531023			103	DANIELS #2-554	BRADFORD (TONKAWA)	18.0	PHILLIPS PETROLEU
-SENTINEL PETROLEUM CORP						RECEIVED: 11/30/81 JA: TX			
8208379	F-78-029797	4213331905			102-4	AUTRY H - 16066	MANGUM WEST (3100)	36.5	ODESSA NATURAL CO
8208402	F 78-035850	4213332541			102-4	AUTRY K	MANGUM WEST 3100	0.0	ODESSA NATURAL CO
8208380	F-78-029882	4213300000			102-4	J V MCCRACKER 16174	MANGUM WEST (3100)	25.6	ODESSA NATURAL CO
-SNOW OIL CO						RECEIVED: 11/30/81 JA: TX			
8208465	F-78-041667	4213332763			103	KIMBRELL #1 (16776)	LAKE LEON (DUFFER)	40.0	LONE STAR GAS CO
-SOUTHLAND ROYALTY CO						RECEIVED: 11/30/81 JA: TX			
8208532	F-08-042657	4249500000			103	SUN JENKINS B #10	KEYSTONE	10.0	TRANSWESTERN PIPE
8208534	F-08-042659	4249500000			103	SUN JENKINS B #8	KEYSTONE	10.0	TRANSWESTERN PIPE
8208533	F-08-042658	4249500000			103	SUN JENKINS B #9	KEYSTONE	10.0	TRANSWESTERN PIPE
8208455	F-03-041202	4218530233			102-3	T H TUCKER #1	CARLTON SPEED (WILCOX 11	592.0	LONE STAR GAS CO
-SUN OIL COMPANY (DELAWARE)						RECEIVED: 11/30/81 JA: TX			
8208374	F-04-020208	4224730896			102-4	A C JONES #72-UT	JONES	973.0	TRANSCONTINENTAL
8208491	F-03-042208	4248132158			103	DUSON-KRUEGER #1	SANDY (YEQUA)	63.0	TEXAS EASTERN TRA
8208475	F-04-041843	4242700000			108	GEORGE H SPEER #7	SUN (F-2-A)	0.0	TRANSCONTINENTAL
-SUNBELT OIL & GAS INC						RECEIVED: 11/30/81 JA: TX			
8208441	F-78-040157	4213300000			103	GRIFFIN #3	EASTLAND COUNTY REGULAR	0.0	LONE STAR GAS CO
-SUNDANCE OIL CO						RECEIVED: 11/30/81 JA: TX			
8208426	F-05-039578	4216100000			102-4	FULTON #1	FARRAR N (COTTON VALLEY	0.0	DELHI GAS PIPELIN
8208426	F-05-039578	4216100000			107-TF	FULTON #1	FARRAR N (COTTON VALLEY	0.0	DELHI GAS PIPELIN
-SUPERIOR OIL CO						RECEIVED: 11/30/81 JA: TX			
8208403	F-03-036399	4205131377			103	F MATCEK #1	GIDDINGS (AUSTIN CHALK)	0.0	
-TAUBERT & STEED						RECEIVED: 11/30/81 JA: TX			
8208443	F-06-040330	4249930693			102-4	VICKERY-LINDLEY UNIT #1	NEUHOFF (COTTON VALLEY S	284.0	UNITED GAS PIPELI
8208443	F-06-040330	4249930693			107-TF	VICKERY-LINDLEY UNIT #1	NEUHOFF (COTTON VALLEY S	284.0	UNITED GAS PIPELI
-TENROC CORP						RECEIVED: 11/30/81 JA: TX			
8208413	F-03-037635	4205130956			102-2	KUHN #1	GIDDINGS (AUSTIN CHALK G	525.0	PHILLIPS PETROLEU
-TEXAS INTERNATIONAL PET CORP						RECEIVED: 11/30/81 JA: TX			
8208456	F-09-041285	4233531893			103	BESSIE WALKER #2	NORTH JAMESON (STRAWN)	0.0	SUN GAS CO
-TEXAS OIL & GAS CORP						RECEIVED: 11/30/81 JA: TX			
8208375	F-06-027026	4240130992			103	CUNNINGHAM A #2	OAK HILL (COTTON VALLEY)	500.0	
8208375	F-06-027026	4240130992			107-TF	CUNNINGHAM A #2	OAK HILL (COTTON VALLEY)	500.0	
8208452	F-06-040997	4240131176			103	FRYMAN #1	PONE (PETTIT OIL)	0.0	
8208378	F-05-029784	4229330512			102-4	MORTON #1	OAKS (COTTON VALLEY LIME	100.0	
8208378	F-05-029784	4229330512			103	MORTON #1	OAKS (COTTON VALLEY LIME	100.0	
8208378	F-05-029784	4229330512			107-TF	MORTON #1	OAKS (COTTON VALLEY LIME	100.0	
-THE MAURICE L BROWN COMPANY						RECEIVED: 11/30/81 JA: TX			
8208371	F-06-015537	4220300000			108	SNEED GAS UNIT #2	BETHANY	10.0	UNITED GAS PIPE L
-TOMLINSON INTERESTS INC						RECEIVED: 11/30/81 JA: TX			
8208425	F-06-039416	4240130839			107-TF	R T BALLENGER #1-89312	HENDERSON S E (COTTON VA	182.5	DELHI GAS PIPELIN
8208424	F-06-039415	4240130823			107-TF	T P CANNON #1-87081	HENDERSON E (COTTON VALL	182.5	DELHI GAS PIPELIN
-TUMBLEWEED PRODUCTION CO						RECEIVED: 11/30/81 JA: TX			
8208439	F-10-040021	4206500000			103	BURNETT 10-41	PANHANDLE	63.9	PANHANDLE EASTERN
8208438	F-10-040020	4206500000			103	BURNETT 7-41	PANHANDLE	71.3	PANHANDLE EASTERN
8208440	F-10-040022	4206500000			103	BURNETT 9-41	PANHANDLE	74.8	PANHANDLE EASTERN
-U S MINERAL OPERATING CO INC						RECEIVED: 11/30/81 JA: TX			
8208478	F-04-041865	4213135266			102-4	LEAL #1	SO INDEPENDENCE 3180*	180.0	VALLEY GAS TRANSM
-U S OPERATING INC						RECEIVED: 11/30/81 JA: TX			
8208423	F-03-039305	4205131417			102-2	KELLEY UNIT 1 RRC	GIDDINGS (AUSTIN CHALK)	155.0	PHILLIPS PETROLEU
8208446	F-03-040470	4247730391			102-2	PENNY #1	GIDDINGS (AUSTIN CHALK-3	0.0	PGP GAS PRODUCTS
-UNION OIL COMPANY OF CALIF						RECEIVED: 11/30/81 JA: TX			
*8208469	F-08-041717	4200332640			103	DOLLARHIDE UNIT #1-9-C	DOLLARHIDE (CLEARFORK)	25.0	DOLLARHIDE GASOLI

BILLING CODE 6717-01-C

JD NO	JA DKT	API NO	D SEC CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
*8208493	F-08-042297	4200332635	103	DOLLARHIDE UNIT #16-14-C	DOLLARHIDE (CLEARFORK)	30.0	DOLLARHIDE GASOLI
*8208490	F-08-042157	4200332638	103	DOLLARHIDE UNIT #19-10-C	DOLLARHIDE (CLEARFORK)	8.0	DOLLARHIDE GASOLI
-VANGUARD EXPLORATION CO INC			RECEIVED: 11/30/81 JA: TX				
8208459	F-09-041421	4223733397	102-4	POWERS #1 RRC OIL LEASE #21204	MAXVILL-23-(MARBLE WELLS	100.0	SOUTHWESTERN GAS
-VORTT EXPLORATION CO INC			RECEIVED: 11/30/81 JA: TX				
8208405	F-7B-036843	4236332613	102-4	D BAUM UNIT III #1	MINERAL WELLS S (STRAWN	0.0	SOUTHWESTERN GAS
8208406	F-7B-036844	4236332482	102-4	D E EATON UNIT I #1	MINERAL WELLS S (STRAWN	0.0	SOUTHWESTERN GAS
8208382	F-7B-030235	4236332481	102-4	W T CUNAWAY UNIT II #1 (91321)	MINERAL WELLS S (STRAWN	0.0	SOUTHWESTERN GAS
-WARREN PETR CO A DIV OF GULF OIL CO			RECEIVED: 11/30/81 JA: TX				
8208474	F-08-041738	4210332579	103	W N WADDELL #1185	SAND HILLS (JUDKINS)	216.0	EL PASO NATURAL G
8208500	F-08-042495	4210332590	103	W N WADDELL ET AL 1201	SAND HILLS (TUBB)	47.0	EL PASO NATURAL G
8208501	F-08-042497	4210332588	103	W N WADDELL 1203	SAND HILLS (TUBB)	23.6	EL PASO NATURAL G
-WESSELY ENERGY CORPORATION			RECEIVED: 11/30/81 JA: TX				
8208412	F-05-037606	4229330545	103	CROW #1	TEAGUE TOWNSITE (COTTON	360.0	UNITED TEXAS TRAN
8208412	F-05-037606	4229330545	107-TF	CROW #1	TEAGUE TOWNSITE (COTTON	360.0	UNITED TEXAS TRAN
-WESTLAND OIL DEVELOPMENT CORP			RECEIVED: 11/30/81 JA: TX				
8208521	F-8A-042628	4203330672	102-4	SHAFER #1	GRAVEL PIT (STRAWN)	0.0	SUN GAS CO
-WILDS INC			RECEIVED: 11/30/81 JA: TX				
8208505	F-14-042535	4202531377	108	B W COX #16 (I D #11608)	LOU ELLA (4400)	13.0	NUE-WELLS PIPE LI
-WINDSOR GAS CORP			RECEIVED: 11/30/81 JA: TX				
8208376	F-7C-027526	4243532280	108	WILSON 21-1X	SHURLEY RANCH (CANYON)	20.0	VALERO GAS TRANSM
-WINDSOR PRODUCING CO			RECEIVED: 11/30/81 JA: TX				
8208427	F-03-039589	4228730957	102-2	JENSEN #5	GIDDINGS (AUSTIN CHALK)	36.5	PGP GAS PRODUCTS
8208427	F-03-039589	4228730957	103	JENSEN #5	GIDDINGS (AUSTIN CHALK)	36.5	PGP GAS PRODUCTS
-WM GRUENERWALD & ASSOC INC			RECEIVED: 11/30/81 JA: TX				
8208518	F-10-042622	4234130681	103	MASTERSON H #18R 03947	PANHANDLE (RED CAVE)	43.8	COLORADO INTERSTA
8208519	F-10-042623	4234130683	103	MASTERSON H#19R 03947	PANHANDLE (RED CAVE)	10.6	COLORADO INTERSTA
-ZONERGY INC			RECEIVED: 11/30/81 JA: TX				
8208383	F-03-033949	4228700000	102-2	MARSHALL WESTBROOK UNIT #1	GIDDINGS	0.0	PGP GAS CO

OTHER PURCHASERS

8208386	LONE STAR GAS CO
8208469	EL PASO NATURAL GAS CO
8208487	AMOCO PROD CO
8208490	EL PASO NATURAL GAS CO
8208493	EL PASO NATURAL GAS CO
8208510	PANHANDLE EASTERN P L CO

The above notices of determination were received from the indicated jurisdictional agencies by the Federal Energy Regulatory Commission pursuant to the Natural Gas Policy Act of 1978 and 18 CFR 274.104. Negative determinations are indicated by a "D" before the section code. Estimated annual production (PROD) is in million cubic feet (MMCF). An (*) before the Control (JD) number denotes additional purchasers listed at the end of the notice.

The applications for determination are available for inspection except to the extent such material is confidential under 18 CFR 275.206, at the Commission's Division of Public Information, Room 1000, 825 North Capitol St., Washington, D.C. Persons objecting to any of these determinations may, in accordance with 18 CFR 275.203 and 275.204, file a protest with the Commission on or before January 20, 1982.

Categories within each NGPA section are indicated by the following codes:

Section 102–1: New OCS lease
102–2: New well (2.5 mile rule)
102–3: New well (1000 ft rule)
102–4: New onshore reservoir
102–5: New reservoir on old OCS lease
Section 107–DP: 15,000 feet or deeper
107–GB: Geopressured brine
107–CS: Coal seams
107–DV: Devonian shale
107–PE: Production enhancement
107–TF: New tight formation
107–RT: Recompletion tight formation
Section 108: Stripper well
108–SA: Seasonally affected
108–ER: Enhanced recovery
108–PB: Pressure buildup

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–149 Filed 1–4–82; 8:45 am]

BILLING CODE 6717–01–M

JD ID	JA DKT	API NO	D SEC CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
CALIFORNIA DEPARTMENT OF CONSERVATION							
-TEXACO INC			RECEIVED: 11/30/81 JA: CA				
8208602	81-6-0001	0409520425	102-4	DIXON EAST UNIT I #3	MILLAR	85.0	PACIFIC GAS & ELE
8208601	80-6-0034	0409520416	102-4	DIXON EAST UNIT 1 #4	MILLAR GAS	182.0	PACIFIC GAS & ELE
MONTANA BOARD OF OIL & GAS CONSERVATION							
-SHELL OIL CO			RECEIVED: 11/30/81 JA: MT				
8208606	3-81-29	2508321386	102-4	BN 14-29	MONDAK WEST	2.0	MONTANA DAKOTA UT
8208605	2-81-16	2508321413	102-4	JACKSON 43-35	MONDAK WEST	50.0	MONTANA DAKOTA UT
8208603	2-81-25	2508321393	102-4	LASSEY 23-14	MONDAK WEST	20.0	MONTANA DAKOTA UT
8208607	2-81-17	2508321387	102-4	PETERSON 13-22	MONDAK WEST	15.0	MONTANA DAKOTA UT
8208604	3-81-28	2508321404	102-4	SCHEETZ 42-30	MONDAK WEST	2.0	MONTANA DAKOTA UT
PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL RESOURCES							
-ADOBE OIL & GAS CORPORATION			RECEIVED: 12/03/81 JA: PA				
8208609	9815	3712921236	103	CHARLES ROBERT & IDA BARR #2-A	MT PLEASANT	24.0	INDUSTRIAL ENERGY
8208610	9817	3705120191	108	JOHN & KATHRYN MCGILL #1	NEW SALEM	5.0	COLUMBIA GAS TRAN
8208612	9819	3706324516	108	JOHN AULD #1	CLYMER	5.0	COLUMBIA GAS TRAN
8208611	9818	3706324656	108	JOHN AULD #3	CLYMER	5.0	COLUMBIA GAS TRAN
8208608	8623	3706522170	103	WILLIAM BENSON #1-B	PUNXSY	21.0	
-AMOCO PRODUCTION CO			RECEIVED: 12/03/81 JA: PA				
8208613	9925	3711120114	102-4	MATTHEW B LUCE GAS UNIT /B/ #1	EAST KIMMEL	44.0	TEXAS EASTERN TRA
-ARROWHEAD GAS PRODUCERS INC			RECEIVED: 12/03/81 JA: PA				
8208614	9587	3712329159	107-TF	SAUNDERS #1	SUGAR GROVE	60.0	COLUMBIA GAS TRAN
-BOYD & SHRIVER			RECEIVED: 12/03/81 JA: PA				
8208617	9915	3706324086	103	ALTMAN & HUEY #482	GRANT	0.0	T W PHILLIPS GAS
8208618	9916	3706324532 D	103	BARLETTA #495	N MAHONING	0.0	T W PHILLIPS GAS
8208616	9914	3706325504	103	MOTTORN #523	N MAHONING	0.0	CONSOLIDATED GAS
-CABOT OIL & GAS CORP			RECEIVED: 12/03/81 JA: PA				
8208645	9647	3703921148	107-TF	ALLAN HART #3	FAIRFIELD	50.0	TENNESSEE GAS PIP
8208619	9633	3708520267	102-2	ANDREW STALLSMITH #1	DEER CREEK	50.0	TENNESSEE GAS PIP
8208640	9601	3708520267	107-TF	ANDREW STALLSMITH #1	DEER CREEK	50.0	TENNESSEE GAS PIP
8208641	9603	3703921219	107-TF	CARMAN VAZZANA #1	UNION	50.0	TENNESSEE GAS PIP
8208646	9649	3703921203	107-TF	CAROL KENNEDY #1	FAIRFIELD	50.0	TENNESSEE GAS PIP
8208625	9230	3703921150	107-TF	CHARLES MORRELL #1	WAYNE	50.0	TENNESSEE GAS PIP
8208631	9345	3703921199	107-TF	CLYDE COLDREN #1	FAIRFIELD	50.0	TENNESSEE GAS PIP
8208624	8603	3703920690	107-TF	DAVID DUNN #3	FAIRFIELD	50.0	TENNESSEE GAS PIP
8208621	9968	3703921371	102-2	DELILAH BELL #1	EAST FAIRFIELD	50.0	TENNESSEE GAS PIP
8208632	9349	3708520251	107-TF	EDWARD GREER #1	FRENCH CREEK	50.0	TENNESSEE GAS PIP
8208642	9605	3703921212	107-TF	ELI TROYER #1	EAST FAIRFIELD	50.0	TENNESSEE GAS PIP

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8208644	9609	3703921259		107-TF		F & H BITENC #7	GREENWOOD	50.0	TENNESSEE GAS PIP
8208643	9607	3703921196		107-TF		FRANCES SIGSBEE #1	EAST FAIRFIELD	50.0	TENNESSEE GAS PIP
8208638	9595	3703920872		107-TF		FRANK NADER #1	GREENWOOD	50.0	TENNESSEE GAS PIP
8208620	9949	3703920837		102-2		GERTRUDE PATTERSON #1	EAST FAIRFIELD	50.0	TENNESSEE GAS PIP
8208622	9973	3703921282		102-2		JAMES BARR #1	EAST FAIRFIELD	50.0	TENNESSEE GAS PIP
8208639	9599	3703921332		107-TF		JENNIE GRINNELL #1	UNION	50.0	TENNESSEE GAS PIP
8208637	9593	3703921289		107-TF		JENNIE GRINNELL #2	UNION	50.0	TENNESSEE GAS PIP
8208633	9351	3703921166		107-TF		JOHN SCHNEIDER #1	FAIRFIELD	50.0	TENNESSEE GAS PIP
8208627	9263	3703921214		107-TF		LILLIAN REESE #1	WAYNE	50.0	TENNESSEE GAS PIP
8208629	9341	3703921169		107-TF		PAUL KAHLER #1	UNION	50.0	TENNESSEE GAS PIP
8208628	9284	3703921260		107-TF		RICHARD BAKER #1	GREENWOOD	50.0	TENNESSEE GAS PIP
8208636	9501	3708520263		107-TF		THEODORE GATES #1	DEER CREEK	50.0	TENNESSEE GAS PIP
8208634	9358	3703920740		107-TF		VANCE RUNG #1	UNION	50.0	TENNESSEE GAS PIP
8208635	9499	3708520240		107-TF		VICTOR BABYAK #2	FRENCH CREEK	50.0	TENNESSEE GAS PIP
8208623	9975	3703921271		102-2		WAGNERCREST FARMS #2	EAST FAIRFIELD	50.0	TENNESSEE GAS PIP
8208630	9343	3703920916		107-TF		WALTER HOOK #1	GREENWOOD	50.0	TENNESSEE GAS PIP
8208626	9281	3703921198		107-TF		WINSTON JEWELL #1	FAIRFIELD	50.0	TENNESSEE GAS PIP
-CARDINAL OIL CO				RECEIVED: 12/03/81 JA: PA					
8208647	8367	3703920523		107-TF		ED ERTMAN #80-22 PA PER CRA-20823	CONNEAUT	0.0	COLUMBIA GAS TRAN
8208649	9822	3703900000		107-TF		EDWARD KOCSIS #79-11 PA PER CRA-20*	CONNEAUT	0.0	COLUMBIA GAS TRAN
8208651	9824	3703920640		107-TF		ELIZABETH KING #79-12 PA PER CRA-2*	CONNEAUT	0.0	COLUMBIA GAS TRAN
8208652	9825	3703920944		107-TF		THOMAS ODONNELL #80-45 PA PER CRA-*	CONNEAUT	0.0	NATIONAL FUEL GAS
8208650	9823	3703920625		107-TF		W F WHEELER #79-13 PA PER CRA-20625	CONNEAUT	0.0	COLUMBIA GAS TRAN
8208648	8368	3703920626		107-TF		WILBUR F WHEELER #80-17 PA PER CRA*	CONNEAUT	0.0	COLUMBIA GAS TRAN
-CENTER BAR GAS CO				RECEIVED: 12/03/81 JA: PA					
8208657	9830	3703920643		107-TF		EARL HAMILTON #79-10 PA PER CRA-20*	CONNEAUT	0.0	COLUMBIA GAS TRAN
8208653	9826	3703900000		107-TF		J GREENE #79-8 PA PER CRA-20654	CONNEAUT	0.0	COLUMBIA GAS TRAN
8208655	9828	3703920645		107-TF		SERBIAN ORTHODOX #79-3 PA PER CRA-*	CONNEAUT	0.0	COLUMBIA GAS TRAN
8208654	9827	3703900000		107-TF		SERBIAN ORTHODOX #79-4 PA PER CRA-*	CONNEAUT	0.0	COLUMBIA GAS TRAN
8208656	9829	3703920646		107-TF		SERBIAN ORTHODOX #79-5 PA PER CRA-*	CONNEAUT	0.0	COLUMBIA GAS TRAN
-COMPASS DEVELOPMENT INC				RECEIVED: 12/03/81 JA: PA					
8208658	8325	3705323044		103		MIKOIL DEEP I	FIELY	0.0	
8208659	8327	3705323227		103		WARRANT 5110 (UGI)	WARRANT 5110 JENKS	0.0	
-CUMBERLAND OIL CORP				RECEIVED: 12/03/81 JA: PA					
8208661	9756	3712329663		107-TF		J RUPCZYK #3	SUGAR GROVE	20.0	NATIONAL FUEL GAS
8208660	9759	3712329661		102-2		MIDWEST CAMPERS #1	SUGAR GROVE	20.0	NATIONAL FUEL GAS
8208662	9758	3712329661		107-TF		MIDWEST CAMPERS #1	SUGAR GROVE	20.0	NATIONAL FUEL GAS
-DAMSON-LOUDEN CO LTD & NCC-LOUDEN L				RECEIVED: 12/03/81 JA: PA					
8208663	9699	3712921343		103		T J SIDLOVSKY B809-1	HUNTINGTON	20.2	TEXAS EASTERN TRA
-ENVIROGAS INC				RECEIVED: 12/03/81 JA: PA					
8208664	9372	3704921416		107-TF		D ROTH #2	CORRY	18.0	NATIONAL FUEL GAS
-FOX OIL & GAS INC				RECEIVED: 12/03/81 JA: PA					
8208667	9094	3706326029		102-4		ALVIN E HENRY 1-A	MONTGOMERY	25.5	COLUMBIA GAS TRAN
8208665	9085	3706325935		102-4		EARL FULMER #2	MONTGOMERY	25.5	COLUMBIA GAS TRAN
8208666	9086	3706325876		102-4		FLORENCE O'HARRAH #5	MONTGOMERY	25.5	COLUMBIA GAS TRAN
8208672	9105	3706324849		102-4		HARRY GARDNER #2	MONTGOMERY	25.5	COLUMBIA GAS TRAN
8208670	9099	3706325672		102-4		HARRY GARDNER #3	MONTGOMERY	25.5	COLUMBIA GAS TRAN
8208668	9095	3706325810		102-4		JACK HAZELET #4	MONTGOMERY	25.5	COLUMBIA GAS TRAN
8208671	9100	3706325066		102-4		JAMES E HEVNER #1	MONTGOMERY	25.5	COLUMBIA GAS TRAN
8208673	9108	3706324848		102-4		JAMES MCANUZTY #1	MONTGOMERY	25.5	COLUMBIA GAS TRAN
8208669	9097	3706325727		102-4		WILLIAM LEWIS #3	MONTGOMERY	25.5	COLUMBIA GAS TRAN
8208674	9109	3706324672		102-4		WM LEWIS #1	MONTGOMERY	25.5	COLUMBIA GAS TRAN
-GOE PRO INC				RECEIVED: 12/03/81 JA: PA					

JD NO	JA DKT	API NO	D SEC CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8208682	9627	3704921466	107-TF	A M GRAVES #1	ALBION WEST	0.0	NATIONAL FUEL GAS
8208677	9548	3704721400	107-TF	FRANK SISAK (SMC)	ALBION WEST	0.0	NATIONAL FUEL GAS
8208675	9544	3704921398	107-TF	J & H HARRINGTON #1	ALBION WEST	0.0	NATIONAL FUEL GAS
8208676	9546	3704921399	107-TF	J RAUSCH SR #1	ALBION WEST	0.0	NATIONAL FUEL GAS
8208680	9623	3704921468	107-TF	JACK WILSON	ALBION WEST	0.0	NATIONAL FUEL GAS
8208679	9621	3704921467	107-TF	JOHN RAUSCH JR #1	ALBION WEST	0.0	NATIONAL FUEL GAS
8208681	9625	3704921442	107-TF	PHYLIS SIMPSON	ALBION WEST	0.0	NATIONAL FUEL GAS
8208678	9550	3704721441	107-TF	RON SIMPSON	ALBION WEST	0.0	NATIONAL FUEL GAS
-HELEN E SOWERS				RECEIVED: 12/03/81 JA: PA			
8208615	9520	3700522633	107-TF	BLOSE GAS WELL #2 27873	COWANSHANNOCK	36.5	PEOPLES NATURAL G
-J & J ENTERPRISES INC				RECEIVED: 12/03/81 JA: PA			
8208685	7067	3700521499	108	ALTMIRE HEIRS #2 (183A)	PLUMCREEK	4.4	PEOPLES NATURAL G
8208683	7065	3700521500	108	ALTMIRE HEIRS #3 (150A)	PLUMCREEK	4.4	PEOPLES NATURAL G
8208688	7210	3706322104	108	BERYL C LYDIC #2	SOUTH MAHONING	3.9	T W PHILLIPS GAS
8208684	7066	3700521530	108	CHARLES DUFF #1	COWANSHANNOCK	4.7	PEOPLES NATURAL G
8208702	7241	3706321991	108	D E MAUK (MOCK) #2	CANOE	15.3	T W PHILLIPS GAS
8208703	7242	3706321992	108	D E MAUK (MOCK) #3	CANOE	15.3	T W PHILLIPS GAS
8208704	7243	3706321993	108	D E MAUK (MOCK) #4	CANOE	15.3	T W PHILLIPS GAS
8208701	7237	3706321978	108	F TANNER #1	CANOE	1.5	T W PHILLIPS GAS
8208693	7215	3706522979	108	J TURNAGE #1 A-B-1-1	BELL	12.4	T W PHILLIPS GAS
8208692	7214	3706520974	108	J TURNAGE #2 A-B #1	BELL	12.4	T W PHILLIPS GAS
8208691	7213	3706522977	108	J TURNAGE #3 A-B-2(2)	BELL	12.4	T W PHILLIPS GAS
8208705	7244	3706520954	108	JAMES HUMBLE #2	BELL	6.6	T W PHILLIPS GAS
8208690	7212	3706520959	108	JOHN DEFLORIA #1	BELL	16.7	T W PHILLIPS GAS
8208686	7174	3706321888	108	KENNETH CARLSON #1	CANOE	8.8	T W PHILLIPS GAS
8208687	7175	3706321889	108	KENNETH CARLSON #2	CANOE	8.8	T W PHILLIPS GAS
8208689	7211	3706322151	108	LEO C CLARK #1	SOUTH MAHONING	6.4	T W PHILLIPS GAS
8208699	7221	3706321947	108	LIONS HEALTH CAMP #1	ARMSTRONG	12.2	T W PHILLIPS GAS
8208700	7222	3706322067	108	LIONS HEALTH CAMP #3	ARMSTRONG	12.3	T W PHILLIPS GAS
8208707	7246	3706321892	108	ROGER RICHARDSON #1	CANOE	11.3	T W PHILLIPS GAS
8208694	7216	3706321926	108	ROYAL OIL & GAS CO #1	GRANT	5.4	T W PHILLIPS GAS
8208698	7220	3706322094	108	S A MCMILLEN #1	SOUTH MAHONING	3.9	T W PHILLIPS GAS
8208695	7217	3706322075	108	S C MONNIE #1	CANOE	8.9	T W PHILLIPS GAS
8208696	7218	3706322119	108	S C MONNIE #1	CANOE	8.9	T W PHILLIPS GAS
8208697	7219	3706322120	108	S C MONNIE #2	CANOE	8.9	T W PHILLIPS GAS
8208706	7245	3706321914	108	T N CUSTER #2	CANOE	12.6	T W PHILLIPS GAS
-MONROE RESOURCES LTD				RECEIVED: 12/03/81 JA: PA			
8208708	9773	3712329967	102-2	F RUSSELL #1	FREEHOLD	15.0	COLUMBIA GAS TRAN
8208710	9774	3712329967	107-TF	F RUSSELL #1	FREEHOLD	15.0	COLUMBIA GAS TRAN
8208709	9783	3712329955	102-2	MILO KOREN #1	FREEHOLD	15.0	COLUMBIA GAS TRAN
8208711	9782	3712329955	107-TF	MILO KOREN #1	FREEHOLD	15.0	COLUMBIA GAS TRAN
-OILMARK & CO INC				RECEIVED: 12/03/81 JA: PA			
8208737	5157	3712327697	102-2	CORNISH #1	SUGARGROVE	30.0	COLUMBIA GAS TRAN
-PHILLIPS PRODUCTION CO				RECEIVED: 12/03/81 JA: PA			
8208716	9747	3706326403	103	CLARENCE K COLEMAN #1	FRANKLIN	25.0	
8208717	9748	3706326427	103	SAM C ROMEO #1	FRANKLIN	25.0	
8208715	9743	3705120285	103	WILLIAM D MILLS #1	FRANKLIN	30.0	
-PIVOT PETROLEUMS INC				RECEIVED: 12/03/81 JA: PA			
8208712	9386	3704921315	107-TF	HAROLD H & DIXIE KLEINFELD #1	FRANKLIN	20.0	COLUMBIA GAS TRAN
8208713	9390	3704921316	107-TF	LYMAN & DORIS LESUER #1	FRANKLIN	20.0	COLUMBIA GAS TRAN
8208714	9459	3704921317	107-TF	PAUL R & MARY R WOODS	FRANKLIN	20.0	COLUMBIA GAS TRAN
-SCOTT AND HUSSING				RECEIVED: 12/03/81 JA: PA			
8208722	9922	3712921898	103	C H WOODWARD #161	SALTSBURG	30.0	T W PHILLIPS GAS

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8208723	9923	3712921889		103		DANIEL FERRI #1 #162	SALTSBURG	30.0	T W PHILLIPS GAS
8208724	9924	3712921890		103		DANIEL FERRI #2 #163	SALTSBURG	30.0	T W PHILLIPS GAS
8208719	9919	3712921892		103		JOHN ROMAN #1 #154	SALTSBURG	30.0	T W PHILLIPS GAS
8208720	9920	3706326092		103		JOSEPH CANALE #1 #156	SALTSBURG	30.0	T W PHILLIPS GAS
8208721	9921	3712921826		103		ORISON FAULK #1 #158	SALTSBURG	30.0	T W PHILLIPS GAS
8208718	9918	3712921748		103		SCOTT AND HUSSING - FEE #153	SALTSBURG	30.0	T W PHILLIPS GAS
-TORCAL RESOURCES INC/GOE PRO INC		RECEIVED: 12/03/81 JA: PA							
8208726	9466	3712328446		107	-TF	EDDY #1	LOTTSVILLE	15.0	COLUMBIA GAS TRAN
8208725	9462	3712328447		107	-TF	EDDY #2	LOTTSVILLE	15.0	COLUMBIA GAS TRAN
-US ENERGY DEVELOPMENT CORP		RECEIVED: 12/03/81 JA: PA							
8208729	9519	3704921292		107	-TF	E WOODS #1	AMITY	20.0	NATIONAL FUEL GAS
8208727	9356	3704921262		107	-TF	HUNT #1	WATERFORD	20.0	NATIONAL FUEL GAS
8208728	9368	3704921263		107	-TF	HUNT #2	WATERFORD	20.0	NATIONAL FUEL GAS
-WAINOCO OIL & GAS CO		RECEIVED: 12/03/81 JA: PA							
8208730	9788	3703920591		107	-TF	BEN J MILLER #1 (W-24)	ATHENS (ROME)	24.0	COLUMBIA GAS TRAN
8208735	9796	3703920647		107	-TF	NEAL & DOROTHY HASBROUCK #1 (W-33)	ATHENS (ROME)	15.0	COLUMBIA GAS TRAN
8208732	9792	3703920651		107	-TF	RICHARD A HEATH #1 (W-35)	ATHENS (ATHENS)	4.0	COLUMBIA GAS TRAN
8208731	9790	3703920612		107	-TF	THEODORE S BOGARDUS #2 (W-13)	ATHENS (ATHENS)	20.0	COLUMBIA GAS TRAN
8208736	9797	3703920592		107	-TF	WALTER FOLTZ #1 (W-32)	ATHENS (ATHENS)	12.5	COLUMBIA GAS TRAN
8208734	9794	3703920600		107	-TF	WALTER J PROCESS #1 (W-16)	ATHENS (ATHENS)	3.5	COLUMBIA GAS TRAN
8208733	9793	3703920619		107	-TF	WILLIAM D BRADLEY #1 (W-17)	ATHENS (ATHENS)	9.0	COLUMBIA GAS TRAN
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WEST VIRGINIA DEPARTMENT OF MINES									
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-CONSOLIDATED GAS SUPPLY CORPORATION		RECEIVED: 11/30/81 JA: WV							
8208561		4703301215		103		C E SNIDER 12474	GRANT	25.4	GENERAL SYSTEM PU
8208583		4705900836		108		CHARLES A HAMILL 11580	STAFFORD DISTRICT	1.6	GENERAL SYSTEM PU
8208582		4705900847		108		CHARLES A HAMILL 11880	STAFFORD DISTRICT	0.0	GENERAL SYSTEM PU
8208544		4703301083		103		EDWIN MAXWELL 12385	UNION	13.3	GENERAL SYSTEM PU
8208560		4703301229		103		FITTRO-GERRARD 12486	COAL	6.2	GENERAL SYSTEM PU
8208558		4703302492		103		GORE CORP 12548	COAL	0.0	GENERAL SYSTEM PU
8208566		4704102095		103		IRA F LINGER 12015	SKIN CREEK	8.7	GENERAL SYSTEM PU
8208562		4703301081		103		J B CUNNINGHAM 12292	UNION	14.3	GENERAL SYSTEM PU
8208563		4703301700		103		J C NICHOLS 12306	ELK	14.1	GENERAL SYSTEM PU
8208545		4703301698		103		LEEMAN MAXWELL 12473	GRANT	5.9	GENERAL SYSTEM PU
8208581		4709701695		108		LON D PERRINE 12212	BANKS DISTRICT	7.7	GENERAL SYSTEM PU
8208565		4703302282		103		M R LODGE 12627	SIMPSON	39.3	GENERAL SYSTEM PU
8208547		4703301137		103		M W SMITH 12280	UNION	10.0	GENERAL SYSTEM PU
8208572		4704700625		108		MCDOWELL POCAHONTAS COAL 11794	SANDY RIVER DISTRICT	8.2	GENERAL SYSTEM PU
8208564		4703302433		103		MOLLIE V BASSELL 12665	GRANT	33.0	GENERAL SYSTEM PU
8208577		4704700543		108		POCAHONTAS LAND CO 11495	NORTHFORK	3.7	GENERAL SYSTEM PU
8208584		4705500036		108		POCAHONTAS LAND CORP	ROCK	3.4	GENERAL SYSTEM PU
8208578		4704700506		108		POCAHONTAS LAND CORP 11380	ADKINS	2.8	GENERAL SYSTEM PU
8208576		4704700567		108		POCAHONTAS LAND CORP 11507	ELKHORN	1.8	GENERAL SYSTEM PU
8208595		4705500019		108		POCAHONTAS LAND CORP 11514	ROCK	3.8	GENERAL SYSTEM PU
8208575		4704700599		108		POCAHONTAS LAND CORP 11601	ADKIN	1.2	GENERAL SYSTEM PU
8208579		4710900737		108		POCAHONTAS LAND CORP 11607	BARKERS RIDGE	4.8	GENERAL SYSTEM PU
8208580		4710900758		108		POCAHONTAS LAND CORP 11609	BAKERS RIDGE	2.8	GENERAL SYSTEM PU
8208574		4704700610		108		POCAHONTAS LAND CORP 11613	ELKHORN	5.7	GENERAL SYSTEM PU
8208573		4704700613		108		POCAHONTAS LAND CORP 11709	NORTH FORK	4.8	GENERAL SYSTEM PU
8208594		4705500028		108		POCAHONTAS LAND CORP 11759	ROCK	20.5	GENERAL SYSTEM PU
8208571		4704700626		108		POCAHONTAS LAND CORP 11760	ELKHORN	3.5	GENERAL SYSTEM PU
8208587		4705500032		108		POCAHONTAS LAND CORP 11761	ROCK	2.9	GENERAL SYSTEM PU

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JD NO	JA DKT	API NO	D SEC CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8208569		4704700627	108	POCAHONTAS LAND CORP 11762	ADKIN	4.3	GENERAL SYSTEM PU
8208585		4705500035	108	POCAHONTAS LAND CORP 11765	ROCK	2.6	GENERAL SYSTEM PU
8208593		4705500030	108	POCAHONTAS LAND CORP 11766	ROCK	3.5	GENERAL SYSTEM PU
8208588		4705500031	108	POCAHONTAS LAND CORP 11767	ROCK	2.5	GENERAL SYSTEM PU
8208586		4705500034	108	POCAHONTAS LAND CORP 11771	ROCK DISTRICT	3.3	GENERAL SYSTEM PU
8208568		4704700634	108	POCAHONTAS LAND CORP 11774	ADKIN DISTRICT	3.5	GENERAL SYSTEM PU
8208596		4704700772	108	POCAHONTAS LAND CORP 12506	ELKORN DISTRICT	16.6	GENERAL SYSTEM PU
8208567		4704102108	103	R V MCCUE 12268	SKIN CREEK	55.4	GENERAL SYSTEM PU
8208559		4703301044	103	SERENA ASHCRAFT 12271	SARDIS	33.5	GENERAL SYSTEM PU
8208546		4703301246	103	T W STUTLER 12063	UNION	14.6	GENERAL SYSTEM PU
8208543		4701701903	103	W B MAXWELL 12258	SOUTHWEST	39.3	GENERAL SYSTEM PU
-FOX DRILLING CO INC				RECEIVED: 11/30/81 JA: WV			
8208599		4700101231	107-DV	D BOSLEY #2	BELINGTON	20.0	COLUMBIA GAS TRAN
8208570		4700101232	107-DV	D BOSLEY #3	BELINGTON	20.0	COLUMBIA GAS TRAN
8208598		4700101233	107-DV	D BOSLEY #4	BELINGTON	20.0	COLUMBIA GAS TRAN
8208600		4700101206	107-DV	O HATHAWAY #2	BELINGTON	10.0	COLUMBIA GAS TRAN
8208597		4700101242	107-DV	R AUVIL #1-A	BELINGTON	10.0	COLUMBIA GAS TRAN
-J & J ENTERPRISES INC				RECEIVED: 11/30/81 JA: WV			
8208549		4701702938	103	J-222	GREENBRIER	0.0	CONSOLIDATED GAS
8208553		4703302439	103	J-324	SARDIS	0.0	CONSOLIDATED GAS
8208550		4701702947	103	J-34	NEW MILTON	0.0	CONSOLIDATED GAS
8208551		4701702784	103	J-40	NEW MILTON	0.0	CONSOLIDATED GAS
8208554		4708505025	103	J-414	CLAY	20.0	CONSOLIDATED GAS
8208552		4701702770	103	J-45	NEW MILTON	0.0	CONSOLIDATED GAS
8208548		4701702789	103	J-50	NEW MILTON	20.0	CONSOLIDATED GAS
-JAMES F SCOTT				RECEIVED: 11/30/81 JA: WV			
8208589		4703302446	103	WILLIAM NEWMAN S-315	SARDIS	0.3	CONSOLIDATED GAS
-NRM PETROLEUM CORPORATION				RECEIVED: 11/30/81 JA: WV			
8208557		4709702200	103	KARICKHOFF #1	BUCKHANNON-CENTURY	0.0	CONSOLIDATED GAS
8208555		4709100191	103	VRABEC #1	GLADE RUN	0.0	
8208556		4709100192	103	WILFONG "A" #1	GLADE RUN	0.0	
-R & B PETROLEUM INC				RECEIVED: 11/30/81 JA: WV			
8208590		4700101068	108	DURRETT #1	VALLEY	10.8	PARTNERSHIP PROPE
8208591		4700101069	108	DURRETT #4	VALLEY	10.8	PARTNERSHIP PROPE
8208592		4700101079	108	GLENDENNING #1 (ZIRKLE)	VALLEY	10.8	PARTNERSHIP PROPE

The above notices of determination were received from the indicated jurisdictional agencies by the Federal Energy Regulatory Commission pursuant to the Natural Gas Policy Act of 1978 and 18 CFR 274.104. Negative determinations are indicated by a "D" before the section code. Estimated annual production (PROD) is in million cubic feet (MMCF). An (*) Before the Control (JD) number denotes additional purchasers listed at the end of the notice.

The applications for determination are available for inspection except to the extent such material is confidential under 18 CFR 275.206, at the Commission's Division of Public Information, Room 1000, 825 North Capitol St., Washington, D.C. Persons objecting to any of these determinations may, in accordance with 18 CFR 275.203 and 275.204, file a protest with the Commission, on or before January 20, 1982.

Categories within each NGPA section are indicated by the following codes:

Section 102–1: New OCS lease
102–2: New well (2.5 mile rule)
102–3: New well (1000 ft rule)
102–4: New onshore reservoir
102–5: New reservoir on old OCS lease

Section 107–DP: 15,000 feet or deeper
107–GB: Geopressured brine
107–CS: Coal seams
107–DV: Devonian shale
107–PE: Production enhancement
107–TF: New tight formation
107–RT: Recompletion tight formation

Section 108: Stripper well
108–SA: Seasonally affected
108–ER: Enhanced recovery
108–PB: Pressure buildup

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–150 Filed 1–4–82; 8:45 am]

BILLING CODE 6717–01–M

Determinations by Jurisdictional Agencies Under the Natural Gas Policy Act of 1978

Issued: December 30, 1981.

JD NO	JA DKT	API NO	D SEC CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
TEXAS RAILROAD COMMISSION							
-ADA OIL EXPLORATION CORP			RECEIVED: 12/03/81	JA: TX			
8208757	F-03-329652	4247730393	102-2	HEITMANN #1	GIDDINGS	182.5	PHILLIPS PETROLEU
8208811	F-03-035117	4205100000	102-2	L M FRANK #1	GIDDINGS	182.5	PHILLIPS PETROLEU
-ALPAR RESOURCES INC			RECEIVED: 12/03/81	JA: TX			
8209038	F-10-042910	4235731089	103	APPLE #1-60	FARNSWORTH CONNER (DES M	25.0	PHILLIPS PETROLEU
-AMERICAN PETROFINA COMPANY OF TEXAS			RECEIVED: 12/03/81	JA: TX			
8209059	F-06-042784	4240130923	103	WYLIE #2	TRUCTON (RODESSA)	365.0	B & A PIPE LINE C
-AMMEX PETROLEUM INC			RECEIVED: 12/03/81	JA: TX			
8208987	F-03-041968	4205131684	102-2	CAB UNIT #1	GIDDINGS (AUSTIN CHALK)	50.4	CLAJON GAS CO
8208987	F-03-041968	4205131684	103	CAB UNIT #1	GIDDINGS (AUSTIN CHALK)	50.4	CLAJON GAS CO
8208986	F-03-041967	4205131705	102-2	MINNIE UNIT #1	GIDDINGS (AUSTIN CHALK)	36.0	CLAJON GAS CO
8208986	F-03-041967	4205131705	103	MINNIE UNIT #1	GIDDINGS (AUSTIN CHALK)	36.0	CLAJON GAS CO
8208985	F-03-041966	4214930772	102-2	PAIGE MARIE UNIT #1	GIDDINGS (AUSTIN CHALK)	3.6	CLAJON GAS CO
8208985	F-03-041966	4214930772	103	PAIGE MARIE UNIT #1	GIDDINGS (AUSTIN CHALK)	3.6	CLAJON GAS CO
-AMOCO PRODUCTION CO			RECEIVED: 12/03/81	JA: TX			
8208977	F-03-088331	4203931518	102-4	B L TURNER #27	HASTINGS EAST (C-3 SAND)	607.0	AMOCO GAS CO
8209012	F-06-042260	4220330841	102-4	CHAUVIN-LANDRY GAS UNIT #1	BLOCKER/COTTON VALLEY/	132.0	UNITED GAS PIPE L
8209012	F-06-042260	4220330841	107-TF	CHAUVIN-LANDRY GAS UNIT #1	BLOCKER/COTTON VALLEY/	132.0	UNITED GAS PIPE L
8208993	F-08-042095	4200332451	103	FULLERTON SAN ANDRES UNIT #69	FULLERTON SAN ANDRES	12.1	AMOCO PRODUCTION
-ARCO OIL AND GAS COMPANY			RECEIVED: 12/03/81	JA: TX			
8208907	F-04-040108	4221531125	103	EVERETT BELL GAS UNIT 1 #6	TABASCO	193.0	TENNESSEE GAS PIP
8208944	F-7C-041210	4241300724	108	HULLDALE (PENN REEF) #2602	HULLDALE	2.5	ARCO OIL & GAS CO
8208943	F-7C-041209	4241300179	108	HULLDALE (PENN REEF) #2901	HULLDALE	3.1	ARCO OIL & GAS CO
8208964	F-7C-041622	4241300741	108	HULLDALE (PENN REEF) UNIT #1502	HULLDALE	8.6	ARCO OIL AND GAS
8208965	F-7C-041623	4241300190	108	HULLDALE (PENN REEF) UNIT #1701	HULLDALE	10.3	ARCO OIL & GAS CO
8208966	F-7C-041624	4241300671	108	HULLDALE (PENN REEF) UNIT #1905	HULLDALE	3.5	ARCO OIL AND GAS
8208967	F-7C-041625	4241300609	108	HULLDALE (PENN REEF) UNIT #2101	HULLDALE	2.1	ARCO OIL & GAS CO
8208968	F-7C-041626	4241300485	108	HULLDALE (PENN REEF) UNIT #2302	HULLDALE	3.0	ARCO OIL & GAS CO
8208939	F-7C-041140	4204130000	108	HULLDALE (PENN REEF) UNIT #2801	HULLDALE	1.2	ARCO OIL & GAS CO
8208962	F-7C-041620	4241300007	108	HULLDALE (PENN REEF) UNIT #2802	HULLDALE	5.8	ARCO OIL AND GAS
8208963	F-7C-041621	4241300639	108	HULLDALE (PENN REEF) UNIT #607	HULLDALE	3.5	ARCO OIL & GAS CO
8208961	F-04-041613	4221531138	103	TEMPLE W WEST #33	TABASCO	94.0	TENNESSEE GAS PIP
*8209000	F-8A-042140	4250131988	103	WILLARD UNIT #25-C	WASSON	14.0	COLTEXO CORP
-B M HESTER			RECEIVED: 12/03/81	JA: TX			
8208740	F-03-022339	4233930402	103	KEYSTONE MILLS 3-W	CONROE SOUTH	300.0	UNITED TEXAS TRAN
-BAR M PETROLEUM CO INC			RECEIVED: 12/03/81	JA: TX			
8209046	F-03-042738	4228730829	103	MARBURGER #1	GIDDINGS (AUSTIN CHALK)	632.0	P G P GAS PRODUCT
-BENCHMARK OIL & GAS CO			RECEIVED: 12/03/81	JA: TX			
8208894	F-03-039706	4220100000	102-4	LEWIS TYRA #1 RRC ID #85753	BENCHMARK RANKIN (COOK M	366.0	UNITED TEXAS TRAN
-BLUESKY OIL & GAS INC			RECEIVED: 12/03/81	JA: TX			
8208858	F-03-037102	4214930664	102-2	ARNIM J UNIT 10	GIDDINGS (AUSTIN CHALK)	0.0	CLAJON GAS CO
8208858	F-03-037102	4214930664	103	ARNIM J UNIT 10	GIDDINGS (AUSTIN CHALK)	0.0	CLAJON GAS CO

JD NO	JA JKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
-BOBBY BROWN & GUEST ENERGY CORP						RECEIVED: 12/03/81 JA: TX			
8208772	F-7B-033256	4236731842		103		GLENN #1	BUCK RANCH (STRAWN LO)	55.0	SOUTHWESTERN GAS
-BORDER EXPLORATION CO						RECEIVED: 12/03/81 JA: TX			
8208815	F-7B-035151	4214330674		103		C C PUSSELL #4	X-RAY (MARBLE FALLS)	154.0	VALERO ENERGY COR
-BRAMMER ENGINEERING INC						RECEIVED: 12/03/81 JA: TX			
8208941	F-06-041175	4220300000		108		DR J F ROSBOROUGH #1	BETHANY (PETTIT)	15.0	UNITED GAS PIPE L
8208942	F-06-041176	4220300000		108		PATTIE GRIFFIN #1	BETHANY (PETTIT) FIELD	15.0	UNITED GAS PIPE L
-BTA OIL PRODUCERS						RECEIVED: 12/03/81 JA: TX			
8208934	F-7C-041071	4238331801		103		COATES #7	SPRABERRY (TREND AREA)	35.0	EL PASO NATURAL G
8208989	F-7C-041990	4238331802		103		COATES A #8	SPRABERRY (TREND AREA)	35.0	EL PASO NATURAL G
-C L GAGE JR						RECEIVED: 12/03/81 JA: TX			
8208742	F-09-023429	4249700000		103		WAGGONER #1	BOONSVILLE (BEND CONGL)	116.1	NATURAL GAS PIPEL
-CANUS PETROLEUM INC						RECEIVED: 12/03/81 JA: TX			
8208821	F-04-035867	4235500000		103		L G TALBERT #1 82856	CORPUS CHRISTI WEST 9700	26.0	TENNGASCO INC
-CANYON CO						RECEIVED: 12/03/81 JA: TX			
8209026	F-7C-042448	4210533488		103		HOOVER ESTATE #1-3A	AMERICAN (CANYON)	45.0	EL PASO NATURAL G
8209026	F-7C-042449	4210533488		107-TF		HOOVER ESTATE #1-3A	AMERICAN (CANYON)	45.0	EL PASO NATURAL G
-CASSELL OIL CO						RECEIVED: 12/03/81 JA: TX			
8208779	F-7B-034532	4213331084		102-4		G N CREECH #1	EASTLAND COUNTY REGULAR	263.5	WEST CEN-TEX GAS
8208779	F-7B-034532	4213331084		103		G N CREECH #1	EASTLAND COUNTY REGULAR	263.5	WEST CEN-TEX GAS
-CHAMPLIN PETROLEUM COMPANY						RECEIVED: 12/03/81 JA: TX			
8208752	F-03-028655	4205130928		102-2		ALTON POEHL #1	GIDDINGS	144.0	FERGUSON CROSSING
8209013	F-04-042263	4235531553		108		BERTRAM HEIRS #2	STRATTON	13.0	TENNESSEE GAS PIP
8208763	F-03-031211	4205130736		102-2		DOROTHY FRENCH #1	GIDDINGS	58.0	FERGUSON CROSSING
8208763	F-03-031211	4205130736		103		DOROTHY FRENCH #1	GIDDINGS	58.0	FERGUSON CROSSING
8208882	F-03-039216	4205100000		102-2		LYDIA P RUBACH #1	GIDDINGS	0.0	FERGUSON CROSSING
8208882	F-03-039216	4205100000		103		LYDIA P RUBACH #1	GIDDINGS	0.0	FERGUSON CROSSING
8208883	F-03-039217	4205100000		102-2		MILDRED MAHLMANN #1	GIDDINGS	0.0	FERGUSON CROSSING
8208883	F-03-039217	4205100000		103		MILDRED MAHLMANN #1	GIDDINGS	0.0	FERGUSON CROSSING
8208893	F-04-039646	4235531431		102-2		MRS EVA M JONES #2-L	STRATTON	19.7	TENNESSEE GAS PIP
8209024	F-02-042387	4212330852		103		PETER JABLONSKI #1	YORKTOWN N (EDWARDS 1385	12.8	ESPERANZA PIPELIN
-CITIES SERVICE COMPANY						RECEIVED: 12/03/81 JA: TX			
8209093	F-08-042939	4213533690		103		DORA ROBERTS RANCH UNIT #S-03	DORA ROBERTS (PENNSYLVAN	12.0	CITIES SERVICE CO
8209089	F-10-042912	4217930979		103		EAKIN A #3	PANHANDLE GRAY	3.7	PHILLIPS PETROLEU
8208816	F-01-035216	4246530340		102-3		WEST-B #1	MASSIE (STRAWN)	365.0	INTRATEX GAS CO
-CLAYTON W WILLIAMS JR						RECEIVED: 12/03/81 JA: TX			
8208877	F-03-038959	4228700000		102-2		CLARA FISCHER #1	GIDDINGS	0.0	VALERO TRANSMISSI
8208764	F-03-031234	4214900000		102-2		CLARENCE PIETSCH #1	GIDDINGS (EDWARDS GAS)	0.0	VALERO TRANSMISSI
8208768	F-03-032244	4214900000		102-2		J T WEYAND #1	GIDDINGS	0.0	VALERO TRANSMISSI
8208890	F-03-039344	4205100000		102-2		MELVIN UBERNOSKY #2	GIDDINGS (AUSTIN CHALK-3	0.0	VALERO TRANSMISSI
8208917	F-03-040653	4205100000		102-2		ROY HERMANN #6	GIDDINGS (AUSTIN CHALK 3	0.0	VALERO TRANSMISSI
-CLYDE MELTON						RECEIVED: 12/03/81 JA: TX			
8209062	F-7B-042800	4204931900		102-4		C W CAREY -A- #2 (14889)	MAGNUM (CONGL)	25.0	ODESSA NATURAL CO
8209063	F-7B-042801	4204931824		102-4		C W CAREY #1 (14674)	MAGNUM (CONGL)	42.0	ODESSA NATURAL CO
8209064	F-7B-042802	4213331983		102-4		THOMAS A FLIPPEN #1 (15567)	MAGNUM (CONGL)	25.0	SOUTHWESTERN GAS
-COASTAL OIL & GAS CORP						RECEIVED: 12/03/81 JA: TX			
8209085	F-10-042892	4237530853		103		PATTERSON "B" 8359P	PANHANDLE (RED CAVE)	19.0	COLORADO INTERSTA
-COLUMBIA GAS DEVELOPMENT CORP						RECEIVED: 12/03/81 JA: TX			
8209072	F-03-042847	4205131809		102-2		M J FILIPPONE #7	GIDDINGS (AUSTIN-CHALK-3	160.0	FERGUSON CROSSING
-CONOCO INC						RECEIVED: 12/03/81 JA: TX			
8208822	F-04-035857	4250531333		103		FELIA R BENAVIDES B #1	HUNDIDO	700.0	
8208822	F-04-035857	4250531333		107-TF		FELIA R BENAVIDES B #1	HUNDIDO	700.0	
8208765	F-08-031760	4238900002		108		FORD GERALDINE UNIT #124 ID #21021	GERALDINE FORD	0.4	EL PASO NATURAL G

JD NO	JA PKT	API NO	D SEC CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8208978	F-08-041895	4210931481	103	J C RUSSELL -4-#6 ID #23725	GERALDINE FORD	4.4	EL PASO NATURAL G
8208834	F-04-036478	4247932958	102-2	VAQUILLAS RANCH A3 #8	WILDCAT	700.0	E I DU PONT DE NE
8208834	F-04-036478	4247932958	107-TF	VAQUILLAS RANCH A3 #8	WILDCAT	700.0	E I DU PONT DE NE
-COURSON OIL & GAS INC				RECEIVED: 12/03/81 JA: TX			
8208777	F-10-034248	4235731052	102-4	ARCHER-DENDY 1-25C	WILDCAT (CLEVELAND)	270.0	TRANSWESTERN PIPE
-CPC EXPLORATION INC				RECEIVED: 12/03/81 JA: TX			
8209041	F-03-042692	4214930912	102-2	REESE LEASE #13858	GIDDINGS (AUSTIN CHALK)	100.0	PHILLIPS PETROLEU
-CRB OIL & GAS INC				RECEIVED: 12/03/81 JA: TX			
8208948	F-03-041372	4214930900	102-2	DOPSLAUF UNIT #1	GIDDINGS (AUSTIN CHALK -	18.0	CLAJON GAS CO
8209017	F-03-042340	4214930933	102-2	KNAPE #2	GIDDINGS (AUSTIN CHALK-3	10.0	CLAJON GAS CO
8208915	F-03-040381	4214930944	102-2	PECAN CREEK UNIT #1	GIDDINGS (AUSTIN CHALK-3	36.0	CLAJON GAS CO
8208879	F-03-038970	4214931055	102-2	VON ROSENBERG #2	GIDDINGS (AUSTIN CHALK-3	36.0	CLAJON GAS CO
-CROWN EXPLORATION CO				RECEIVED: 12/03/81 JA: TX			
8208971	F-7C-041683	4239900000	102-4	HUDON WHITE #1 (07468)	CECILE (GARDNER)	58.0	LONE STAR GAS CO
-CRYSTAL OIL COMPANY				RECEIVED: 12/03/81 JA: TX			
8208935	F-04-041108	4221500000	108	E C SHOEMAKE ET AL #1	MCALLEN-PHARR	19.9	VALERO INTERSTATE
-D & G GAS & OIL CO				RECEIVED: 12/03/81 JA: TX			
8208957	F-01-041491	4228330782	102-4	SOUTH TEXAS SYNDICATE #113-1	WASHBURN RANCH W (WILCOX	292.0	TRANSCO CO INC
-DALLAS TRUST CO				RECEIVED: 12/03/81 JA: TX			
8208760	F-7B-030436	4236332160	102-4	BRANSON #1	SANTO (MARBLE FALLS)	80.7	SOUTHWESTERN GAS
8208760	F-7B-030436	4236332160	103	BRANSON #1	SANTO (MARBLE FALLS)	80.7	SOUTHWESTERN GAS
8208761	F-7B-030437	4236332350	102-4	STONE C #1	SANTO EAST (3,800 CONGL)	568.7	SOUTHWESTERN GAS
8208761	F-7B-030437	4236332350	103	STONE C #1	SANTO EAST (3,800 CONGL)	568.7	SOUTHWESTERN GAS
-DALTON H COBB				RECEIVED: 12/03/81 JA: TX			
8208852	F-08-037061	4238930940	102-4	STATE SCHOOL BOARD NB #1	ARNO N	385.0	INTRATEX GAS CO
-DAVID A SCHLACHTER OIL & GAS				RECEIVED: 12/03/81 JA: TX			
8208771	F-7C-03011	4210500000	108	V I PIERCE #3 ID#47043	V I P CLEARFORK	18.0	LADD PETROLEUM CO
-DELTA DRILLING CO				RECEIVED: 12/03/81 JA: TX			
8208812	F-7C-035138	4210500000	103	BEAN 26 #3	OZONA (CANYON)	0.0	NORTHERN NATURAL
8208812	F-7C-035138	4210500000	107-TF	BEAN 26 #3	OZONA (CANYON)	0.0	NORTHERN NATURAL
8208841	F-06-036776	4236500000	102-2	BIGGS #1	CARTHAGE SE (CV)	0.0	WESTERN GAS CORP
8208841	F-06-036776	4236500000	103	BIGGS #1	CARTHAGE SE (CV)	0.0	WESTERN GAS CORP
8208945	F-06-041258	4236500000	102-2	BOWEN #1	NORTH BECKVILLE	1191.0	NATURAL GAS PIPEL
8208874	F-06-037866	4236500000	102-2	D B HARDY #1 76949	BECKVILLE N (CV)	0.0	NATURAL GAS PIPE
8208874	F-06-037866	4236500000	103	D B HARDY #1 76949	BECKVILLE N (CV)	0.0	NATURAL GAS PIPE
-DEPCO INC				RECEIVED: 12/03/81 JA: TX			
8208996	F-8A-040034	4207931368	103	WHITEFACE UNIT #132	LEVELLAND	9.7	CITIES SERVICE CO
-DIAMEX CO				RECEIVED: 12/03/81 JA: TX			
8208781	F-04-034637	4247932826	102-4	MARTIN VOLZ #1	WILDCAT	110.0	UNITED TEXAS TRAN
8208781	F-04-034637	4247932826	103	MARTIN VOLZ #1	WILDCAT	110.0	UNITED TEXAS TRAN
-DIAMOND SHAMROCK CORPORATION				RECEIVED: 12/03/81 JA: TX			
8208956	F-10-041453	4229530969	103	ALEX BORN 2-373	LIPSCOMB SW	562.0	
-DINERO OIL CO				RECEIVED: 12/03/81 JA: TX			
8208830	F-02-036227	4217531422	102-4	HOFF #2	MAETZE (3315)	180.0	TRUNKLINE GAS CO
8209056	F-04-042767	4227331506	103	KING RANCH INC #2	KINGSVILLE	55.0	VALERO TRANSMISSI
-DIVERSE ENERGY INC				RECEIVED: 12/03/81 JA: TX			
8208991	F-7B-042025	4236332692	103	TOMERLIN #1A	TOMERLIN (CONGL)	35.5	SOUTHWESTERN GAS
-DORCHESTER EXPLORATION INC				RECEIVED: 12/03/81 JA: TX			
8208983	F-08-041941	4243130907	103	L R FOSTER 4-2	CONGER (PENN)	274.0	ESPERANZA PIPELIN
-DUKE OIL & GAS CO				RECEIVED: 12/03/81 JA: TX			
8208922	F-06-040921	4220300000	108	ABNEY ABNEY WHELAN G 16	LONGWOOD (GOODLAND LIME)	48.0	ARKANSAS LOUISIAN
8208927	F-06-040936	4220300000	108	BELL DANIELS G 10	LONGWOOD (GOODLAND LIME)	48.0	ARKANSAS LOUISIAN
8208928	F-06-040937	4220300000	108	BELL DANIELS G 11	LONGWOOD (GOODLAND LIME)	48.0	ARKANSAS LOUISIAN

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8208923	F-06-040931	4220300000		108		BELL DANIELS G 5	LONGWOOD (GOODLAND LIME)	48.0	ARKANSAS LOUISIAN
8208924	F-06-040932	4220300000		108		BELL DANIELS G 6	LONGWOOD (GOODLAND LIME)	48.0	ARKANSAS LOUISIAN
8208925	F-06-040934	4220300000		108		BELL DANIELS G 8	LONGWOOD (GOODLAND LIME)	48.0	ARKANSAS LOUISIAN
8208926	F-06-040935	4220300000		108		BELL DANIELS G 9	LONGWOOD (GOODLAND LIME)	48.0	ARKANSAS LOUISIAN
						RECEIVED: 12/03/81 JA: TX			
-ED S SPRAGINS									
8208753	F-09-029138	4249731724		103		L J JOHNSON #1-076124	BOONESVILLE (BEND CONGLO	100.0	LONE STAR GAS CO
						RECEIVED: 12/03/81 JA: TX			
-EL PASO NATURAL GAS COMPANY									
8209061	F-10-042793	4217923709		108		GRIFFIN #1	PANHANDLE WEST	15.0	EL PASO NATURAL G
8209043	F-10-042713	4248326096		108		HALL B #1	PANHANDLE EAST	19.0	EL PASO NATURAL G
8208869	F-10-037519	4217923744		108		REEVES #1	PANHANDLE WEST	16.0	EL PASO NATURAL G
						RECEIVED: 12/03/81 JA: TX			
-ELSBURY & MCGREW									
8208998	F-03-042127	4219900000		107-PE		SOUTH HAMPTON UNIT #3L ID #41189	HAMPTON SOUTH (YEGUA I)	60.0	ARCO OIL & GAS CO
						RECEIVED: 12/03/81 JA: TX			
-ENERGY RESERVES GROUP INC									
8208940	F-10-041160	4235700000		108		HAWK #809	FARNSWORTH	1.9	PHILLIPS PETROLEU
8208933	F-09-041065	4207700000		108		OLSEN A #3	DILLARD S E	2.4	CITIES SERVICE OI
						RECEIVED: 12/03/81 JA: TX			
-ENERGY SOURCES INC									
8208813	F-03-035139	4216730809		103		MACO STEWART 2L-S/N (NOT AVAILABLE)	HITCHCOCK (4780')	182.5	VALERO TRANSMISSI
8208814	F-03-035140	4216730809		103		MACO STEWART 2U-S/N (NOT AVAILABLE)	HITCHCOCK (4590')	140.5	VALERO TRANSMISSI
						RECEIVED: 12/03/81 JA: TX			
-ENSERCH EXPLORATION INC									
8208819	F-05-035408	4221330309		103		C A PEACOCK #2	OPELIKA	0.0	LONE STAR GAS CO
8208819	F-05-035408	4221330309		107-TF		C A PEACOCK #2	OPELIKA	0.0	LONE STAR GAS CO
8208689	F-05-039328	4221330319		103		M E KILLINGSWORTH #2	OPELIKA	0.0	LONE STAR GAS CO
						RECEIVED: 12/03/81 JA: TX			
-EVERGREEN OIL CORP									
8208975	F-01-041780	4217730657		102-2		WILLIAMS #1	COST (AUSTIN CHALK)	35.0	TIPPERARY GATHERI
8208975	F-01-041780	4217730657		103		WILLIAMS #1	COST (AUSTIN CHALK)	35.0	TIPPERARY GATHERI
						RECEIVED: 12/03/81 JA: TX			
-EXXON CORPORATION									
8209028	F-08-042494	4200332792		103		FULLERTON CLEARFORK UNIT #1517	FULLERTON	15.0	PHILLIPS PETROLEU
8208880	F-08-038997	4200332547		103		FULLERTON CLEARFORK UNIT #1825	FULLERTON	15.0	PHILLIPS PETROLEU
8208947	F-08-041359	4210332494		103		J B TUBB D #3U	SAND HILLS (MCKNIGHT)	100.0	EL PASO NATURAL G
*8209037	F-04-042670	4227331315		102-4		K R ALAZAN 325-F (06998)	ALAZAN (ZONE H-10 C)	620.0	ARMCO STEEL CORP
*8209039	F-04-042672	4227331501		102-4		K R ALAZAN 360 (06998)	ALAZAN (F-77)	32.0	ARMCO STEEL CORP
*8209038	F-04-042671	4227331540		102-4		K R BORREGOS 564 (06544)	BORREGOS (ZONE S-7,SW)	100.0	ARMCO STEEL CORP
*8209091	F-04-042914	4235530856		102-4		K R CHILTIPIN 52 (79150)	ARNOLD-DAVID (10,400)	256.5	ARMCO STEEL CORP
8208949	F-10-041396	4235700000		108		M C JONES #2L	DUDE WILSON	13.8	TRANSWESTERN PIPE
*8208896	F-06-039737	4207330398		102-4		REKLAW GAS UNIT 3 #3	REKLAW (TRAVIS PEAK)	400.0	ARMCO STEEL CORP
8208960	F-08-041608	4200332847		103		STATE UNIVERSITY EH #2	MCFARLAND (QUEEN)	4.0	
						RECEIVED: 12/03/81 JA: TX			
-FLORIDA EXPLORATION COMPANY									
8208913	F-7C-040233	4243532527		103		FLORENCE 27 #1	PHYLLIS (SONORA)	0.0	INTRATEX GAS CO
8208913	F-7C-040233	4243532527		107-TF		FLORENCE 27 #1	PHYLLIS (SONORA)	0.0	INTRATEX GAS CO
8208776	F-7C-034145	4243500000		107-TF		HUNT 36 #1	PHYLLIS SONORA (CANYON L	275.0	INTRATEX
8208844	F-08-036795	4222731871		103		NEEL #1	FLORAC	73.0	ODESSA NATURAL CO
8208847	F-08-036848	4222731711		103		STELLA PETTY #1-32	FLORAC	75.0	ODESSA NATURAL CO
						RECEIVED: 12/03/81 JA: TX			
-FOREST OIL CORPORATION									
8208919	F-04-040832	4247933024		102-2		VAQUILLAS RANCH STATE GAS UNIT #2	GATO CREEK (LOBO 3)	150.0	UNITED TEXAS TRAN
8208919	F-04-040832	4247933024		107-TF		VAQUILLAS RANCH STATE GAS UNIT #2	GATO CREEK (LOBO 3)	150.0	UNITED TEXAS TRAN
						RECEIVED: 12/03/81 JA: TX			
-FUNK EXPLORATION INC									
8208823	F-10-035988	4235700000		102-2		LATHAM #1	WILDCAT	0.0	
						RECEIVED: 12/03/81 JA: TX			
-G C HERRMANN CO									
8209082	F-10-042878	4217930902		103		MELTON 04595 #2	PANHANDLE	16.8	CABOT PIPELINE CO
						RECEIVED: 12/03/81 JA: TX			
-GENERAL AMERICAN OIL COMPANY OF TEX									
8209014	F-08-042291	42103325?3		103		CENTRAL DUNE UNIT #3018	DUNE	2.2	WARREN PETROLEUM
						RECEIVED: 12/03/81 JA: TX			
-GENERAL PRODUCTION CORP									
8208758	F-03-030099	4205131115		103		L J SANDERS #1	WILLARD SE (NAVARRO B) F	0.0	FERGUSON CROSSING

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
-GEOCHEMICAL SURVEYS INC						RECEIVED: 12/03/81 JA: TX			
8208767	F-7C-032026	4243500000		103		SIMMONS RANCH #3	SONORA (CANYON UPPER)	115.0	EL PASO NATURAL G
8208767	F-7C-032026	4243500000		107-TF		SIMMONS RANCH #3	SONORA (CANYON UPPER)	115.0	EL PASO NATURAL G
-GETTY OIL COMPANY						RECEIVED: 12/03/81 JA: TX			
8208937	F-08-041125	4238931134		103		AVA FARWELL TRUST #1	FARWELL (BRUSHY CANYON 6	7.0	
8209075	F-08-042852	4210332521		103		NORTH MCELROY UNIT #2156	MCELROY	3.0	PHILLIPS PETROLEU
8209073	F-08-042850	4210332480		103		NORTH MCELROY UNIT #2821	MCELROY	3.0	PHILLIPS PETROLEU
8209074	F-08-042851	4210332472		103		NORTH MCELROY UNIT #2829	MCELROY	4.0	PHILLIPS PETROLEU
8209076	F-08-042853	4210332475		103		NORTH MCELROY UNIT #2836	MCELROY	5.0	PHILLIPS PETROLEU
-GLEN COVE OPERATING CO						RECEIVED: 12/03/81 JA: TX			
8209030	F-7B-042522	4208331350		103		BILLIE MCCORD #1 (77611)	GLEN COVE E (FRY)	165.0	UNION TEXAS PETRO
8209032	F-7B-042526	4208331280		103		L P WHITTINGTON #2 (77449)	GLEN COVE EAST (JENNINGS	201.0	VALERO TRANSMISSI
8209031	F-7B-042523	4208331645		103		R HAMON #1 (85191)	GLEN COVE EAST (JENNINGS	125.0	VALERO TRANSMISSI
-GOLDKING PRODUCTION COMPANY						RECEIVED: 12/03/81 JA: TX			
8208970	F-02-041656	4239100000		102-4		HYNES #2-T	PAPALOTE E	96.0	HOUSTON PIPE LINE
-GHR ENERGY CORP						RECEIVED: 12/03/81 JA: TX			
8208954	F-04-041420	4250531095		102-4		LA PERLA #A-1	LA PERLA RANCH (9100)	657.0	VALERO TRANSMISSI
8208954	F-04-041420	4250531095		107-TF		LA PERLA #A-1	LA PERLA RANCH (9100)	657.0	VALERO TRANSMISSI
8208929	F-04-041028	4247932477		102-4		LUNDELL #8	LUNDELL (LOBO)	183.0	VALERO TRANSMISSI
8208929	F-04-041028	4247932477		107-TF		LUNDELL #8	LUNDELL (LOBO)	183.0	VALERO TRANSMISSI
-GRACE PETROLEUM CORPORATION						RECEIVED: 12/03/81 JA: TX			
8208903	F-04-039838	4224931039		103		STELZIG-ZWERNEMAN #13	AMARGOSA (2200)	144.0	NATURAL GAS PIPEL
-GREAT WEST OPERATING CO INC						RECEIVED: 12/03/81 JA: TX			
8208982	F-09-041927	4223733844		103		DAWKINS #3	DAWKINS CONGLOMERATE	144.0	CITIES SERVICE CO
-GULF OIL CORPORATION						RECEIVED: 12/03/81 JA: TX			
8208900	F-10-039753	4223301094		103		C L DIAL #282	PANHANDLE HUTCHINSON	98.0	PHILLIPS PETROLEU
8208783	F-10-034848	4223330906		103		E COCKRELL TR C (NCT-8) #51	PANHANDLE HUTCHINSON	35.0	GETTY OIL CO
-H L HAWKINS JR						RECEIVED: 12/03/81 JA: TX			
8208974	F-04-041775	4235531655		102-4		S M SCARBOROUGH EST #1-C	ROBSTOWN 5200*	300.0	HOUSTON PIPELINE
-HANSON MINERALS CO						RECEIVED: 12/03/81 JA: TX			
8208873	F-01-037854	4231131564		102-4		HAGIST RANCH GAS UNIT #1	HAGIST RANCH (1200*)	54.0	SEAGULL PIPELINE
-HARKINS & COMPANY						RECEIVED: 12/03/81 JA: TX			
8208860	F-04-037266	4213134435		102-4		LA VENADA-STATE #1	LA VENADA (HERBST III) F	109.5	VALERO TRANSMISSI
8208860	F-04-037266	4213134435		103		LA VENADA-STATE #1	LA VENADA (HERBST III) F	109.5	VALERO TRANSMISSI
-HENDERSON CLAY PRODUCTS INC						RECEIVED: 12/03/81 JA: TX			
8208827	F-06-036115	4240131061		103		F L JENNINGS WELL #1	RUFUS (TRAVIS PEAK)	160.0	HENDERSON CLAY PR
-HILLIARD OIL & GAS INC						RECEIVED: 12/03/81 JA: TX			
8209079	F-04-042858	4204730885		102-4		BARBARA LIPS B #2	LOPEZ RANCH (VICKSBURG 1	720.0	CHANNEL INDUSTRIE
8209077	F-04-042856	4204730909		102-4		BARBARA LIPS B #3	LOPEZ RANCH (VICKSBURG 1	725.0	CHANNEL INDUSTRIE
-HINSON BROTHERS A PARTNERSHIP						RECEIVED: 12/03/81 JA: TX			
8209016	F-02-042335	4223900000		108		J H FENNER #1 50828	FENNER CATAHOULA #2700	9.6	TRUNKLINE GAS CO
-HINTON PRODUCTION COMPANY						RECEIVED: 12/03/81 JA: TX			
8208931	F-05-041057	4246730478		102-4		H P HUCKABAY #1	MARTINS MILL (RODESSA)	500.0	LONE STAR GAS CO
8208931	F-05-041057	4246730478		103		H P HUCKABAY #1	MARTINS MILL (RODESSA)	500.0	LONE STAR GAS CO
-HNG OIL COMPANY						RECEIVED: 12/03/81 JA: TX			
8209002	F-7C-042165	4243500000		108		BROWN 78 #4	SAWYER (WOLFCAMP)	15.8	INTRATEX GAS CO
8209004	F-7C-042167	4243500000		108		FIELDS 20 #1	SAWYER (CANYON)	44.1	INTRATEX GAS CO
8209005	F-7C-042175	4243500000		108		FIELDS 20 #4	SAWYER (CANYON)	32.0	INTRATEX GAS CO
8209003	F-7C-042166	4243500000		108		GALBREATH 80 #1	SAWYER (CANYON)	53.9	INTRATEX GAS CO
8209006	F-7C-042178	4243500000		108		HICKS 61 #2	SAWYER (CANYON)	38.9	INTRATEX GAS CO
8209052	F-7C-042745	4243500000		108		JONES 120 #3	SAWYER CANYON	59.3	INTRATEX GAS CO
8209010	F-7C-042244	4243500000		108		KELLY 115 #4	SAWYER (CANYON)	57.2	INTRATEX GAS CO
8208988	F-04-041981	4250531134		107-TF		SERAPIO VELA HEIRS #2	ROLETA (8150)	570.0	HOUSTON PIPE LINE

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8208840	F-7C-036705	4243532183		103		SIMMONS 72 #2	SAWYER (CANYON)	41.5	INTRATEX GAS CO
8209033	F-7C-042527	4243532541		103		SIMMONS 73 #2	SAWYER CANYON	406.0	INTRATEX GAS CO
8209033	F-7C-042527	4243532541		107-TF		SIMMONS 73 #2	SAWYER CANYON	406.0	INTRATEX GAS CO
-HUMBLE EXPLORATION CO INC				RECEIVED: 12/03/81 JA: TX					
8208824	F-03-036015	4247700000		102-4		HESTIA #1	GIDDINGS (AUSTIN CHALK)	0.0	PHILLIPS PETROLEU
8208824	F-03-036015	4247700000		103		HESTIA #1	GIDDINGS (AUSTIN CHALK)	0.0	PHILLIPS PETROLEU
8208831	F-03-036305	4214930918		102-2		KATE ELIZABETH G #1	GIDDINGS (AUSTIN CHALK)	181.0	PHILLIPS PETROLEU
8208831	F-03-036305	4214930918		103		KATE ELIZABETH G #1	GIDDINGS (AUSTIN CHALK)	181.0	PHILLIPS PETROLEU
8208843	F-03-036787	4228730862		102-2		LAUREN B #1	GIDDINGS (AUSTIN CHALK)	468.5	PHILLIPS PETROLEU
8208843	F-03-036787	4228730862		103		LAUREN B #1	GIDDINGS (AUSTIN CHALK)	468.5	PHILLIPS PETROLEU
8208832	F-03-036306	4214930659		102-2		MILDRED KRAUTZ #1	GIDDINGS (AUSTIN CHALK)	13.7	PHILLIPS PETROLEU
8208832	F-03-036306	4214930659		103		MILDRED KRAUTZ #1	GIDDINGS (AUSTIN CHALK)	13.7	PHILLIPS PETROLEU
-INDIAN WELLS OIL CO				RECEIVED: 12/03/81 JA: TX					
8208951	F-7C-041412	4223531657		102-2		RICHEY 42A-3	PROBANDT (CANYON)	100.0	NORTHERN NATURAL
8208950	F-7C-041411	4223531696		102-2		RICHEY 54A-4	PROBANDT (CANYON)	72.0	NORTHERN NATURAL
8208952	F-7C-041413	4223531697		102-2		RICHEY 54A-5	PROBANDT (CANYON)	145.0	NORTHERN NATURAL
8208953	F-7C-041414	4223531659		102-2		RICHEY 55A-3	PROBANDT (CANYON)	105.0	NORTHERN NATURAL
-INVESTEK INC				RECEIVED: 12/03/81 JA: TX					
8208920	F-09-040862	4223700000		103		OWENS	JACK COUNTY REGULAR	146.9	SOUTHWESTERN GAS
-J B PRODUCTION CO				RECEIVED: 12/03/81 JA: TX					
8208969	F-7C-041632	4239931810		103		TREADAWAY UNIT #1 WELL	SLB (MORRIS SAND)	0.0	ODESSA NATURAL CO
-J CLEO THOMPSON & JAMES CLEO THOMPS				RECEIVED: 12/03/81 JA: TX					
8208992	F-7C-042027	4210533436		102-4		UNIVERSITY 29-31 #1	UNIVERSITY 29 (STRAWN DE	245.0	
-JACKSON EXPLORATION INC				RECEIVED: 12/03/81 JA: TX					
8208904	F-7C-039902	4246131771		103		VENABLE #2-A	SPRABERRY (TREND AREA)	30.0	EL PASO NATURAL G
-JAMES B HARBIN				RECEIVED: 12/03/81 JA: TX					
8208838	F-7B-036694	4208300000		108		NORRIS 4 01094	DUNHAM YOUNG	2.0	LONE STAR GAS CO
8208839	F-7B-036695	4208300000		108		NORRIS 7 01094	DUNHAM YOUNG	34.0	LONE STAR GAS CO
-JOE C RICHARDSON JR				RECEIVED: 12/03/81 JA: TX					
8209087	F-10-042898	4219530799		103		COLDWATER #1	GRUVER NW (UPPER MORROW)	180.0	PHILLIPS PETROLEU
-JUSTISS OIL CO INC				RECEIVED: 12/03/81 JA: TX					
8208842	F-06-036785	4220330042		107-TF		RONALD C MATTHEWS GAS UNIT #1	WOODLAWN (COTTON VALLEY)	525.0	EAST TEXAS INDUST
-KEITH D GRAHAM				RECEIVED: 12/03/81 JA: TX					
8209034	F-03-042602	4205131683		102-2		RIES #1	GIDDINGS (AUSTIN CHALK-3	58.4	CHAMPLIN PETROLEU
-KERR-MCGEE CORPORATION				RECEIVED: 12/03/81 JA: TX					
8208846	F-10-036824	4221131308		102-2		BOWERS 1-257	ALLISON PARKS (MORROW U)	0.0	
8209083	F-10-042885	4234130712		103		WELLS OIL #2	PANHANDLE (MOORE)	912.0	PHILLIPS PETROLEU
-L & L PETROLEUM CORPORATION				RECEIVED: 12/03/81 JA: TX					
8208738	F-02-012639	4246931383		103		C K MCCAN JR #5	SALEM (2860)	0.0	TEXAS EASTERN TRA
-L R SPRADLING				RECEIVED: 12/03/81 JA: TX					
8208750	F-10-027865	4217900000		108		M C DOSS #12	PANHANDLE	1.9	PHILLIPS PETROLEU
8208751	F-10-027865	4217900000		108		M C DOSS #7	PANHANDLE	1.9	PHILLIPS PETROLEU
-LA ACEITE ENERGY INC				RECEIVED: 12/03/81 JA: TX					
8208973	F-7B-041731	4205933094		103		NEUMAN-2041 #1	PUTNAM N (DUFFER)	18.0	LONE STAR GAS CO
-LA SALLE ENERGY CORP				RECEIVED: 12/03/81 JA: TX					
8208775	F-03-033959	4214900000		102-2		BYLER #1	GIDDINGS	0.0	FALCON GAS CO
8208835	F-02-036508	4225500000		102-2		NANCE #1	WILDCAT	0.0	
-LADD PETROLEUM CORPORATION				RECEIVED: 12/03/81 JA: TX					
8209015	F-7B-042305	4236731402		103		BLAIR-WOODY #2-T	TOTO (BEND CONGL LOWER)	293.8	LONE STAR GAS CO
-LONGHORN GAS CO INC				RECEIVED: 12/03/81 JA: TX					
8208739	F-06-014968	4240100000		103		MARY ROGERS #1	POD (COTTON VALLEY)	144.0	DELHI GAS PIPELIN
-MCBRIDE PRODUCTION CO				RECEIVED: 12/03/81 JA: TX					
8208990	F-7B-042009	4242931848		103		W FAMBROUGH #1 16361	WAYLAND	15.0	SOUTHWESTERN GAS

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
-MCCORMICK OPERATING CO						RECEIVED: 12/03/81 JA: TX			
8208866	F-06-037349	4240131154		102-2		FORBUS ESTATE GAS UNIT #4	OAK HILL (COTTON VALLEY)	245.0	HYDROCARBON TRANS
8208866	F-06-037349	4240131154		107-TF		FORBUS ESTATE GAS UNIT #4	OAK HILL (COTTON VALLEY)	245.0	HYDROCARBON TRANS
-MCFARLANE OIL CO INC						RECEIVED: 12/03/81 JA: TX			
8208817	F-02-035325	4246931602		103		PICKERING & BUHLER #26	PLACEDO	0.0	TENNECO CHEMICALS
-MCMORAN PRODUCTION CO						RECEIVED: 12/03/81 JA: TX			
8208870	F-04-037735	4270030035		102-4		STATE TRACT 1064-L #B4L	BLOCK 1064-L	1000.0	VALLEY PIPE LINES
8208866	F-04-039227	4270030041		102-4		STATE TRACT 1064-L A-6AL	BLOCK 1064-L	1825.0	VALLEY PIPE LINE
8208887	F-04-039228	4270030032		102-4		STATE TRACT 1064-L A-8 U	BLOCK 1064-L	900.0	VALLEY PIPE LINE
8208884	F-04-039225	4270030034		102-4		STATE TRACT 1064-L B-3 L	BLOCK 1064-L	1460.0	VALLEY PIPE LINE
8208872	F-04-037768	4270030035		102-4		STATE TRACT 1064-L B-4U	BLOCK 1064-L	1500.0	VALLEY PIPE LINES
8208885	F-04-039226	4270030027		102-4		STATE TRACT 1064-L SW/4 B-2 L	BLOCK 1064-L	1095.0	VALLEY PIPE LINE
-MEWBOURNE OIL COMPANY						RECEIVED: 12/03/81 JA: TX			
8208748	F-10-027111	4235730797		108		BROWNIE #1 ID #78669	ELLIS RANCH (CLEVELAND)	14.0	DIAMOND SHAMROCK
-MGF OIL CORP						RECEIVED: 12/03/81 JA: TX			
8208976	F-08-041804	4231732324		103		CLINE "A" #1	SPRABERRY (TREND AREA)	16.7	PHILLIPS PETROLEU
-MITCHELL ENERGY CORPORATION						RECEIVED: 12/03/81 JA: TX			
8208825	F-09-036047	4249700000		108		ADELE CLOUGH #4 87010	BOONSVILLE (BEND CONGL G	4.6	NATURAL GAS PIPEL
8208762	F-09-030971	4249731771		103		ASCCU #5-7	ALVORD SOUTH (CADDO CONG	0.0	NATURAL GAS PIPEL
8208865	F-09-037325	4249732036		103		C HOLLAND #1	BOONSVILLE (BEND CONGLOM	150.0	SOUTHWESTERN GAS
8208876	F-09-038774	4249731942		103		DAVID W BRYANT #2	MORRIS (CONSOLIDATED CON	350.0	NATURAL GAS PIPEL
8209022	F-78-042361	4236700000		108		DON SPRINGFIELD #1 79604	RENO (CONGL)	10.8	NATURAL GAS PIPEL
8209019	F-09-042352	4223733596		103		ETHEL WORTHINGTON #1 21360	JACK (COUNTY REGULAR)	33.8	
8208864	F-09-037324	4249732109		103		FLOYD MCCURDY #1	BOONSVILLE (BEND CONGL G	50.0	SOUTHWESTERN GAS
8208850	F-09-036927	4249732041		103		FRANCES LAMM #2	BOONSVILLE (BEND CONGLOM	300.0	NATURAL GAS PIPEL
8208766	F-09-031588	4223700000		108		G F WIMBERLY #1	RICHARD W R (MARBLE FALL	0.0	NATURAL GAS PIPEL
8208849	F-09-036881	4249700000		108		H J DEAVERS #1 28622	BOONSVILLE (BEND CONGL G	13.6	NATURAL GAS PIPEL
8208778	F-09-034516	4249700000		108		J B BURNS #1	BOONSVILLE (BEND CONGL G	12.0	LONE STAR GAS CO
8209021	F-09-042360	4223700000		108		J B OWEN #1 71227	GATES (WEST CONGL)	10.7	LONE STAR GAS CO
8208898	F-09-039742	4249731997		103		M F GERBER #2	BOONSVILLE (BEND CONGLOM	125.0	NATURAL GAS PIPEL
8209008	F-09-042228	4249700000		108		MARIE WAGGONER #2 43636	BOONSVILLE (BEND CONGL G	9.5	NATURAL GAS PIPEL
8208871	F-09-037744	4249732080		103		MARY F STEWART #2	BOONSVILLE (BEND CONGLOM	130.0	NATURAL GAS PIPEL
8209020	F-05-042354	4228900000		108		O K TAYLOR #1 78477	BUFFALO (SOUTH 8700)	12.2	LONE STAR GAS CO
8208897	F-09-039740	4249732159		103		ROBERT STUTT #2	BOONSVILLE (BEND CONGLOM	335.0	NATURAL GAS PIPEL
8208980	F-09-041913	4249732145		103		TCWB #28-T	BOONSVILLE (BEND CONGL G	170.0	NATURAL GAS PIPEL
8209009	F-09-042231	4223700000		108		WILLIE R RICHARDS #1 43024	CARY-MAG (SOUTH CONGL)	10.6	SOUTHWESTERN GAS
-MOBIL PRDG TEXAS & NEW MEXICO INC						RECEIVED: 12/03/81 JA: TX			
8209084	F-08-042890	4232931005		103		SHACKELFORD SPRABERRY UNIT #6197	SPRABERRY (TREND AREA)	21.5	EL PASO NATURAL G
8209060	F-08-042787	4232931004		103		SHACKELFORD SPRAYBERRY UNIT #6207	SPRABERRY (TREND AREA)	12.1	EL PASO NATURAL G
*8209040	F-08-042675	4247532291		103		STATE AK #7	CAPRITO (DELAWARE MIDDLE	47.1	INTRATEX GAS CO
-MONSANTO COMPANY						RECEIVED: 12/03/81 JA: TX			
8209057	F-8A-042777	4207931385		103		MASTEN #62	LEVELLAND	5.0	CITIES SERVICE CO
8209058	F-8A-042778	4207931384		103		MASTEN #64	LEVELLAND	5.0	CITIES SERVICE CO
8209047	F-8A-042739	4250131951		103		SAWYER #1	WASSON	10.0	SHELL OIL CO
8209048	F-8A-042740	4250131994		103		SAWYER #2	WASSON	10.0	SHELL OIL CO
8209049	F-8A-042741	4250132025		103		SAWYER #3	WASSON	10.0	SHELL OIL CO
8209050	F-8A-042742	4250132123		103		SAWYER #4	WASSON	10.0	SHELL OIL CO
8209051	F-8A-042743	4250132122		103		SAWYER #5	WASSON	10.0	SHELL OIL CO
-MONTERREY PETROLEUM CORP						RECEIVED: 12/03/81 JA: TX			
8209070	F-04-042838	4247932898		103		M M A CATTLE CO #1 (93207)	LAREDO (LOBO)	120.0	SOUTHERN PIPELINE
-MORAN EXPLORATION INC						RECEIVED: 12/03/81 JA: TX			
8208741	F-7C-022361	4238300000		108-ER		S E STOUT #1	SPRABERRY	10.6	EL PASO NATURAL G
-MWJ PRODUCING CO						RECEIVED: 12/03/81 JA: TX			

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209027	F-7C-042450	4223512051		103		UNIVERSITY 3 #1	SPRABERRY (TREND AREA)	0.0	PHILLIPS PETROLEU
-NATURAL GAS ANADARKO INC				RECEIVED: 12/03/81 JA: TX					
8208895	F-10-039712	4235731118		102-4		KILE #1-300C	TURNER SE (MORROW UPPER)	180.0	TRANSWESTERN PIPE
-NORTH AMERICAN ROYALTIES INC				RECEIVED: 12/03/81 JA: TX					
8208859	F-03-037203	4232131045		102-4		CORNELIUS #2 (#94733)	WADSWORTH S (11,100) FIE	600.0	HOUSTON PIPE LINE
-NUGGET OIL CORP				RECEIVED: 12/03/81 JA: TX					
8208918	F-01-040756	4212732218		103		MCKNIGHT UNIT #16	WINTER GARDEN (OLMOS)	73.0	VALERO TRANSMISSI
-OJB INC				RECEIVED: 12/03/81 JA: TX					
8208820	F-7C-035597	4210500000		103		DOROTHY PIERCE 51-1	OZONA (CANYON SAND)	72.0	
8208820	F-7C-035597	4210500000		107-TF		DOROTHY PIERCE 51-1	OZONA (CANYON SAND)	72.0	
-PALO PETROLEUM INC				RECEIVED: 12/03/81 JA: TX					
8208755	F-7B-029385	4213331713		103		JOHNSON B #1	FOSTER (MARBLE FALLS)	26.0	ODESSA NATURAL CO
-PANCAKE-WATTS				RECEIVED: 12/03/81 JA: TX					
8208999	F-7B-042135	4205932940		102-4		HILL EST #1 (92340)	PANCAKE-WATTS (ELLENBURG	193.0	VALERO TRANSMISSI
-PEARSON-SIBERT OIL CO OF TEXAS				RECEIVED: 12/03/81 JA: TX					
8209081	F-7C-042876	4208131016		103		KEYES A #1	FRANK PEARSON (STRAWN RE	45.0	SUN OIL CO
8209092	F-7C-042918	4208130994		103		MILLICAN REEF UNIT #1-S	MILLICAN	133.0	SUN OIL CO
8209080	F-7C-042875	4208131007		103		MILLICAN REEF UNIT #6-P	MILLICAN	38.0	SUN OIL CO
-PETRO-LEWIS CORPORATION				RECEIVED: 12/03/81 JA: TX					
8208878	F-06-038968	4241900000		103		F W COCKRELL UNIT #1	JOAQUIN (PETTIT L)	189.8	UNITED GAS PIPELI
8208981	F-02-041925	4229700000		108		SANGER HEIRS #1-C	SIERRA VISTA (SLICK A)	17.0	TEXAS EASTERN TRA
8208912	F-03-040223	4215700000		103		SIDNEY BEARD #3	LONG POINT DOME (FRIO)	47.8	DOW CHEMICAL CO U
-PHILLIPS PETROLEUM COMPANY				RECEIVED: 12/03/81 JA: TX					
8208997	F-08-042124	4249531355		103		BASH - #15 (16091)	KEYSTONE (COLBY)	7.3	SID RICHARDSON GA
8209011	F-08-042253	4249531359		103		BASH-16 (16091)	KEYSTONE (COLBY)	21.5	SID RICHARDSON GA
8208853	F-10-037090	4223331053		103		DUBOISE #4	PANHANDLE HUTCHINSON	0.0	EL PASO NATURAL G
8208854	F-10-037091	4223331054		103		DUBOISE #5	PANHANDLE HUTCHINSON	0.0	EL PASO NATURAL G
8208984	F-06-041960	4213507898		108		GOLDSMITH ANDECTOR UNIT L17 (21193)	GOLDSMITH (CLEARFORK)	22.9	EL PASO NATURAL G
8208856	F-10-037093	4234130674		103		JARVIS #3	PANHANDLE MOORE	0.0	EL PASO NATURAL G
8208857	F-10-037094	4234130676		103		JARVIS #4	PANHANDLE MOORE	0.0	EL PASO NATURAL G
8208799	F-10-035088	4217900000		108		JOHNSON AA #14	PANHANDLE GRAY	0.0	
8208808	F-10-035100	4217900000		108		JOHNSON BB #10	PANHANDLE GRAY	0.0	
8208787	F-10-035031	4217900000		108		JOHNSON BB #11	PANHANDLE GRAY	0.0	
8208789	F-10-035033	4217900000		108		JOHNSON BB #12	PANHANDLE GRAY	0.0	
8208790	F-10-035034	4217900000		108		JOHNSON BB #13	PANHANDLE GRAY	0.0	
8208792	F-10-035036	4217900000		108		JOHNSON BB #14	PANHANDLE GRAY	0.0	
8208791	F-10-035035	4217900000		108		JOHNSON BB #15	PANHANDLE GRAY	0.0	
8208793	F-10-035037	4217900000		108		JOHNSON BB #18	PANHANDLE GRAY	0.0	
8208797	F-10-035061	4217900000		108		JOHNSON BB #2	PANHANDLE GRAY	0.0	
8208798	F-10-035063	4217900000		108		JOHNSON BB #6	PANHANDLE GRAY	0.0	
8208788	F-10-035032	4217900000		108		JOHNSON BB #8	PANHANDLE GRAY	0.0	
8208809	F-10-035107	4217900000		108		JOHNSON CC #11	PANHANDLE GRAY	0.0	
8208810	F-10-035108	4217900000		108		JOHNSON CC #12	PANHANDLE GRAY	0.0	
8208785	F-10-035023	4217900000		108		JOHNSON CC #13	PANHANDLE GRAY	0.0	
8208786	F-10-035024	4217900000		108		JOHNSON CC #14	PANHANDLE GRAY	0.0	
8208784	F-10-035022	4217900000		108		JOHNSON CC #15	PANHANDLE GRAY	0.0	
8208805	F-10-035097	4217900000		108		JOHNSON CC #16	PANHANDLE GRAY	0.0	
8208806	F-10-035098	4217900000		108		JOHNSON CC #17	PANHANDLE GRAY	0.0	
8208807	F-10-038099	4217900000		108		JOHNSON CC #18	PANHANDLE GRAY	0.0	
8208795	F-10-035058	4217900000		108		JOHNSON CC #4	PANHANDLE GRAY	0.0	
8208796	F-10-035059	4217900000		108		JOHNSON CC #5	PANHANDLE GRAY	0.0	
8208804	F-10-035096	4217900000		108		JOHNSON CC #7	PANHANDLE GRAY	0.0	
8208803	F-10-035095	4217900000		108		JOHNSON CC #8	PANHANDLE GRAY	0.0	

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8208794	F-10-035038	4217900000		108		JOHNSON CC #9	PANHANDLE GRAY	0.0	
8208800	F-10-035089	4217900000		108		JOHNSON Z #3	PANHANDLE GRAY	0.0	
8208802	F-10-035094	4217900000		108		JOHNSON Z #8	PANHANDLE GRAY	0.0	
8208801	F-10-035093	4217900000		108		JOHNSON Z #9	PANHANDLE GRAY	0.0	
8208828	F-10-036163	4217900000		103		LEHMAN #5	PANHANDLE GRAY	0.0	
8208855	F-10-037092	4217930877		103		LEHMAN #6	PANHANDLE GRAY	0.0	
8208867	F-10-037448	4217930899		103		LEHMAN #7	PANHANDLE GRAY	0.0	
8208829	F-10-036209	4217900000		103		M DAVIDSON #12	PANHANDLE GRAY	0.0	
8209053	F-7C-042758	4246104346		108		N PEMBROOK S #91-01	SPRABERRY TREND AREA	1.3	NORTHERN NATURAL
8209055	F-08-042761	4213504646		108		SLAT #2	TXL (SILURIAN)	19.2	SHELL OIL CO
8209035	F-09-042613	4249729142		108		WEST B #1	BOONSVILLE BEND CONGLOME	0.0	CITIES SERVICE CO
8209054	F-8A-042758	4203300580		108		WEST JO MILL #9-03	JO MILL SPRABERRY	12.3	GETTY OIL CO
-PIONEER PRODUCTION CORPORATION				RECEIVED: 12/03/81 JA: TX					
8208833	F-10-036476	4229530985		103		FILE UNIT #2-956	MAMMOTH CREEK NORTH (CLE	0.0	NORTHERN NATURAL
8208901	F-10-039790	4229531009		103		J L FRY #2-977	MAMMOTH CREEK NORTH (CLE	0.0	NORTHERN NATURAL
-PITTS OIL CO & DALLAS PROD INC				RECEIVED: 12/03/81 JA: TX					
8208958	F-06-041492	4207330415		102-4		TRAVIS #3	PERCY WHEELER (TRAVIS PE	186.0	UNITED GAS PIPELI
-R L FOREE				RECEIVED: 12/03/81 JA: TX					
8209018	F-7B-042341	4235331134		102-4		J P AYCOCK #1 17474	J & J (CADDO)	54.0	PALO DURO PIPELIN
8209018	F-7B-042341	4235331134		103		J P AYCOCK #1 17474	J & J (CADDO)	54.0	PALO DURO PIPELIN
-RALPH L WAY INC				RECEIVED: 12/03/81 JA: TX					
8209095	F-7C-042972	4238332046		103		UNIVERSITY 10 #5	FARMER (SAN ANDRES)	18.7	NORTHERN NATURAL
8209094	F-7C-042971	4238332047		103		UNIVERSITY 10 #6	FARMER (SAN ANDRES)	18.7	NORTHERN NATURAL
-RAW HIDE OIL & GAS INC				RECEIVED: 12/03/81 JA: TX					
8208979	F-10-041903	4217930909		103		LANGHAM #1	PANHANDLE/GRAY COUNTY/	61.0	COLTEXO CORP
-RELIANCE DEVELOPMENT CORP				RECEIVED: 12/03/81 JA: TX					
8208908	F-10-040172	4223300009		108		RELIANCE-SANFORD #1 (23827)	PANHANDLE WEST	22.0	PANHANDLE PRODUCI
-RETAMCO INC				RECEIVED: 12/03/81 JA: TX					
8208909	F-03-040197	4214939074		103		LORENZ #1	GIDDINGS (BUDA)	19.7	PHILLIPS PETROLEU
-ROBINSON BROS DRILLING CO INC				RECEIVED: 12/03/81 JA: TX					
8208938	F-01-041139	4211730551		103		ROSELLA KIFER #1	COST (AUSTIN CHALK)	73.0	TIPPERARY GATHERI
-RODMAN PETROLEUM CORP				RECEIVED: 12/03/81 JA: TX					
8208996	F-7C-042115	4210500000		108		PIERCE 105	VIP (CLEARFORK)	20.0	NORTHERN NATURAL
8209036	F-7B-042664	4213333010		103		TALLEY #1	EASTLAND COUNTY REGULAR	12.0	LONE STAR GAS CO
-SABINE PRODUCTION COMPANY				RECEIVED: 12/03/81 JA: TX					
8208899	F-04-039745	4235531761		103		DOUGHTY 1-L	WILDCAT	182.5	HOUSTON PIPE LINE
-SAMSON RESOURCES COMPANY				RECEIVED: 12/03/81 JA: TX					
8208914	F-06-040238	4241930328		102-4		R E STRAHAN GAS UNIT #1	NORTH TIMPSON (TRAVIS PE	545.1	DELHI GAS PIPELIN
-SANCHEZ-OBRIEN OIL & GAS CORP				RECEIVED: 12/03/81 JA: TX					
8208921	F-08-040864	4217331152		103		GLENN W HILLGER 1-A	BLALOCK LAKE E (WOLFCAMP	500.0	PHILLIPS PETROLEU
8208891	F-04-039493	4250531363		102-4		VAQUILLAS RANCH LTD #1	LAS OVEJAS (LOBO)	500.0	UNITED TEXAS TRAN
-SCANDRILL CO				RECEIVED: 12/03/81 JA: TX					
8208745	F-09-026019	4250333815		103		KURK #3	YOUNG COUNTY REGULAR	17.9	SUN GAS GATHERING
8208744	F-09-026018	4250333874		103		KURK #4	YOUNG COUNTY REGULAR	21.9	SUN GAS GATHERING
8208826	F-09-036066	4250334616		103		MORRIS STEPHENS #1	KNOX (MISS)	18.3	SUN GAS GATHERING
-SEQUOIA FOSSIL FUELS INC				RECEIVED: 12/03/81 JA: TX					
8209025	F-7B-042419	4241733236		103		WILLIAMS (SEC 70) #1	SHACKELFORD COUNTY REGUL	70.0	DELHI GAS PIPELIN
-SHELL OIL CO				RECEIVED: 12/03/81 JA: TX					
8208936	F-04-041121	4204730912		102-4		HECTOR LOPEZ NO 3	LOPEZ RANCH (VICKSBURG 1	750.0	CHANNEL INDUSTRIE
-SHOW PETROLEUM INC				RECEIVED: 12/03/81 JA: TX					
8208848	F-7B-036859	4204932648		103		BATES #3	BROWN COUNTY REGULAR (MA	196.0	ODESSA NATURAL CO
-SIKES ARLAS M				RECEIVED: 12/03/81 JA: TX					
8209045	F-7B-042725	4204932356		103		G A DAY #1 (16493)	BROWN COUNTY REGULAR	2.0	SIOUX PIPELINE CO

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209044	F-7B-042724	4204932563		103		G A DAY #2 (16493)	BROWN COUNTY REGULAR	2.0	SIOUX PIPELINE CO
-STEVE JERNIGAN INC						RECEIVED: 12/03/81 JA: TX			
8208749	F-10-027390	4229500000		103		BATTIN #2	LIPSCOMB-CLEVELAND	0.0	PHILLIPS PETROLEU
-STUART DEVELOPMENT CO						RECEIVED: 12/03/81 JA: TX			
8208769	F-7B-032540	4236731811		103		J K BRADSHAW #1	SPRINGTOWN (5700)	150.0	LONE STAR GAS CO
8208770	F-7B-032543	4236700000		103		RUTH MARTIN #1	SPRINGTOWN 5500	150.0	LONE STAR GAS CO
-SUBURBAN PROPANE GAS CORP						RECEIVED: 12/03/81 JA: TX			
8208845	F-7C-036820	4210533115		103		MCMULLAN C #2	DAVIDSON RANCH (PENN 789	0.0	NORTHERN NATURAL
8208845	F-7C-036820	4210533115		107-TF		MCMULLAN C #2	DAVIDSON RANCH (PENN 789	0.0	NORTHERN NATURAL
8208868	F-7C-037455	4210533109		103		WILKINS B #2	DAVIDSON RANCH (PENN 789	0.0	NORTHERN NATURAL
8208868	F-7C-037455	4210533109		107-TF		WILKINS B #2	DAVIDSON RANCH (PENN 789	0.0	NORTHERN NATURAL
-SUN BELT PETROLEUM INC						RECEIVED: 12/03/81 JA: TX			
8208862	F-7B-037298	4213332805		103		KING #1	EASTLAND COUNTY REGULAR	41.0	LONE STAR GAS CO
8208863	F-7B-037299	4213332714		103		THOMPSON #4	EASTLAND COUNTY REGULAR	40.0	LONE STAR GAS CO
8208861	F-7B-037297	4213332715		103		THOMPSON 1-A	EASTLAND COUNTY REGULAR	43.0	LONE STAR GAS CO
-SUN OIL COMPANY (DELAWARE)						RECEIVED: 12/03/81 JA: TX			
8208930	F-7C-041036	4244330253		102-4		ELLEN A WORD D #1	MCKAY CREEK (TENSUS)	1.0	EL PASO NATURAL G
-SUPERIOR OIL CO						RECEIVED: 12/03/81 JA: TX			
8208881	F-03-039115	4205131428		103		J L KUCHERA #1	GIDDINGS (AUSTIN CHALK)	0.0	
-TAMARACK PETROLEUM CO INC						RECEIVED: 12/03/81 JA: TX			
8208888	F-7C-039296	4238331799		103		SAUNDERS #1	SPRABERRY (TREND AREA)	30.0	PHILLIPS PETROLEU
8209078	F-7C-042857	4210533188		103		SUTTON 14 #4	OZONA (CANYON SAND)	0.0	NORTHERN NATURAL
-TANA OIL & GAS CORP						RECEIVED: 12/03/81 JA: TX			
8208851	F-02-037013	4229700000		102-4		EL PASO NATURAL GAS #1	CHAPA E (9750)-PROPOSED	70.0	EL PASO NATURAL G
-TDC ENGINEERING INC						RECEIVED: 12/03/81 JA: TX			
8209086	F-01-042895	4217730950		102-4		HOFFMANN #1 (07243)	PEACH CREEK (AUSTIN CHAL	5.0	VALERO TRANSMISSI
-TEMAGAMI OIL & GAS INC						RECEIVED: 12/03/81 JA: TX			
8208972	F-03-041726	4205131547		102-2		J P CALLAS #1	CALDWELL (AUSTIN CHALK)	33.0	CLAJON GAS CO
-TENNECO OIL COMPANY						RECEIVED: 12/03/81 JA: TX			
8208756	F-08-029419	4230130240		107-DP		BRUNSON #48-1	BRUNSON RANCH (LOWER PEN	0.0	TENNESSEE GAS PIP
-TERRA RESOURCES INC						RECEIVED: 12/03/81 JA: TX			
8209090	F-8A-042913	4241531948		102-4		L WILLIAMS #1	LAKE THOMAS (STRAWN)	90.0	
-TERRELL OPERATING CO						RECEIVED: 12/03/81 JA: TX			
8209001	F-7B-042151	4215131253		103		REVIS ROBERTSON (NORTH) #1	KEELER-WIMBERLY (CANYON	26.0	PALO DURO PIPELIN
-TEXACO INC						RECEIVED: 12/03/81 JA: TX			
8208910	F-04-040213	4242731529		102-4		GUERRA SHARE 20 #16	ROMA EAST (QUEEN CITY)	0.0	
8208911	F-04-040214	4242731513		102-4		GUERRA SHARE 22 #19	ROMA EAST (QUEEN CITY)	18.0	
8209071	F-7C-042840	4245100000		108		W G KENT B NCT-3 #3	KENT (STRAWN)	4.4	ARCO OIL & GAS CO
8208875	F-8A-038121	4211531404		103		SPRABERRY DEEP UNIT #620	SPRABERRY DEEP	16.0	WESTAR TRANSMISSI
-TEXAS INTERNATIONAL PET CORP						RECEIVED: 12/03/81 JA: TX			
8208946	F-08-041284	4233531239		103		EDWIN PARKS #11	DIXON (STRAWN)	13.0	SUN GAS CO
-TEXAS OIL & GAS CORP						RECEIVED: 12/03/81 JA: TX			
8208743	F-05-024918	4216130588		103		HEGGINS #1	TEAGUE TOWNSITE (COTTON	500.0	
8208743	F-05-024918	4216130588		107-TF		HEGGINS #1	TEAGUE TOWNSITE (COTTON	500.0	
8208754	F-05-029293	4216130177		103		WORTHY UNIT #1	FREESTONE (BOSSIER SAND)	2.0	DELHI GAS PIPELIN
8208754	F-05-029293	4216130177		107-TF		WORTHY UNIT #1	FREESTONE (BOSSIER SAND)	2.0	DELHI GAS PIPELIN
-TRACE PETROLEUM CORP						RECEIVED: 12/03/81 JA: TX			
8209029	F-7B-042503	4204932716		103		KING #1	BROWN CO REGULAR (MARBLE	37.0	SIOUX PIPELINE CO
-TURNER PETROLEUM CO						RECEIVED: 12/03/81 JA: TX			
8209042	F-08-042693	4222734341		103		READ #1	COAHOMA (MISS)	58.4	GETTY OIL CO
-TXO PRODUCTION CORP						RECEIVED: 12/03/81 JA: TX			
8208818	F-04-035405	4213135181		102-4		BARRERA B-1 RRC ID #94162	J R (6030)	0.0	VALERO TRANSMISSI
-U S OPERATING INC						RECEIVED: 12/03/81 JA: TX			

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JD NO	JA PRT	API NO	D	SEC	CAT	WELL NAME
8208955	F-03-041428	4205131617		102-2		BESS UNIT #1
8208892	F-03-039594	4228730876		102-2		STORMY #1
-UNION TEXAS PETROLEUM				RECEIVED: 12/03/81 JA: TX		
8208916	F-7C-040413	4223531736		103		SUGG "21" #1
-VANGUARD EXPLORATION CO INC				RECEIVED: 12/03/81 JA: TX		
8208746	F-7B-026349	4204932296		103		NEWTON #C-1
-VENUS OIL COMPANY				RECEIVED: 12/03/81 JA: TX		
8208905	F-03-039986	4203931633		102-4		STEVENS UNIT #1
8208932	F-02-041064	4217531413		102-4		WILKINSON B #1
-VORTT EXPLORATION CO INC				RECEIVED: 12/03/81 JA: TX		
8208759	F-7B-030239	4236332412		102-4		VELMA KELLY #1
8208836	F-7B-036623	4236332592		102-4		W T DUNAWAY UNIT III #1
-W H TAYLOR ESTATE				RECEIVED: 12/03/81 JA: TX		
8208837	F-10-036686	4217900000		108		TAYLOR RANCH (WHT) 17 25358
-W L BRUCE OPERATOR				RECEIVED: 12/03/81 JA: TX		
8208747	F-10-026944	4234100000		103		PRITCHARD #11
-WARD OIL CO				RECEIVED: 12/03/81 JA: TX		
8209069	F-05-042827	4221300000		108		BEN HEARNE #1-T
-WHITEHEAD PRODUCTION CO INC				RECEIVED: 12/03/81 JA: TX		
8208902	F-7B-039797	4204932530		102-2		NEINDORFF 1-B
-WINDSOR PRODUCING CO				RECEIVED: 12/03/81 JA: TX		
8208995	F-03-042107	4228731005		103		DAVIS #1
8208994	F-03-042106	4228730892		103		FISCHER #1
8209007	F-03-042191	4228731019		103		SYMM #1
-WINN EXPLORATION/DULCE CO				RECEIVED: 12/03/81 JA: TX		
8208959	F-01-041514	4250731171		102-4		SMYTH 1
-WJC ENGINEERING & MANAGEMENT				RECEIVED: 12/03/81 JA: TX		
8209065	F-08-042803	4222732305		103		DAVIS #1
8209066	F-08-042804	4210332549		103		DAWSON #4
-WOOD MCSHANE & THAMS				RECEIVED: 12/03/81 JA: TX		
8209023	F-08-042373	4200331020		108		CREWS & MAST UNIT #1 RRC #68151
-WOODS PETROLEUM CORPORATION				RECEIVED: 12/03/81 JA: TX		
8208780	F-10-034621	4221131237		103		THIERSTIEN #75-1
-WY-VEL CORP				RECEIVED: 12/03/81 JA: TX		
8209067	F-10-042812	4223330964		103		SOUTHLAND (04341) #6
8209068	F-10-042813	4206530888		103		WEINHEIMER #1 (04876)
-ZONERGY INC				RECEIVED: 12/03/81 JA: TX		
8208773	F-03-033956	4205100000		102-2		BATES #3-A
8208774	F-03-033957	4205100000		102-2		HOUSTON #2
8208782	F-03-034644	4205100000		102-2		HOUSTON A-2

OTHER PURCHASERS

8208896	E I DUPONT DE NEMOURS & CO INC
8209090	SHELL OIL CO
8209037	E I DUPONT DE NEMOURS & CO INC
8209038	E I DUPONT DE NEMOURS & CO INC
8209039	E I DUPONT DE NEMOURS & CO INC
8209040	LONE STAR GAS CO
8209091	E I DUPONT DE NEMOURS & CO INC

FIELD NAME	PROD	PURCHASER
GIDDINGS (AUSTIN CHALK -	0.0	FERGUSON CROSSING
GIDDINGS (AUSTIN CHALK-3	0.0	PGP GAS PRODUCTS
ANDREW A (CANYON)	109.5	CRA INC
BROWN COUNTY REGULAR	18.0	SOUTHWESTERN GAS
LAKE ALASKA (FRIO 8480')	0.0	VALERO TRANSMISSI
BERCLAIR E (3260')	0.0	UNITED TEXAS TRAN
MINERAL WELLS S (STRAWN	0.0	SOUTHWESTERN GAS
MINERAL WELLS (STRAWN A)	0.0	SOUTHWESTERN GAS
WEST PANHANDLE (GAS)	16.0	PHILLIPS PETROLEU
PANHANDLE MOORE COUNTY	225.0	PHILLIPS PETROLEU
OPELIKA (PETTIT)	18.0	LONE STAR GAS CO
HAYNES (CROSS CUT SAND)	80.0	ODESSA NATURAL CO
GIDDINGS (AUSTIN CHALK)	36.5	PGP GAS PRODUCTS
GIDDINGS (AUSTIN CHALK)	36.5	PGP GAS PRODUCTS
GIDDINGS (AUSTIN CHALK)	36.5	PGP GAS PRODUCTS
JUDGE MILLS	97.0	NORTHERN NATURAL
HUTTO SOUTH (WOLFCAMP)	36.5	PHILLIPS PETROLEU
WYNNE (CLFR)	91.0	PHILLIPS PETROLEU
BLOCK A-34 (YATES)	2.0	EL PASO NATURAL G
WILDCAT	153.3	NORTHERN NATURAL
PANHANDLE HUTCHINSON COU	29.0	PHILLIPS PETROLEU
PANHANDLE CARSON COUNTY	125.0	GETTY OIL CO
GIDDINGS	0.0	CLAJON GAS CO
GIDDINGS	0.0	
GIDDINGS (AUSTIN CHALK 3	0.0	CLAJON GAS CO

The above notices of determination were received from the indicated jurisdictional agencies by the Federal Energy Regulatory Commission pursuant to the Natural Gas Policy Act of 1978 and 18 CFR 274.104. Negative determinations are indicated by a "D" before the section code. Estimated annual production (PROD) is in million cubic feet (MMCF). An (*) before the Control (JD) number denotes additional purchasers listed at the end of the notice.

The applications for determination are available for inspection except to the extent such material is confidential under 18 CFR 275.206, at the Commission's Division of Public Information, Room 1000, 825 North Capitol St., Washington, D.C. Persons objecting to any of these determinations may, in accordance with 18 CFR 275.203 and 275.204, file a protest with the Commission on or before January 20, 1982.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-151 Filed 1-4-82; 8:45 am]

BILLING CODE 6717-01-M

Determinations by Jurisdictional Agencies Under the Natural Gas Policy Act of 1978

Issued: December 30, 1981.

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
NEW MEXICO DEPARTMENT OF ENERGY & MINERALS									
-ALPHA TWENTY-ONE PRODUCTION CO						RECEIVED: 12/03/81 JA: NM			
8209138		3002526812		103		LANSFORD #4	EUMONT (GAS)	110.0	EL PASO NATURAL G
-AMOCO PRODUCTION CO						RECEIVED: 12/03/81 JA: NM			
8209116		3002527061		102-4		WATKINS A GAS COM #1	UND WEST OSUDO MORROW	246.4	EL PASO NATURAL G
-APOLLO ENERGY INC						RECEIVED: 12/03/81 JA: NM			
8209131		3002500000		102-4		LEE	VACUUM ABO REEF	35.0	PHILLIPS PETROLEU
-ARCO OIL AND GAS COMPANY						RECEIVED: 12/03/81 JA: NM			
8209123		3001521673		108		STATE BT COM #1	AVALON MORROW GAS	0.9	GAS CO OF NEW MEX
-BELCO PETROLEUM CORPORATION						RECEIVED: 12/03/81 JA: NM			
8209163		3001523215		102-4		GUITAR EST #1 23215	LOVING	0.0	EL PASO NATURAL G
-COLLIER ENERGY INC						RECEIVED: 12/03/81 JA: NM			
8209117		3002527397		102-4		MESA STATE #1	VACUUM SOUTH QUEEN	0.0	UNITED GAS PL CO
-CONOCO INC						RECEIVED: 12/03/81 JA: NM			
8209121		3002500580		108		MCA UNIT #5	BAISH-MALJAMAR-PEARSALL	0.3	TRANSWESTERN PIPE
8209120		3002526179		108		STATE KN-12 #6	EUMONT-MONUMENT	9.5	EL PASO NATURAL G
-COUGAR PETROLEUM CO						RECEIVED: 12/03/81 JA: NM			
8209156		3004524901		103		STATE 36-21	LYBROOK GALLUP EXT	70.0	MESA PETROLEUM CO
8209155		3004524900		103		STATE 36-31	LYBROOK GALLUP EXT	70.0	MESA PETROLEUM CO
8209157		3004524904		103		STATE 36-43	LYBROOK GALLUP EXT	40.0	MESA PETROLEUM CO
-DUGAN PRODUCTION CORP						RECEIVED: 12/03/81 JA: NM			
8209136		3003922808		103		BROWN #1	SOUTH BLANCO PICTURED CL	30.0	EL PASO NATURAL G
8209135		3003922809		103		BROWN #2	SOUTH BLANCO PICTURED CL	27.0	EL PASO NATURAL G
-EL PASO NATURAL GAS COMPANY						RECEIVED: 12/03/81 JA: NM			
8209132		3003900000		108-PB		SAN JUAN 32-5 UNIT #10	BLANCO MESAVERDE	0.0	EL PASO NATURAL G
-ENERGY RESERVES GROUP INC						RECEIVED: 12/03/81 JA: NM			
8209112		3004120601		103		CRUME #1	SOUTH PETERSON (CISCO)	194.4	WARREN PETROLEUM
-EXXON CORPORATION						RECEIVED: 12/03/81 JA: NM			
8209162		3001523217		102-4		NEW MEXICO CY STATE COM #1	ATOKA	329.0	
8209161		3002527360		103		NEW MEXICO DA STATE #1	UNDESIGNATED MORROW-WOLF	767.0	
-FRED POOL JR						RECEIVED: 12/03/81 JA: NM			
8209111		3000560935		107-TF		MACHO #1	UND WILDCAT	0.0	TRANSWESTERN PIPE
-GETTY OIL COMPANY						RECEIVED: 12/03/81 JA: NM			
8209133		3002500000		108		STATE BL #1	LOVINGTON QUEEN	18.0	PHILLIPS PETROLEU
-HNG OIL COMPANY						RECEIVED: 12/03/81 JA: NM			
8209137		3001500000		103		GOLDEN LANE 1 FEDERAL #1	WILDCAT MORROW	511.0	EL PASO NATURAL G
8209109		3002500000		102-2		VACA DRAW 16 STATE #1	WILDCAT ATOKA	733.0	EL PASO NATURAL G
8209140		3002500000		102-2		VACA DRAW 16 STATE #1	WILDCAT ATOKA	733.0	EL PASO NATURAL G
-HOLLY ENERGY INC						RECEIVED: 12/03/81 JA: NM			
8209119		3001500000		102-4		COWTOWN LOYD #1	TRAVIS UPPER PENN	110.6	
-KAISER-FRANCIS OIL COMPANY						RECEIVED: 12/03/81 JA: NM			
8209110		3002500000		108		MURPHY STATE A-2	INBE-PERMO PENN	3.0	WARREN PETROLEUM

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
-LAYTON ENTERPRISES INC						RECEIVED: 12/03/81 JA: NM			
A209122		3002502656		10S		RETENBOUGH B #1	BOUGH SAN ANDRES	10.0	WARREN PETROLEUM
-MADDOX ENERGY CORPORATION						RECEIVED: 12/03/81 JA: NM			
A209159		3001500000			103	PARDUE FARMS 27 #4	SOUTH CULEBRA BLUFF-BONE	36.5	
-MESA PETROLEUM						RECEIVED: 12/03/81 JA: NM			
A209141		3000560869			107-TF	DAVIS #2	WILDCAT ABO	720.0	TRANSWESTERN PIPE
-NORTHWEST PIPELINE CORPORATION						RECEIVED: 12/03/81 JA: NM			
A209160		3003922678			103	SAN JUAN 30-5 #41A	BLANCO MESAVERDE	91.0	NORTHWEST PIPELIN
-PHILLIPS PETROLEUM COMPANY						RECEIVED: 12/03/81 JA: NM			
A209128		3002526925			103	E VACUUM GB/SA UNIT TR 2913 #010	VACUUM GB/SA POOL	9.1	EL PASO NATURAL G
A209127		3002526680			103	E VACUUM GB/SA UNIT TR 3333 #005	VACUUM GB/SA	29.0	EL PASO NATURAL G
A209118		3002527306			102-4	SAN SIMON 32 A STATE #1	EAST GRAMA RIDGE	108.3	EL PASO NATURAL G
-SOUTHLAND ROYALTY CO						RECEIVED: 12/03/81 JA: NM			
A209129		3003922779			103	CHICOSA CANYON #1	UNDESIGNATED	480.0	NORTHWEST PIPELIN
A209145		3003922413			103	JOHNSON #1	BLANCO	198.0	EL PASO NATURAL G
A209147		3003922413			103	JOHNSON #1	OJITO	51.0	EL PASO NATURAL G
A209146		3002527377			103	SCHARB 9 #1	SCHARB	10.0	WARREN PETROLEUM
A209130		3003922756			103	SIMMS FEDERAL #1	UNDESIGNATED	450.0	NORTHWEST PIPELIN
A209158		3001523460			103	STATE 30-A COM #1	UNDESIGNATED SOUTH MILLM	187.0	EL PASO NATURAL G
-STEVENS OPERATING CORP						RECEIVED: 12/03/81 JA: NM			
A209153		3000561006			103	O' BRIEN FF #4	TWIN LAKES-SAN ANDRES AS	13.0	TRANSWESTERN PIPE
A209150		3000560994			103	O'BRIEN FF #3	TWIN LAKES-SAN ANDRES AS	9.0	TRANSWESTERN PIPE
A209151		3000561022			103	O'BRIEN FF #5	TWIN LAKES-SAN ANDRES AS	18.0	TRANSWESTERN PIPE
A209148		3000561033			103	O'BRIEN FF #6	TWIN LAKES-SAN ANDRES AS	8.0	TRANSWESTERN PIPE
A209152		3000561076			103	O'BRIEN GG #1	TWIN LAKES-SAN ANDRES AS	3.0	TRANSWESTERN PIPE
A209149		3000560995			103	O'BRIEN L #9	TWIN LAKES-SAN ANDRES AS	31.0	TRANSWESTERN PIPE
-SUPERIOR OIL CO						RECEIVED: 12/03/81 JA: NM			
A209113		3002526958			103	SIMS #1	SOUTH BELL LAKE (MORROW)	0.0	
-SUPRON ENERGY CORPORATION						RECEIVED: 12/03/81 JA: NM			
A209134		3004524653			103	STATE COM A 2-E	BLANCO MESAVERDE	476.0	SOUTHERN UNION GA
A209139		3004524653			103	STATE COM A 2-E	BASIN DAKOTA	260.0	EL PASO NATURAL G
-YATES PETROLEUM CORPORATION						RECEIVED: 12/03/81 JA: NM			
A209143		3000561026			107-TF	CONEJO RH STATE #1	UND ABO	0.0	TRANSWESTERN PIPE
A209144		3000500000			102-2	CURTIS OR COM #1	UND ABO	0.0	TRANSWESTERN PIPE
A209144		3000500000			107-TF	CURTIS OR COM #1	UND ABO	0.0	TRANSWESTERN PIPE
A209114		3001523763			103	EMMA QE COM #1	UND WOLDCAMP	0.0	TRANSWESTERN PIPE
A209124		3000520826			103	LOVELESS "LG" STATE #3	UND TOMAHAWK SA	0.0	
A209125		3000520821			103	PAUL "LR" #7	TOM TOM SA	0.0	TRANSWESTERN PIPE
A209142		3000520816			103	PAUL LR #5	TOM TOM SA	0.0	
A209126		3000520822			103	PAUL LR #8	TOM TOM SA	0.0	
A209154		3001523793			103	SHARP OS COM #1	UNDES POW MORROW	0.0	TRANSWESTERN PIPE
A209115		3001522554			103	STONEWALL EP STATE COM #4	UND W BURTON FLAT ATOKA	0.0	TRANSWESTERN PIPE
**********									
OHIO DEPARTMENT OF NATURAL RESOURCES									
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-ATWOOD RESOURCES INC						RECEIVED: 12/07/81 JA: OH			
A209164		3410322675			103	MAUCH-REITER UNIT #1	SPENCER	10.0	
A209164		3410322675			107-TF	MAUCH-REITER UNIT #1	SPENCER	10.0	
-BILL BLAIR INCORPORATED						RECEIVED: 12/07/81 JA: OH			
A209168		3402920858			103	GROVE #6	HOMEWORTH	22.0	EAST OHIO GAS CO
A209168		3402920858			107-TF	GROVE #6	HOMEWORTH	22.0	EAST OHIO GAS CO
A209170		3402920860			103	GROVE #7	HOMEWORTH	16.0	EAST OHIO GAS CO
A209170		3402920860			107-TF	GROVE #7	HOMEWORTH	16.0	EAST OHIO GAS CO

JD NO	JA PKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209167		3402920853		103		KIBLER #5	HOMEWORTH	14.0	EAST OHIO GAS CO
8209167		3402920853		107-TF		KIBLER #5	HOMEWORTH	14.0	EAST OHIO GAS CO
8209169		3402920859		103		SANOR #1	HOMEWORTH	21.0	EAST OHIO GAS CO
8209169		3402920859		107-TF		SANOR #1	HOMEWORTH	21.0	EAST OHIO GAS CO
8209166		3402920846		103		SCHOENI #1	HOMEWORTH	33.0	COLUMBIA GAS TRAN
8209166		3402920846		107-TF		SCHOENI #1	HOMEWORTH	33.0	COLUMBIA GAS TRAN
-CAMERON BROS				RECEIVED: 12/07/81 JA: OH					
8209171		3411925833		103		CORDER #1	BRUSH CREEK	12.0	
8209171		3411925833		107-TF		CORDER #1	BRUSH CREEK	12.0	
-CARL M POSTON				RECEIVED: 12/07/81 JA: OH					
8209291		3400922029		107-TF		MILLFIELD COAL & MINING CO #8	MILLFIELD	110.0	COLUMBIA GAS TRAN
8209293		3400922066		107-TF		MILLFIELD COAL & MINING CO 10	MILLFIELD	22.0	COLUMBIA GAS TRAN
8209292		3400922031		107-TF		SUGAR CREEK COAL & MINING CO 7	MILLFIELD	36.5	COLUMBIA GAS TRAN
-DORAN & ASSOCIATES INC				RECEIVED: 12/07/81 JA: OH					
8209173		3407523207		103		ELI D A YODER #1	PAINT	12.0	COLUMBIA GAS TRAN
8209173		3407523207		107-TF		ELI D A YODER #1	PAINT	12.0	COLUMBIA GAS TRAN
8209174		3411925217		107-TF		MARVIN YOST #1 KA-43	HOPEWELL	12.0	NATIONAL GAS & OI
8209172		3407522969		103		MELVIN MEYERS #1	PRAIRIE	12.0	COLUMBIA GAS TRAN
8209172		3407522969		107-TF		MELVIN MEYERS #1	PRAIRIE	12.0	COLUMBIA GAS TRAN
8209175A		3412725272		103		YAYOI LANIER #1	JACKSON	12.0	COLUMBIA GAS TRAN
8209175B		3412725272	D	107-TF		YAYOI LANIER #1	JACKSON	12.0	COLUMBIA GAS TRAN
-DORFMAN PRODUCTION CO				RECEIVED: 12/07/81 JA: OH					
8209177		3409921344		103		HINTON #1	DAMASCUS	11.0	COLUMBIA GAS TRAN
8209177		3409921344		107-TF		HINTON #1	DAMASCUS	11.0	COLUMBIA GAS TRAN
8209176		3409921335		103		PHILLIS #1	DAMASCUS	12.0	COLUMBIA GAS TRAN
8209176		3409921335		107-TF		PHILLIS #1	DAMASCUS	12.0	COLUMBIA GAS TRAN
8209178		3409921346		103		WEIK #1	DAMASCUS	11.0	COLUMBIA GAS TRAN
8209178		3409921346		107-TF		WEIK #1	DAMASCUS	11.0	COLUMBIA GAS TRAN
-EDCO DRILLING & PRODUCING INC				RECEIVED: 12/07/81 JA: OH					
8209181		3403124197		103		CULLISON BL-3A	BETHLEHEM	18.0	
8209181		3403124197		107-TF		CULLISON BL-3A	BETHLEHEM	18.0	
8209180		3403124196		103		CULLISON BL-4A	BEDFORD	18.0	
8209180		3403124196		107-TF		CULLISON BL-4A	BEDFORD	18.0	
8209182		3403124200		103		INFIELD KB-1A	WARSAW	18.0	
8209182		3403124200		107-TF		INFIELD KB-1A	WARSAW	18.0	
8209183		3415723578		103		MCDONNELL KB-1B	NEWCOMERSTOWN	18.0	
8209183		3415723578		107-TF		MCDONNELL KB-1B	NEWCOMERSTOWN	18.0	
8209179		3403124183		103		POWELL BL-1A	BEDFORD	18.0	
8209179		3403124183		107-TF		POWELL BL-1A	BEDFORD	18.0	
-ENERGY DEVELOPMENT CORP				RECEIVED: 12/07/81 JA: OH					
8209184		3400721802		103		SPANG #2	DENMARK	14.0	
8209184		3400721802		107-TF		SPANG #2	DENMARK	14.0	
-GASEARCH INC				RECEIVED: 12/07/81 JA: OH					
8209185		3415521837		103		CITY OF NILES #1	WEATHERSFIELD	20.0	
8209185		3415521837		107-TF		CITY OF NILES #1	WEATHERSFIELD	20.0	
-GEO ENERGY INC				RECEIVED: 12/07/81 JA: OH					
8209186		3403521114		103		BUCKLEY-HAAS UNIT #5-1	ALMSTED	8.0	COLUMBIA GAS OF O
8209186		3403521114		107-TF		BUCKLEY-HAAS UNIT #5-1	ALMSTED	8.0	COLUMBIA GAS OF O
8209187		3410322607		103		HUTTINGER W & J #10-2-1	LIVERPOOL	15.0	COLUMBIA GAS TRAN
8209187		3410322607		107-TF		HUTTINGER W & J #10-2-1	LIVERPOOL	15.0	COLUMBIA GAS TRAN
8209188		3411925037		107-TF		MCINTIRE #3	RICH HILL	5.0	COLUMBIA GAS TRAN
-GUERNSEY PETROLEUM CORPORATION				RECEIVED: 12/07/81 JA: OH					
8209190		3411925836		107-TF		OHIO POWER 2-P	MEIGS	6.0	COLUMBIA GAS TRAN

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209189		3411925709			107-TF	OHIO POWER 7-N	MEIGS	0.0	COLUMBIA GAS TRAN
-HADCO INC						RECEIVED: 12/07/81 JA: OH			
8209191		3410322622			103	HARRIS #2	GRANGER	20.0	
8209191		3410322622			107-TF	HARRIS #2	GRANGER	20.0	
-HARDIN & SHERRY						RECEIVED: 12/07/81 JA: OH			
8209192		3412724986			107-TF	MORTON #2	MADISON	0.0	
-HOPCO RESOURCES INC						RECEIVED: 12/07/81 JA: OH			
8209193		3403124391			103	PEOPLES INC #1	KEENE	12.0	COLUMBIA GAS TRAN
8209193		3403124390			107-TF	PEOPLES INC #1	KEENE	12.0	COLUMBIA GAS TRAN
-HOPEWELL OIL AND GAS DEVELOPMENT CO						RECEIVED: 12/07/81 JA: OH			
8209195		3411925429			107-TF	IRVIN & MYRTLE GILLESPIE #1	SPRINGFIELD	12.0	NATIONAL GAS CORP
8209196		3412725013			107-TF	NURUM/WALTERS #1	MONROE	12.0	COLUMBIA GAS TRAN
8209194		3411522327			107-TF	ROY PLITCHER #1	YORK	12.0	COLUMBIA GAS TRAN
-INLAND DRILLING CO INC						RECEIVED: 12/07/81 JA: OH			
8209200		3413322503			103	BALDWIN #2	CHARLESTOWN	0.5	
8209200		3413322503			107-TF	BALDWIN #2	CHARLESTOWN	0.5	
8209198		3413322368			103	DREGER-HAUCK #1	FREEDOM	0.3	
8209198		3413322368			107-TF	DREGER-HAUCK #1	FREEDOM	0.3	
8209197		3413321823			103	FORGACS #1	CHARLESTOWN	0.5	
8209197		3413321823			107-TF	FORGACS #1	CHARLESTOWN	0.5	
8209199		3413322427			103	GRABER #1	CHARLESTOWN	0.5	
8209199		3413322427			107-TF	GRABER #1	CHARLESTOWN	0.5	
8209202		3413322506			103	M POCHEDLY #1	FREEDOM	0.3	
8209202		3413322506			107-TF	M POCHEDLY #1	FREEDOM	0.3	
8209201		3413322504			103	RICHARDS #1	CHARLESTOWN	0.5	
8209201		3413322504			107-TF	RICHARDS #1	CHARLESTOWN	0.5	
-IRVIN PRODUCING COMPANY						RECEIVED: 12/07/81 JA: OH			
8209204A		3412725237			103	EVERETT BROWN B-1	MADISON	10.0	COLUMBIA GAS TRAN
8209204B		3412725237	D		107-TF	EVERETT BROWN B-1	MADISON	10.0	COLUMBIA GAS TRAN
8209203		3411925794			103	RALPH D THORTON #1	FALLS	10.0	COLUMBIA GAS TRAN
8209203		3411925794			107-TF	RALPH D THORTON #1	FALLS	10.0	COLUMBIA GAS TRAN
-J P WHITE						RECEIVED: 12/07/81 JA: OH			
8209340		3400721711			103	BAILEY-SHADLE #1	CHERRY VALLEY	0.0	COLUMBIA GAS TRAN
8209340		3400721711			107-TF	BAILEY-SHADLE #1	CHERRY VALLEY	0.0	COLUMBIA GAS TRAN
8209341		3400721712			103	LUCE DEBOW #1	CHERRY VALLEY	0.0	COLUMBIA GAS TRAN
8209341		3400721712			107-TF	LUCE DEBOW #1	CHERRY VALLEY	0.0	COLUMBIA GAS TRAN
8209342		3415521332			107-TF	NEWCOMB LUMBER #1	NEWTON FALLS	50.0	COLUMBIA GAS TRAN
8209343		3415521412			107-TF	NEWCOMB LUMBER #3	NEWTON	50.0	COLUMBIA GAS TRAN
-JAMES R BERNHARDT						RECEIVED: 12/07/81 JA: OH			
8209165		3410322653			103	J V P STABLES #1	HINKLEY	7.0	COLUMBIA GAS TRAN
8209165		3410322653			107-TF	J V P STABLES #1	HINKLEY	7.0	COLUMBIA GAS TRAN
-JOHN C MASON						RECEIVED: 12/07/81 JA: OH			
8209219		3407523121			107-TF	BIRD UNIT #1	HARDY	10.0	COLUMBIA GAS TRAN
8209218		3407523050			107-TF	HAROLD OBERMILLER #2	PRAIRIE	10.0	COLUMBIA GAS TRAN
8209217		3407522500			107-TF	HORNER-MULLET UNIT #1	HARDY	10.0	COLUMBIA GAS TRAN
8209220		3407523130			107-TF	JOHN HIPP 1A	HARDY	10.0	COLUMBIA GAS TRAN
-L & M OPERATING INC						RECEIVED: 12/07/81 JA: OH			
8209205		3412725070			103	CLAYCRAFT #10	SALT LICK	10.0	COLUMBIA GAS TRAN
8209205		3412725070			107-TF	CLAYCRAFT #10	SALT LICK	10.0	COLUMBIA GAS TRAN
-L & M PETROLEUM INC						RECEIVED: 12/07/81 JA: OH			
8209206		3412725216			107-TF	NED UNDERWOOD #1	PIKE	2.0	COLUMBIA GAS TRAN
-LAKE REGION OIL INC						RECEIVED: 12/07/81 JA: OH			
8209210		3407523150			103	RALPH & GEORGE STRAITS #4	KILLBUCK	10.0	COLUMBIA GAS TRAN
8209210		3407523160			107-TF	RALPH & GEORGE STRAITS #4	KILLBUCK	10.0	COLUMBIA GAS TRAN

JD NO	JA TKT	API NO	D SEC CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209207		3407522806	107-TF	RONALD & H ELAINE LANDON #1	KILLBUCK	10.0	COLUMBIA GAS TRAN
8209209		3407522901	103	RUSSELL MADISON #3	KILLBUCK	10.0	COLUMBIA GAS TRAN
8209209		3407522901	107-TF	RUSSELL MADISON #3	KILLBUCK	10.0	COLUMBIA GAS TRAN
8209208		3407522819	107-TF	WILLIS CHANAY #3	KILLBUCK	10.0	COLUMBIA GAS TRAN
-LEADER EQUITIES INC			RECEIVED: 12/07/81 JA: OH				
8209214		3412122609	103	E ALLEN #2	CENTER	15.0	
8209214		3412122609	107-TF	E ALLEN #2	CENTER	15.0	
8209213		3411925344	103	GARBAS-ROSS #1	MONROE	0.0	
8209213		3411925344	107-TF	GARBAS-ROSS #1	MONROE	0.0	
8209211		3411522322	103	HANN #1	MEIGSVILLE	0.0	
8209211		3411522322	107-TF	HANN #1	MEIGSVILLE	0.0	
8209212		3411522451	103	KIDD #1	MEIGSVILLE	0.0	
8209212		3411522451	107-TF	KIDD #1	MEIGSVILLE	0.0	
-NEW FRONTIER EXPLORATION INC			RECEIVED: 12/07/81 JA: OH				
8209224		3413322555	103	INGLADO-DIEHL UNIT #1	DEERFIELD	24.0	BARTLO OIL & GAS
8209224		3413322555	107-TF	INGLADO-DIEHL UNIT #1	DEERFIELD	24.0	BARTLO OIL & GAS
-NOBLE OIL CORP			RECEIVED: 12/07/81 JA: OH				
8209227		3413322623	107-TF	AEMMER #2	PALMYRA	20.0	GENERAL ELECTRIC
8209225		3413322536	107-TF	DELAGRANGE #1	PALMYRA	20.0	GENERAL ELECTRIC
8209226		3413322562	107-TF	ZIMMERMAN-CLIMES #1	PALMYRA	20.0	GENERAL ELECTRIC
-NORTHEASTERN ENERGY			RECEIVED: 12/07/81 JA: OH				
8209228		3410322646	103	BAIRD #2	GUILFORD	21.0	EAST OHIO GAS CO
8209228		3410322646	107-TF	BAIRD #2	GUILFORD	21.0	EAST OHIO GAS CO
-OHIO OIL & GAS CO			RECEIVED: 12/07/81 JA: OH				
8209230		3415521907	107-TF	GUTHRIE #1	JOHNSTON	20.0	COLUMBIA GAS TRAN
8209231		3415521909	107-TF	GUTHRIE #3	JOHNSTON	20.0	COLUMBIA GAS TRAN
8209232		3415521911	107-TF	POWELL #2	FOWLER	20.0	COLUMBIA GAS TRAN
8209229		3415521821	107-TF	SMITH #2	JOHNSTON	20.0	COLUMBIA GAS TRAN
-OHIO PARTNERS OIL CO			RECEIVED: 12/07/81 JA: OH				
8209234		3400721752	103	SHEFFIELD-KELLOGG #3	SHEFFIELD	20.0	
8209234		3400721752	107-TF	SHEFFIELD-KELLOGG #3	SHEFFIELD	20.0	
8209233		3400721505	103	WOLFGANG #3	SHEFFIELD	20.0	EAST OHIO GAS CO
8209233		3400721505	107-TF	WOLFGANG #3	SHEFFIELD	20.0	EAST OHIO GAS CO
-OXFORD OIL CO			RECEIVED: 12/07/81 JA: OH				
8209235		3403124453	103	AMMON REED UNIT #2	CLARK	11.0	
8209235		3403124453	107-TF	AMMON REED UNIT #2	CLARK	11.0	
8209237		3411925415	103	ARNOLD SHEPARD #1	CLAY	11.0	
8209237		3411925415	107-TF	ARNOLD SHEPARD #1	CLAY	11.0	
8209240		3416922955	103	HARVEY WEAVER #1	CHESTER	11.0	
8209240		3416922955	107-TF	HARVEY WEAVER #1	CHESTER	11.0	
8209239		3411925736	103	PAUL UNIT #1	WAYNE	12.0	
8209239		3411925736	107-TF	PAUL UNIT #1	WAYNE	12.0	
8209236		3407523168	103	RICHARD UHL #2	KILLBUCK	12.0	
8209236		3407523168	107-TF	RICHARD UHL #2	KILLBUCK	12.0	
8209238		3411925669	103	ROBERT ELLERMAN #3	WAYNE	11.0	
8209238		3411925669	107-TF	ROBERT ELLERMAN #3	WAYNE	11.0	
-PAROCO DRLG FUNDS INC			RECEIVED: 12/07/81 JA: OH				
8209289		3413322639	103	NORMAN UNIT #1	WINDHAM	20.0	
8209289		3413322639	107-TF	NORMAN UNIT #1	WINDHAM	20.0	
8209290		3415521929	103	WEST #1	BRISTOL	20.0	
8209290		3415521929	107-TF	WEST #1	BRISTOL	20.0	
-PETROLEUM ENERGY DEVELOPMENT CORP			RECEIVED: 12/07/81 JA: OH				
8209294		3407322379	107-TF	MORGAN RICHARD #1	WASHINGTON	30.0	

JD NO	JA DKT	API NO	P SEC CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209295		3411925407	103	REVENNAUGH JOHN D #2	RICH HILL	30.0	
8209295		3411925407	107-TF	REVENNAUGH JOHN D #2	RICH HILL	30.0	
-PETROLEUM SECURITIES FUND - 80			RECEIVED: 12/07/81 JA: OH				
8209296		3416922457	103	AMSTUTZ #1	WAYNE	12.0	COLUMBIA GAS TRAN
8209296		3416922457	107-TF	AMSTUTZ #1	WAYNE	12.0	COLUMBIA GAS TRAN
8209304		3416922698	103	CHANCE #2	PLAIN	12.0	COLUMBIA GAS TRAN
8209304		3416922698	107-TF	CHANCE #2	PLAIN	12.0	COLUMBIA GAS TRAN
8209298		3416922530	103	FAIR #1	CHESTER	12.0	COLUMBIA GAS TRAN
8209298		3416922530	107-TF	FAIR #1	CHESTER	12.0	COLUMBIA GAS TRAN
8209307		3416922712	103	HINES #2	CHESTER	12.0	COLUMBIA GAS TRAN
8209307		3416922712	107-TF	HINES #2	CHESTER	12.0	COLUMBIA GAS TRAN
8209297		3416922525	103	HOHENSHIL #1	CHESTER	12.0	COLUMBIA GAS TRAN
8209297		3416922525	107-TF	HOHENSHIL #1	CHESTER	12.0	COLUMBIA GAS TRAN
8209301		3416922689	103	HOWMAN #2	CHESTER	12.0	COLUMBIA GAS TRAN
8209301		3416922689	107-TF	HOWMAN #2	CHESTER	12.0	COLUMBIA GAS TRAN
8209302		3416922692	103	LADRACH #2	CHESTER	12.0	COLUMBIA GAS TRAN
8209302		3416922692	107-TF	LADRACH #2	CHESTER	12.0	COLUMBIA GAS TRAN
8209299		3416922532	103	MANN #2	FRANKLIN	12.0	COLUMBIA GAS TRAN
8209299		3416922532	107-TF	MANN #2	FRANKLIN	12.0	COLUMBIA GAS TRAN
8209300		3416922686	103	MANN #3	FRANKLIN	12.0	COLUMBIA GAS TRAN
8209300		3416922686	107-TF	MANN #3	FRANKLIN	12.0	COLUMBIA GAS TRAN
8209303		3416922696	103	MYKRANTZ #4	PLAIN	12.0	COLUMBIA GAS TRAN
8209303		3416922696	107-TF	MYKRANTZ #4	PLAIN	12.0	COLUMBIA GAS TRAN
8209308		3416922713	103	REICHERT #3	CHESTER	12.0	COLUMBIA GAS TRAN
8209308		3416922713	107-TF	REICHERT #3	CHESTER	12.0	COLUMBIA GAS TRAN
8209306		3416922702	103	SNURE #3	WAYNE	12.0	COLUMBIA GAS TRAN
8209306		3416922702	107-TF	SNURE #3	WAYNE	12.0	COLUMBIA GAS TRAN
8209309		3416922812	103	W HARTMAN #2-A	CHESTER	12.0	COLUMBIA GAS TRAN
8209309		3416922812	107-TF	W HARTMAN #2-A	CHESTER	12.0	COLUMBIA GAS TRAN
8209305		3416922701	103	WISE #2	WAYNE	12.0	COLUMBIA GAS TRAN
8209305		3416922701	107-TF	WISE #2	WAYNE	12.0	COLUMBIA GAS TRAN
-POI ENERGY INC			RECEIVED: 12/07/81 JA: OH				
8209267		3400721388	107-TF	ARMSTRONG #1	ORWELL	40.0	EAST OHIO GAS CO
8209280		3413321863	107-RT	BECK-GRIFFITH-WILSON #2	STREETSBORO	100.0	
8209279		3413321858	107-RT	BECK-GRIFFITH-WILSON #3	STREETSBORO	70.0	
8209244		3400721104	107-TF	BENTON #1	COLEBROOK	15.0	
8209257		3400721299	107-TF	BOGDON #1	ROME	5.0	
8209256		3400721279	107-TF	BOYD #1	ROME	27.0	
8209260		3400721318	107-TF	BOYD #2	ROME	20.0	
8209245		3400721116	107-TF	BRASS #1	NEW LYME	45.0	
8209281		3413321869	107-RT	BRITTAN #1	STREETSBORO	40.0	
8209276		3400721617	103	CARROLL #1	CHERRY VALLEY	10.0	EAST OHIO GAS CO
8209276		3400721617	107-TF	CARROLL #1	CHERRY VALLEY	10.0	EAST OHIO GAS CO
8209275		3400721616	103	CIZDZIEL #1	ORWELL	30.0	EAST OHIO GAS CO
8209275		3400721616	107-TF	CIZDZIEL #1	ORWELL	30.0	EAST OHIO GAS CO
8209266		3400721369	107-TF	CLARK #3	WAYNE	15.0	
8209246		3400721179	107-TF	CRO-LAND CORP #1	NEW LYME	85.0	
8209247		3400721203	107-TF	DROWN #1	ROME	25.0	
8209258		3400721301	107-TF	DROWN #3	ROME	10.0	
8209241		3400721093	107-TF	GRANT #1	COLEBROOK	20.0	
8209286		3413321915	107-RT	HACH #1	AURORA	10.0	
8209259		3400721312	107-TF	KRIEG #1	COLEBROOK	20.0	
8209255		3400721284	107-TF	LAUTENAN #1	NEW LYME	50.0	

JD NO	JA DAT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209268		3400721395		107-TF		MAICHROWICZ #2	ORWELL	15.0	
8209265		3400721351		107-TF		MARRISON #1	NEW LYME	60.0	
8209264		3400721345		107-TF		MARRISON #2	NEW LYME	60.0	
8209263		3400721344		107-TF		MARRISON #3	NEW LYME	60.0	
8209273		3400721489		107-TF		MURCKO-BAUMAN #1	ORWELL	16.0	
8209243		3400721101		107-TF		NITA #2	COLEBROOK	15.0	
8209261		3400721323		107-TF		PAVILONIS #2	COLEBROOK	20.0	
8209262		3400721324		107-TF		PAVILONIS #3		70.0	
8209270		3400721453		107-TF		PECK #2	NEW LYME	45.0	
8209282		3413321891		107-RT		PIERCE #1	FRANKLIN	30.0	
8209283		3413321891		107-TF		PIERCE #2	FRANKLIN	35.0	
8209285		3413322073		107-TF		PIERCE #3	FRANKLIN	35.0	
8209254		3400721234		107-TF		PROHONIC #1	NEW LYME	55.0	
8209277		3400721637		103		PROSSER #1	NEW LYME	25.0	EAST OHIO GAS CO
8209277		3400721637		107-TF		PROSSER #1	NEW LYME	25.0	EAST OHIO GAS CO
8209269		3400721427		107-TF		RIGBY #2	ORWELL	9.0	
8209248		3400721202		107-TF		ROBINSON #1	ROME	30.0	
8209242		3400721099		107-TF		ROMAN #1	COLEBROOK	55.0	
8209252		3400721225		107-TF		RUNYAN #1	NEW LYME	40.0	
8209264		3400721986		107-TF		SEDEVIC #1	ROME	20.0	
8209288		3415320686		107-RT		SHAW #1	HUDSON	35.0	
8209274		3400721493		107-TF		SHELTON #1	COLEBROOK	22.0	
8209278		3400721652		107-TF		STANEK #1	ROME	40.0	EAST OHIO GAS CO
8209249		3400721210		107-TF		STRINGFELLOW #4	NEW LYME	18.0	
8209250		3400721212		107-TF		STRINGFELLOW #5	NEW LYME	90.0	
8209287		3415320671		107-RT		THOMAS-DREW #2	HUDSON	25.0	
8209253		3400721226		107-TF		WESOLOWSKI #1	NEW LYME	20.0	
8209251		3400721214		107-TF		WYNN #2	NEW LYME	8.0	
8209271		3400721474		103		WYNN #5	ROME	20.0	
8209271		3400721474		107-TF		WYNN #5	ROME	20.0	
8209272		3400721475		107-TF		WYNN #6	ROME	30.0	
-PREMIER ENERGY CORP		RECEIVED: 12/07/81 JA: OH							
8209353		3407522699		107-TF		ELMER J KICK #1	HARDY	0.0	COLUMBIA GAS TRAN
-REPUBLIC STEEL CORP		RECEIVED: 12/07/81 JA: OH							
8209310		3411925735		103		CONSOLIDATION COAL CO - CR #5	MADISON	19.0	COLUMBIA GAS TRAN
8209310		3411925735		107-TF		CONSOLIDATION COAL CO - CR #5	MADISON	19.0	COLUMBIA GAS TRAN
8209311		3411925823		103		CONSOLIDATION COAL CO - CR #9	WASHINGTON	15.0	COLUMBIA GAS TRAN
8209311		3411925823		107-TF		CONSOLIDATION COAL CO - CR #9	WASHINGTON	15.0	COLUMBIA GAS TRAN
-RIMCO OPERATING INC		RECEIVED: 12/07/81 JA: OH							
8209316		3416922849		103		GOOD #2	CHESTER	12.0	COLUMBIA GAS TRAN
8209316		3416922849		107-TF		GOOD #2	CHESTER	12.0	COLUMBIA GAS TRAN
8209312		3416922524		103		JONES #1	CONGRESS	12.0	COLUMBIA GAS TRAN
8209312		3416922524		107-TF		JONES #1	CONGRESS	12.0	COLUMBIA GAS TRAN
8209313		3416922586		103		MORRISON #2	GREEN	12.0	COLUMBIA GAS TRAN
8209313		3416922586		107-TF		MORRISON #2	GREEN	12.0	COLUMBIA GAS TRAN
8209314		3416922649		103		R MARTIN #5	CHESTER	12.0	COLUMBIA GAS TRAN
8209314		3416922649		107-TF		R MARTIN #5	CHESTER	12.0	COLUMBIA GAS TRAN
8209315		3416922770		103		STOUT #1	WAYNE	12.0	COLUMBIA GAS TRAN
8209315		3416922770		107-TF		STOUT #1	WAYNE	12.0	COLUMBIA GAS TRAN
-SUPERIOR PETROLEUM INC		RECEIVED: 12/07/81 JA: OH							
8209317		3409921257		107-TF		ALESI-OVINGTON #2	GOSHEN	0.0	EAST OHIO GAS CO
-THE MUTUAL OIL & GAS COMPANY		RECEIVED: 12/07/81 JA: OH							
8209223		3413321627		103		KOSTALEK #1	NELSON	0.0	EAST OHIO GAS CO
8209223		3413321627		107-TF		KOSTALEK #1	NELSON	0.0	EAST OHIO GAS CO

JD NO	JA DKT	API NO	D SEC CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209222		3413321565	103	NEIMI #1	NELSON	0.0	EAST OHIO GAS CO
8209222		3413321565	107-TF	NEIMI #1	NELSON	0.0	EAST OHIO GAS CO
8209221		3410322601	103	RUHLIN DEVELOPMENT #1	SHARON	0.0	COLUMBIA GAS TRAN
8209221		3410322601	107-TF	RUHLIN DEVELOPMENT #1	SHARON	0.0	COLUMBIA GAS TRAN
-TOWNER PETROLEUM CO			RECEIVED: 12/07/81 JA: OH				
8209323		3405923034	107-TF	ALBAUGH #2	GUERNSEY	0.0	TENNESSEE GAS PIP
8209319		3405922957	107-TF	BLACK-DEIOMA #1	GUERNSEY	0.0	TENNESSEE GAS PIP
8209322		3405923030	107-TF	BLACKWOOD #3	GUERNSEY	0.0	TENNESSEE GAS PIP
8209324		3405923035	107-TF	HEINISH #1	GUERNSEY	0.0	TENNESSEE GAS PIP
8209320		3405923004	107-TF	ST CLAIR #1	GUERNSEY	0.0	TENNESSEE GAS PIP
8209321		3405923021	107-TF	T WARNER #1	GUERNSEY	0.0	TENNESSEE GAS PIP
-UNIVERSAL EXPLORATION			RECEIVED: 12/07/81 JA: OH				
8209325		3410322588	103	FRITZ UNIT #1	GUILFORD	75.0	
8209325		3410322588	107-TF	FRITZ UNIT #1	GUILFORD	75.0	
8209326		3410322655	103	WELTZIEN UNIT #1	WADSWORTH	75.0	
8209326		3410322655	107-TF	WELTZIEN UNIT #1	WADSWORTH	75.0	
-VANLOCO INC			RECEIVED: 12/07/81 JA: OH				
8209327		3410322746	103	VANSELOW #1	GRANGER	20.0	
8209327		3410322746	107-TF	VANSELOW #1	GRANGER	20.0	
-VIKING RESOURCES CORP			RECEIVED: 12/07/81 JA: OH				
8209334		3409921376	103	DARBY UNIT #1	BERLIN	30.0	
8209334		3409921376	107-TF	DARBY UNIT #1	BERLIN	30.0	
8209335		3409921377	103	DARBY UNIT #2	BERLIN	30.0	
8209335		3409921377	107-TF	DARBY UNIT #2	BERLIN	30.0	
8209336		3409921378	103	DARBY UNIT #3	BERLIN	30.0	
8209336		3409921378	107-TF	DARBY UNIT #3	BERLIN	30.0	
8209333		3409921375	103	EMMA I BEAN #2	BERLIN	30.0	
8209333		3409921375	107-TF	EMMA I BEAN #2	BERLIN	30.0	
8209332		3409921374	103	EMMA 1 BEAN #1	BERLIN	30.0	
8209332		3409921374	107-TF	EMMA 1 BEAN #1	BERLIN	30.0	
8209328		3409921328	103	HARTZELL #1	BERLIN	30.0	
8209328		3409921328	107-TF	HARTZELL #1	BERLIN	30.0	
8209329		3409921327	103	HARTZELL #2	BERLIN	30.0	
8209329		3409921327	107-TF	HARTZELL #2	BERLIN	30.0	
8209330		3409921366	103	HEISER #1	BERLIN	30.0	
8209330		3409921366	107-TF	HEISER #1	BERLIN	30.0	
8209331		3409921368	103	HEISER #3	BERLIN	30.0	
8209331		3409921368	107-TF	HEISER #3	BERLIN	30.0	
8209339		3413322608	103	STADER-ZUCHOWSKI UNIT #2	PALMYRA	30.0	
8209339		3413322608	107-TF	STADER-ZUCHOWSKI UNIT #2	PALMYRA	30.0	
8209338		3413322607	103	STADER/ZUCHOWSKI UNIT #1	PALMYRA	30.0	
8209338		3413322607	107-TF	STADER/ZUCHOWSKI UNIT #1	PALMYRA	30.0	
8209337		3409921379	103	TOKICH #1	BERLIN	30.0	
8209337		3409921379	107-TF	TOKICH #1	BERLIN	30.0	
-W J LYDIC INC			RECEIVED: 12/07/81 JA: OH				
8209215		3407522954	103	KINER 1-17	KINER-1-17	20.0	COLUMBIA GAS TRAN
8209215		3407522954	107-TF	KINER 1-17	KINER-1-17	20.0	COLUMBIA GAS TRAN
8209216		3407522955	103	KINER 1-18	KINER 1-18	2.0	COLUMBIA GAS TRAN
8209216		3407522955	107-TF	KINER 1-18	KINER 1-18	2.0	COLUMBIA GAS TRAN
-WILLIAM N TIPKA			RECEIVED: 12/07/81 JA: OH				
8209318		3410322545	103	SLAVICK #1	GRANGER	0.0	COLUMBIA GAS TRAN
8209318		3410322545	107-TF	SLAVICK #1	GRANGER	0.0	COLUMBIA GAS TRAN
-WRAY PETROLEUM CORP OF OHIO			RECEIVED: 12/07/81 JA: OH				

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JD NO	JA DKT	API NO	D SEC CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209349		3413322468	103	BROM #1	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209349		3413322468	107-TF	BROM #1	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209347		3413322403	103	FINNEY #1	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209347		3413322403	107-TF	FINNEY #1	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209345		3413322398	103	FINNEY VANCURA #2	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209345		3413322398	107-TF	FINNEY VANCURA #2	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209351		3413322483	103	L VANCURA #1	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209351		3413322483	107-TF	L VANCURA #1	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209348		3413322424	103	LINDQUIST #1	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209348		3413322424	107-TF	LINDQUIST #1	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209344		3413322351	103	MORAN VANCURA #1	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209344		3413322351	107-TF	MORAN VANCURA #1	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209350		3413322482	103	R VANCURA #1	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209350		3413322482	107-TF	R VANCURA #1	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209352		3413322486	103	R VANCURA #2	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209352		3413322486	107-TF	R VANCURA #2	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209346		3413322399	103	STROUP KUBINEC #1	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
8209346		3413322399	107-TF	STROUP KUBINEC #1	NELSON TOWNSHIP	18.0	EAST OHIO GAS CO
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** U.S. GEOLOGICAL SUPVEY - DENVER,CO							
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-COSEKA RESOURCES (USA) LIMITED			RECEIVED: 12/01/81 JA: CO 1				
8209105	CD 0420-81	0510308603	103	FEDERAL #2-34-4-101	TRAIL CANYON	50.0	SOUTHWEST GAS COR
-GULF OIL CORPORATION			RECEIVED: 12/01/81 JA: CO 1				
8209101	CD 0421-81	0510308548	103	DRAGON TRAIL FEDERAL 4-8-3C	DRAGON TRAIL	54.0	WESTERN SLOPE GAS
-KOCH INDUSTRIES INC			RECEIVED: 12/01/81 JA: CO 1				
8209107	UD 0425-81	0507708383	107-TF	HORSESHOE CANYON NO 2-28	ROBERTS CANYON	109.5	NORTHWEST PIPELIN
-MESA PETROLEUM			RECEIVED: 12/01/81 JA: CO 1				
8209104	CD 0414-81	0512506579	102-2	ECKLEY FEDERAL 29 #3	ECKLEY	142.0	CITIES SERVICE GA
-RAINBOW RESOURCES INC			RECEIVED: 12/01/81 JA: CO 1				
8209106	CD 0416-81	0508106270	108	FEDERAL 1-19T & 1-19C C-0128223	STATELINE III	15.0	NORTHWEST PIPELIN
-TENNECO OIL COMPANY			RECEIVED: 12/01/81 JA: CO 1				
8209102	CD 0406-81	0504506158	108	FEDERAL #18-2	UNAMED	7.0	COLORADO INTERSTA
-TWIN ARROW INC			RECEIVED: 12/01/81 JA: CO 1				
8209098	CD 0195-81	0510308524	103	C & K 1-18	CATHEDRAL	0.0	NORTHWEST PIPELIN
8209097	CD 0240-81	0510308234	103	CONTINENTAL 1-9	CATHEDRAL	0.0	NORTHWEST PIPELIN
8209103	CD 0202-81	0510308408	103	CONTINENTAL 4-28	CATHEDRAL	0.0	NORTHWEST PIPELIN
8209096	CD 0278-81	0510308415	107-TF	SHENANDOAH 2-32	CATHEDRAL	0.0	NORTHWEST PIPELIN
8209099	CD 027-81	0510308415	103	SHENANDOAH 2-32	CATHEDRAL	0.0	NORTHWEST PIPELIN
-COTTON PETROLEUM CORPORATION			RECEIVED: 12/01/81 JA: UT 1				
8209108	UD 0417-81	4304730617	107-TF	LOVE UNIT #11-1	WILDCAT	300.0	MESA PIPELINE CO
-TEXACO INC			RECEIVED: 12/01/81 JA: UT 1				
8209100	UD 0424-81	4303730224	103	ANETH UNIT #K-330	ANETH	41.1	EL PASO NATURAL G

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CORRECTIONS TO PREVIOUS NOTICES OF DETERMINATION

JD No.	JA	Applicant	Well Name	Orig. FERC Vol. No.	Date Pub. in Federal Register	C:	Correction to prior Fed. Register notice
79-03569	NM	Conoco Inc	South Eunice Phase 2 #46			C:	Well name
81-11317	LA	Peterman-Sturlese et al	Jacke E Lawton #1	355		R.	102-4 Approved 11-30-81
81-17508	NY	SCG Gas Quest Inc.	Lardo B #1			C:	103 Approved
81-17509	NY	SCG Gas Quest Inc.	M. Williams #1			C:	103 Approved
81-17510	NY	SCG Gas Quest Inc.	Vereerstraeten #1			C:	103 Approved
81-21136	TX	Parafinne Oil Corp.	P. H. Welder C 1-U	394	03-31-81	C:	102-4 Approved
81-24214	TX	William Perlman	Dan Cauthorn D-2	412		C:	103, 107-TF & 108 Approved
81-24215	TX	William Perlman	Dan Cauthorn 22-1	412		C:	103 & 107-TF Approved
81-24216	TX	William Perlman	ADA Cauthorn 7-1	412		C:	103, 107-TF & 108 Approved
81-24553	TX	Delta Drilling Co	Tallent #1	413	05-01-81	C:	102, 103 & 107-TF Approved
81-33791	NY	Bounty Oil & Gas	Barton #1	453	06-30-81	C:	Well Name
81-34887	WV	J & J Enterprises Inc	R-231	458	07-02-81	C:	103 Denied
81-46277	NM	Amoco Production Co	Gallegos Canyon Unit #262	503	09-17-81	C:	108-ER Approved
81-48699	OH	Doran & Associates	#1 James Moreland	515	10-09-81	C:	103 Approved, 107-TF Denied
81-50364	TX	Kerr-McGee Corp	Campbell Hahn Unit No. 1	521	10-26-81	C:	107-PE Approved, not 107-TF
81-50495	TX	Enserch Pet. Inc.	Hande Saylors "B" No. 2-7	521	10-26-81	C:	107-PE Approved, not 107-TF
81-50516	TX	Amoco Production Co	V H Weber #1	521	10-26-81	C:	102-4 approved; not 107-TF
81-50534	TX	Kilroy Co. of Texas	Patricia Crawford #A-4	521	10-26-81	C:	102-4 Approved
81-50904	OK	Texoma Resources Inc	Grabow #1-27			R:	103 Denied
82-00425	TX	Saxon Oil Company	Amacker #67-1	527	10-30-81	C:	103 Approved, 107-TF withdrawn
82-01161	LA	Lamson Onshore Pet. Corp	Bayou Pigeon Oil Co. #1	530	11-09-81	C:	102-4 & 103 Approved
82-01249	WVA	Roy G Hildreth Jr.	Offutt #2	530	11-09-81	C:	108 Denied
82-01297	TX	Mithcell Energy Offsh	State Tract 179-S #2	531	11-09-81	C:	Well Name
82-01721	PA	Cabot Oil & Gas Corp	Vance Rung #1	532	11-09-81	C:	Well Name
82-01765	PA	Boyd & Shriver	Brothers 410	532	11-09-81	C:	108 Denied
82-01767	PA	Boyd & Shriver	Work 407	532	11-09-81	C:	108 Denied
82-01810	PA	Meridian Expl. Corp	D Klie #552-1	532	11-09-81	C:	Well Name
82-02224	MI	Don Yohe Enterprises	Thieman-Pearson #1-12	535	11-09-81	C:	Well Name
82-02525	WV	Waco Oil & Gas Co. Inc	Ray Patterson 1A	536	11-09-81	C:	107-DV Approved
82-02626	PA	Quaker State Oil Refin.	Bright Wolfe 050	536	11-09-81	C:	Well Name
82-02650	PA	R. Wesley Smith & Raymond A. Smith	Taylor #2	536	11-09-81	C:	Well Name
82-02654	PA	Vineyard Oil & Gas Co	Niemeyer #1	536	11-09-81	C:	102-2 Approved, not 108
82-02888	NM	Getty Oil Co	Farming C #1	538	11-19-81	C:	108-SA Approved
82-02916	NM	Apollo Energy Inc.	Lee	538	11-19-81	C:	103 Denied
82-02927	NM	Southland Royalty Co.	State #4	538	11-19-81	C:	108 Denied
82-02940	NM	Getty Oil Company	Paul Williams #2	538	11-19-81	C:	108-SA Approved
82-03055	TX	Gould Oil Inc.	St. Regis #1-A	539		C:	103 Denied
82-03815	OK	Caddo Energy	Oxley #1-A	541	11-24-81	C:	Well Name
82-03834	OK	Phillips Petroleum Co	Zum-Mallan B#1	541	11-24-81	C:	108-ER Approved
82-04544	OK	Phillips Petroleum Co	Brooks "D" #2	547		C:	Well Name
82-06151	NM	Ike Lovelady Inc	Pennzoil State #1	553		C:	103 and 107-TF Approved

The above notices of determination were received from the indicated jurisdictional agencies by the Federal Energy Regulatory Commission pursuant to the Natural Gas Policy Act of 1978 and 18 CFR 274.104. Negative determinations are indicated by a "D" before the section code. Estimated annual production (PROD) is in million cubic feet (MMCF). An (*) before the Control (JD) number denotes additional puchasers listed at the end of the notice.

The applications for determination are available for inspection except to the extent such material is confidential under 18 CFR 275.206, at the Commission's Division of Public Information, Room 1000, 825 North Capitol St., Washington, D.C. Persons objecting to any of these determinations may, in accordance with 18 CFR 275.203 and 275.204, file a protest with the Commission on or before January 20, 1982.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-152 Filed 1-4-82; 8:45 am]

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Determinations by Jurisdictional Agencies Under the Natural Gas Policy Act of 1978

Issued: December 30, 1981.

JD NO	JA DKT	API NO	D SEC CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
KANSAS CORPORATION COMMISSION							
-GETTY OIL COMPANY			RECEIVED: 12/04/81	JA: KS			
8209355	K80-0619	1504700000	108-SA	EMMA SMITH #1	EDSTAFF	0.0	NORTHERN NATURAL
-HOFFMANN OIL CO			RECEIVED: 12/04/81	JA: KS			
8209354	K81-0749	1518920537	103	HOFFMANN 2-17	PANOMA COUNCIL GROVE	24.0	PANHANDLE EASTERN
8209356	K81-0748	1518920538	103	HOFFMANN 2-21	PANOMA COUNCIL GROVE	273.0	PANHANDLE EASTERN
NEW YORK DEPARTMENT OF ENVIRONMENTAL CONSERVATION							
-BEREA OIL AND GAS CORPORATION			RECEIVED: 12/02/81	JA: NY			
8209361	1293	3101315362	102-2	CLAUDE HALLER UNIT #2	WILDCAT	30.0	COLUMBIA GAS TRAN
8209379	1691	3101316065	103	N WILSON #1	GERRY	25.0	COLUMBIA GAS TRAN
8209362	1289	3101315360	102-2	ROBERT BARGAR #1	WILDCAT	30.0	COLUMBIA GAS TRAN
8209377	1662	3101316051	103	W G TOMPSETT #2	GERRY	25.0	COLUMBIA GAS TRAN
8209380	1663	3101315950	103	W G TOMPSETT UNIT #1	GERRY	25.0	COLUMBIA GAS TRAN
-CHAUTAUQUA ENERGY INC			RECEIVED: 12/02/81	JA: NY			
8209370	1694	3101314154	108	VALARDO #1	LAKESHORE	10.8	NATIONAL FUEL GAS
8209367	1695	3101314154	103	VILARDO #1	LAKESHORE	10.8	NATIONAL FUEL GAS
8209369	1646	3101314155	108	VILARDO #2	LAKE SHORE	10.8	NATIONAL FUEL GAS
8209366	1648	3101314156	108	VILARDO #3	LAKE SHORE	10.8	NATIONAL FUEL GAS
8209368	1647	3101314157	108	VILARDO #4	LAKE SHORE	10.8	NATIONAL FUEL GAS
8209363	1697	3101314158	103	VILARDO #5	LAKESHORE	10.8	NATIONAL FUEL GAS
-ENERGY OIL INC			RECEIVED: 12/02/81	JA: NY			
8209357	1309	3102915242	103	HENSHAW #1	ORCHARD PARK	50.0	TENNESSEE GAS PIP
8209359	1048	3102914411	103	RIEDESEL #1	ALDEN	50.0	TENNESSEE GAS PIP
8209360	1040	3102914412	103	RUPP #1	MEDINA	0.0	NATIONAL FUEL GAS
8209358	1532	3102915339	103	SNYDER #1	MARILLA ELMA BUFFALO CRE	12.0	NATIONAL FUEL GAS
-ENVIROGAS INC			RECEIVED: 12/02/81	JA: NY			
8209378	1642	3101315890	103	A NIXON #4	LAKESHORE	18.0	NATIONAL FUEL GAS
-NORD/MONTARA PETROLEUM CO			RECEIVED: 12/02/81	JA: NY			
8209365	1711	3112113790	108	JOS G ZIELINSKI #1	JAVA MEDINA	8.0	COLUMBIA GAS TRAN
8209364	1712	3112113725	108	LUCILLE SICLARI #1	JAVA MEDINA	9.0	COLUMBIA GAS TRAN
-SINCLAIRVILLE PETROLEUM CORP			RECEIVED: 12/02/81	JA: NY			
8209375	1637	3102915844	103	BOLDT #1	BUFFALO CREEK	15.0	NATIONAL FUEL SUP
8209371	1634	3102915791	103	MUNDT #1	BUFFALO CREEK	17.0	NATIONAL FUEL SUP
8209374	1636	3102915919	103	PHILLIPS #1	WILDCAT	18.0	NATIONAL FUEL SUP
8209373	1635	3102915895	103	ROBINSON #1	BUFFALO CREEK	15.0	NATIONAL FUEL SUP
8209372	1633	3102915734	103	SCHICHTEL #1	WILDCAT	18.0	NATIONAL FUEL SUP
8209376	1638	3102916014	103	SICURELLA #2	EVANS	17.0	NATIONAL FUEL SUP
-WARNER BROTHERS WELL DRILLING INC			RECEIVED: 12/02/81	JA: NY			
8209383	1144	3102914586	108	CARL BRUNING 31-029-14586	AKRON	5.6	NATIONAL FUEL GAS
8209382	1145	3103714421	108	CARL BRUNING 31-037-14421	AKRON	6.7	NATIONAL FUEL GAS

JD NO	JA DKT	API NO	D SEC CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209381	1143	3102913880	108	CHAUNCEY E VANICE 31-029-13880	AKRON	8.4	NATIONAL FUEL GAS
8209384	1146	3102914322	108	EUGENE BRENDA 31-029-14322	AKRON	8.4	NATIONAL FUEL GAS
8209385	1147	3102914263	108	GEORGE HYDER 31-029-14263	AKRON	8.4	NATIONAL FUEL GAS
8209386	1141	3102913947	103	ZIMMERMAN-KRAATZ 31-029-13947	AKRON	0.0	NATIONAL FUEL GAS

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OKLAHOMA CORPORATION COMMISSION

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-AMAREX INC			RECEIVED: 12/04/81 JA: OK				
8209479	13565	3514917987	102-2	AARON #1-29		365.0	
-AMCANA OIL CORP			RECEIVED: 12/04/81 JA: OK				
8209476	11622	3508320787	103	PHILLIPS #1-32	RINGWOOD	90.0	PANHANDLE EASTERN
-ANADARKO PRODUCTION COMPANY			RECEIVED: 12/04/81 JA: OK				
8209525	14684	3500722100	102-4	BUNYARD A #1	DOMBEY NORTH	7.0	PANHANDLE EASTERN
8209524	10922	3513920772	108	INTERSTATE K-1	GOFF CREEK	7.0	PANHANDLE EASTERN
-ARCO OIL AND GAS COMPANY			RECEIVED: 12/04/81 JA: OK				
8209481	14685	3504321179	102-4	PRESLEY UNIT #1-U	PUTNAM	146.0	MOBIL OIL CORP
-B R POLK INC			RECEIVED: 12/04/81 JA: OK				
8209513	11316	3508320830	103	HULS HEIRS #1	N CRESCENT	25.0	EASON OIL CO
-BOBBY J DARNELL			RECEIVED: 12/04/81 JA: OK				
8209502	11510	3508321692	103	LEAFGREEN #2	WILDCAT	24.0	EASON OIL CO
-CALVERT DRILLING CO			RECEIVED: 12/04/81 JA: OK				
8209514	11318	3510920395	103	ROBERTS #1	WEST EDMOND	13.0	PHILLIPS PETROLEU
-CARSTAN OIL CO INC			RECEIVED: 12/04/81 JA: OK				
8209478	14322	3510721003	102-4	HARIO #1	KEATON POOL	25.0	PHILLIPS PETROLEU
-CHAMPLIN PETROLEUM COMPANY			RECEIVED: 12/04/81 JA: OK				
8209488	11575	3509300000	108	ADKISSON UNIT #1	E CHANEY DELL	4.0	UNION TEXAS PETRO
8209491	11579	3510900000	108	C TEUSCHER #1	PEAVINE	5.5	CITIES SERVICE GA
8209493	11582	3510900000	108	C TEUSCHER #6	PEAVINE	15.0	CITIES SERVICE GA
8209492	11581	3500300000	108	CLAIR E SPRAGUE #1	E CHANEY DELL	8.0	CHAMPLIN PETROLEU
8209495	11586	3500300000	108	HENRY WEBER UNIT #1	E CHANEY DELL	6.5	CHAMPLIN PETROLEU
8209487	11574	3513700000	108	IRL NICHOLS #2	MILROY	0.0	AMINOIL USA INC
8209496	11587	3509300000	108	LYDIA KOEHN #1	E CHANEY DELL	3.0	CHAMPLIN PETROLEU
8209489	11577	3509300000	108	MILDRED E VOLZ #1	E CHANEY DELL	12.0	CHAMPLIN PETROLEU
8209494	11583	3508300000	108	R G BECK #2	CASHION	16.0	CITIES SERVICE GA
8209490	11578	3500300000	108	SIMON B UNRUH #2	E CHANEY DELL	15.0	CHAMPLIN PETROLEU
-CHASE EXPLORATION CORP			RECEIVED: 12/04/81 JA: OK				
8209497	11502	3507121817	103	JOHNSON 2-15	UNNAMED	1.0	CITIES SERVICE GA
8209498	11503	3507121831	103	LEVEN 1-35	UNNAMED	2.3	CITIES SERVICE GA
8209499	11504	3507121821	103	WALKER 1-10	UNNAMED	7.1	CITIES SERVICE GA
-CLARK RESOURCES INC			RECEIVED: 12/04/81 JA: OK				
8209517	11297	3507322994	103	CHARLENE 22-1	SOONER TREND	60.0	CITIES SERVICE GA
-DLB ENERGY CORP			RECEIVED: 12/04/81 JA: OK				
8209519	11488	3501721918	103	AKEMAN #1	NORTHEAST OF PIEDMONT	3.0	CONOCO INC
-DOME PETROLEUM CORP			RECEIVED: 12/04/81 JA: OK				
8209474	10120	3515321113	103	MADDUX #1	NORTH MOORELAND	385.1	
-ECC OIL CO			RECEIVED: 12/04/81 JA: OK				
8209515	11320	3514720998	108	GREENWOOD #1A SW/4 SE/4 17-25N-14E	OGLESBY GAS FIELD	0.2	OKAN GAS CO
-EDWIN L COX			RECEIVED: 12/04/81 JA: OK				
8209526	11060	3509120105	108	LOVELACE #1	PIERCE	9.5	PHILLIPS PETROLEU
-ENSERCH EXPLORATION INC			RECEIVED: 12/04/81 JA: OK				
8209477	13928	3512900000	107-PE	J R POWELL #2	CRAWFORD	14.0	DELHI GAS PIPELIN
-F C D OIL CORP			RECEIVED: 12/04/81 JA: OK				
8209512	11439	3507323088	103	RATTS 1-1	NW LOVELL	146.0	EASON OIL CO

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
-FUNK EXPLORATION INC						RECEIVED: 12/04/81 JA: OK			
8209470	09579	3500721835		133		AMEN #1	NW GREENOUGH	0.0	WESTERN GAS INTER
-GETTY OIL COMPANY						RECEIVED: 12/04/81 JA: OK			
*8209531	11453	3513722550		103		CROSBIE-MUDGE #6 (SYCAMORE)	SHO-VEL-TUM	300.0	OKLAHOMA NATURAL
*8209532	11454	3513722550		103		CROSBIE-MUDGE NO 6 (HUNTON)	SHO-VEL-TUM	0.0	OKLAHOMA NATURAL
*8209533	11501	3513722683		103		TEMPLES UNIT #3	SHO-VEL-TUM	350.0	OKLAHOMA NATURAL
-GIBRALTAR EXPLORATION LTD						RECEIVED: 12/04/81 JA: OK			
8209527	11267	3504520882		103		WHITE #1	N CHANEY	275.0	NORTHERN NATURAL
-GRACE PETROLEUM CORPORATION						RECEIVED: 12/04/81 JA: OK			
8209518	11482	3507920228		108		SEBO 1-6		17.0	ARKANSAS LOUISIAN
-GRAHAM OIL & GAS LTD						RECEIVED: 12/04/81 JA: OK			
8209529	11447	3505921005		103		WEIBENER HEIRS #1A		190.1	DELHI GAS PIPELIN
-HESTON OIL CO						RECEIVED: 12/04/81 JA: OK			
8209501	11509	3506321232		103		KAMPERMAN #30-1	E YEAGER	0.0	
-JICO EXPLORATION INC						RECEIVED: 12/04/81 JA: OK			
8209528	11278	3509322029		103		JICO-GRAHAM #1	RINGWOOD	20.0	PIONEER GAS PRODU
-KAISER-FRANCIS OIL COMPANY						RECEIVED: 12/04/81 JA: OK			
8209506	11557	3504720806		108		JOHNSON #1	SPRING VALLEY	5.9	GRACE PETROLEUM C
8209507	11558	3504700000		108		LANDES #1	SPRING VALLEY	4.6	GRACE PETROLEUM C
8209509	11560	3504700000		108		LUDWIG #1	SPRING VALLEY	5.7	GRACE PETROLEUM C
8209510	11562	3504700000		108		O'NEILL #1	SPRING VALLEY	6.8	GRACE PETROLEUM C
8209508	11559	3504720500		108		TOEWS #1-6	SPRING VALLEY	4.7	GRACE PETROLEUM C
-M M RESOURCES INC						RECEIVED: 12/04/81 JA: OK			
8209511	11568	3510321325		103		HODGE #1		0.0	AMINOIL USA INC
-MACKELLAR INC						RECEIVED: 12/04/81 JA: OK			
8209480	14631	3507300000		107	-PE	HELLWEGE #1	SOONER TREND	32.9	CONOCO INC
-NOBLE OPERATING INC						RECEIVED: 12/04/81 JA: OK			
8209468	10946	3509322159		103		CASE #1	NW PHROSO	0.0	PHILLIPS PETROLEU
8209467	09344	3509322002		103		EARL WAHL #1	RINGWOOD	0.0	PIONEER GAS PRODU
8209466	09339	3509321901		103		PARKER #1	NW OKEENE	0.0	DELHI GAS PIPELIN
-OLEUM INC						RECEIVED: 12/04/81 JA: OK			
8209475	10709	3501922201		103		J L WILLIAMS #2	JOINER CITY	51.0	AMINOIL USA INC
-OMNI OIL & GAS INC						RECEIVED: 12/04/81 JA: OK			
8209503	11512	3507322835		103		JUNE "22" #1	SOONER TREND	25.6	CITIES SERVICE GA
-P-T LTD 80						RECEIVED: 12/04/81 JA: OK			
8209538	11467	3504722518		103		HIXON 19-1	SOONER TREND	35.0	WELLHEAD ENTERPRI
-P-T LTD 81						RECEIVED: 12/04/81 JA: OK			
8209536	11462	3509322191		103		DITTMEYER 29-1	SOONER TREND	35.0	WELLHEAD ENTERPRI
8209537	11463	3504722550		103		RIEKENBERG 16-1	SOONER TREND	35.0	WELLHEAD ENTERPRI
-PETRO-ENERGY EXPLORATION INC						RECEIVED: 12/04/81 JA: OK			
8209520	11498	3504722432		103		DIERKSEN-PETRO #1	SOONER TREND	110.0	CITIES SERVICE GA
8209521	11506	3504722559		103		GOODWIN #1-33	SOONER TREND	100.0	WELLHEAD ENTERPRI
-POLARIS ENERGY CORP						RECEIVED: 12/04/81 JA: OK			
8209485	11572	3511122724		103		DOUBLE W T-2		0.0	PHILLIPS PETROLEU
-QUINTIN LITTLE CO						RECEIVED: 12/04/81 JA: OK			
8209486	11573	3509500000		133		CARRIE LOU LITTLE #1-13	CUMBERLAND	182.5	LONE STAR GAS CO
-SAMEDAN OIL CORPORATION						RECEIVED: 12/04/81 JA: OK			
8209535	11456	3501721758		133		DONNA J #1		175.0	PHILLIPS PETROLEU
8209516	11283	3501721755		103		SCHROEDER #1		550.0	PHILLIPS PETROLEU
-SEIGEL PETROLEUM CO						RECEIVED: 12/04/81 JA: OK			
8209534	11455	3511921461		103		STATE #1	CUSHING	18.0	ARCO OIL & GAS CO
-SENECA OIL COMPANY						RECEIVED: 12/04/81 JA: OK			
8209500	11505	3504321220		103		COX-GREBEL #1-15	OAKWOOD	157.0	DELHI GAS PIPELIN

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
-SITCO INC				RECEIVED: 12/04/81 JA: OK					
8209482	14742	3508321607		103		BOB #1	CRESCENT	0.0	EASON OIL CO
-SKYHAWK ENERGY CORP				RECEIVED: 12/04/81 JA: OK					
8209469	9411	3511122650		103		GEORGE MILNER #1	BALD HILL	91.0	PHILLIPS PETROLEU
-SOUTHLAND ROYALTY CO				RECEIVED: 12/04/81 JA: OK					
8209523	10914	3513921208		108		JAMES #1-29	CAPLE	11.0	NORTHERN NATURAL
8209522	10912	3509321528		108		PITTMAN #1-24	W CHEYENNE VALLEY	5.0	PANHANDLE EASTERN
-ST JOE PETROLEUM (US) CORP				RECEIVED: 12/04/81 JA: OK					
8209505	11516	3510300000		103		LAVINGTON #1		182.0	CITIES SERVICE GA
-TEXOMA RESOURCES INC				RECEIVED: 12/04/81 JA: OK					
8209504	11513	3507323097		103		MITCHELL #1	SOONER TREND	100.0	EXXON CO USA
-TRANSCO OIL CO				RECEIVED: 12/04/81 JA: OK					
8209530	11452	3511100000		103		HAYNES 1-10	BEGGS OIL SE-1/4 SEC 10	70.0	PHILLIPS PETROLEU
-UNIVERSAL RESOURCES CORPORATION				RECEIVED: 12/04/81 JA: OK					
8209473	10039	3501721826		103		SCHLECHT C #1-24	SOONER TREND	73.0	DELHI GAS PIPELIN
-WHITSON OIL CO INC				RECEIVED: 12/04/81 JA: OK					
8209471	09660	3510120438		108		STEELE 1-12 101 56511	STEELE	2.5	PHILLIPS PETROLEU
8209472	09668	3510120521		108		STEELE 3-12 101 56511	STEELE	2.5	PHILLIPS PETROLEU
-WOOD ENTERPRISES INC				RECEIVED: 12/04/81 JA: OK					
8209483	14851	3511900000		102-4		STOOPS #1 (119-58669)	MARKHAM	25.0	PARKS ENERGY INVE
8209483	14851	3511900000		103		STOOPS #1 (119-58669)	MARKHAM	25.0	PARKS ENERGY INVE
8209484	14852	3511900000		102-4		STOOPS #2	MARKHAM	19.0	PARKS ENERGY INVE
8209484	14852	3511900000		103		STOOPS #2	MARKHAM	19.0	PARKS ENERGY INVE
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** U.S. GEOLOGICAL SURVEY - ALBUQUERQUE,NM									
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-AMOCO PRODUCTION CO				RECEIVED: 12/04/81 JA: NM 4					
8209398	NM 1153-81	3003922453		103		JICARILLA APACHE 102 #7E (GALLUP)	B S MESA-GALLUP	30.0	EL PASO NATURAL G
-BLACKWOOD & NICHOLS CO LTD				RECEIVED: 12/04/81 JA: NM 4					
8209427	NM-1522-81	3003922564		103		NORTHEAST BLANCO UNIT #24R	BLANCO MESAVERDE O-17-30	100.0	EL PASO NATURAL G
8209430	NM-1526-81	3004525001		103		NORTHEAST BLANCO UNIT #26A	BLANCO MESAVERDE O-8-30N	110.0	EL PASO NATURAL G
8209431	NM-1528-81	3004524858		103		NORTHEAST BLANCO UNIT #46A	BLANCO MESAVERDE O-33-31	120.0	EL PASO NATURAL G
8209428	NM-1523-81	3004525093		103		NORTHEAST BLANCO UNIT #54A	BLANCO MESAVERDE O-33-31	90.0	EL PASO NATURAL G
8209429	NM-1525-81	3004524891		103		NORTHEAST BLANCO UNIT #71	BLANCO MESAVERDE A-23-31	190.0	EL PASO NATURAL G
8209432	NM-1529-81	3004525095		103		NORTHEAST BLANCO UNIT #72	BLANCO MESAVERDE H-29-31	200.0	EL PASO NATURAL G
-CHACE OIL COMPANY INC				RECEIVED: 12/04/81 JA: NM 4					
8209402	NM-1389-81	3004320541		103		CHACE APACHE 54-9	CHACON-DAKOTA	80.0	EL PASO NATURAL G
-CHAMA PETROLEUM CO				RECEIVED: 12/04/81 JA: NM 4					
8209392	NM-1782-80	3002525805		102-4		PENNZOIL FEDERAL #1	UNDESIGNATED NORTH QUAIL	750.0	EL PASO NATURAL G
-COLONIAL PRODUCTION COMPANY				RECEIVED: 12/04/81 JA: NM 4					
8209387	NM21-81ER	3003900000		108		JICARILLA APACHE CONTRACT #398 #9	BALLARD PICTURED CLIFF	0.0	EL PASO NATURAL G
-CONOCO INC				RECEIVED: 12/04/81 JA: NM 4					
8209404	NM-1402-81	3002526967		103		HAWK A NO 8	NMFU-BLINEBRY	120.0	GETTY OIL CO
-COTTON PETROLEUM CORPORATION				RECEIVED: 12/04/81 JA: NM 4					
8209405	NM-1403-81	3003908088		108		CINCO DIABLOS 2-Y	BALLARD PICTURED CLIFFS	5.0	NORTHWEST PIPELIN
-DOME PETROLEUM CORP				RECEIVED: 12/04/81 JA: NM 4					
8209449	NM-1563-81	3004320542		102-2		DOME TESORO 22 #4	UNDESIGNATED GALLUP	87.6	SOUTHWEST GAS COR
-EL PASO EXPLORATION CO				RECEIVED: 12/04/81 JA: NM 4					
8209389	NM0664-81	3003921162		108		JICARILLA 123 C #20	BLANCO SOUTH-PICTURED CL	18.0	NORTHWEST PIPELIN
-EL PASO NATURAL GAS COMPANY				RECEIVED: 12/04/81 JA: NM 4					
8209394	NM-0471-81	3004500000		108		BLANCO #15 MV & PC	BLANCO-MESAVERDE AND SOU	22.0	EL PASO NATURAL G
8209393	NM0083-81	3003920535		108		CANYON LARGO UNIT #184 CH	OTERO CHACRA	21.0	EL PASO NATURAL G
8209395	NM-0533-81	3004521839		108		HUERFANO UNIT #265 GL & DK	ANGELS PEAK GAL GAS BASI	20.0	EL PASO NATURAL G

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209407	NM-1405 81 A	3003922394		103		SAN JUAN 27-5 UNIT #86M	BLANCO MESAVERDE	160.0	EL PASO NATURAL G
8209408	NM 1405 81-B	3003922394		103		SAN JUAN 27-5 UNIT #86M	BASIN DAKOTA	50.0	EL PASO NATURAL G
8209411	NM141481-A	3003922399		103		SAN JUAN 29-7 UNIT #109M	BLANCO MESAVERDE	350.0	EL PASO NATURAL G
8209412	NM1414818	3003922399		103		SAN JUAN 29-7 UNIT #109M	BASIN DAKOTA	110.0	EL PASO NATURAL G
8209413	NM-141581A	3003922401		103		SAN JUAN 29-7 UNIT #110M	BLANCO MESAVERDE	300.0	EL PASO NATURAL G
8209414	NM141581-B	3003922401		103		SAN JUAN 29-7 UNIT #110M	BASIN DAKOTA	105.0	EL PASO NATURAL G
8209415	NM-141681-A	3003922398		103		SAN JUAN 29-7 UNIT #112M	BLANCO MESAVERDE	350.0	EL PASO NATURAL G
8209416	NM-1416-81-B	3003922398		103		SAN JUAN 29-7 UNIT #112M	BASIN DAKOTA	150.0	EL PASO NATURAL G
8209417	NM-1417-81	3003922633		103		SAN JUAN 29-7 UNIT #118	BLANCO PICTURED CLIFFS	60.0	EL PASO NATURAL G
						RECEIVED: 12/04/81 JA: NM 4			
-EL PASO NATURAL GAS COMPANY									
8209390	NM-1446-80-B	3004523830		103		SUNRAY J #1A	AZTEC PICTURED CLIFFS	30.0	EL PASO NATURAL G
						RECEIVED: 12/04/81 JA: NM 4			
-ENERGY RESERVES GROUP INC									
8209447	NM-1560-81	3004524947		103		E H PIPKIN #14	FULCHER KUTZ PICTURED CL	39.9	SOUTHERN UNION GA
8209446	NM 1559-81	3004524970		103		E H PIPKIN #15	FULCHER KUTZ PICTURED CL	81.0	SOUTHERN UNION GA
8209448	NM 1561-81	3004524990		103		GALLEGOS CANYON UNIT #319	PINON FRUITLAND EXTENSIO	10.4	EL PASO NATURAL G
						RECEIVED: 12/04/81 JA: NM 4			
-GRACE PETROLEUM CORPORATION									
8209401	NM-1221-81	3003922171		103		FEDERAL 24-1	DEVILS FORK (GALLUP)	0.0	GAS CO OF NEW MEX
8209399	NM-1213-81	3003922443		103		MCBEE B #2	LYBROOK (GALLUP)	0.0	GAS CO OF NEW MEX
8209400	NM 1219-81	3003922322		103		VANDENBURG #2	LYBROOK (GALLUP)	0.0	GAS CO OF NEW MEX
						RECEIVED: 12/04/81 JA: NM 4			
-KENAI OIL AND GAS INC									
8209424	NM-1487-81	3004524519		102-2		FEDERAL #3-23	NAGEEZI	0.0	GAS CO OF NEW MEX
8209423	NM-1486-81	3004524521		102-2		FEDERAL #34-43	WILDCAT	0.0	GAS CO OF NEW MEX
8209425	NM-1488-81	3004524213		102-2		FEDERAL #6-41	NAGEEZI	0.0	GAS CO OF NEW MEX
8209426	NM-1491-81	3004524201		102-2		UNION NAVAJO ALLOTED #5-21	NAGEEZI	0.0	GAS CO OF NEW MEX
						RECEIVED: 12/04/81 JA: NM 4			
-KIMBELL OIL COMPANY									
8209465	NM-1586-81	3004505577		108		HANSON #1	BASIN DAKOTA A-5-25N-10W	8.7	EL PASO NATURAL G
						RECEIVED: 12/04/81 JA: NM 4			
-MCCLELLAN OIL CORPORATION									
8209397	NM1018-81	3000560858		102-2		COYOTE DRAW FEDERAL #1 (NM-28306)	WILDCAT (ABO)	128.0	TRANSWESTERN PIPE
8209397	NM1018-81	3000560858		107-TF		COYOTE DRAW FEDERAL #1 (NM-28306)	WILDCAT (ABO)	128.0	TRANSWESTERN PIPE
8209406	NM-1404-81	3000560978		102-4		COYOTE DRAW FEDERAL #2 (NM-16069)	UNDESIGNATED (ABO) POOL	365.0	TRANSWESTERN PIPE
8209406	NM-1404-81	3000560978		107-TF		COYOTE DRAW FEDERAL #2 (NM-16069)	UNDESIGNATED (ABO) POOL	365.0	TRANSWESTERN PIPE
						RECEIVED: 12/04/81 JA: NM 4			
-MESA PETROLEUM									
8209438	NM-1543-81	3003922758		103		SOUTH BLANCO NAVAJO 31 #1	LYBROOK GALLUP EXT	44.0	GAS CO OF NEW MEX
8209439	NM-1544-81	3003922759		103		SOUTH BLANCO NAVAJO 31 #2	LYBROOK GALLUP EXT	37.0	GAS CO OF NEW MEX
						RECEIVED: 12/04/81 JA: NM 4			
-MOBIL PRDG TEXAS & NEW MEXICO INC									
8209410	NM-1408-81	3003920167		108		JICARILLA D #13	GAVILAN PICTURED CLIFFS	15.0	NORTHWEST PIPELIN
8209409	NM-1407-81	3003900000		108		JICARILLA F #2	BLANCO MESA VERDE GAS	16.0	NORTHWEST PIPELIN
						RECEIVED: 12/04/81 JA: NM 4			
-NORTHWEST PIPELINE CORPORATION									
8209462	NM-1580-81	3003907963		108		ROSA UNIT #16	BLANCO MV	0.0	EL PASO NATURAL G
8209455	NM-1574-81-A	3003922534		103		SAN JUAN 29-5 #100 MV	BLANCO MESAVERDE	79.0	NORTHWEST PIPELIN
8209457	NM-1576-81-A	3003922469		103		SAN JUAN 29-5 #104 MV	BLANCO MESAVERDE	0.0	NORTHWEST PIPELIN
8209458	NM-1576-81-B	3003922469		103		SAN JUAN 29-5 #104/PC	UNDESIGNATED PICTURED CL	0.0	NORTHWEST PIPELIN
8209459	NM-1577-81-A	3003922471		103		SAN JUAN 29-5 #73 MV	BLANCO MESAVERDE	80.0	NORTHWEST PIPELIN
8209460	NM-1577-81-B	3003922471		103		SAN JUAN 29-5 #73 PC	GOBERNADOR PICTURED CLIF	103.0	NORTHWEST PIPELIN
8209456	NM-1574-81-B	3003922534		103		SAN JUAN 29-5#100 PC	GOBERNADOR PICTURED CLIF	155.0	NORTHWEST PIPELIN
8209461	NM-1579-81	3003922763		103		SAN JUAN 31-6 #5A	BLANCO MESAVERDE	0.0	NORTHWEST PIPELIN
8209464	NM-1584-81	3003920779		108		SAN JUAN 31-6 UNIT #24	BASIN DAKOTA	0.0	NORTHWEST PIPELIN
						RECEIVED: 12/04/81 JA: NM 4			
-PERRY R BASS									
8209391	NM1733-80	3001523131		102-4		BIG EDDY UNIT #64	UNDESIGNATED	180.0	NATURAL GAS PIPEL
						RECEIVED: 12/04/81 JA: NM 4			
-READ & STEVENS INC									
8209454	NM-1572-81	3000560781		103		HARRIS FEDERAL #4	BUFFALO VALLEY PENN	36.0	EL PASO NATURAL G
8209437	NM-1542-81	3000560798		103		HARRIS FEDERAL COM #5	BUFFALO VALLEY PENN	110.0	EL PASO NATURAL G
						RECEIVED: 12/04/81 JA: NM 4			
-SOUTHLAND ROYALTY CO									

BILLING CODE 6717-01-C

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209388		3004522642		108	ER	BROWNING STEWART #5	FULCHER KUTZ	6.0	SOUTHERN UNION GA
8209442	NM-1548-81	3004524127		103		COZZENS #6-E	BASIN	257.0	SOUTHERN UNION GA
8209443	NM-1549-81	3004524872		103		NYE #10-E	BASIN	168.0	SOUTHERN UNION GA
-SUN OIL COMPANY (DELAWARE)				RECEIVED: 12/04/81 JA: NM 4					
8209403	NM-1401 81	3002526916		103		JENNINGS B FEDERAL #1	LUSK YATES NE	54.0	PHILLIPS PETROLEU
-SUPRON ENERGY CORPORATION				RECEIVED: 12/04/81 JA: NM 4					
8209418	NM-1418-81	3003922528		103		JICARILLA L 6-E	BASIN DAKOTA	504.0	GAS CO OF NEW MEX
8209419	NM-1419-81	3004524721		103		NEWSOM B-10E	BASIN DAKOTA	422.0	EL PASO NATURAL G
8209420	NM-1420-81	3004524748		103		NEWSOM B-13E	BASIN DAKOTA	303.0	EL PASO NATURAL G
8209450	NM-1569-81A	3004524361		103		REID B 1-E	BASIN DAKOTA	219.0	SOUTHERN UNION GA
8209451	NM-1569-81-B	3004524361		103		REID B 1-E	WILDCAT CHACRA	103.6	SOUTHERN UNION GA
8209452	NM-1570-81-A	3004524433		103		REID B 2-E	BASIN DAKOTA	293.0	SOUTHERN UNION GA
8209453	NM-1570-81-B	3004524433		103		REID B 2-E	WILDCAT CHACRA	629.0	SOUTHERN UNION GA
8209421	NM-1421-81-A	3004524746		103		TALIAFERRO 5-M	BLANCO MESAVERDE	761.0	SOUTHERN UNION GA
8209422	NM-1421-81-B	3004524746		103		TALIAFERRO 5-M	BASIN DAKOTA	203.0	EL PASO NATURAL G
-TENNECO OIL COMPANY				RECEIVED: 12/04/81 JA: NM 4					
8209444	NM 1553-81	3003922586		103		JICARILLA A #5E	BASIN DAKOTA	500.0	NORTHWEST PIPELIN
8209433	NM-1530-81	3003922578		103		JICARILLA C #6E	BASIN DAKOTA	500.0	NORTHWEST PIPELIN
8209435	NM-1532-81	3003922576		103		JICARILLA C #7E	BASIN DAKOTA	500.0	NORTHWEST PIPELIN
8209434	NM-1531-81	3003922577		103		JICARILLA C #8E	BASIN DAKOTA	500.0	NORTHWEST PIPELIN
8209445	NM 1556-81	3004524692		103		MANSFIELD A #1E	BASIN DAKOTA	500.0	EL PASO NATURAL G
8209436	NM-1533-81	3004525009		103		ROOLOFS #3E	BASIN DAKOTA	500.0	EL PASO NATURAL G
-YATES PETROLEUM CORPORATION				RECEIVED: 12/04/81 JA: NM 4					
8209463	NM-1583-81	3001523644		103		FEDERAL AB #10	PENASCO DRAW-SA-YESO	0.0	TRANSWESTERN PIPE
8209440	NM-1545-81	3001523770		103		FEDERAL BQ COM #7	UND STRAWN	0.0	TRANSWESTERN PIPE
8209441	NM-1546-81	3001523726		103		SCOUT EH FEDERAL #5	UND MORROW	0.0	TRANSWESTERN PIPE
-SUPERIOR OIL CO				RECEIVED: 12/04/81 JA: UT 4					
8209396	UA-0669-81	4303730633		103		MCELMO CREEK UNIT U-15	GREATER ANETH	0.0	EL PASO NATURAL G

OTHER PURCHASERS

8209531 LONE STAR GAS CO
8209532 LONE STAR GAS CO
8209533 LONE STAR GAS CO

The above notices of determination were received from the indicated jurisdictional agencies by the Federal Energy Regulatory Commission pursuant to the Natural Gas Policy Act of 1978 and 18 CFR 274.104. Negative determinations are indicated by a "D" before the section code. Estimated annual production (PROD) is in million cubic feet (MMCF). An (*) before the Control (JD) number denotes additional purchasers listed at the end of the notice.

The applications for determination are available for inspection except to the extent such material is confidential under 18 CFR 275.206, at the Commission's Division of Public Information, Room 1000, 825 North Capitol St., Washington, D.C. Persons objecting to any of these determinations may, in accordance with 18 CFR 275.203 and 275.204, file a protest with the Commission or or before January 20, 1982.

Categoreis within each NGPA section are indicated by the following codes:

Section 102–1: New OCS lease
102–2: New well (2.5 mile rule)
102–3: New well (1000 ft rule)
102–4: New onshore reservoir
102–5: New resevoir on old OCS lease

Section 107–DP: 15,000 feet or deeper
107–GB: Geopressured brine
107–CS: Coal seams
107–DV: Devonian shale
107–PE: Production enhancement
107–TF: New tight formation
107–RT: Recompletion tight formation

Section 108: Stripper well
108–SA: Sesonnally affected
108–ER: Enhanced recovery
108–PB: Pressure buildup

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–153 Filed 1–4–82; 8:45 am]

BILLING CODE 6717–01–M

Determinations by Jurisdictional Agencies Under the Natural Gas Policy Act of 1978

Issued: December 30, 1981.

JD NO	JA DKT	API NO	D SEC CAT WELL NAME	FIELD NAME	PROD	PURCHASER
ARKANSAS OIL & GAS COMMISSION						
-ARKANSAS LOUISIANA GAS CO		RECEIVED: 12/08/81 JA: AR				
8209543	0311510092	102-4	SILEX GAS UNIT #5	SILEX	300.0	ARKANSAS LOUISIAN
-ARKLA EXPLORATION COMPANY		RECEIVED: 12/08/81 JA: AR				
8209566	0313110162	103	MIDDLETON #1-30	BONANZA	400.0	ARKANSAS LOUISIAN
-B J BROWN		RECEIVED: 12/08/81 JA: AR				
8209557	0308300000	103	WILLIAMS #1 26605	UNIONVILLE	110.0	ARKANSAS LOUISIAN
-BROOKINGS WADDLE & ASSOCIATES INC		RECEIVED: 12/08/81 JA: AR				
8209547	0309110315	102-4	EP WILLIAMS #2 SER #26539	ROCKY MOUND SOUTH	365.0	
-CHARLES E MCRAY DBA MCRAY AND ASSOC		RECEIVED: 12/08/81 JA: AR				
8209540	0311510087	102-4	WM G BLACKWELL #1-C	MORELAND	0.0	ARKANSAS LOUISIAN
8209541	0311510087	102-4	WM G BLACKWELL #1-T	MORELAND	0.0	ARKANSAS LOUISIAN
-DIAMOND SHAMROCK CORPORATION		RECEIVED: 12/08/81 JA: AR				
8209574	0313100000	103	ROYCE DEAN JONES #1-UT	MANSFIELD	447.0	ARKANSAS LOUISIAN
-GETTY OIL COMPANY		RECEIVED: 12/08/81 JA: AR				
8209542	0311510072	102-4	BLAIR-LAWS #4-1	FURGERSON	639.0	ARKANSAS LOUISIAN
-GETTY RESERVE OIL INC		RECEIVED: 12/08/81 JA: AR				
8209556	0308310035	103	YANCY #1-1	CHISMVILLE	200.0	ARKANSAS LOUISIAN
-HADSON OHIO OIL COMPANY		RECEIVED: 12/08/81 JA: AR				
8209579	0307100000	103	CLINE 1-4	SPADRA	0.0	ARKANSAS LOUISIAN
-HAWKINS OIL & GAS INC		RECEIVED: 12/08/81 JA: AR				
8209590	0304710146	103	HUDSPETH #1-32 C	OZARK	182.5	
8209591	0304710146	103	HUDSPETH #1-32 T	OZARK	182.5	
-JAMES W PARHAM		RECEIVED: 12/08/81 JA: AR				
8209549	0309110333	102-4	SEWELL #1	NORTH FOUKE	200.0	ARKANSAS LOUISIAN
-JIM L HANNA DBA HANNA OIL AND GAS C		RECEIVED: 12/08/81 JA: AR				
8209561	0308310059	102-2	HUCK #1	CAULKSVILLE	250.0	ARKANSAS WESTERN
8209551	0308300000	102-4	RATTLESNAKE #1-C	BOONEVILLE	185.0	
8209550	0308300000	102-4	RATTLESNAKE #1-T	BOONEVILLE	50.0	
-JOHN C OXLEY		RECEIVED: 12/08/81 JA: AR				
8209580	0307110214	103	DIXON #1-C	KNOXVILLE	814.0	ARKANSAS LOUISIAN
8209581	0307110214	102-4	DIXON NO 1-T	KNOXVILLE	1445.0	ARKANSAS LOUISIAN
-MCCORMICK OPERATING CO		RECEIVED: 12/08/81 JA: AR				
8209548	0309110183	102-4	S W CUMMINGS #1	CUMMINGS	0.0	TEXAS EASTERN TRA
-O B MOBLEY		RECEIVED: 12/08/81 JA: AR				
8209545	0309110273	102-4	MUDFORD #1	SOUTH TEXARKANA	892.0	NATURAL GAS PIPEL
-SANTA FE ENERGY COMPANY		RECEIVED: 12/08/81 JA: AR				
8209560	0308310058	103	ARKANSAS REAL EST #1-C	PRAIRIE VIEW (BARTON)	46.0	ARKANSAS LOUISIAN
8209559	0308310058	103	ARKANSAS REAL EST #1-T	PRAIRIE VIEW (ORR)	246.0	ARKANSAS LOUISIAN
-SEECO INC		RECEIVED: 12/08/81 JA: AR				
8209588	0304710175	102-4	KING #2-21	LONE ELM	35.0	
8209586	0304710148	103	LESSLEY #5-14-LT	LONE ELM	80.0	ARKANSAS WESTERN

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209584		0304710148		102-4		LESSLEY #5-14-MT	LONE ELM	500.0	ARKANSAS WESTERN
8209585		0304710148		103		LESSLEY #5-14-UT	LONE ELM	65.0	ARKANSAS WESTERN
8209587		0304710165		103		LEWIS #2-32	CECIL	600.0	
8209589		0304710155		102-4		STURDIVANT #1-15	ROCK CREEK	318.2	
8209575		0307190000		102-4		THOMPSON #2-26	SCRANTON	80.0	
-STEPHENS PRODUCTION COMPANY		RECEIVED: 12/08/81 JA: AR							
8209571		0313110177		103		ANNIE BRYANT #2 C	EWING	365.0	ARKANSAS OKLAHOMA
8209572		0313110177		102-4		ANNIE BRYANT #2 T	EWING	125.0	ARKANSAS OKLAHOMA
8209564		0313110167		102-4		WOODS #1 LT	BONANZA	100.0	ARKANSAS OKLAHOMA
8209562		0313110167		103		WOODS #1 UT	BONANZA	100.0	ARKANSAS OKLAHOMA
8209563		0313110167		103		WOODS #1-C	BONANZA	100.0	ARKANSAS OKLAHOMA
-T L JAMES & COMPANY INC		RECEIVED: 12/08/81 JA: AR							
8209544		0313911291		103		NATURAL RESOURCES #E-1 SERIAL #263*	TUBAL	73.0	ARKANSAS LOUISIAN
-TENNECO OIL COMPANY		RECEIVED: 12/08/81 JA: AR							
8209577		0307110202		103		ANDERSON (BARTON) 2-29T	SCRANTON	57.6	ARKANSAS LOUISIAN
8209576		0307110202		103		ANDERSON (CASEY) 2-29C	SCRANTON	360.0	ARKANSAS LOUISIAN
8209578		0307110193		102-4		DAVIS 1-32	ALTUS	44.3	
-TEXAS OIL & GAS CORP		RECEIVED: 12/08/81 JA: AR							
8209565		0313110179		103		ACME BRICK #1	MASSARD	150.0	
8209592		0304710172		103		BOND C #1-C	CECIL	100.0	ARKANSAS LOUISIAN
8209573		0313110158		102-4		CARNEY #1-C	EWING	600.0	
8209568		0313110161		103		CATES "B" #1-T	GRAGG	400.0	ARKANSAS LOUISIAN
8209567		0313110161		103		CATES B #1-C	GRAGG	600.0	ARKANSAS LOUISIAN
8209583		0304710162		102-4		HEINRICHS #1	CAULKSVILLE	350.0	ARKANSAS LOUISIAN
8209539		0303310076		102-4		LOVEGROVE #1	HOLLIS LAKE	200.0	
8209569		0313110157		103		PURDOM #1-C	URSULA	120.0	
8209570		0313110157		102-4		PURDOM #1-T	URSULA	250.0	ARKANSAS LOUISIAN
8209554		0308310057		103		ROBBERSON #1-C	AETNA	150.0	ARKANSAS LOUISIAN
8209555		0308310057		103		ROBBERSON #1-T	AETNA	350.0	ARKANSAS LOUISIAN
8209552		0308310064		103		STROUPE #1-C	PARIS	300.0	
8209553		0308310064		102-4		STROUPE #1-T	PARIS	300.0	
-TOWNER PETROLEUM CO		RECEIVED: 12/08/81 JA: AR							
8209558		0308310062		103		TAYLOR #2-1	CHISMVILLE	175.0	ARKANSAS LOUISIAN
-WEAVER EXPLORATION CO		RECEIVED: 12/08/81 JA: AR							
8209546		0309110290		102-4		COX-MEEK NO 1	BOYCE LAKE	547.0	NATURAL GAS PIPEL
-WESTLAND EXPLORATION CO		RECEIVED: 12/08/81 JA: AR							
8209582		0307110184		102-4		LUCY HERBERT #1-RUSSELL	SPADRA	82.0	ARKANSAS LOUISIAN
8209593		0304710159		102-4		PRICE UNIT #1-ORR	PETERPENDER	109.5	ARKANSAS LOUISIAN
8209594		0304710159		103		PRICE UNIT NO 1-LOWER HALE	PETERPENDER	182.5	ARKANSAS LOUISIAN
**********									
OHIO DEPARTMENT OF NATURAL RESOURCES									
**********									
-AMERICAN WELL MANAGEMENT COMPANY		RECEIVED: 12/01/81 JA: OH							
8209595		3412724921		103		RALPH VESS #1	MONROE	18.0	
8209595		3412724921		107-TF		RALPH VESS #1	MONROE	18.0	
-ARAPAHO VENTURES OF NEW YORK INC		RECEIVED: 12/01/81 JA: OH							
8209599		3416725252		103		GOLDIE HAAS #1	AURELIUS	0.0	
8209600		3416725605		103		GOLDIE HAAS #2	AURELIUS	0.0	
8209601		3416725606		103		GOLDIE HAAS #3	AURELIUS	0.0	
8209596		3416725607		103		GOLDIE HAAS #7	AURELIUS	0.0	
8209597		3412122537		103		RAYLE COAL #3	JACKSON	1.9	
8209598		3412122538		103		RAYLE COAL #4	JACKSON	2.6	
-B T SIMPSON JR		RECEIVED: 12/01/81 JA: OH							

JD FO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209702A		3403124219		103		EVERETT KASNER #3	BLISSFIELD	0.0	COLUMBIA GAS TRAN
8209702B		3403124219	D	107	TF	EVERETT KASNER #3	BLISSFIELD	0.0	COLUMBIA GAS TRAN
-BATES OIL & GAS INC		RECEIVED: 12/01/81 JA: OH							
8209608		3407322459		103		JOHN SPENCER #1	WASHINGTON	1.5	COLUMBIA GAS TRAN
-BAY STATE EXPLORATION CO		RECEIVED: 12/01/81 JA: OH							
8209607		3416320482		103		C & G GRAY #1	VINTON	36.0	COLUMBIA GAS TRAN
8209607		3416320482		107	TF	C & G GRAY #1	VINTON	36.0	COLUMBIA GAS TRAN
8209605		3416320500		103		C & O FREELAND #1	VINTON	36.0	COLUMBIA GAS TRAN
8209605		3416320500		107	TF	C & O FREELAND #1	VINTON	36.0	COLUMBIA GAS TRAN
8209606		3416320497		103		L & F DAFT #1	VINTON	36.0	COLUMBIA GAS TRAN
8209606		3416320497		107	TF	L & F DAFT #1	VINTON	36.0	COLUMBIA GAS TRAN
-BELDEN & BLAKE & CO. 78		RECEIVED: 12/01/81 JA: OH							
8209609A		3415123401		103		H DEHOFF #1 341036	CANTON	36.5	EAST OHIO GAS CO
8209609B		3415123401	D	107	TF	H DEHOFF #1 341036	CANTON	36.5	EAST OHIO GAS CO
-BERMAN J SHAFER		RECEIVED: 12/01/81 JA: OH							
8209703		3415321008		103		KIEHL UNIT #1	BATH	5.0	COLUMBIA GAS TRAN
-BERRESFORD ENTERPRISES INC		RECEIVED: 12/01/81 JA: OH							
8209610		3408322852		103		JOHN FROST #1	JACKSON	0.0	
-BILL D VAUGHT DBA VAUGHT OIL CO		RECEIVED: 12/01/81 JA: OH							
8209706		3403124284		107	TF	JOHN R BENDER #1	KEENE	36.5	COLUMBIA GAS TRAN
-CRYSTAL ENERGY		RECEIVED: 12/01/81 JA: OH							
8209611		3416922814		103		HAYES #I	WOOSTER	10.0	
8209611		3416922814		107	TF	HAYES #I	WOOSTER	10.0	
-CYCLOPS CORP		RECEIVED: 12/01/81 JA: OH							
8209612		3403124361		103		E SPEAKS UNIT #1	JACKSON	30.0	
8209612		3403124361		107	TF	E SPEAKS UNIT #1	JACKSON	30.0	
-DAVID SHAFER OIL PRODUCERS INC		RECEIVED: 12/01/81 JA: OH							
8209613		3415320958		103		RAYMOND C FIRESTONE #1-F	BATH	5.0	EAST OHIO GAS CO
8209614		3415320959		103		RAYMOND C FIRESTONE #2-F	BATH	5.0	EAST OHIO GAS CO
-DORAN & ASSOCIATES INC		RECEIVED: 12/01/81 JA: OH							
8209616A		3412724968		103		MARQUERITE GORDON #1	JACKSON	12.0	COLUMBIA GAS TRAN
8209616B		3412724968	D	107	TF	MARQUERITE GORDON #1	JACKSON	12.0	COLUMBIA GAS TRAN
8209615A		3412724967		103		MARQUERITE GORDON #3	JACKSON	12.0	COLUMBIA GAS TRAN
8209615B		3412724967	D	107	TF	MARQUERITE GORDON #3	JACKSON	12.0	COLUMBIA GAS TRAN
8209617A		3412725251		103		PAUL MUSSER #3	JACKSON	12.0	COLUMBIA GAS TRAN
8209617B		3412725251	D	107	TF	PAUL MUSSER #3	JACKSON	12.0	COLUMBIA GAS TRAN
-ENTERPRISE ENERGY CORP		RECEIVED: 12/01/81 JA: OH							
8209618		3405922785		103		MILEY #1	VALLEY	37.0	COLUMBIA GAS TRAN
-GLACIER ENERGY CORP		RECEIVED: 12/01/81 JA: OH							
8209619		3410522158		103		JAMES HEBNER #2	SCIPIO	19.0	COLUMBIA GAS TRAN
-GNC ENERGY CORP		RECEIVED: 12/01/81 JA: OH							
8209620		3411522107		103		DAVIS #9	MALTA	15.0	
8209621		3411522119		103		K MORIN #4	MALTA	15.0	
-GREEN GAS COMPANY		RECEIVED: 12/01/81 JA: OH							
8209622		3403520989		107	TF	P D K CO #1	OLMSTEAD	10.0	COLUMBIA GAS OF O
8209624		3409321145		103		PDK-MCBRIDE #2	COLUMBIA	1.0	COLUMBIA GAS TRAN
8209623		3403521115		103		WYLES-JUSTAVICH UNIT #1	OLMSTEAD	1.0	COLUMBIA GAS OF O
-HOPEWELL OIL AND GAS DEVELOPMENT CO		RECEIVED: 12/01/81 JA: OH							
8209626		3411522531		103		EARL CAMPBELL #2	DEERFIELD	10.0	COLUMBIA GAS TRAN
8209627		3411925063		103		JOHN SHAW #2	JACKSON	12.0	COLUMBIA GAS TRAN
-J D DRILLING CO		RECEIVED: 12/01/81 JA: OH							
8209630		3410521806		103		ALBERT ROUSH #1	SALISBURY	4.0	COLUMBIA GAS TRAN
8209629		3410522020		103		ALPHA RAMEY #2	BEDFORD	4.0	COLUMBIA GAS TRAN

JD NO	JA DKT	API NO	O	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209631		3410522108		103		HANSON & HOWELL #1	RUTLAND	3.0	COLUMBIA GAS TRAN
8209632		3410522109		103		LELAND CLONCH #1	RUTLAND	4.0	COLUMBIA GAS TRAN
8209628		3410522110		103		LELAND CLONCH #2	RUTLAND	3.0	COLUMBIA GAS TRAN
-JACOB POLLOCK				RECEIVED: 12/01/81 JA: OH					
8209668		3407523204		103		JOHNSON #1	RIPLEY	30.0	COLUMBIA GAS TRAN
-JERRY C OLDS				RECEIVED: 12/01/81 JA: OH					
8209667		3403123285		108		KISER #1	LAFAYETTE	9.0	COLUMBIA GAS TRAN
-KENOIL				RECEIVED: 12/01/81 JA: OH					
8209633		3416922799		103		TED ACKER #1-S	CLINTON	6.0	COLUMBIA GAS TRAN
-KRAMER EXPLORATION CO				RECEIVED: 12/01/81 JA: OH					
8209635		3410522023		103		GOEGLEIN #1	RUTLAND	15.0	COLUMBIA GAS TRAN
8209636		3410522073		103		HYSELL #1	RUTLAND	20.0	COLUMBIA GAS TRAN
8209634		3405320577		103		SISSON #1	CHESHIRE	15.0	COLUMBIA GAS TRAN
-L & M OPERATING INC				RECEIVED: 12/01/81 JA: OH					
8209644		3412724624		107-TF		CLAYCRAFT #2	SALT LICK	2.0	COLUMBIA GAS TRAN
8209643		3412725069		107-TF		CLAYCRAFT #9	SALT LICK	2.0	COLUMBIA GAS TRAN
-L & M PETROLEUM INC				RECEIVED: 12/01/81 JA: OH					
8209641		3412725097		107-TF		ESSINGTON/LEWIS/PEABODY/CHRISTY #4	PIKE	2.0	COLUMBIA GAS TRAN
8209642		3412725131		107-TF		HAROLD SHAHAN #1	READING	2.0	COLUMBIA GAS TRAN
8209640		3412725249		103		LEWIS/PEABODY/FLOWERS #1	CLAYTON	10.0	COLUMBIA GAS TRAN
8209640		3412725249		107-TF		LEWIS/PEABODY/FLOWERS #1	CLAYTON	10.0	COLUMBIA GAS TRAN
-LAKE REGION OIL INC				RECEIVED: 12/01/81 JA: OH					
8209639		3407522893		103		CARL ROMIG #1	KILLBUCK	5.0	COLUMBIA GAS TRAN
-LANDPROVEST INC				RECEIVED: 12/01/81 JA: OH					
8209645		3411925688		107-TF		EVERETT & FLORENCE LEEDOM #5	PERRY	25.0	
-LBJ DRILLING DBA JEFF MORAN				RECEIVED: 12/01/81 JA: OH					
8209638		3403124467		103		JEAN BOYD #2	MONROE	18.0	
-LEADER EQUITIES INC				RECEIVED: 12/01/81 JA: OH					
8209646		3411522325		103		DANIELSON #1	MEIGSVILLE	15.0	
8209646		3411522325		107-TF		DANIELSON #1	MEIGSVILLE	15.0	
8209647		3411522324		103		DANIELSON #2	MEIGSVILLE	15.0	
8209647		3411522324		107-TF		DANIELSON #2	MEIGSVILLE	15.0	
-LEW BATES JR				RECEIVED: 12/01/81 JA: OH					
8209604		3407322305		103		DYKES REAL EST RENTALS #1	WASHINGTON	1.5	COLUMBIA GAS TRAN
8209603		3407322164		103		RUTH WOLF #1	WASHINGTON	1.5	COLUMBIA GAS TRAN
8209602		3407322475		103		RUTH WOLF #2A	WASHINGTON	1.5	COLUMBIA GAS TRAN
-LOMAK PETROLEUM INC				RECEIVED: 12/01/81 JA: OH					
8209648		3416922362		107-TF		ALEXANDER #3	WOOSTER	26.0	COLUMBIA GAS TRAN
-MID-ATLANTIC OIL CO				RECEIVED: 12/01/81 JA: OH					
8209651		3411521868		102-4		HUCK #9 UNIT	MORGAN	40.0	COLUMBIA GAS TRAN
8209651		3411521868		107-TF		HUCK #9 UNIT	MORGAN	40.0	COLUMBIA GAS TRAN
-MONROE & KEUSINK INC				RECEIVED: 12/01/81 JA: OH					
8209649		3403124311		103		LUTHER & VIRGINIA WHEATCRAFT #1	NEW CASTLE EAST	12.0	
-MORGAN JOINT VENTURE				RECEIVED: 12/01/81 JA: OH					
8209650		3411522467		103		JOHN & PAT NEMETH #1 2467	MALTA	9.0	
-NEIL STULL JR				RECEIVED: 12/01/81 JA: OH					
8209701		3408322905		103		IMOGENE GAY HUGHES TRUSTEE #2	CLAY	18.0	
-OILTECH INC				RECEIVED: 12/01/81 JA: OH					
8209654		3407522383		107-TF		CARLOS SMITH #1	MECHANIC	0.0	COLUMBIA GAS TRAN
8209655		3407522316		107-TF		ERNEST PAPAY #2	MECHANIC	0.0	COLUMBIA GAS TRAN
8209665		3407523094		107-TF		GERALD HIPP #3	HARDY	0.0	COLUMBIA GAS TRAN
8209657		3407522557		107-TF		H MABEL BRUMME #1	MECHANIC	0.0	COLUMBIA GAS TRAN
8209652		3407522392		107-TF		HORACE A DUTTON #6	MECHANIC	0.0	COLUMBIA GAS TRAN

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209660		3407522393			107-TF	HORACE A DUTTON #7	MECHANIC	0.0	COLUMBIA GAS TRAN
8209661		3407523012			107-TF	JOHN LANE #1	KILLBUCK	0.0	COLUMBIA GAS TRAN
8209653		3407522385			107-TF	KAUFFMAN #2	MECHANICS	0.0	COLUMBIA GAS TRAN
8209662		3407523010			107-TF	KENNETH BRUMME #1	MECHANIC	0.0	COLUMBIA GAS TRAN
8209656		3407522872			107-TF	PAUL HARTMAN #1	MECHANIC	0.0	COLUMBIA GAS TRAN
8209663		3407522873			107-TF	PAUL HARTMAN #2	MECHANIC	0.0	COLUMBIA GAS TRAN
8209658		3407522526			107-TF	RAYMOND J MILLER #3	MECHANIC	0.0	COLUMBIA GAS TRAN
8209659		3407522529			107-TF	RAYMOND J MILLER #4	MECHANIC	0.0	COLUMBIA GAS TRAN
8209664		3407523055			107-TF	T F MCCOLLUM UNIT #1	MECHANIC	0.0	COLUMBIA GAS TRAN
-OXFORD OIL CO		RECEIVED: 12/01/81 JA: OH							
8209666		3411522518			103	KENNETH SWANSON #1	DEERFIELD	10.0	
-POI ENERGY INC		RECEIVED: 12/01/81 JA: OH							
8209676		3413322314			107-TF	AURORA COUNTRY CLUB #3	AURORA	13.0	
8209684		3413322123			107-TF	BECK-DAVIS #1	STREETSBORO	20.0	
8209686		3413322120			107-TF	BECK-DAVIS #2	RICHLAND	10.0	
8209685		3413321855			107-TF	BECK-GRIFFITH-WILSON #4	STREETSBORO	120.0	
8209692		3415320724			107-TF	BERGIN-RARDIN #1	HUDSON	10.0	
8209669		3400721679			103	BUCK #1	CHERRY VALLEY	10.0	
8209669		3400721679			107-TF	BUCK #1	CHERRY VALLEY	10.0	
8209678		3400716140			103	BUCK #2	CHERRY VALLEY	10.0	
8209678		3400716140			107-TF	BUCK #2	CHERRY VALLEY	10.0	
8209693		3415320720			107-TF	CLINE #1	HUDSON	50.0	
8209673		3400721544			103	CROSBY #3	ORWELL	15.0	
8209673		3400721544			107-TF	CROSBY #3	ORWELL	15.0	
8209677		3400721620			103	EGART #1	ORWELL	15.0	
8209677		3400721620			107-TF	EGART #1	ORWELL	15.0	
8209690		3415320707			107-TF	FALCONE #1	HUDSON	45.0	
8209694		3415320708			107-TF	FALCONE #2	HUDSON	45.0	
8209689		3415320711			107-TF	FORTUNA #2	HUDSON	30.0	
8209674		3413322515			103	GOLFWORLD #3	FRANKLIN	45.0	
8209674		3413322515			107-TF	GOLFWORLD #3	FRANKLIN	45.0	
8209695		3415320818			107-TF	HALE-HERITAGE FARMS #1	HUDSON	55.0	
8209680		3400721676			107-TF	HARTSTOCK #1	ROME	30.0	
8209691		3415320748			107-TF	HOPKINS #1	HUDSON	10.0	
8209679		3400721645			103	LAMBERT #3	ROME	10.0	
8209679		3400721645			107-TF	LAMBERT #3	ROME	10.0	
8209681		3400721669			103	M KELLOG #1	RICHLAND	18.0	
8209681		3400721669			107-TF	M KELLOG #1	RICHLAND	18.0	
8209687		3407523114			103	MACKEY #1	BOSTON	15.0	COLUMBIA GAS TRAN
8209682		3407523099			103	MCPHERSON #1	STREETSBORO	20.0	COLUMBIA GAS TRAN
8209670		3400721691			103	METZDORF-CARDINAL #1	HARTSGROVE	15.0	
8209670		3400721691			107-TF	METZDORF-CARDINAL #1	HARTSGROVE	15.0	
8209675		3413322375			103	PIERCE-EVERGREEN #1	FRANKLIN	25.0	
8209675		3413322375			107-TF	PIERCE-EVERGREEN #1	FRANKLIN	25.0	
8209688		3413320963			107-TF	ROOSA #1	HUDSON	10.0	
8209671		3413322271			107-TF	WHITTINGTON #1	FRANKLIN	25.0	
8209683		3413322233			107-TF	WILLIAMS #1	STREETSBORO	35.0	
8209672		3413322239			107-TF	WILLIAMS #2	STREETSBORO	35.0	
-QUAKER STATE OIL REFINING CORP		RECEIVED: 12/01/81 JA: OH							
8209698		3401921449			103	C MAYLE #1	BROWN	27.4	MB OPERATING CO I
8209699		3401921453			103	CASPER #1	BROWN	27.4	MB OPERATING CO I
8209696		3401921439			103	EPPLER UNIT #1	BROWN	27.0	MB OPERATING CO I
8209697		3401921448			103	FARNER UNIT #1	BROWN	27.4	MB OPERATING CO I

BILLING CODE 6717-01-C

JD NO	JA TKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
-ROWLEY & BROWN PETROLEUM CORP				RECEIVED: 12/01/81 JA: OH					
8209700		3403520915		107	TF	CLEVELAND CATHOLIC DIOCESE #1 (CCD*	PARMA	10.0	COLUMBIA GAS TRAN
-STOCKER&SITLER INC				RECEIVED: 12/01/81 JA: OH					
8209704		3401921441		103		GROSENBAUGH UNIT #5-5S	ROSE	1.0	
-TERRY M KRAMER				RECEIVED: 12/01/81 JA: OH					
8209637		3405320576		103		SHAYER #1	ADDISON	20.0	COLUMBIA GAS TRAN
-THUNDERBIRD PETROLEUM CORP				RECEIVED: 12/01/81 JA: OH					
8209707		3411122213		103		HARRY ARMSTRONG WELL #4	WASHINGTON	50.0	
-TITAN ENERGY CORP				RECEIVED: 12/01/81 JA: OH					
8209706		3415521361		103		A LUCHETTE #1	BROOKFIELD	20.0	COLUMBIA GAS TRAN
8209706		3415521361		107	TF	A LUCHETTE #1	BROOKFIELD	20.0	COLUMBIA GAS TRAN
8209705		3415521883		103		GOYNES-UNIT 1	NEWTON	20.0	COLUMBIA GAS TRAN
8209705		3415521883		107	TF	GOYNES-UNIT 1	NEWTON	20.0	COLUMBIA GAS TRAN
-VIKING RESOURCES CORPORATION				RECEIVED: 12/01/81 JA: OH					
8209709		3415123502		103		HAWN-QUINTELLA UNIT #2	PARIS	30.0	
8209709		3415123502		107	TF	HAWN-QUINTELLA UNIT #2	PARIS	30.0	
8209710		3415123505		103		TUTTLE #1	OSNABURG	30.0	
8209710		3415123505		107	TF	TUTTLE #1	OSNABURG	30.0	
-W J LYDIC INC				RECEIVED: 12/01/81 JA: OH					
8209713		3405323030		103		R FITCH #1	R FITCH #1	2.8	COLUMBIA GAS OF O
8209714		3405323020		103		R FITCH #2	R FITCH #2	2.8	COLUMBIA GAS OF O
8209711		3405323090		103		R FITCH #3	R FITCH #3	0.8	COLUMBIA GAS OF O
8209712		3405323050		103		WAREHIME #1	WAREHIME #1	1.2	COLUMBIA GAS OF O
-WENNER PETROLEUM CORPORATION				RECEIVED: 12/01/81 JA: OH					
8209715		3416922383		107	TF	ROBERT E HART #4	MILTON-WAYNE POOL	2.2	COLUMBIA GAS TRAN
-WESTMORELAND INVESTORS LTD.				RECEIVED: 12/01/81 JA: OH					
8209716		3416725500		107	DV	EARL & BEULAH CONGLETON #3	LIBERTY	50.0	
-WILLIAM F HILL				RECEIVED: 12/01/81 JA: OH					
8209625		3407523157		103		ROBERT STARNER #2	RICHLAND	9.0	

The above notices of determination were received from the indicated jurisdictional agencies by the Federal Energy Regulatory Commission pursuant to the Natural Gas Policy Act of 1978 and 18 CFR 274.104. Negative determinations are indicated by a "D" before the section code. Estimated annual production (PROD) is in million cubic feet (MMCF). An (*) before the Control (JD) number denotes additional purchasers listed at the end of the notice.

The applications for determination are available for inspection except to the extent such material is confidential under 18 CFR 275.206, at the Commission's Division of Public Information, Room 1000, 825 North Capitol St., Washington, D.C. Persons objecting to any of these determinations may, in accordance with 18 CFR 275.203 and 275.204, file a protest with the Commission on or before January 20, 1982.

Categories within each NGPA section are indicated by the following codes:

Section 102–1: New OCS lease
102–2: New well (2.5 mile rule)
102–3: New well (1000 ft rule)
102–4: New onshore reservoir
102–5: New reservoir on old OCS lease

Section 107–DP: 15,000 feet or deeper
107–GB: Geopressured brine
107–CS: Coal seams
107–DV: Devonian shale
107–PE: Production enhancement
107–TF: New tight formation
107–RT: Recompletion tight formation

Section 108: Stripper well
108–SA: Seasonally affected
108–ER: Enhanced recovery
108–PB: Pressure buildup

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–154 Filed 1–4–82; 8:45 am]

BILLING CODE 6717–01–M

Determinations by Jurisdictional Agencies Under the Natural Gas Policy Act of 1978

Issued: December 30, 1981.

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
KANSAS CORPORATION COMMISSION									
-IMPERIAL OIL COMPANY						RECEIVED: 12/07/81 JA: KS			
8209781	K-81-0768	1509700241		102-4		ROSE #1	CARVER ROBBINS W	10.0	PANHANDLE EASTERN
NEW MEXICO DEPARTMENT OF ENERGY & MINERALS									
-AMOCO PRODUCTION CO						RECEIVED: 12/07/81 JA: NM			
8209849		3004508644		108		STATE GAS COM Y #1	BLANCO-PICTURED CLIFFS	17.0	EL PASO NATURAL G
-ANADARKO PRODUCTION COMPANY						RECEIVED: 12/07/81 JA: NM			
8209844		3002527404		103		M W COLL #4	LANGLIE MATTIX QUEEN	34.0	GETTY OIL CO
-BEARD OIL COMPANY						RECEIVED: 12/07/81 JA: NM			
8209851		3001522534		108		HANLAD #1	EAST HIGH HOPE	10.0	TRANSWESTERN PIPE
-BTA OIL PRODUCERS						RECEIVED: 12/07/81 JA: NM			
8209855		3002527362		102-2		HUDSON-STATE 8006 JV-P #1-Y	ANTELOPE RIDGE (MORROW)	1425.0	UNITED GAS PIPE L
-COLLIER ENERGY INC						RECEIVED: 12/07/81 JA: NM			
8209842		3001522008		103		QUAIL STATE #1	RED LAKE GRAYBURG SAN AN	50.0	PHILLIPS PETROLEU
8209843		3001523127		103		YALTY #1	WILDCAT QUEEN	125.0	PHILLIPS PETROLEU
-CONOCO INC						RECEIVED: 12/07/81 JA: NM			
8209848		3002527016		103		STATE D NO 15	ARROWHEAD E-M-E	20.0	WARREN PETROLEUM
-DOYLE HARTMAN OIL OPERATOR						RECEIVED: 12/07/81 JA: NM			
8209861		3002527531		103		HUSKY-WOOLWORTH #1	JALMAT (GAS)	53.0	EL PASO NATURAL G
-EL PASO NATURAL GAS COMPANY						RECEIVED: 12/07/81 JA: NM			
8209852		3004510103		108		FARMINGTON COM #1	BASIN-DAKOTA	22.0	EL PASO NATURAL G
8209840		3004525041		103		SAN JUAN 32-9 UNIT #25A	BLANCO MESAVERDE	270.0	EL PASO NATURAL G
-MESA PETROLEUM						RECEIVED: 12/07/81 JA: NM			
8209858		3000560895		102-2		ACME #3	UNDESIGNATED ABO	500.0	TRANSWESTERN PIPE
8209854		3000560890		102-2		BELL ESTATE #1	UNDESIGNATED ABO	180.0	TRANSWESTERN PIPE
-MILLARD DECK						RECEIVED: 12/07/81 JA: NM			
8209860		3002527044		103		POSSH #3	LANGLIE MATTIX	7.3	EL PASO NATURAL G
8209841		3002526536		103		POSSH #4	LANGLIE MATTIX-SEVEN RIV	36.5	EL PASO NATURAL G
-MTS LTD PARTNERSHIP						RECEIVED: 12/07/81 JA: NM			
8209857		3000560999		102-2		NED STATE #3	UNDESIGNATED ABO	200.0	TRANSWESTERN PIPE
8209837		3003922743		103		SOUTH BLANCO STATE 32A #1	LYBROOK GALLUP EXT	18.0	GAS CO OF NEW MEX
-PHILLIPS PETROLEUM COMPANY						RECEIVED: 12/07/81 JA: NM			
8209839		3002527118		103		EAST VAC GB/SA TR 2739 #008	VACUUM GB/SA	7.7	EL PASO NATURAL G
8209838		3002527402		103		PHILMEX #15	LEAMEX (PADDOCK) POOL	43.1	EL PASO NATURAL G
-SOUTHLAND ROYALTY CO						RECEIVED: 12/07/81 JA: NM			
8209865		3004524511		103		CHAMBERLAIN #2	BLANCO	370.0	SOUTHERN UNION GA
8209867		3004524511		103		CHAMBERLAIN #2	UNDESIGNATED	350.0	SOUTHERN UNION GA
8209862		3004524675		103		HARPER #3	UNDESIGNATED	500.0	SOUTHERN UNION GA
8209863		3004524675		103		HARPER #3	AZTEC	190.0	SOUTHERN UNION GA
-TAHOE OIL & CATTLE CO						RECEIVED: 12/07/81 JA: NM			

JO NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209853		3002524642		108		JUDY #2	LANGLIE MATTIX	1.4	EL PASO NATURAL G
-TENNECO OIL COMPANY				RECEIVED: 12/07/81 JA: NM					
8209866		3001523753		103		STATE FP-13 COMM #2	CATCLAW DRAW MORROW	480.0	TUCO INC
8209864		3004524436		103		VALDEZ COM "B" #1	BLOOMFIELD CHACRA	500.0	EL PASO NATURAL G
-TXO PRODUCTION CORP				RECEIVED: 12/07/81 JA: NM					
8209850		3001522694		108		INDIAN HILLS STATE COM #2	CEMETARY (MORROW)	3.7	NATURAL GAS PIPEL
-UNION OIL COMPANY OF CALIF				RECEIVED: 12/07/81 JA: NM					
8209845		3002527417		103		STATE "HH" #1	UNDESIGNATED (GEM MORROW	200.0	
-YATES PETROLEUM CORPORATION				RECEIVED: 12/07/81 JA: NM					
8209859		3000561133		107-TF		DEE "OO" STATE #2	UND ABO	0.0	TRANSWESTERN PIPE
8209846		3001520827		103		LOVELESS "LQ" STATE #4	TOMAHAWK SA	0.0	
8209847		3000520828		103		LOVELESS "LQ" STATE #5	UNDES TOMAHAWK SA	0.0	
8209856		3001523793		102-4		SHARP "QS" COM #1	POW MORROW	0.0	TRANSWESTERN PIPE
8209868		3001522554		102-4		STONEWALL "EP" STATE COM #4	UND W BURTON FLAT ATOKA	0.0	TRANSWESTERN PIPE
**********									
NEW YORK DEPARTMENT OF ENVIRONMENTAL CONSERVATION									
**********									
-ALDEN AURORA GAS CO INC				RECEIVED: 12/09/81 JA: NY					
8209809	1632	3102900000		108		JOHN FISHER #1	ALDEN-LANCASTER	2.1	NATIONAL FUEL GAS
8209806	1627	3102900000		108		S MILES #1	ALDEN-LANCASTER	1.7	NATIONAL FUEL GAS
8209810	1631	3102900000		108		W PACYON #1	ALDEN-LANCASTER	1.1	NATIONAL FUEL GAS
8209804	1628	3102900000		108		W WADEL #1	ALDEN-LANCASTER	1.1	NATIONAL FUEL GAS
8209805	1626	3102900000		108		WILT #1	ALDEN-LANCASTER	3.8	NATIONAL FUEL GAS
8209808	1630	3102900000		108		WM SMITH #1	ALDEN-LANCASTER	3.9	NATIONAL FUEL GAS
8209807	1629	3102900000		108		WM SMITH #2	ALDEN-LANCASTER	3.9	NATIONAL FUEL GAS
-AMERICAN PENN ENERGY INC				RECEIVED: 12/09/81 JA: NY					
8209789	2402	3102914542		108		A & H UPSHUR UNIT #1 1482	BRANT-EVANS	10.0	NATIONAL FUEL GAS
8209788	2403	3102914543		108		C C VOLLMAR UNIT #1 1429	BRANT-EVANS	10.0	NATIONAL FUEL GAS
8209786	2401	3102914435		108		JEWITT #1 1483	LAKESHORE	10.0	NATIONAL FUEL GAS
8209790	2405	3102914541		108		K & M TAYLOR UNIT #1 1424	BRANT-EVANS	10.0	NATIONAL FUEL GAS
8209791	2404	3102914540		108		M FORSTER #1 1428	BRANT-EVANS	10.0	NATIONAL FUEL GAS
8209787	2400	3102914436		108		MASCIO UNIT #1 1484	LAKESHORE	10.0	NATIONAL FUEL GAS
8209784	2399	3102914437		108		SAGER UNIT #1 1485	LAKESHORE	10.0	NATIONAL FUEL GAS
-ARAPAHO VENTURES OF NEW YORK INC				RECEIVED: 12/09/81 JA: NY					
8209801	1052	3112113919		102-2		FRANK LABIN #1	WILDCAT	20.0	COLUMBIA GAS TRAN
-BEREA OIL AND GAS CORPORATION				RECEIVED: 12/09/81 JA: NY					
8209783	1330	3101315356		103		NYS FOREST AREA #10 #5	GERRY	30.0	COLUMBIA GAS TRAN
-BLOSSOM GAS CO				RECEIVED: 12/09/81 JA: NY					
8209799	2162	3101314402		108		WESTFIELD TIMBER PRODUCTS 3134	LAKE SHORE	19.0	NATIONAL FUEL GAS
-COLUMBIA GAS TRANSMISSION CORP				RECEIVED: 12/09/81 JA: NY					
8209803	1174	3109713796		102-2		JOHN PRATT/WM MEEHAN	GINGERBREAD CORNERS	30.0	COLUMBIA GAS TRAN
-J M RESOURCES				RECEIVED: 12/09/81 JA: NY					
8209785	1599	3101314326		103		LEPP #4	LAKESHORE	25.0	NATIONAL FUEL GAS
-MAYNARD OIL COMPANY				RECEIVED: 12/09/81 JA: NY					
8209782	2431	3102916602		103		OAR #1	WILDCAT	0.0	NATIONAL FUEL GAS
-PENNZOIL COMPANY				RECEIVED: 12/09/81 JA: NY					
8209802	1476	3100913026		102-4		QUINLAN E-2	ROCK CITY	0.0	
-SHAWNEE EXPLORATION INC				RECEIVED: 12/09/81 JA: NY					
8209811	2413	3102916517		103		MILIUS UNIT #1	BRANT	15.0	SCG GAS QUEST INC
8209815	2408	3102916518		103		P J PHILLIPS ET AL #1	BRANT	15.0	SCG GAS QUEST INC
8209798	2406	3102916449		103		TURNBULL UNIT #1	BRANT	15.0	SCG GAS QUEST INC
8209812	2412	3102916448		103		VACCO UNIT #1	BRANT	15.0	SCG GAS QUEST INC
8209797	2407	3102916351		103		WAY-PHILLIPS UNIT #1	BRANT	15.0	SCG GAS QUEST INC

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209814	2410	3102916352		103		WAY-PHILLIPS UNIT #2	BRANT	15.0	SCG GAS QUEST INC
8209813	2411	3102916353		103		WAY-PHILLIPS UNIT #3	BRANT	15.0	SCG GAS QUEST INC
-TRAHAN PETROLEUM INC				RECEIVED: 12/09/81 JA: NY					
8209792	1941	3101315212		102-2		B RENDELL #1 - N Y 8 31-013-15212	PANAMA	36.0	COLUMBIA GAS TRAN
8209796	1401	3101315213		102-2		B RENDELL #2 N Y 80 31-013-15213	PANAMA	36.0	COLUMBIA GAS TRAN
8209794	2262	3101315284		102-2		C STRATTON #1 - N Y 79 31-013-15284	PANAMA	36.0	COLUMBIA GAS TRAN
8209795	1320	3101315373		102-2		LEFFINGWELL - CRONER 1 31-013-15373	PANAMA	36.0	COLUMBIA GAS TRAN
8209793	1552	3101315866		102-2		THOMAS POTTER #2 31-013-15866	LAKEWOOD	36.0	NATIONAL FUEL GAS
-WILLIAM M TEMPLETON				RECEIVED: 12/09/81 JA: NY					
8209800	2451	3100911147		108		GREEN BROS - HAMMERMILL UNIT #1	SKINNER HOLLOW	7.0	NATIONAL FUEL GAS
**********									
OKLAHOMA CORPORATION COMMISSION									
**********									
-AMCANA OIL CORP				RECEIVED: 12/07/81 JA: OK					
8209738	11621	3500320791		103		FRECH #1-3	RINGWOOD	60.0	PANHANDLE EASTERN
8209737	11620	3504722435		103		SIMUNEK 1-17	SOONER TREND	60.0	PANHANDLE EASTERN
-ANCOR PETROLEUM INC				RECEIVED: 12/07/81 JA: OK					
8209760	09376	3508121108		102-4		OMA #1-4	WILDCAT	365.0	COLORADO GAS COMP
-ARCO OIL AND GAS COMPANY				RECEIVED: 12/07/81 JA: OK					
8209717	14898	3510321380		102-4		AMY OPLINGER #1	N W STILLWATER AIRPORT	36.5	
8209779	14890	3504722726		102-4		GLENDA WILLIAMS #1	SOUTH DOUGLAS	36.5	
-BOGERT OIL CO				RECEIVED: 12/07/81 JA: OK					
8209753	11315	3507322933		103		EVERETT 1-4	SOONER TREND	150.0	PHILLIPS PETROLEU
-CHAMPLIN PETROLEUM COMPANY				RECEIVED: 12/07/81 JA: OK					
8209748	10992	3507300000		108		STURGEON BUFORD UNIT #1	SOONER TREND	14.0	PHILLIPS PETROLEU
-CIMARRON PETROLEUM CORPORATION				RECEIVED: 12/07/81 JA: OK					
8209768	11493	3507323062		103		CPC #106-4 BEARD		54.8	PHILLIPS PETROLEU
-CITIES SERVICE COMPANY				RECEIVED: 12/07/81 JA: OK					
8209762	09618	3513921337		102-4		SLEEPER C #2	NE TRIUMPH	180.0	
8209763	09620	3513921339		102-4		SLEEPER C #4	NE TRIUMPH	25.0	
8209764	9768	3500721854		102-4		SMITH G #1	E LORENA	284.0	SOUTHERN UNION CO
-CLARK RESOURCES INC				RECEIVED: 12/07/81 JA: OK					
8209756	11406	3504722604		103		TABORSKY VANCE 11-2	SOONER TREND	25.0	UNION TEXAS PETRO
-CLAYTON W WILLIAMS JR				RECEIVED: 12/07/81 JA: OK					
8209759	09242	3501520916		102-2		R COX #1	EAKLEY (RED FORK)	700.0	
-CLEMENTS ENERGY INC				RECEIVED: 12/07/81 JA: OK					
8209754	11371	3504921149		103		ADAMS #1-B	N W ANTIOCH	365.0	BUCKEYE NATURAL G
-CONOCO INC				RECEIVED: 12/07/81 JA: OK					
8209765	10318	3513900000		108		A M CAMP #1	HUGOTON	10.0	CITIES SERVICE GA
8209766	10320	3513900000		108		FECHTLER #1	HUGOTON	8.0	CITIES SERVICE GA
8209743	10321	3513900000		108		S GURWELL #1	HUGOTON	8.0	CITIES SERVICE GA
8209744	10326	3513900000		108		STONEBRAKER #1	HUGOTON	6.0	CITIES SERVICE GA
8209745	10327	3513900000		108		STONEBRAKER #2	HUGOTON	7.0	CITIES SERVICE GA
8209746	10329	3513900000		108		UNITED PRODUCING CO #1	HUGOTON	6.0	CITIES SERVICE GA
-COTTON PETROLEUM CORPORATION				RECEIVED: 12/07/81 JA: OK					
8209777	15208	3505121127		107-DP		LOVELESS #1-5	SOUTH VERDEN	0.0	UNITED GAS PIPELI
-DAWN ENERGY CO				RECEIVED: 12/07/81 JA: OK					
8209739	11644	3509322138		103		NICHELSON #1-7	N E CEDARDALE	240.0	DELHI GAS PIPELIN
-ENERGY RESERVES GROUP INC				RECEIVED: 12/07/81 JA: OK					
8209757	11441	3510321113		103		DEVORE #8	POLO	36.0	AMINOIL USA INC
-ENERGY SERVICES INC				RECEIVED: 12/07/81 JA: OK					
8209761	09408	3501721499		103		BANNER CO-OP #1-17	NORTH YUKON	138.4	DELHI GAS PIPELIN
-F C D OIL CORP				RECEIVED: 12/07/81 JA: OK					

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209731	11494	3508321682		103		CHARLOTTE 1-26	N CRESCENT	36.5	EASON OIL CO
8209728	11663	3510321328		103		DON 1-23	BILLINGS	21.9	ARCO OIL & GAS CO
8209730	15074	3504722936		102-4		MARY 1A-9	N W KREMLIN	81.0	CRA INC
8209727	11661	3510321348		103		MIKE 1-23	BILLINGS	18.3	ARCO OIL & GAS CO
8209729	11664	3507322871		103		REHERMAN 1-21	N E OKARCHE	94.9	PHILLIPS PETROLEU
8209726	11276	3504722586		102-4		ROBBINS 1-16	KREMLIN	91.3	C R A INC
-GMC OIL AND GAS CORP				RECEIVED: 12/07/81 JA: OK					
8209755	11380	3511921419		103		SHEPARD "A"-1	W YALE	100.0	PHILLIPS PETROLEU
-HUNGERFORD OIL & GAS INC				RECEIVED: 12/07/81 JA: OK					
8209723	14970	3508321372		103		HORSLEY #1			
8209721	14966	3504722526		103		HORSLEY #2	NORTHWEST ELKHORN	226.1	AMINOIL USA INC
8209722	14969	3504722525		103		HORSLEY #3	NORTHWEST ELKHORN	109.1	AMINOIL USA INC
8209724	14971	3504722686		103		HORSLEY NO 4	NORTHWEST ELKHORN	251.8	AMINOIL USA INC
-INEXCO OIL COMPANY				RECEIVED: 12/07/81 JA: OK			NORTHWEST ELKHORN	112.7	AMINOIL USA INC
8209725	14976	3512920604		102-4		ESSIE #1-34			
-JRHOP INC				RECEIVED: 12/07/81 JA: OK			NORTH EAST STRONG CITY	400.0	PRODUCER'S GAS CO
8209767	11569	3510920444		103		GILMORE 1-15 B	W EDMOND	18.0	PHILLIPS PETROLEU
-KAISER-FRANCIS OIL COMPANY				RECEIVED: 12/07/81 JA: OK					
8209778	15236	3501521069		107-DP		BELCHER #1	EAST APACHE	300.0	EL PASO NATURAL G
-L O WARD				RECEIVED: 12/07/81 JA: OK					
8209735	11613	3509322076		103		ENSMINGER FREED 1	N E OKEENE	275.0	TRANSOK PIPE LINE
8209736	11614	3504700000		103		REIM #2	N E ENID	0.0	CHAMPLIN PETROLEU
8209752	11307	3502720457		103		ROBERTS #2	SOUTH MOORE	36.5	SUN GAS CO
-LRF CORP				RECEIVED: 12/07/81 JA: OK					
8209751	11244	3506120300		103		AVERY #1	KINTA	109.5	DELHI GAS PIPELIN
-MAR-BAR ENTERPRISES INC				RECEIVED: 12/07/81 JA: OK					
8209747	10706	3513166429		103		EDENGER #1	WEST OOLAGAH	36.0	DIAMOND-S GAS SYS
-MORGAN & STEINERT INC				RECEIVED: 12/07/81 JA: OK					
8209770	11571	3507322423		103		BARKER #1	SOONER TREND	120.0	EXXON CO U S A
-MUSTANG PRODUCTION CO.				RECEIVED: 12/07/81 JA: OK					
8209741	14888	3504520925		102-2		DISHEN #1-17	SOUTHWEST ARNETT	150.0	PRODUCER'S GAS CO
8209742	14889	3500920401		102-3		ROSSON #1-5	NORTH ERIC	300.0	ARKANSAS LOUISIAN
-PORTS OF CALL OIL CO				RECEIVED: 12/07/81 JA: OK					
8209773	11596	3501520979		103		HELEN CONSTIEN #13-1	NORTH EAST-HINTON	200.0	OKLAHOMA NATURAL
-POST PETROLEUM COMPANY INC				RECEIVED: 12/07/81 JA: OK					
8209733	11607	3513921411		103		MONROE #1	GUYMON-HUGOTON	0.0	PHILLIPS PETROLEU
8209732	11603	3513921400		103		MURRAY #1	CAMRICK DIST	0.0	KANSAS-NEBRASKA N
-RICKS EXPLORATION CO				RECEIVED: 12/07/81 JA: OK					
8209780	14897	3501521050		102-4		MARY LOU #1	S W BINGER	484.0	MICHIGAN WISCONSI
-ROYAL OIL & GAS CORPORATION				RECEIVED: 12/07/81 JA: OK					
8209771	11592	3511921472		103		H C ROBINSON #4	NORTHEAST PRATT	35.0	ENTERPRISE DEVELO
8209772	11593	3511921074		103		MARATHON #1	NORTHEAST PRATT	30.0	ENTERPRISE DEVELO
-TRIPLEDEE DRILLING CO				RECEIVED: 12/07/81 JA: OK					
8209740	14794	3501900000		102-4		EMZIE JOY #1		180.0	AMINOIL USA INC
-UNIT OPERATIONS				RECEIVED: 12/07/81 JA: OK					
8209769	08883	3507121702		103		FOSTER GAS UNIT #1	DILWORTH	38.6	CITIES SERVICE GA
8209758	09512	3507122029		102-4		SHOFFNER GAS UNIT #1	DILWORTH	88.3	CITIES SERVICE GA
-UNIVERSAL RESOURCES CORPORATION				RECEIVED: 12/07/81 JA: OK					
8209749	11054	3507300000		103		S O #1-16	SOONER TREND	210.6	PHILLIPS PETROLEU
8209750	11056	3509322132		103		SONS 1-28	DANE	43.8	DELHI GAS PIPELIN
-WALLACE OIL & GAS INC				RECEIVED: 12/07/81 JA: OK					
8209734	11611	3501721875		103		HOLMAN #1	WATONGA CHICKASHA TREND	364.8	MUSTANG FUEL CORP
-WOOD ENTERPRISES INC				RECEIVED: 12/07/81 JA: OK					

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209776	14856	3511900000		102-4		DAWES #1 (119-68530)	MARKHAM	0.8	PARKS ENERGY INVE
8209776	14856	3511900000		103		DAWES #1 (119-68530)	MARKHAM	0.8	PARKS ENERGY INVE
8209774	14854	3511900000		102-4		STOOPS "A" #2 (119-68885)	MARKHAM	18.0	PARKS ENERGY INVE
8209774	14854	3511900000		103		STOOPS "A" #2 (119-68885)	MARKHAM	18.0	PARKS ENERGY INVE
8209775	14855	3511900000		102-4		STOOPS A #1 (119-63886)	MARKHAM	22.0	PARKS ENERGY INVE
8209775	14855	3511900000		103		STOOPS A #1 (119-63886)	MARKHAM	22.0	PARKS ENERGY INVE
-WOODS PETROLEUM CORP				RECEIVED: 12/07/81 JA: OK					
8209720	14917	3503920414		102-2		LEWIS #8-1	WILD CAT	913.0	MICHIGAN WISCONSI
8209719	14916	3503920464		102-2		WADE COULSON #1	WILD CAT	201.0	MICHIGAN WISCONSI
8209718	14915	3503920505		102-2		WEBB #2-1	WILD CAT	1204.0	MICHIGAN WISCONSI
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PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL RESOURCES									
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-ADOBE OIL & GAS CORPORATION				RECEIVED: 12/10/81 JA: PA					
8209869	9816	3706324655		108		JOHN AULD #2	CLYMER	5.0	COLUMBIA GAS TRAN
-ANGERMAN ASSOCIATES INC				RECEIVED: 12/10/81 JA: PA					
8209871	9836	3706326129		103		CLAIR M BOTHEL #3-IND-26129	W PA-UPPER DEVONIAN SAND	25.0	PEOPLES NATURAL G
8209881	9847	3700522574		103		JANET L MILLER #3 - ARM-22574	W PENNA - UPPER DEVONIAN	15.0	PEOPLES NATURAL G
8209880	9846	3706326149		103		JOHN KOSIS #2 IND-26149	W PENNA - UPPER DEVONIAN	35.0	PEOPLES NATURAL G
8209876	9841	3706326091		103		JOHN L SWASY #3-IND-26091	W PENNA - UPPER DEVONIAN	45.0	PEOPLES NATURAL G
8209882	9848	3706326101		103		JOSEPH F NESBIT #8 - IND-26106	W PENNA - UPPER DEVONIAN	45.0	PEOPLES NATURAL G
8209872	9837	3706326064		103		M B BOWMAN #4-IND-26064	W PA - UPPER DEVONIAN SA	35.0	PEOPLES NATURAL G
8209874	9839	3706326202		103		MARGARET CROWNOVER #1-IND-26202	W PENNA - UPPER DEVONIAN	45.0	PEOPLES NATURAL G
8209877	9842	3706326083		103		MELVIN B TROYER #1-IND-26083	W PENNA - UPPER DEVONIAN	45.0	PEOPLES NATURAL G
8209870	9835	3706326079		103		PAUL J BECK #4-IND-26079	W PA - UPPER DEVONIAN SA	25.0	PEOPLES NATURAL G
8209878	9843	3712921849		103		ROBERT H WHITTAKER #1 - WES-21849	W PENNA - UPPER DEVONIAN	75.0	PEOPLES NATURAL G
8209875	9840	3712921838		103		RUSSELL C SHANK #2-WES-21838	W PENNA - UPPER DEVONIAN	75.0	PEOPLES NATURAL G
8209879	9844	3706326402		103		SLOAN CORNELL #1 - IND-26402	W PA - UPPER DEVONIAN SA	35.0	PEOPLES NATURAL G
8209873	9838	3706326090		103		TODD R CLAWSON #3-IND-26090	W PA - UPPER DEVONIAN SA	25.0	PEOPLES NATURAL G
-BEREA OIL AND GAS CORPORATION				RECEIVED: 12/10/81 JA: PA					
8209885	8862	3704921196		107-TF		C A BROWN UNIT #1	NORTH EAST	25.0	NATIONAL FUEL GAS
8209884	8861	3704921199		107-TF		F C GEBHARDT #1	NORTH EAST	25.0	NATIONAL FUEL GAS
8209883	8860	3704921200		107-TF		LARIMER & NORTON UNIT #1	NORTH EAST	25.0	NATIONAL FUEL GAS
-CONSOLIDATED GAS SUPPLY CORPORATION				RECEIVED: 12/10/81 JA: PA					
8209887	6994	3706521900		108		R & P COAL COMPANY WN-1764	BELL TOWNSHIP	0.4	GENERAL SYSTEM PU
8209888	6995	3706521893		108		R SPRAGUE WN-1762	WINSLOW TOWNSHIP	2.9	GENERAL SYSTEM PU
8209889	6997	3706521686		108		ROBERT WALTMAN WN-1714	MCCALMONT TOWNSHIP	2.5	GENERAL SYSTEM PU
-DALE H CAMPBELL				RECEIVED: 12/10/81 JA: PA					
8209886	7750	3712921681		108		WILLIAM G SMAIL #3	ARMBRUST - GREENSBURG	7.6	PEOPLES NATURAL G
-DAMSON-LOUDEN CO LTD & NCC-LOUDEN L				RECEIVED: 12/10/81 JA: PA					
8209893	9832	3700500000		108		C YOUNG B81X-1	PLUMCREEK	6.8	APOLLO GAS CO
8209892	9831	3700500000		108		DESALVO B1101-1	SOUTH BUFFALO	8.8	APOLLO GAS CO
8209894	9833	3700520073		108		E HANKINSON B76X-1	PLUMCREEK	9.2	APOLLO GAS CO
8209891	9821	3701900000		108		J M ELLIOTT B1102-1	BUFFALO	5.8	APOLLO GAS CO
8209890	9820	3700500000		108		MYERS (JOHN HECK) B1119-1	SOUTH BUFFALO	21.1	APOLLO GAS CO
8209895	9834	3700521089		108		R BOYER B34X-1	PLUMCREEK	19.7	APOLLO GAS CO
-J & J ENTERPRISES INC				RECEIVED: 12/10/81 JA: PA					
8209904	7195	3706321979		108		B TYGER #1	CANOE	8.7	T W PHILLIPS GAS
8209910	7249	3706322105		108		BYRON M FRICK #1	SOUTH MAHONING	5.2	T W PHILLIPS GAS
8209915	7260	3706321982		108		C ADAMSON #2	WASHINGTON	6.2	T W PHILLIPS GAS
8209901	7186	3706322023		108		C W LYDIC #1	SOUTH MAHONING	1.6	T W PHILLIPS GAS
8209903	7190	3706322106		108		C W LYDIC #1	SOUTH MAHONING	10.8	T W PHILLIPS GAS
8209896	7070	3700521533		108		CHARLES DUFF #4	COWANSHANNOCK	4.7	PEOPLES NATURAL G

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8209902	7189	3706322157		108		CHARLES WELLS #1	SOUTH MAHONING	8.8	T W PHILLIPS GAS
8209911	7251	3706321990		108		D E MAUK (MOCK) #1	CANOE	15.3	T W PHILLIPS GAS
8209898	7182	3706322073		108		EFFIE BAUN #1	CANOE	2.1	T W PHILLIPS GAS
8209927	7419	3703320584		108		GLEN E MILLER #2	BELL	2.3	T W PHILLIPS GAS
8209914	7259	3706321881		108		HAROLD DOMB #2	CANOE	12.2	T W PHILLIPS GAS
8209909	7232	3700521883		108		HARRY E SMITH #1	COVANSHANNOCK	4.4	T W PHILLIPS GAS
8209916	7261	3706529500		108		ISABEL R HAWK #2	BELL	10.8	T W PHILLIPS GAS
8209919	7264	3706321880		108		JACOB CASADAY #2	CANOE	7.1	T W PHILLIPS GAS
8209913	7258	3706321937		108		JACOB CASADAY #3	CANOE	7.1	T W PHILLIPS GAS
8209912	7257	3706321977		108		JACOB CASADAY #4	CANOE	7.1	T W PHILLIPS GAS
8209923	7353	3706323206		108		JOHN FABIN #1	ARMSTRONG	21.8	T W PHILLIPS GAS
8209922	7347	3706323207		108		JOHN FABIN #2	ARMSTRONG	21.8	T W PHILLIPS GAS
8209921	7331	3706323208		108		JOHN FABIN #3	ARMSTRONG	21.8	T W PHILLIPS GAS
8209918	7263	3706321907		108		K C SUMMERS #2	CANOE	2.5	T W PHILLIPS GAS
8209906	7203	3706321948		108		LIONS HEALTH CAMP #2	ARMSTRONG	12.2	T W PHILLIPS GAS
8209897	7181	3706321906		108		LUTHER T GASTON #3	CANOE	2.1	T W PHILLIPS GAS
8209917	7262	3706529570		108		M LELLOCK #1	BELL	15.1	T W PHILLIPS GAS
8209899	7183	3706529550		108		MARLIN BISHOP #2	BELL	8.5	T W PHILLIPS GAS
8209907	7204	3706321980		108		N WHITE #1	CANOE	2.7	T W PHILLIPS GAS
8209908	7205	3706321981		108		N WHITE #2	CANOE	10.7	T W PHILLIPS GAS
8209905	7198	3706322129		108		RICHARD MABON #1	SOUTH MAHONING	12.8	T W PHILLIPS GAS
8209900	7184	3706321893		108		ROGER RICHARDSON #2	CANOE	8.5	T W PHILLIPS GAS
8209920	7298	3706321469		108		WENDELL MARSH #1	WEST MAHONING	3.0	T W PHILLIPS GAS
-PHILLIPS PRODUCTION CO			RECEIVED: 12/10/81 JA: PA						
8209925	6925	3706325144		108		CHARLES S BEATTY #2	GRANT	4.0	COLUMBIA GAS TRAN
8209926	6936	3706521775		108		EMMI M QUANTZ #1	GRANT	15.0	CONSOLIDATED GAS
8209924	6924	3706325314		108		LEONARD MUMAU #2	GRANT	5.0	COLUMBIA GAS TRAN
-WAINOCO OIL & GAS CO			RECEIVED: 12/10/81 JA: PA						
8209934	9801	3703920594		107-TF		DANIEL & SANDRA FOLTZ #1 (W-22)	ATHENS	22.0	COLUMBIA GAS TRAN
8209933	9800	3703920595		107-TF		EDWARD MILLS #1 (W-19)	ATHENS (ATHENS)	3.5	COLUMBIA GAS TRAN
8209940	9875	3703920648		107-TF		GEORGE & MAXWELL CLARK #2 (W-36)	ATHENS	5.5	COLUMBIA GAS TRAN
8209937	9872	3703920669		107-TF		GERALD SCOUTEN #1 (W-49)	ATHENS (BLOOMFIELD)	3.5	COLUMBIA GAS TRAN
8209931	9798	3703920597		107-TF		JACK PRESTON #2 (W-20)	ATHENS	3.5	COLUMBIA GAS TRAN
8209929	9791	3703920659		107-TF		LILLIAN F K LORENZ #1 (W-29)	ATHENS (ROME)	14.5	COLUMBIA GAS TRAN
8209935	9802	3703920652		107-TF		M PAUL M P POST & M PAUL #1 (W-28)	ATHENS (ROME)	24.0	COLUMBIA GAS TRAN
8209939	9874	3703920596		107-TF		MICHAEL & GLORIA J KELLY #1 (W-37)	ATHENS	7.0	COLUMBIA GAS TRAN
8209936	9866	3703920665		107-TF		O RAYMOND CREACRAFT #1 (W-44)	ATHENS (ATHENS)	9.0	COLUMBIA GAS TRAN
8209928	9789	3703920614		107-TF		THEODORE BOGARDUS #5 (W-27)	ATHENS (ATHENS)	9.0	COLUMBIA GAS TRAN
8209930	9795	3703920611		107-TF		THEODORE S BOGARDUS #3 (W-18)	ATHENS (ATHENS)	14.5	COLUMBIA GAS TRAN
8209932	9799	3703920613		107-TF		THEODORE S BOGARDUS #4 (W-21)	ATHENS (ATHENS)	3.5	COLUMBIA GAS TRAN
8209938	9873	3703920653		107-TF		THEODORE S BOGARDUS #6 (W-38)	ATHENS (ATHENS)	18.0	COLUMBIA GAS TRAN
8209941	9876	3703920664		107-TF		WILLIAM E STEIN #1 (W-43)	ATHENS (ATHENS)	9.0	COLUMBIA GAS TRAN
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** U.S. GEOLOGICAL SURVEY - DENVER,CO									
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-MITCHELL ENERGY CORPORATION			RECEIVED: 12/07/81 JA: CO 1						
8209833	CD 0439-81	0507708215		102-2		LIPAN WASH UNIT #1-14-2-2	WILDCAT	30.0	NORTHWEST PIPELIN
8209831	CD 0438-81	0507708216		102-2		LIPAN WASH UNIT #3-15-2-2 13660	WILDCAT	150.0	NORTHWEST PIPELIN
8209834	CD 0441-81	0507708211		102-2		PERSIGO WASH UNIT #2-33-9-100	WILDCAT	26.0	NORTHWEST PIPELIN
8209830	CD 0440-81	0507708306		102-2		PERSIGO WASH UNIT #4-33-9-100	WILDCAT	55.0	NORTHWEST PIPELIN
8209832	CD 0437-81	0507708235		102-2		RUBY LEE UNIT 1-2-9-101	WILDCAT	46.0	
-NORTHWEST PIPELINE CORPORATION			RECEIVED: 12/07/81 JA: CO 1						
8209822	CD 0450-81	0506705719		108		IGNACIO 33-7 #10	IGNACIO BLANCO DK/MV	21.0	NORTHWEST PIPELIN

BILLING CODE 6717-01-C

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JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME			FIELD NAME	PROD	PURCHASER
-TETON ENERGY CO INC						RECEIVED: 12/07/81	JA: CO	1			
8209836	CD 0449-81	0507708171		102-2		FEDERAL 29-2			DEBEQUE	202.0	NORTHWEST PIPELIN
-TWIN ARROW INC						RECEIVED: 12/07/81	JA: CO	1			
8209819	CD 0451-8	0510308524		107-TF		C & K 1-18			CATHEDRAL	0.0	NORTHWEST PIPELIN
8209821	CD 0452-81	0510308399		107-TF		CONTINENTAL 2-21			CATHEDRAL	0.0	NORTHWEST PIPELIN
8209820	CD 0453-81	0510308524		107-TF		CONTINENTAL 4-28			CATHEDRAL	0.0	NORTHWEST PIPELIN
-BELCO PETROLEUM CORPORATION						RECEIVED: 12/07/81	JA: UT	1			
8209817	UD036581	4304730642		102-4		DUCK CREEK 4-17			DUCK CREEK	0.0	NORTHWEST PIPELIN
8209816	UD0320-81	4304730807		102-4		DUCK CREEK 41-8			DUCK CREEK	0.0	NORTHWEST PIPELIN
-CIG EXPLORATION INC						RECEIVED: 12/07/81	JA: UT	1			
8209825	UD 0427-81	4304730950		107-TF		CIGE 64D-33-9-22-P			NATURAL BUTTES	355.0	COLORADO INTERSTA
8209826	UD 0431-81	4304730952		107-TF		CIGE 73D-5-10-22-P			NATURAL BUTTES	369.0	COLORADO INTERSTA
8209824	UD 0428-81	4304730870		107-TF		CIGE 78C-16-9-21-P			NATURAL BUTTES	410.0	COLORADO INTERSTA
-COASTAL OIL & GAS CORP						RECEIVED: 12/07/81	JA: UT	1			
8209827	UD 0433-81	4304730967		103		COG 2-22-9-20-GR			NATURAL BUTTES	295.0	COLORADO INTERSTA
-CONOCO INC						RECEIVED: 12/07/81	JA: UT	1			
8209835	UD 0436-81	4304730966		102-3		CONOCO UTE TRIBAL 12 #33			OURAY	120.0	MOUNTAIN FUEL SUP
-CORDILLERA CORPORATION						RECEIVED: 12/07/81	JA: UT	1			
8209823	UD 0323-81	4303730464		102-4		FEDERAL #1-20			LITTLE VALLEY	730.0	TRANS-COLORADO PI
-COTTON PETROLEUM CORPORATION						RECEIVED: 12/07/81	JA: UT	1			
8209818	UD 0419-81	4304730706		107-TF		LOVE UNIT #A1-18			WILDCAT	0.0	MESA PIPE LINE CO
-PAGE PETROLEUM INC						RECEIVED: 12/07/81	JA: UT	1			
8209829	UD 0447-81	4301330500		103		UTE TRIBAL E-2			ALTAMONT	300.0	KOCH HYDROCARBON
8209828	UD 0445-81	4301300000		103		UTE TRIBAL 2-23-C6				100.0	KOCH HYDROCARBON

The above notices of determination were received from the indicated jurisdictional agencies by the Federal Energy Regulatory Commission pursuant to the Natural Gas Policy Act of 1978 and 18 CFR 274.104. Negative determinations are indicated by a "D" before the section code. Estimated annual production (PROD) is in million cubic feet (MMCF). An (*) before the Control (JD) number denotes additional purchasers listed at the end of the notice.

The applications for determination are available for inspection except to the extent such material is confidential under 18 CFR 275.206, at the Commission's Division of Public Information, Room 1000, 825 North Capitol St., Washington, D.C. Persons objecting to any of these determinations may, in accordance with 18 CFR 275.203 and 275.204, file a protest with the Commission on or before January 20, 1982.

Categories within each NGPA section are indicated by the following codes:

Section 102–1: New OCS Lease
102–2: New well (2.5 mile rule)
102–3: New well (1000 ft rule)
102–4: New onshore reservoir
102–5: New reservoir on old OCS lease
Section 107–DP: 15,000 feet or deeper
107–GB: Geopressured brine
107–CS: Coal seams
107–DV: Devonian shale
107–PE: Production enhancement
107–TF: New tight formation
107–RT: Recompletion tight formation
Section 108: Stripper well
108–SA: Seasonally affected
108–ER: Enhanced recovery
108–PB: Pressure buildup

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–155 Filed 1–4–82; 8:45 am]

BILLING CODE 6717–01–M

Determinations by Jurisdictional Agencies Under the Natural Gas Policy Act of 1978

Issued: December 30, 1981.

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
LOUISIANA OFFICE OF CONSERVATION									
-AMOCO PRODUCTION CO				RECEIVED: 12/14/81 JA: LA					
8209981	81-2183	1711321068		103		ELIZABETH M WATKINS #37	SOUTH FLORENCE	14.6	FLORIDA GAS TRANS
-ARKANSAS LOUISIANA GAS CO				RECEIVED: 12/14/81 JA: LA					
8209969	81-2088	1711100000		108		FROST LUMBER CO #1	MONROE	0.0	ARKANSAS LOUISIAN
-BETHLAN PRODUCTION CORP				RECEIVED: 12/14/81 JA: LA					
8210023	81-2096	1707320013		108		LIEBER EST #1 SERIAL #116958	MONROE	8.0	STRAHAN OIL & GAS
8209999	81-2174	1707321750		103		LUCAS #1	MONROE GAS	29.2	IMC PIPELINE CO I
8209973	81-2175	1707321751		103		LUCAS #2	MONROE GAS FIELD	27.4	IMC PIPELINE CO I
8209972	81-2176	1707321753		103		LUCAS #3	MONROE GAS	28.5	IMC PIPELINE CO I
8209974	81-2177	1707321752		103		LUCAS #4	MONROE GAS	25.6	IMC PIPELINE CO I
8210022	81-2097	1707320014		108		MORRIS #1 SERIAL #116959	MONROE	3.0	STRAHAN OIL & GAS
-ELSBURY & MCGREW				RECEIVED: 12/14/81 JA: LA					
8210057	81-2075	1705500181		102-4		C A STUTES #1	JUDICE	144.0	TRANSCONTINENTAL
-ERGON INC				RECEIVED: 12/14/81 JA: LA					
8209963	81-2082	1711122992		103		CLARA E SAVAGE #1	MONROE	16.8	TEXAS GAS TRANSMI
8209963	81-2082	1711122992		107-TF		CLARA E SAVAGE #1	MONROE	16.8	TEXAS GAS TRANSMI
8209964	81-2083	1711122993		103		MAMIE DELL EDWARDS #1	MONROE	13.3	TEXAS GAS TRANSMI
8209964	81-2083	1711122993		107-TF		MAMIE DELL EDWARDS #1	MONROE	13.3	TEXAS GAS TRANSMI
8209966	81-2085	1711123183		103		P S SMITH #1	MONROE	10.2	TEXAS GAS TRANSMI
8209966	81-2085	1711123183		107-TF		P S SMITH #1	MONROE	10.2	TEXAS GAS TRANSMI
8209965	81-2084	1711123125		103		TIM GREEN #4	MONROE	11.5	TEXAS GAS TRANSMI
8209965	81-2084	1711123125		107-TF		TIM GREEN #4	MONROE	11.5	TEXAS GAS TRANSMI
-EXXON CORPORATION				RECEIVED: 12/14/81 JA: LA					
8209956	81-2189	1711320908		103		EXXON FEE-PECAN ISLAND #74	PECAN ISLAND	156.0	COLUMBIA GAS TRAN
-GAS DEVELOPMENT CORP				RECEIVED: 12/14/81 JA: LA					
8210035	81-2095	1711121397		108		JIMMY TRAYLOR #1	MONROE GAS	47.1	IMC PIPELINE CO I
8210034	81-2094	1711121358		108		NOLAN #1	MONROE GAS	15.3	IMC PIPELINE CO I
8210032	81-2092	1711121242		108		SIMPSON #1	MONROE GAS	28.4	IMC PIPELINE CO I
8210021	81-2091	1711121177		108		UNION SCHOOL #1	MONROE GAS	45.7	IMC PIPELINE CO I
8210033	81-2093	1707321032		108		W WILSON ET AL #1	MONROE GAS	9.6	IMC PIPELINE CO I
8210025	81-2089	1707320888		108		WALL #1	MONROE GAS	6.9	IMC PIPELINE CO I
8210024	81-2090	1707320906		108		WILLIAMS #1	MONROE GAS	8.8	IMC PIPELINE CO I
-GOLDKING PRODUCTION COMPANY				RECEIVED: 12/14/81 JA: LA					
8210036	81-2188	1705320632		103		LAWRENCE BROWN #1	HAYES	73.0	LOUISIANA INTRAST
-HADDOX PETROLEUM CORP				RECEIVED: 12/14/81 JA: LA					
8209996	81-2170	1711123288		103		MANVILLE 794 #1	MONROE	18.3	IMC PIPELINE CO I
8210000	81-2173	1711123094		103		NORMAN #1	MONROE	14.6	IMC PIPELINE CO I
8209997	81-2172	1711123003		103		TAUNTON #1	MONROE 6824	14.6	IMC PIPELINE CO I
-IMC EXPLORATION COMPANY				RECEIVED: 12/14/81 JA: LA					
8209967	81-2086	1707321803		103		MYHRE #3	MONROE	11.0	UNITED GAS PIPELI
8209968	81-2087	1707321804		103		MYHRE #4	MONROE	11.0	UNITED GAS PIPELI

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JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
-KERR-MCGEE CORPORATION						RECEIVED: 12/14/81 JA: LA			
8210006	81-2178	1772620194		103		S L 1999 #41	BRETON SOUND BLOCK 20	20.0	SOUTHERN NATURAL
-MARATHON OIL COMPANY						RECEIVED: 12/14/81 JA: LA			
8209983	81-2110	1711900708		108-ER		CUSU HUNT CRAWFORD #2	COTTON VALLEY	0.0	UNITED GAS P L CO
8209978	81-2109	1711900713		108		CVOC HUNT STEWART #3 CVSU	COTTON VALLEY	9.5	UNITED GAS PIPE L
8209960	81-2108	1711900859		108		CVOC OHIO GRANT #2 CVSU	COTTON VALLEY	3.0	UNITED GAS PIPE L
8209958	81-2106	1711901105		108-ER		CVSU HUNT DAVIS #2	COTTON VALLEY	0.0	UNITED GAS PL CO
8210053	81-2101	1711900739		108-ER		CVSU MAGNOLIA CRICHTON #1	COTTON VALLEY	0.0	UNITED GAS P L CO
8210055	81-2103	1711900896		108-ER		CVSU MAGNOLIA MAY PRUITT #1	COTTON VALLEY	0.0	UNITED GAS P L CO
8210056	81-2102	1711900907		108-ER		HODGES HODGES #1 CVSU	COTTON VALLEY	0.0	UNITED GAS P L CO
8210026	81-2104	1711900765		108		OHIO TILLMAN GLEASON #1 CVSU	COTTON VALLEY	3.0	UNITED GAS PIPE L
8209961	81-2107	1711900802		108-ER		SUNRAY MCCOOK & HIBBLER #2 CVSU	COTTON VALLEY	0.0	UNITED GAS P L CO
-MARSHALL EXPLORATION INC						RECEIVED: 12/14/81 JA: LA			
8209990	81-2149	1703120995		103		A E ATWOOD #2 FBG RA SU 129	LOGANSPORT	32.0	TENNESSEE GAS PIP
8209991	81-2148	1703120994		103		A E ATWOOD #3 FBG RA SU 147	LOGANSPORT	30.0	TENNESSEE GAS PIP
8210027	81-2143	1703120942		103		ADAMS #1 FBG RA SU 128	LOGANSPORT	300.0	TENNESSEE GAS PIP
8210031	81-2141	1703121222		103		ALSTON #1 FBG RA SU 83	LOGANSPORT	400.0	TENNESSEE GAS PIP
8210013	81-2150	1703120983		103		AVERETT #3 FBG RA SU 160	LOGANSPORT	30.0	SOUTHERN NATURAL
8210020	81-2153	1703121148		103		AVERETT #4 FBG RA SU 166	LOGANSPORT	50.0	SOUTHERN NATURAL
8210038	81-2164	1703120967		103		BARNES #1 FBG RA SU 96	LOGANSPORT	33.0	TENNESSEE GAS PIP
8210029	81-2142	1703120992		103		BLUE #1 FBG RA SU 124	LOGANSPORT	200.0	TENNESSEE GAS PIP
8210045	81-2133	1703120980		103		BLUE #2 FBG RA SU 125	LOGANSPORT	90.0	TENNESSEE GAS PIP
8209994	81-2145	1703120943		103		BOLDEN #1 FBG RA SU 123	LOGANSPORT	70.0	TENNESSEE GAS PIP
8210046	81-2131	1703120895		103		CATER #1 FBG RA SU 130	LOGANSPORT	44.0	TENNESSEE GAS PIP
8210018	81-2155	1703120892		103		CORA BARNES #1 FBG RA SU 105	LOGANSPORT	46.0	TENNESSEE GAS PIP
8210005	81-2161	1703120897		103		COVINGTON #6 FBG RA SU 144	LOGANSPORT	30.0	TENNESSEE GAS PIP
8210028	81-2144	1703120945		103		CURRY #1 FBG RA SU 103	LOGANSPORT	177.0	TENNESSEE GAS PIP
8210039	81-2137	1703120966		103		EDWARDS #1 FBG RA SU 79	LOGANSPORT	36.0	TENNESSEE GAS PIP
8210042	81-2136	1703120969		103		EDWARDS #2 FBG RA SU 97	LOGANSPORT	36.0	TENNESSEE GAS PIP
8210044	81-2132	1703121128		103		ELLIOTT #1 FBG RA SU 127	LOGANSPORT	75.0	TENNESSEE GAS PIP
8209992	81-2147	1703121025		103		FIELDS A #1 FBG RA SU 148	LOGANSPORT	35.0	TENNESSEE GAS PIP
8210004	81-2162	1703121160		103		FREDERICK #1 FBG RA SU 92	LOGANSPORT	33.0	TENNESSEE GAS PIP
8210030	81-2140	1703121232		103		GAMBLE #3 FBG RA SU 69	LOGANSPORT	200.0	TENNESSEE GAS PIP
8210043	81-2134	1703120991		103		GUY #1 FBG RA SU 93	LOGANSPORT	23.0	TENNESSEE GAS PIP
8210012	81-2151	1703121142		103		HALL #1 FBG RA SU 167	LOGANSPORT	33.0	SOUTHERN NATURAL
8210048	81-2130	1703120899		103		KATIE ROBINSON #1 FBG RA SU 145	LOGANSPORT	40.0	TENNESSEE GAS PIP
8209995	81-2169	1703120874		103		LUM #1 FBG RA SU 120	LOGANSPORT	0.0	TENNESSEE GAS PIP
8210019	81-2154	1703120875		103		LUM #2 FBG RA SU 121	LOGANSPORT	33.0	TENNESSEE GAS PIP
8210010	81-2159	1703121132		103		MATTHEWS LBR CO #1 FBG RA SU 117	LOGANSPORT	33.0	TENNESSEE GAS PIP
8210001	81-2168	1703121133		103		NABORS #1 FBG RA SU 134	LOGANSPORT	34.0	TENNESSEE GAS PIP
8210041	81-2135	1703120990		103		PRICE #1 FBG RA SU 94	LOGANSPORT	55.0	TENNESSEE GAS PIP
8210014	81-2163	1703121087		103		RAMSEY #8 FBG RA SU 10	LOGANSPORT	91.0	TENNESSEE GAS PIP
8210015	81-2158	1703120971		103		ROBERTS #1 FBG RA SU 109	LOGANSPORT	33.0	TENNESSEE GAS PIP
8210037	81-2165	1703121093		103		SABBATH #1 HOSS'T RA SUE	BETHANY-LONGSTREET	270.0	TENNESSEE GAS PIP
8210002	81-2167	1703120905		103		SANDERS .. FBG RA SU 110	LOGANSPORT	25.0	TENNESSEE GAS PIP
8210016	81-2157	1703120973		103		SANDERS #2 FBG RA SU 116	LOGANSPORT	45.0	TENNESSEE GAS PIP
8210003	81-2166	1703121288		103		SANDERS #3 U HOSS RA SUU	BELLE BOWER	547.5	TENNESSEE GAS PIP
8209993	81-2146	1703120963		103		SELLERS #1 FBG RA SU 104	LOGANSPORT	20.0	TENNESSEE GAS PIP
8210058	81-2139	1703120964		103		SMITH #1 FBG RA SU 98	LOGANSPORT	32.0	TENNESSEE GAS PIP
8210040	81-2138	1703120965		103		SMITH #2 FBG RA SU 78	LOGANSPORT	30.0	TENNESSEE GAS PIP
8210009	81-2160	1703120926		103		T G CHANDLER #1 FBG RA SU/41	LOGANSPORT	44.0	TENNESSEE GAS PIP
8210017	81-2156	1703120974		103		WHITEHEAD #1 FBG RA SU 142	LOGANSPORT	33.0	TENNESSEE GAS PIP
8210011	81-2152	1703120998		103		WHITEHEAD #2 FBG RA SU 159	LOGANSPORT	39.0	SOUTHERN NATURAL

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
-MEDDERS OIL COMPANY						RECEIVED: 12/14/81 JA: LA			
8210008	81-2180	1701920898		103		CHOUPIQUE ENTERPRISES INC #1	NORTH CHOUPIQUE	292.0	CONOCO INC
-MID LOUISIANA GAS COMPANY						RECEIVED: 12/14/81 JA: LA			
8209971	81-2025	1711122821		108		MLGC FEE GAS #1004	MONROE GAS	13.2	MID LOUISIANA GAS
8209947	81-2117	1711123116		103		MLGC FEE GAS #1038	MONROE GAS	36.5	MID LOUISIANA GAS
8209946	81-2118	1711123120		103		MLGC FEE GAS #1042	MONROE GAS	36.5	MID LOUISIANA GAS
8209945	81-2119	1711123121		103		MLGC FEE GAS #1043	MONROE GAS	36.5	MID LOUISIANA GAS
8209944	81-2120	1711123145		103		MLGC FEE GAS #1044	MONROE GAS	36.5	MID LOUISIANA GAS
8209943	81-2121	1711123148		103		MLGC FEE GAS #1047	MONROE GAS	46.7	MID LOUISIANA GAS
8209942	81-2122	1711123154		103		MLGC FEE GAS #1053	MONROE GAS	0.0	MID LOUISIANA GAS
8209970	81-2123	1711123174		103		MLGC FEE GAS #1054	MONROE GAS FIELD	31.0	MID LOUISIANA GAS
8210054	81-2124	1711123168		103		MLGC FEE GAS #1056	MONROE GAS	25.5	MID LOUISIANA GAS
8210051	81-2125	1711123169		103		MLGC FEE GAS #1057	MONROE GAS	36.5	MID LOUISIANA GAS
8210052	81-2126	1711123246		103		MLGC FEE GAS #1058	MONROE GAS	36.5	MID LOUISIANA GAS
8210049	81-2127	1711123247		103		MLGC FEE GAS #1059	MONROE GAS	36.5	MID LOUISIANA GAS
8209952	81-2111	1711123251		103		MLGC FEE GAS #1063	MONROE GAS	12.7	MID LOUISIANA GAS
8209953	81-2112	1711123253		103		MLGC FEE GAS #1065	MONROE GAS	14.6	MID LOUISIANA GAS
8209954	81-2113	1711123254		103		MLGC FEE GAS #1066	MONROE GAS	13.5	MID LOUISIANA GAS
8209951	81-2018	1707321464		108		MLGC FEE GAS #978	MONROE GAS	7.1	MID LOUISIANA GAS
8209984	81-2019	1711122707		108		MLGC FEE GAS #979	MONROE GAS	6.1	MID LOUISIANA GAS
8209985	81-2020	1711122708		108		MLGC FEE GAS #980	MONROE GAS	5.6	MID LOUISIANA GAS
8209986	81-2021	1711122739		108		MLGC FEE GAS #986	MONROE GAS	13.8	MID LOUISIANA GAS
8209987	81-2022	1711122743		108		MLGC FEE GAS #994	MONROE GAS	7.5	MID LOUISIANA GAS
8209988	81-2023	1711122746		108		MLGC FEE GAS #997	MONROE GAS	3.7	MID LOUISIANA GAS
8209989	81-2024	1711122747		108		MLGC FEE GAS #998	MONROE GAS	6.8	MID LOUISIANA GAS
-PELICAN DRILLING						RECEIVED: 12/14/81 JA: LA			
8209998	81-2171	1707321408		108		CULPEPPER #1	MONROE	12.3	MID LOUISIANA GAS
-PINTAIL MINERALS CORP						RECEIVED: 12/14/81 JA: LA			
8209962	81-2081	1703120577		108		LAFITTE #1	CANNISNIA LAKE	13.0	UNITED GAS PIPELI
-QUINTANA PETROLEUM CORP						RECEIVED: 12/14/81 JA: LA			
8209976	81-2099	1700720318		107-DP		HEIRS OF NUMA COUPEL #1	BAY NATCHEZ	0.0	SOUTHERN NATURAL
-RELIANCE & HOOTKINS-SMITH						RECEIVED: 12/14/81 JA: LA			
8209949	81-2115	1711121711		108		BARRON #1	MONROE	5.0	TEXAS GAS TRANSMI
8209950	81-2114	1711121803		108		H D GREEN #1	MONROE	3.0	TEXAS GAS TRANSMI
-SHADRACK PRODUCTION CO						RECEIVED: 12/14/81 JA: LA			
8209948	81-2116	1711123323		103		J C BRIGHT #1	MONROE	13.0	WEST MONROE GAS G
8209948	81-2116	1711123323		107-TF		J C BRIGHT #1	MONROE	13.0	WEST MONROE GAS G
-SOUTH LOUISIANA PRODUCTION CO INC						RECEIVED: 12/14/81 JA: LA			
8210059	81-2100	1703320090		107-DP		MEAD #1 17,600' TUSC RA SUC-H	IRENE	3321.0	TRANSCONTINENTAL
-SUN OIL COMPANY (DELAWARE)						RECEIVED: 12/14/81 JA: LA			
8209979	81-2185	1708320457		103		DELHI UT #196-2 DELHI HOLT BRYANT	DELHI	13.5	TEXAS EASTERN TRA
8209959	81-2105	1703120346		108-ER		SOUTHWOOD A #2	SPIDER	0.0	J-W OPERATING CO
-SUPERIOR OIL CO						RECEIVED: 12/14/81 JA: LA			
8209982	81-2182	1711321066		103		S L 3057 #40	LAC BLANC	750.0	TENNESSEE GAS PIP
-TARGET OIL & GAS INC						RECEIVED: 12/14/81 JA: LA			
8209957	81-2187	1703121281		103		MARTIN TIMBER #1	LOGANSPORT FIELD	36.0	LOUISIANA INTRAST
-TEXACO INC						RECEIVED: 12/14/81 JA: LA			
8209955	81-2186	1705721694		103		BDC UB 126 VUB	BAY DE CHENE	250.0	KAISER ALUMINUM &
8209977	81-2098	1710922407		107-DP		SL 188 CAILLOU ISLAND #698	CAILLOU ISLAND	1569.0	
-TEXAS INTERNATIONAL PET CORP						RECEIVED: 12/14/81 JA: LA			
8209980	81-2184	1772720112		103		STATE LEASE 4039 #10-D	HALF MOON LAKE	51.0	SOUTHERN NATURAL
-THE STONE OIL CORPORATION						RECEIVED: 12/14/81 JA: LA			
8210007	81-2179	1711320983		103		EXXON FEE #11	LAC BLANC	273.8	TENNESSEE GAS PIP

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
-UNION OIL COMPANY OF CALIF			RECEIVED: 12/14/81 JA: LA						
8209975	81-2181	1710922346		103		LL&E B #50	LAKE HATCH	1000.0	COLUMBIA GAS TRAN
-VISTA INVESTMENTS			RECEIVED: 12/14/81 JA: LA						
9210050	81-2128	1711123278		103		MANVILLE #1	MONROE	13.0	IMC EXPLORATION C
8210047	81-2129	1711123279		103		MANVILLE #2	MONROE	13.0	IMC EXPLORATION C
MONTANA BOARD OF OIL & GAS CONSERVATION									
-AMINOIL USA INC			RECEIVED: 12/14/81 JA: MT						
8210062	4-81-39	2508321383		102-4		BIDEGARAY #1	RIDGELAWN	54.8	MONTANA DAKOTA UT
8210064	4-81-40	2508321383		103		BIDEGARAY #1	RIDGELAWN	54.8	MONTANA DAKOTA UT
8210061	4-81-37	2508321410		102-4		STEINBEISSER #1	RIDGELAWN	91.3	MONTANA DAKOTA UT
8210063	4-81-38	2508321410		103		STEINBEISSER #1	RIDGELAWN	91.3	MONTANA DAKOTA UT
-FALCON-COLORADO EXPLORATION INC			RECEIVED: 12/14/81 JA: MT						
8210065	3-81-35	2507121755		102-2		LEWIS 1-23	SWANSON CREEK	8.0	MONTANA-DAKOTA UT
-PATRICK PETROLEUM CORP OF MICHIGAN			RECEIVED: 12/14/81 JA: MT						
8210068	3-81-33	2509121331		102-4		WILLIAMS #1-34	WILDCAT	38.0	PHILLIPS PETROLEU
-SUN OIL COMPANY (DELAWARE)			RECEIVED: 12/14/81 JA: MT						
8210069	3-81-34	2508521207		102-2		V T TORGERSON #1	WILDCAT	6.0	
-SUPERIOR OIL CO			RECEIVED: 12/14/81 JA: MT						
8210066	3-81-32	2508321403		103		HUNTER-VANDERHOOF #1	FAIRVIEW	0.0	MONTANA-DAKOTA UT
-TEXACO INC			RECEIVED: 12/14/81 JA: MT						
8210067	3-81-31	2510121576		108		B M WILKINS #1	KEVIN SUNBURST	13.0	MONTANA POWER CO
-WILLIAM HERBERT HUNT TRUST ESTATE			RECEIVED: 12/14/81 JA: MT						
8210060	3-81-6	2509121310		102-2		SNELLMAN #1	KATY LAKE	8.4	TRUE OIL CO
NORTH DAKOTA INDUSTRIAL COMMISSION									
-AMERADA HESS CORPORATION			RECEIVED: 12/09/81 JA: ND						
8210078	397	3305301107		102-3		U S A YTTREDAHL 2-34	CHARLSON	400.0	MONTANA DAKOTA UT
-COASTAL OIL & GAS CORP			RECEIVED: 12/09/81 JA: ND						
8210074	401	3300700224		102-2		COG/ALAQ 23-142-101 BN #2	BIG STICK	229.0	WESTERN GAS PROCE
-GULF OIL CORPORATION			RECEIVED: 12/09/81 JA: ND						
8210073	402	3310500867		102-2		GORDER 1-19-2B	FORT BUFORD	3.0	
8210071	404	3300700632		102-2		LEDA TERRES 2-13-2B	LITTLE KNIFE	2.0	MONTANA DAKOTA UT
8210070	405	3300700595		102-2		LENA ROMANYSHYN 1-33-3B	LITTLE KNIFE	26.0	MONTANA DAKOTA UT
8210072	403	3302500148		102-2		MARY SABROSKY 1-7-1A	LITTLE KNIFE	23.0	MONTANA DAKOTA UT
-GULF OIL CORPORATION			RECEIVED: 12/11/81 JA: ND						
8210080		3302500180		102-2		ECKES 1-7-4A	LITTLE KNIFE	11.0	MONTANA DAKOTA UT
8210079	406	3302500176		102-2		SEIDLE 1-34-2C	LITTLE KNIFE	25.0	MONTANA DAKOTA UT
8210081		3302500116		102-2		SHIRLEY DOLEZAL 2-20-2D	LITTLE KNIFE	5.0	MONTANA DAKOTA UT
-TEXACO INC			RECEIVED: 12/09/81 JA: ND						
8210076	399	3305301237		102-2		C M LOOMER #13	BLUE BUTTES SOUTH	61.0	MONTANA DAKOTA UT
8210077	398	3305301246		102-2		C M LOOMER #14	BLUE BUTTES SOUTH	135.0	MONTANA DAKOTA UT
8210075	400	3305301187		102-2		M MOSHOLDER #4	BLUE BUTTES SOUTH	196.0	MONTANA DAKOTA UT
OREGON DEPARTMENT OF GEOLOGY & MINERAL INDUSTRIES									
-REICHHOLD ENERGY CORP			RECEIVED: 12/14/81 JA: OR						
8210084		3600900084		102-2		COLUMBIA COUNTY 13-1	MIST GAS FIELD	400.0	NORTHWEST NATURAL
8210083		3600900047		102-2		CROWN ZELLERBACH 42-1	MIST GAS FIELD	252.0	NORTHWEST NATURAL
8210082		3600900091		102-2		LONGVIEW FIBRE 12-33 REDRILL	MIST GAS FIELD	400.0	NORTHWEST NATURAL
UTAH DIVISION OF OIL,GAS, & MINING									
-CONOCO INC			RECEIVED: 12/15/81 JA: UT						

JD NO	JA DKT	API NO	D	SEC	CAT	WELL NAME	FIELD NAME	PROD	PURCHASER
8210085	K 117-5	4304730754		107	TF	CONOCO STATE 32 #21	OURAY	182.0	MOUNTAIN FUEL SUP
VIRGINIA DEPARTMENT OF LABOR & INDUSTRY									
-COLUMBIA GAS TRANSMISSION CORP		RECEIVED: 11/24/81 JA: VA							
8053692A		4502719961		108		BIG SANDY FUEL CO 809548	VIRGINIA FIELD AREA HAYS	7.3	COLUMBIA GAS TRAN
8053703A		4502719963		108		BIG SANDY FUEL CO 809549	VIRGINIA FIELD AREA HAYS	1.6	COLUMBIA GAS TRAN
8053691A		4502719956		108		BIG SANDY FUEL CO 809551	VIRGINIA FIELD AREA HAYS	3.6	COLUMBIA GAS TRAN
8053693A		4505119861		108		BIG SANDY FUEL CO 809554	VIRGINIA FIELD AREA HAYS	12.8	COLUMBIA GAS TRAN
8053701A		4502720209		108		BULL CREEK COAL CO 820214	VIRGINIA FIELD AREA HAYS	2.4	COLUMBIA GAS TRAN
8053697A		4502720151		108		LONDON HACKNEY 809766	VIRGINIA FIELD AREA HAYS	6.0	COLUMBIA GAS TRAN
8053696A		4502720039		108		PITTSTON CO #1 809581	VIRGINIA FIELD AREA HAYS	13.8	COLUMBIA GAS TRAN
8053707A		4505120069		108		PITTSTON CO #16 809644	VIRGINIA FIELD AREA HAYS	11.0	COLUMBIA GAS TRAN
8053694A		4502720074		108		PITTSTON CO #21 809680	VIRGINIA FIELD AREA HAYS	2.6	COLUMBIA GAS TRAN
8053705A		4505120124		108		PITTSTON CO #21 809760	VIRGINIA FIELD AREA HAYS	9.1	COLUMBIA GAS TRAN
8053702A		4505120145		108		PITTSTON CO #39 809764	VIRGINIA HAYSI	9.6	COLUMBIA GAS TRAN
8053709A		4505120043		108		PITTSTON CO #7 809588	VIRGINIA FIELD AREA HAYS	12.8	COLUMBIA GAS TRAN
8106623A		4502720267		108		PITTSTON CO NO 51 820469	HAYSI FIELD	2.8	COLUMBIA GAS TRAN
8053700A		4502720053		108		PITTSTON CO 809584	VIRGINIA FIELD AREA HAYS	2.1	COLUMBIA GAS TRAN
8053706A		4502720046		108		PITTSTON CO 809586	VIRGINIA FIELD AREA HAYS	9.1	COLUMBIA GAS TRAN
8053708A		4505120104		108		PITTSTON CO 809689	VIRGINIA FIELD AREA HAYS	15.3	COLUMBIA GAS TRAN
8053699A		4505120132		108		PITTSTON CO 809757	VIRGINIA FIELD AREA HAYS	9.2	COLUMBIA GAS TRAN
8053698A		4505120133		108		PITTSTON CO 809758	VIRGINIA FIELD AREA HAYS	10.4	COLUMBIA GAS TRAN
8053704A		4505120123		108		PITTSTON CO 809761	VIRGINIA FIELD AREA HAYS	1.2	COLUMBIA GAS TRAN
8106622A		4502720298		108		PITTSTON CO 820554	HAYSI FIELD	14.6	COLUMBIA GAS TRAN
8053695A		4505120138		108		THE PITTSTON CO #37 809834	VIRGINIA FIELD AREA HAYS	5.0	COLUMBIA GAS TRAN

BILLING CODE 6717-01-C

The above notices of determination were received from the indicated jurisdictional agencies by the Federal Energy Regulatory Commission pursuant to the National Gas Policy Act of 1978 and 18 CFR 274.104. Negative determinations are indicated by a "D" before the section code. Estimated annual production (PROD) is in million cubic feet HMCF). An (*) before the Control (JD) number denotes additional purchasers listed at the end of the notice.

The applications for determination are available for inspectioin except to the extent such material is confidential under 18 CFR 275.206, at the Commission's Division of Public Information, Room 1000, 825 North Capitol St., Washington, D.C. Persons objecting to any of these determinations may, in accordance with 18 CFR 275.203 and 275.204, file a protest with the Commission, on or before January 20, 1982.

Categories within each NGPA section are indicated by the following codes:

Section 102–1: New OCS lease
102–2: New well (2.5 mile rule)
102–3: New well (1000 ft. rule)
102–4: New onshore reservoir
102–5: New reservoir on old OCS lease
Section 107–DP: 15,000 feet or deeper
107–GB: Geopressured brine
107–C5: Coal seams
107–DV: Devaonian shale
107–PE: Production enhancement
107–TF: New tight formation
107–RT: Recompletion tight formation
Section 108: Stripper well
108–SA: Seasonally affected
108–ER: Enhanced recovery
108–PB: Pressure buildup

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–156 Filed 1–4–82; 8:45 am]

BILLING CODE 6717–01–M

Office of Hearings and Appeals

Implementation of Special Refund Procedures

AGENCY: Office of Hearings and Appeals, Energy.

ACTION: Notice of Implementation of Special Refund Procedures and Solicitation of Further Comments.

SUMMARY: The Office of Hearings and Appeals of the Department of Energy announces the procedures for filing Applications for Refund from funds obtained from Lewtex Oil and Gas Corporation, a natural gas processor, in settlement of enforcement proceedings brought by the DOE's Office of Enforcement.

DATES AND ADDRESSES: Applications for refund must be postmarked on or before April 5, 1982, and should be addressed to Lewtex Oil and Gas Corporation Consent Order Refund Proceeding, Office of Hearings and Appeals, Department of Energy, 2000 M Street NW., Washington, D.C. 20461. Comments must be postmarked on or before February 4, 1982, and should be addressed to the Office of Hearings and Appeals, Department of Energy, 2000 M Street NW., Washington, D.C. 20461.

FOR FURTHER INFORMATION CONTACT: Thomas O. Mann, Deputy Director, Office of Hearings and Appeals, Department of Energy, 2000 M Street NW., Washington, D.C. 20461, (202) 653–3137.

SUPPLEMENTARY INFORMATION: In accordance with § 205.282(c) of the procedural regulations of the Department of Energy, 10 CFR 205.282(c), notice is hereby given of the issuance of the final decision and order set out below. The final decision and order relates to a consent order between Lewtex Oil and Gas Corporation and the Office of Enforcement of the DOE's Economic Regulatory Administration. *See* 44 FR 47396 (1979). The consent order is intended to settle all disputes between the DOE and the firm with regard to prices charged by Lewtex in sales of natural gas liquids (NGLs). Under the terms of the consent order, Lewtex has deposited $251,384.58 into an escrow account. It is stipulated in the consent order that the refund amount is in settlement of possible enforcement actions based upon allegations that Lewtex had overcharged its purchasers of NGLs during the period September 1973 through March 1977.

The Office of Hearings and Appeals had previously issued a proposed decision and order which tentatively established a two-stage refund procedure and solicited comments from interested parties concerning the proper disposition of the consent order fund. The proposed decision and order discussing the distribution of funds obtained through the Lewtex consent order was issued on May 1, 1981. 46 FR 25535 (1981).

The final decision and order, pubished concurrently with this notice, reflects our analysis of comments received from interested parties. As we indicate in the final decision, applications for refund from the escrow fund may now be filed. Applications will be accepted provided they are postmarked no later than April 5, 1982. *See* 10 CFR 205.283. We will accept applications from all persons who purchased NGLs which originated with Lewtex during the period covered by the consent order. In order to establish entitlement to a portion of the consent order fund, a purchaser must establish, in addition to proof of purchase of the volume claimed, that the purchaser did not pass through price increases to its own customers. The specific information required in an application for refund is set forth in the final decision and order.

The final decision does not address the issue of the proper disposition in a second-stage proceeding of the remainder, if any, of the consent order fund after all meritorious claims have been paid in the first stage outlined above. Instead, the final decision and order reserves the question of the proper disposition of the remaining consent order fund until after all meritorious applications for refund have been paid in the first-stage proceeding, since the most appropriate disposition of the remaining funds may be determined, to a great extent, by the amount of money that remains after the first-stage proceeding. The final decision states that if the remainder is small, it may well be most efficient simply to turn the remainder over to the United States Treasury. *See* 10 CFR 205.287(c). However, the final decision also states that the second-stage procedure outlined in the proposed decision may well be implemented if sufficient funds remain. Therefore, the final decision solicits further comments on the appropriate disposition of the remainder, if any, of the consent order fund after all meritorious claims have been paid.

Commenting parties are requested to submit two copies of their comments. Comments should be postmarked on or before February 4, 1982, and should be addressed to the address set forth at the beginning of that notice. All comments received in this proceeding will be available for public inspection in the Public Docket Room of the Office of Hearings and Appeals, located in Room B–120, 2000 M Street NW., Washington, D.C., between the hours of 1:00 to 5:00 p.m., Monday through Friday, except Federal holidays.

Dated: December 28, 1981.

George B. Breznay,

Director, Office of Hearings and Appeals.

December 28, 1981.

Decision and Order of the Department of Energy

Special Refund Procedures

Name of Petitioner: Office of Enforcement, Economic Regulatory Administration: In the Matter of Lewtex Oil & Gas Corporation.
Date of Filing: February 11, 1981.

Case Number: BEF-0033.

Under the procedural regulations of the Department of Energy, the Economic Regulatory Administration's Office of Enforcement (OE) may request the Office of Hearings and Appeals (OHA) to formulate and implement special procedures to make refunds to injured persons in order to remedy the effects of alleged violations of the DOE regulations. *See* 10 CFR Part 205, Subpart V.

In accordance with these regulatory provisions, the OE filed a Petition for the Implementation of Special Refund Procedures in connection with a consent order entered into with Lewtex Oil & Gas Corporation (Lewtex). Under the terms of the consent order Lewtex agreed to remit to the DOE $251,384.58 for its alleged violations of the DOE price regulations in sales of natural gas liquids (NGLs). The funds have been paid to the DOE and are now being held in an escrow account under the jurisdiction of the DOE pending receipt of instructions from the Office of Hearings and Appeals regarding their distribution.

Background

In its audits of Lewtex's Olney, Throckmorton, and Graham gas plants, the OE found possible violations of DOE price regulations with respect to first sales of NGLs during the period September 1973 through March 1977. Lewtex sold NGLs from these three plants to only two companies during this period: Warren Petroleum Company, a wholly-owned subsidiary of Gulf Oil, Corporation (Gulf), and Enterprise Products, Inc. (Enterprise). On July 31, 1979, the OE and Lewtex entered into a Consent Order under which Lewtex agreed to refund $189,744 plus applicable interest to the DOE in settlement of all claims and disputes between the parties arising from the audits of Lewtex's gas plants. The parties stipulated that the funds were to be distributed by the DOE pursuant to Subpart V proceedings. The terms of the final consent order were published in the **Federal Register** on August 13, 1979. *See* 44 FR 47396 (1979). Interested parties were given an opportunity to comment on the terms of the Consent Order and to submit written notice of potential claims against the refund account. Gulf submitted comments identifying itself as a potential claimant.

On February 11, 1981, the OE filed a Petition for the Implementation of Special Refund Procedures for the Lewtex consent order funds. A proposed decision and order which tentatively established special refund procedures to be used in adjudicating claims to the Lewtex settlement funds was issued on May 1, 1981 by the OHA. *See* 46 FR 25535 (1981). In the proposed decision we tentatively established a two-stage special refund procedure for the Lewtex consent order fund. In the first stage, those firms who were the first purchasers of NGLs during the relevant period from Lewtex and who believed they were eligible for a portion of the consent order fund could file Applications for Refund pursuant to 10 CFR 205.283. Downstream purchasers would also be permitted to file Applications for Refund. Each application would be analyzed, and individual determinations on the merits of each would be made. All meritorious claims would then be paid. Finally, we suggested as the second stage of the refund process that the first purchasers, Gulf and Enterprise, submit proposals which set forth appropriate mechanisms for returning moneys to the parties who likely paid increased prices as a result of the alleged overcharges. We alternatively proposed that if such plans proved infeasible, any portion of the settlement fund which, because of prohibitive administrative costs, might otherwise go undistributed be deposited in the Treasury of the United States. *See* 10 CFR 205.287(c).

The proposed decision and order was published in the **Federal Register**, and a copy was sent to all interested parties. The comment period specified in the **Federal Register** has passed. Both Gulf and Enterprise have submitted notices of claim and comments regarding the proposed procedures. Since both firms maintain that they did not pass on any of the overcharges to their customers, neither firm submitted a plan for distribution. Several other parties also submitted comments; however, most of these comments concerned either the proposed distribution of funds through the first purchasers or the possible deposit of residual moneys into the United States Treasury.

The purpose of this decision will be to establish the mechanism by which firms that purchased NGLs from Lewtex may file applications for refund. We shall first discuss the comments which we received concerning the first-stage refund procedures which we announced in the proposed decision and order in this case. Then we shall discuss in detail the Application for Refund procedures that we have decided to adopt. We shall not, however, discuss the second stage of the refund process in this decision. As noted above, the first purchasers identified in this case have filed claims which, if meritorious, could thoroughly deplete the consent order fund. In that event no second stage would be necessary. Moreover, our determination concerning the final disposition of any residual funds will necessarily depend on the size of the fund. *Office of Enforcement*, 9 DOE ¶ 82,508 (1981) (hereinafter cited as *Coline*). It is therefore unnecessary at this time for us to reach the issues raised by the commenters concerning the proposed disposition of funds remaining after all meritorious claims have been paid. (*1*)

Jurisdiction and Authority to Fashion Refund Procedures

We previously determined that the jurisdictional requirements of Subpart V have been satisfied with regard to Lewtex. We therefore asserted jurisdiction over this case in an Interlocutory Order issued on April 8, 1981. *See Office of Enforcement*, 8 DOE ¶ 82,516 (1981).

Only Gulf submitted substantive comments concerning the first-stage procedures following the issuance of the proposed decision and order for this case. Enterprise confined its submission to a notification of its claim against the fund. With respect to the OHA's jurisdiction and authority to adopt the proposed refund procedures, Gulf contended that we may fashion refund procedures only for entities that were direct purchasers from Lewtex. If Gulf's contention were sustained, only it and Enterprise would be eligible to file Applications for Refund in the first stage of this refund proceeding.

With respect to the OHA's jurisdiction to fashion special refund procedures, the DOE Subpart V regulations provide that "[T]his subpart shall be applicable to those situations in which the Department of Energy is unable to readily identify persons who are entitled to refunds specified in * * * a Consent Order, or to readily ascertain the amounts that such persons are entitled to receive." 10 CFR 205.280. After reviewing the record compiled in this proceeding, we have concluded that the implementation of Subpart V proceedings is appropriate. Even if there are only one or two first purchasers in a particular case, it may be difficult to determine who was injured because those first purchasers may have passed on the overchargers. Moreover, although the OHA has occasionally refused to assert jurisdiction where the OE could identify the first purchaser who was overcharged, *see, e.g., Armour Oil Co.*, 5 DOE ¶ 82,528 (1980) at 85,112 n.2, recent changes in the regulatory system have caused us to reconsider our position. Until recently, crude oil and refined

petroleum products were subject to a comprehensive price regulation scheme which could be utilized to facilitate the channeling of refunds to persons who were adversely affected by alleged violations of the DOE price regulations. For example, the DOE could issue an order directing a firm that had overcharged its customers to roll back its prices for a period of time in order to refund overcharge amounts. *(2)* However, on January 28, 1981, the President exempted crude oil and all refined petroleum products from the DOE regulatory program. Exec. Order No. 12287, 46 FR 9909 (1981). As a result of decontrol, there is no maximum lawful price upoon which a rollback order may be based. In order to refund money to the parties affected by the alleged overcharges, a determination must therefore be made regarding the extent to which purchasers of the NGLs involved absorbed the overcharges or passed the higher costs through to downstream customers by raising their own sales prices. Consequently, even in cases where a potentially injured first purchaser can be identified, it is difficult to ascertain the amount, if any, that such a firm or individual should receive. In these cases, therefore, the persons who were injured and therefore entitled to refunds are not readily identifiable, and the amount of the refunds that those persons should receive is not readily ascertainable. For these reasons, the Office of Hearings and Appeals has decided to exercise jurisdiction over the funds received by the DOE in settlement of the enforcement proceedings underlying the Petition for Implementation of Special Refund Proceedings in this case.

Gulf additionally contends that the OHA does not have authority to fashion refund procedures that would result in funds being disbursed to firms that were not direct purchasers from Lewtex. Gulf apparently objects to both the proposed first and second stages of the refund procedures on the grounds that downstream purchasers and consumers may obtain refunds at either state. Gulf argues that because only direct purchasers may maintain an action for overcharges under section 210 of the Economic Stabilization Act (ESA), 12 U.S.C. 1904 note (1976), only direct purchasers should be able to recover from DOE settlements. Furthermore, Gulf particularly objects to our proposals that first purchasers be obliged to demonstrate that they did not pass on the overcharges to their customers and, if a first purchaser cannot make such a showing, that downstream purchasers may qualify for refunds. Gulf maintains that such a requirement is beyond the OHA's authority. Gulf therefore contends that the entire consent order fund must be distributed among first purchasers only.

Inasmuch as the present determination only establishes procedures for the filing of Applications for Refunds, we will not address Gulf's objections to out proposals for the distribution of residual funds. In addition, we shall reserve our discussion of whether the OHA may require a showing of injury until later in this Decision. As for its objections to the first-stage procedures, Gulf consistently confuses a party's private right of action under section 210 of the ESA with DOE enforcement actions on behalf of the general public that are authorized by section 209 of the ESA as well as other statutory provisions. The cases which Gulf cites concerning private remedies under section 210 of the ESA are simply inapposite to special refund procedures, which are based upon section 209 of the ESA and "the broad purposes of the Congressional mandate in both the ESA and the EPAA." *Bonray Oil Co. v. DOE,* 472 F. Supp. 899, 904 (W.D. Okla. 1978), *aff'd on basis of district court opinion,* 601 F.2d 1191 (Temp. Emer. Ct. App. 1979). *(3)* The Temporary Emergency Court of Appeals has expressly held that private actions authorized by section 210 and governmental actions authorized by section 209 serve different purposes and may be maintained separately at the same time. *Bulzan v. Atlantic Richfield Co.,* 620 F.2d 278 (Temp Emer. Ct. App. 1980); *see also S.O.S. Gasoline Enterprises v. Doe,* 3 Fed. Energy Guidelines ¶ 26,231 (D.D.C. 1981).

Gulf also contends that *United States* v. *Ringer,* 492 f. supp. 350 (D. Colo. 1980), and certain opinions of the Comptroller General of the United States support the proposition that the DOE may not order restitution to indirect purchasers.

In *Ringer* the court refused to enforce a price rollback provision because it was not evident that future purchasers, who would benefit from the rollback, were the same parties as previously overcharged customers. Similarly, the Comptroller General has objected to certain proposals for distribution of settlement funds on the basis of his belief that there was not a sufficient nexus to the overcharged parties. *(4)* We believe that those opinions, which are not binding upon this office, are inconsistent with the DOE's broad restitutionary authority as outlined by the courts. The Temporary Emergency Court of Appeals has construed § 209 of the ESA as conferring extremely broad remedial authority on DOE and the courts. For example, in *Sauder v. DOE,* 648 F.2d 1341 (Temp. Emer. Ct. App. 1981), the court stated that it did not "believe that Congress intended to limit the agency's and courts' power to restore overcharges." The court further stated that "[t]here is no indication * * * that (section 209) * * * attempts to limit the power of the courts or the agency to restitution or to a particularly strict interpretation of restitution." *id.* Thus, nothing in the governing statutes nor in judicial interpretation of those statutes prohibits the DOE from refunding moneys to indirect purchasers. Moreover, the refund procedures which we adopt today expressly require that an applicant must establish, *inter alia,* that it purchased NGLs produced by Lewtex in order to qualify for a refund. We believe that the adoption of this criterion will alleviate the concerns of the *Ringer* court and the Comptroller General. Accordingly, we reject Gulf's contention and hold that first purchasers *and* downstream customers may file Applications for Refund.

Comments on the Proposed First Stage Procedures

In the proposed decision which we issued for this case, we tentatively concluded that as the first stage of the refund process we would accept Applications for Refunds from parties which had purchased NGLs produced by Lewtex. In addition to satisfying the filing requirements of 10 CFR 205.283, the applicant would be required to demonstrate that it purchased during the relevant time period a specific quantity of products which were produced with or from the NGSs sold by Lewtex. In addition, unless the applicant was an ultimate consumer, a party claiming that it was injured would also have to demonstrate that it absorbed any cost increase resulting from the alleged overcharges. We also stated that we would accept and evaluate on a case-by-case basis applications filed on behalf of groups of claimants identifying themselves as adversely affected purchasers. Finally, we solicited comments from all interested parties concerning our proposals.

In its comments, Gulf disputed the OHA's authority to require a showing that a claimant did not pass on overcharges to its customer,s even though the firm stated in its submission that its subsidiary had banks of unrecouped product cost increases that equalled its refund claim. *See* Gulf Comments at 3–6.

Gulf made identical claims in *Coline,* our most recent Subpart V

determination. In that Decision, we found that:

[O]ur examination of the seminal cases discussing the use of passing on in antitrust cases has led us to the conclusion that the principles adopted there are inapplicable to these proceedings as a matter of law. In addition, we have concluded that the policies which led the Supreme Court to adopt its position in those cases are inapplicable to special refund cases.

Coline, slip op. at 11. We concluded in *Coline* that although the cases cited by Gulf might be applicable to private enforcement actions brought pursuant to section 210 of the ESA, we are not legally bound by them in Subpart V proceedings, which deal with the distribution of funds obtained through section 209 of the ESA. *Id.* at 11–12. Moreover, we determined that the two policy reasons underlying the courts' rejection of passing on evidence in antitrust cases—difficulty of proof of passing on and the possible deterrence of plaintiffs due to the likely diminished amount of recovery—were inapplicable to special refund cases. Specifically, we concluded that the difficulty of proof problem envisioned by the courts was obviated in the present situation because the products involved had been the subject of an extensive regulatory scheme and, moreover, the OHA has substantial expertise in making determinations of this sort. *Id.* at 13. Furthermore, we concluded that our requirement of evidence establishing that an applicant was injured would not deter future enforcement actions by the OE. Specifically, we noted that:

Unlike the plaintiff in a private action, the agency has no pecuniary interest in the funds. The DOE's purpose in prosecuting these cases is to remedy violations of the regulations by forcing disgorgement of illegally obtained funds, thereby fostering the goal in Section 4(b)(1)(F) of the Emergency Petroleum Allocation Act of providing for the "equitable distribution of * * * refined petroleum products at equitable prices * * * among all users." 15 U.S.C. 753(b)(1)(F).

Id. at 12–13. Accordingly, we have concluded that Gulf's contentions concerning our determination to require a showing that an applicant was injured by the alleged overcharges are without merit.

Application for Refund Procedures

After having considered the comments received concerning the first stage proceedings tentatively adopted in our Proposed Decision and Order we have concluded that: (i) The OHA has properly asserted jurisdiction over this case pursuant to 10 CFR Part 205, Subpart V; (ii) the OHA has authority to implement all of the procedures which were tentatively adopted in the proposed Decision for this case; (iii) Applications for Refund should now be accepted from firms which purchases NGLs from Lewtex. Before we discuss the particular refund procedures which we have decided to adopt, however, there remains one issue that needs to be considered.

In reviewing the Lewtex consent order in order to be certain that the procedures which we proposed for the distribution of the settlement fund were consistent with the underlying consent order, we noted a possible conflict with Paragraph 9 of the order. That section provides that:

Should 10 CFR Part 205, Subpart V be finally determined to be invalid or should claims be asserted against Lewtex by third parties pursuant to Section 210 of the Economic Stabilization Act of 1970, which claims allege that said third parties were overcharged with respect to the Specified Transactions in the Audit Period, DOE agrees that any and all sums paid hereunder shall be remitted by DOE to the party or parties finally determined to be entitled thereto so that in making the refunds required by this Consent Order, Lewtex shall not thereafter be subjected to double liability as to any amounts refunded hereunder to DOE with respect to the Specified Transactions.

Consent Order at 9.

The record in this proceeding indicates that claims have been filed by Lewtex's first purchasers which, if meritorious, would exhaust the consent order fund. Consequently, there is some danger that claimants could obtain refunds through Subpart V proceedings and subsequently, when those funds have run out, seek further funds through a private, section 210 action. If the private plaintiff were to be successful and there was none of the settlement money left, Lewtex might be subjected to double liability in contradiction to the expressed intent of the parties in the consent order. None of the parties who have participated in this proceeding have commented on the effect which Paragraph 9 has on the proposed refund procedures.

There are two courses of action which we have considered adopting in order to effectuate the intent of the parties to the consent order. First, we could delay distribution of the funds until the statute of limitations had run for section 210 actions. We have concluded that this would be an undesirable choice. Our particular concern is that because the applicable statute of limitations would be determined by the law of the jurisdiction in which the action was brought, the appropriate waiting period is uncertain. *See Ashland Oil Co.* v. *Union Oil Co.*, 567 F.2d 984 (Temp. Emer. Ct. App. 1977). A lengthy delay in distribution would be contrary to the DOE's policy of expeditiously concluding pending enforcement matters.

Another possible solution for avoiding potential double liability would be to require any claimant to sign an election of remedies or waiver agreement before actually receiving funds from the escrow account. We adopted an election of remedies provision in *Office of Enforcement*, 8 DOE ¶82,597 (1981) (hereinafter cited as *Vickers*). In that case the OE and Vickers agreed as part of the consent order to recommend a waiver provision in the resulting petition for special refund procedures. In that case we concluded that "(A)doption of the election provision is appropriate because it is not inconsistent with the purposes of Subpart V, it furthers important policies, and it implements the expressed intent of the Consent order." *Vickers* at 85,395. We also found that no rights of any injured party would be prejudiced by the adoption of the election provision since the party would be permitted to prove its claim through an Application for Refund under 10 CFR 205.283 prior to any requirement that it waive its section 210 claims.

We believe that the adoption of a similar provision is warranted in this case. Although not expressly called for by either the consent order or the petition, the adoption of this provision would appear to be consistent with the expressed intent of the parties that Lewtex not be subjected to potential double liability. Moreover, it is not inconsistent with the provisions of 10 CFR 205.292(e), which states that "(I)n establishing standards and procedures for implementing refund distribution, the Office of Hearings and Appeals shall take into account the desirability of * * * resolving to the maximum extent practicable all outstanding claims." Finally, as in *Vickers*, no rights of any injured party will be prejudiced. In fact, since a lengthy period of time has passed since the period of alleged overcharges, which apparently ended November 30, 1976, Consent order at Paragraph 10, it may well be that the statute of limitations has run on all potential section 210 claims. Consequently, we have concluded on the basis of the circumstances present in this case that we should adopt an election of remedies requirment. (5) Accordingly, prior to receipt of any moneys from the Lewtex settlement fund, all applicants shall be required to execute the election of remedies provision which is attached to this Decision as Appendix A.

With the exception of the above-discussed waiver provision, we have decided to adopt the refund procedures which we proposed in our May 1, 1981 determination. We have determined to accept Applications for Refund of a portion of the Lewtex consent order funds filed on or before April 5, 1982. *See* 10 CFR 205.283. We will consider all applications, although we may later impose a lower dollar limit on claims. *See* 10 CFR 205.286(b). Applications made on behalf of a class of claimants will be considered on a case-by-case basis. An application must be in writing, signed by the applicant, and specify that it pertains to the Lewtex consent order fund, case number BEF–0033. If the applicant is not a first purchaser from Lewtex, it should indicate from whom the NGLs were purchased and indicate what basis the applicant has for its belief that the NGLs which it purchased originated from the natural gas processing plants named in the consent order.

Any application for a refund in excess of $100 must be filed in duplicate, and a copy of that application will be available for public inspection in the Public Docket Room of the Office of Hearings and Appeals, Room B–120, 2000 M Street, NW., Washington, D.C. Any applicant who believes that this application contains confidential information must so indicate on the first page of his application and submit two additional copies of his application from which the information that the applicant claims is confidential has been deleted, together with a statement specifying why any such information is privileged or confidential. Each application shall indicate whether the applicant or any person acting on his instructions has filed or intends to file any other application or claim of whatever nature regarding the matters at issue in this proceeding or in the underlying enforcement proceeding. Each application shall also include the following statement: "I swear (or affirm) that the information submitted is true and accurate to the best of my knowledge and belief." *See* 10 CFR 205.283(c); 18 U.S.C. 1001. In addition, the applicant should furnish the name, position title, and telephone number of a person who may be contacted by the OHA for additional information concerning the Application. All applications should be sent to: Lewtex Consent Order Refund Proceeding, Office of Hearings and Appeals, Department of Energy, 2000 M Street, NW., Washington, D.C. 20461. All Applications for Refund received within the time limit specified will be processed pursuant to 10 CFR 205.284.

In order to assist applicants in establishing eligibility for a portion of the consent order funds, the following section discusses the showing that should be made by refiners, resellers, retailers and end-users of the NGLs covered by the consent order:

A. Each applicant should report its volume of purchases of NGLs by calendar quarter for the period of time for which it is claiming it was injured by the alleged overcharges.

B. Each applicant should specify how it used the NGLs—*e.g.*, as a petrochemical producer, refiner, reseller or ultimate user.

C. If the applicant is a refiner or reseller, it should state whether it maintained banks of unrecouped product cost increases from the date of the alleged violation through January 27, 1981. It should furnish the OHA with quarterly bank calculations for the entire period.

D. The applicant must state whether it or any of its affiliates have submitted any other Applications for Refunds.

E. The applicant must submit evidence to establish that it did not pass on the overcharges to its customers. For example, a firm may submit market surveys to show that price increases to recover overcharges were infeasible.

F. The applicant should report whether it is currently involved as a party in a DOE enforcement action or a private, section 210 action that may affect its unrecovered ("banked") costs of NGLs. The applicant should briefly describe the action and its current status. Of course, the applicant is under a continuing obligation to notify the OHA of any new or newly discovered information that is relevant to its Application for Refund. *See* 10 CFR 205.9(d).

Distribution of the Remainder of the Consent Order Funds

Several commenters in addition to Gulf addressed our proposed distribution of the remainder, if any, of the consent order funds after all meritorious claims have been paid. Those comments can be divided into two groups. First, some comments contend that the Office of Hearings and Appeals lacks the statutory or regulatory authority to implement the proposed distribution. Second, some comments acknowledge that this Office possesses the authority to fashion such a restitutionary mechanism, but suggest alternatives to or modifications of our original proposal. In this Decision, we are not implementing the second stage refund procedure. Such a step would be difficult to initiate before the analysis and processing of Applications for Refund filed in the first stage of the distribution of the Consent Order funds to claimants, since the amount remaining after all meritorious claims have been paid directly affects the appropriateness of the second stage distribution scheme. Moreover, in the present case claimants have asserted claims which, if meritorious, would completely exhaust the consent order fund. However, in order for members of the public to be made aware of outstanding issues and be able to comment on them, we summarized and briefly addressed the comments received concerning the proposed second stage procedure in the *Vickers* decision. *See Vickers*, 8 DOE at 85,398–99. Many of the same parties who commented on the second-stage procedures proposed for the *Vickers* case submitted virtually identical comments in the present case. We will not reiterate our discussion of these issues. We continue to seek additional comments on these issues.

It is therefore ordered that:

The refund amount provided by Lewtex Oil & Gas Corporation will be distributed in the manner set forth in the foregoing Decision.

Dated: December 28, 1981.

George B. Breznay,

Director, Office of Hearings and Appeals.

Footnotes

(*1*) We discussed many of these comments in *Office of Enforcement*, 8 DOE ¶ 82,597 (1981).

(*2*) If a purchasing firm was a refiner or reseller rather than an ultimate consumer, the rolled back price would reduce its "increased product costs" and therefore reduce the maximum lawful selling price which it could charge consumers. *See* 10 CFR 212.83 *and* 212.93.

(*3*) While Gulf has cited cases holding that only direct purchasers may sue under ESA section 210, *e.g.*, *Stertz v. Gulf Oil Corp.*, F.2d (Temp. Emer. Ct. App. 1981), *Arnson v. General Motors Corp.*, 377 F. Supp. 209 (N.D. Ohio 1974), and *Go-Tane Service Stations v. Ashland Oil, Inc.*, No. 79–C–1675 (N.D. Ill. 1981), none of those cases state that the DOE's remedial authority is limited to refunding monies only to direct purchasers. Additionally, Gulf cited *Bow Valley Coal Resources, Inc. v. DOE*, Civ. Action No. C–80–0162W (D. Utah 1980). We are unable to understand the relevance of that citation because the only reported opinions in that case hold that (i) a certain first purchaser may maintain a section 210 action and (ii) the action was dismissed as to the DOE.

(*4*) In his October 10, 1980, letter the Comptroller General discussed a proposal for distribution of funds obtained through a consent order with Getty Oil Company and

specifically held that "in order for any distribution of the Getty funds to satisfy the statutory and regulatory requirements for restitution, it must be made in approximate proportion to the injury actually sustained to Getty customers and to *ultimate customers of Getty products* who were the victims of the overcharges." GAO letter at 7 (Emphasis added). In his April 1, 1981 letter, while espousing a view of our authority to institute the proposed second-stage refund procedures which we find overly narrow, *see Office of Enforcement*, 8 DOE ¶ 82,597 (1981) at 85,398, the Comptroller General again directed his criticism towards refunds "to persons or organizations with no necessary nexus to the alleged violations which gave rise to the consent orders." April 1, 1981 Letter at 8.

(5) We wish to emphasize that although we have determined that we shall adopt an election of remedies provision in this case in order to effectuate the apparent intent of the parties, this determination is limited to the facts present in this case. We perceive an internal inconsistency in a consent order which provides that the funds should be distributed through Subpart V proceedings and that the fund shall be distributed to successful private litigants. Were it not for the staleness of the potential claims in this particular case, we might be reluctant to even accept jurisdiction of this case.

Appendix A—Election of Remedies Provision

In consideration of the sum of money obtained through Subpart V proceedings before the Office of Hearings and Appeals of the Department of Energy in Case No. BEF-0033, I, (give name), with full knowledge of the provisions of section 210 of the Economic Stabilization Act, 12 U.S.C. 1904 note, and my rights thereunder, expressly waive and release any and all rights under that section to bring a private action against Lewtex Oil & Gas Corporation for alleged overcharges in transactions that occurred between September 1973 and March 1977 in any products covered by the Consent Order entered into between the Department of Energy and Lewtex Oil & Gas Corporation on July 31, 1979. Section 210 permits me to bring an action for damages, including an action for treble damages in the case of a willful violation, for any prices charged by my supplier in excess of the prices permitted by the Mandatory Petroleum Price Regulations. Notice to my supplier may be necessary prior to my bringing an action under section 210. My right to bring an action under section 210 expires on September 30, 1981 with respect to any act committed or liability incurred on or after that expiration date. My right to bring such an action may also be limited by the statute of limitations applicable to such actions.

(Signature) _____

(Date) _____

[FR Doc. 82-29 Filed 1-4-82; 8:45 am]

BILLING CODE 6450-01-M

Special Refund Procedures and Solicitation of Comments

AGENCY: Office of Hearings and Appeals, DOE.

ACTION: Notice of implementation of special refund procedures and solicitation of comments.

SUMMARY: The Office of Hearings and Appeals of the Department of Energy solicits comments concerning the appropriate procedures to be followed in refunding to adversely affected parties $3,000,000 obtained by the DOE under the terms of a consent order entered into with the Pennzoil Company. The funds were provided by the firm in order to settle enforcement proceedings brought by the Office of Special Counsel.

DATE AND ADDRESS: Comments must be filed on or before February 4, 1982, and should be addressed to the Office of Hearings and Appeals, Department of Energy, 2000 M Street NW., Washington, D.C. 20461. All comments should display conspicuously a reference to case number BEF-0072.

FOR FURTHER INFORMATION CONTACT: Thomas O. Mann, Deputy Director, Office of Hearings and Appeals, Department of Energy, 2000 M Street NW., Washington, D.C. 20461, (202) 653-3137.

SUPPLEMENTARY INFORMATION: In accordance with § 205.282(b) of the procedural regulations of the Department of Energy, 10 CFR 205.282(b), notice is hereby given of the issuance of the Proposed Decision and Order set out below. The Proposed Decision and Order tentatively establishes procedures to distribute to adversely affected parties a total of $3,000,000 obtained by the DOE under the terms of a consent order entered into with the Pennzoil Company. The funds were provided to the DOE by the firm in order to settle all claims and disputes between Pennzoil and the DOE regarding the manner in which Pennzoil applied the federal price and allocation regulations with respect to its importation, refining, and sale of crude oil and covered petroleum products during the period between March 6, 1973 and December 31, 1980. In the consent order, the parties stipulated that the funds were to be distributed by the DOE pursuant to 10 CFR Part 205, Subpart V.

The Proposed Decision and Order sets forth the procedures and standards that the DOE has tentatively formulated to distribute the contents of the escrow account funded by Pennzoil. The DOE has tentatively decided that Applications for Refund should be accepted from the initial purchasers of covered products from Pennzoil during the audit period. In addition, the DOE determined that Applications for Refund also should be accepted from all persons who bought Pennzoil products during the relevant time periods. The Proposed Decision and Order provides that in order to be entitled to receive any portion of the settlement funds, a purchaser must furnish the DOE with evidence which demonstrates that the claimant was injured by the alleged unlawful prices for covered products charged by Pennzoil, including specific documentation concerning the date, place, price, and volume of product purchased, whether the increased costs were absorbed by the claimant or passed through to other purchasers, and the extent of any injury alleged to have been suffered.

The Proposed Decision and Order also provides for the distribution of any funds remaining after all valid claims are paid. The Proposed Decision and Order states DOE's view that refunds might be made in the form of lowered energy or energy-related costs in the areas where the persons who are likely to have been injured by the alleged overcharges may reside. The DOE also solicits proposals from the public concerning the distribution of any funds remaining after claims have been paid. In the alternative, the DOE suggests that any remaining funds which would otherwise go undistributed be deposited in the Treasury of the United States.

It should be pointed out that until final procedures are adopted, no claims for refunds will be accepted. Applications for Refund therefore should *not* be filed at this time. Appropriate public notice, including notice published in the Federal Register, will be provided prior to the acceptance of claims.

Any member of the public may submit written comments regarding the proposed refund procedures. Commenting parties are requested to submit two copies of their comments. Comments should be submitted by February 4, 1982 and should be sent to the address set forth at the beginning of this notice. All comments received in this proceeding will be available for public inspection in the Public Docket Room of the Office of Hearings and Appeals, Room B-120, 2000 M Street NW., Washington, D.C. between the hours of 1:00 to 5:00 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, D.C. on December 29, 1981.

George B. Breznay,

Director, Office of Hearings and Appeals.

December 29, 1981.

Proposed Decision and Order of the Department of Energy—Special Refund Procedures

Name of Petitioner: Office of Special Counsel: In the Matter Of Pennzoil Company.

Date of Filing: August 11, 1981.

Case Number: BEF–0072.

Under the procedural regulations of the Department of Energy, the Economic Regulatory Administration's Office of Special Counsel (OSC) may request the Office of Hearings and Appeals to formulate and implement special procedures to make refunds in order to remedy the effects of alleged violations of the DOE regulations. *See* 10 CFR Part 205, Subpart V.

In accordance with these regulatory provisions, the OCS recently filed a Petition for the Implementation of Special Refund Proceedings in connection with a consent order entered into with the Pennzoil Company (Pennzoil). Under the terms of this consent order, the firm agreed to make refunds for its alleged violations of the DOE price regulations in the following amounts: (i) $3 million to be distributed in accordance with the directives of the OHA pursuant to special refund proceedings; (ii) $3.5 million to certain electric utility companies subject to fuel adjustment clauses, provided that such entities agreed to execute an appropriate release and waiver of claims against Pennzoil; (iii) $3.5 million to the Defense Fuel Supply Center. *See* Consent Order, §§ 402–03. The consent order further provided that to the extent any funds remained from category (ii), all residual funds would be deposited with the category (i) funds for disposition through special refund proceedings. All category (ii) funds were distributed by Pennzoil. Consequently, the sum of $3 million is now being held in an escrow account under the jurisdiction of the DOE pending receipt of instructions from the Office of Hearings and Appeals regarding its final distribution.

I. Background

Pennzoil is a "refiner" as that term was defined in 10 CFR 212.31. During the relevant time periods, Pennzoil was subject to the Mandatory Petroleum Price Regulations set forth in 10 CFR Part 212, Subpart E. That Subpart governed the maximum prices that could lawfully be charged by refiners in the sale of fuel oil, motor gasoline, and other covered products. In addition, Pennzoil was subject to the Mandatory Petroleum Allocation Regulations set forth in 10 CFR Part 211.

In connection with its compliance activities, the OSC conducted an extensive audit of Pennzoil's pricing and allocation practices, including the manner in which the firm applied the federal petroleum price and allocation regulations with respect to its importation, refining, and sale of crude oil and covered petroleum products during the period March 6, 1973 through December 31, 1980. Following extensive negotiations, the DOE and Pennzoil entered into a consent order in order to resolve all of the issues raised during the OSC's audit except the following: (1) The matters involved in the case of *Pennzoil Company v. DOE, et al.*, No. 78–335 (D.Del.); (2) Pennzoil's compliance with the entitlements regulations with respect to certain transactions occurring during the period July 1976 through December 1977 between Pennzoil and certain small refiners as part of a general industry investigation by DOE; and (3) Pennzoil's compliance with DOE's regulations regarding marginal and newly discovered crude oil properties. The proposed consent order was executed on January 18, 1981 and published for public comment in the **Federal Register** on January 26, 1981. *See* 46 FR 8101 (1981). The OSC received comments from two parties.(*1*) After the regulatory comment period had expired and the OSC had considered all of the comments which it had received, a slightly modified consent order was adopted as a final order on July 9, 1981. *See* 46 FR 36927 (1981).(*2*)

II. Jurisdiction

The OSC filed a Petition for the Implementation of Special Refund Procedures in connection with the Pennzoil consent order on August 11, 1981. We have previously discussed the jurisdictional prerequisites for such petitions in *Office of Enforcement*, 8 DOE ¶ 82,515 (1981). The Subpart V process is to be used in situations where the Department of Energy is unable to readily identify persons who are entitled to refunds or to readily ascertain the amounts that such persons are entitled to receive as a result of enforcement proceedings. 10 CFR 205.280. After reviewing the record developed in the Pennzoil case, we have concluded that the implementation of Subpart V proceedings is also appropriate here. In this case there is a significant degree of difficulty inherent in identifying the persons who were injured by the alleged overcharges and ascertaining the level of refunds that such persons should receive. Until recently, crude oil and refined petroleum products were subject to a comprehensive price regulation scheme which could be utilized to facilitate the channeling of refunds to adversely affected purchasers through price rollbacks. However, on January 28, 1981, the President exempted crude oil and all refined petroleum products from the DOE regulatory program. Exec. Order No. 12287, 46 FR 9909 (1981). As a result of decontrol, price rollbacks can no longer be used to refund moneys to purchasers who were overcharged in the past. Therefore, to make restitution to the parties affected by the alleged overcharges, a determination must generally be made regarding the extent to which purchasers of the products involved absorbed the overcharges or passed the higher costs through to their customers by raising their own sales prices. Moreover, the Pennzoil consent order has already provided for substantial refunds to certain identifiable direct purchasers of its petroleum products. The remaining persons entitled to refunds are not readily identifiable, and the amount of the refunds that any particular person should receive is not readily ascertainable. Under these circumstances, we believe that Subpart V provides the most useful mechanism to refund money to persons who were likely to have been injured by alleged pricing violations. The Office of Hearings and Appeals therefore has decided to exercise jurisdiction over the funds received by the DOE in settlement of the enforcement proceedings underlying the Petition for Implementation of Special Refund Procedures in the case of Pennzoil.

III. Authority to Fashion Refund Procedures

In several recent decisions we have considered Petitions for the Implementation of Special Refund Procedures under Subpart V. *See, e.g., Office of Enforcement*, 9 DOE ¶ ——, No. BEF–0033 (December 28, 1981) (hereinafter referred to as *Lewtex*); *Office of Enforcement*, 9 DOE ¶ 82,508 (1981) (hereinafter referrred to as *Coline*); *Office of Enforcement*, No. BEF–0049 (August 18, 1981) (proposed decision) (hereinafter referred to as *Worldwide*); *Office of Enforcement*, 8 DOE ¶ 82,597 (1981) (hereinafter referred to as *Vickers*). The December 28, 1981 *Lewtex* Decision is the most recent determination issued by the Office of Hearings and Appeals pursuant to Subpart V which establishes final procedures for the filing of applications for refunds of moneys received by the DOE under a consent order.

Subpart V authorizes the Office of Hearings and Appeals, upon request by

the appropriate enforcement official, to fashion special procedures to distribute moneys obtained as part of settlement agreements. 10 CFR 205.281, 205.282. This special refund process is part of an overall regulatory program which is intended to implement several different statutes. Congress provided for mandatory allocation and price ceilings for crude oil, residual fuel oil, and refined petroleum products in the Emergency Petroleum Allocation Act of 1973 (EPAA) (15 U.S.C. 751 *et seq.* (1976)). The authority to enforce regulations issued under the EPAA was granted by Section 5 of the EPAA, which incorporated enforcement authorities established in the Economic Stabilization Act (ESA) (12 U.S.C. 1904 note (1970)); EPAA, section 5(a) (15 U.S.C. 754(a)). The statutory authority to enforce the regulations governing the allocation and pricing of petroleum products was delegated to the Administrator of the Federal Energy Administration, and subsequently to the Secretary of Energy. Federal Energy Administration Act (FEAA), section 5 (15 U.S.C. 765 (1974)); Department of Energy Organization Act (DOE Act), section 201 (a) (42 U.S.C. § 7151(a) (1979)). The carry out these statutory mandates, the regulations of the Cost of Living Council, the Federal Energy Office, the Federal Energy Administration, and the DOE have provided throughout the existence of the price control program for the issuance of remedial orders "requiring a person to cease a violation or to eliminate or compensate for the effects of a violation, or both." 6 CFR 155.81(b) (1973); 10 CFR 205.2 (1974) (defining "remedial order").

As we have noted in previous Subpart V decisions, restitution is designed to accomplish two purposes: disgorgement of the fruits of a regulatory violation from the wrongdoer, and refunds to persons injured by the regulatory violation. *See generally Vickers; Sauder* v. *DOE,* 648 F.2d 1341 (Temp. Emer. Ct. App. 1981). The latter objective—refunds to overcharged persons—furthers the specific EPAA goal of providing for the "equitable distribution of * * * refined petroleum products at equitable prices * * * among all users." (15 U.S.C. §§ 753(b)(1)(F)).

IV. Proposed Refund Procedures

In view of the objectives expressed in the statutes and regulations discussed above, and the Pennzoil consent order itself, the procedures to be implemented in this case should, to the maximum extent practicable, provide for the distribution of the refund amount to parties who were adversely affected by the alleged violations.

As we have stated before, refunding moneys obtained through DOE enforcement proceedings is the primary focus of Subpart V. 10 CFR 205.280; *see Coline.* Subpart V offers a means of compensating many individuals who, because they either lack the resources or do not have a sufficient financial stake in the outcome to institute private lawsuits under section 210 of the ESA, have suffered injuries which would otherwise go unredressed. The Subpart V process is also an efficient administrative mechanism for returning alleged overcharges to injured parties because it eliminates the need for long and costly court actions.

Based upon our experience with Subpart V cases, we believe that the distribution of funds to overcharged persons should generally take place in two stages. In the first stage of the process, payment should be made to persons and firms who file applications for refund and demonstrate that they are entitled to a portion of the funds received by the DOE. After meritorious claims are paid in the first stage, a second stage may be necessary. In the second stage, there are a number of alternative procedures which could be adopted. Under one alternative, payments for the benefit of injured persons could be made to entities that are in a position to effectuate the restitutionary purposes discussed above. As a second alternative, or in the event that implementation of the methods discussed above would not accomplish their intended objectives or fails to exhaust all of the settlement fund, § 205.287(c) provides that "any remaining funds * * * shall be deposited in the United States Treasury or distributed in any manner specified in the Decision and Order referred to in § 205.282(c)." (10 CFR 205.287(c).

In the present determination, we shall propose first stage procedures and suggest possible second stage procedures for the distribution of the Pennzoil consent order funds. This Proposed Decision and Order shall be sent to all parties on the service list for this case and shall be published in the **Federal Register.** We are soliciting comments concerning the proposed disposition of these funds contained in this determination. Comments should be submitted on or before February 4, 1982. All comments will be made available for public inspection in the Public Docket Room of the Office of Hearings and Appeals, Room B–120, 2000 M Street, NW., Washington, D.C., between the hours of 1:00 and 5:00 p.m., Monday through Friday, except Federal holidays.

A. *Refunds to Identifiable Purchasers.*

1. *Eligible parties.* During the first stage in the refund process, the consent order funds should be distributed to claimants who satisfactorily demonstrate that they have been adversely affected by Pennzoil's alleged violations of the DOE regulations. We note that the first purchasers of the relevant products from the firm are likely to be claimants in this proceeding. These purchasers can be categorized as follows: (1) Resellers of petroleum products, (2) firms or individuals who used the product in question for the production or distribution of goods and services which were purchased by the public, and (3) entities which were ultimate consumers of the product they purchased from Pennzoil or an intermediate reseller. Many of these parties have already been identified and have received a refund through the non-Subpart V provisions of the consent order. The record in this proceeding indicates that Pennzoil paid $7 million to approximately seven parties pursuant to section 403 of the consent order prior to the OSC's submission of this Petition. Absent special circumstances, those parties which already received refunds will not be eligibile for further refunds.

To the extent that first purchasers who are resellers or who are involved in the production or distribution of goods and services can establish that they absorbed the alleged overcharges rather than passed them on to their customers, they will be entitled to a *pro rata* share of the consent order funds. In order to qualify for a refund, these first purchasers will be required to demonstrate that during the period covered by the consent order they would have kept their prices for petroleum products or goods and services at the same level had the alleged overcharges not occurred. While there are a variety of means by which a claimant could make this showing, a reseller or firm engaged in the production or distribution of goods and services generally should demonstrate that at the time it purchased covered products from its supplier, market conditions would not permit it to increase its prices to pass through the additional costs associated with the alleged overcharges. In addition, a reseller of petroleum products must have maintained until January 28, 1981, the date on which the President decontrolled all remaining covered products, a "bank" of unrecovered costs in order to demonstrate that it did not subsequently recover these costs by increasing its prices.

With respect to first purchasers who are ultimate consumers, we believe that

the above showing should not be necessary in order for a firm to qualify for a refund. The types of organizations and individuals that would be included in this group include home owners, schools, religious institutions, federal, state, and local government entities, research foundations, and any other individual or organization which is not engaged in the direct sale of goods or services. It is unlikely that these types of first purchasers would have passed the alleged overcharges through to others because they are non-profit entities which are not involved in the direct sale of goods or services to other consumers. In order to establish a claim, this type of first purchaser need demonstrate only that it purchased a specific quantity of product which was sold by Pennzoil during the relevant time period.

If the first purchasers are able to make the showings described above, the entire amount of the funds at issue in this proceeding may be disbursed to them. In the event that they are unable to make a satisfactory showing, firms and individuals who purchased products from the first purchasers will be eligible to receive a portion of these funds. However, all purchasers of products sold by Pennzoil may file refund applications.

2. Proposed procedures. In order to establish an entitlement to a refund, a person claiming to be an injured party must satisfactorily demonstrate that it purchased, during the relevant time period, a specific quantity of product which was sold by Pennzoil. Privity with either Pennzoil or one of its first purchasers need not be established; evidence need only be presented that the products purchased by the claimant flowed through a chain of distribution leading back to Pennzoil. In addition, unless the purchaser is an ultimate consumer, it should generally demonstrate that it did not pass through the cost increases resulting from the alleged overecharges to its own customers. For example, a purchaser who resold the identified product should be in a position to show that market conditions did not permit it to raise prices charged to downstream customers, and that consequently it was forced to absorb the cost increases that are represented by Pennzoil's alleged overcharges. In the absence of that showing, we could conclude that the claimant was not injured in a monetary sense by the alleged overcharge. However, in *Vickers* we noted that this showing could be too complicated for those individuals and firms who might otherwise be entitled to apply for refunds and who purchased relatively small amounts of product from the firm. We also observed that many of those purchasers might lack the type of records required to support such a showing. We therefore established in that case a threshold level of purchases under which applicants, primarily smaller firms and individuals, were not required to make a detailed showing of actual injury. For those applicants who were claiming a refund based on less than that level of purchases, we required only proof of the amount of product purchased by the applicant during the consent order period. This Proposed Decision is being published in the **Federal Register** so that interested parties will have an opportunity to submit comments on the tentative distribution scheme. We will consider a similar treatment for smaller claimants in this proceeding, and we specifically request comments from the public on this issue. *See Vickers; Office of Special Counsel for Compliance,* 4 DOE ¶ 82,511, at 85,043–44. Refunds to persons who establish an entitlement to a refund will be made on a volumetric basis—*i.e.*, based on the proportion of the product purchased by the applicant to the total amount of those products (whether motor gasoline, diesel fuel, or No. 2 fuel oil) sold by Pennzoil during the relevant period.

Any purchaser claiming a portion of the refund amount should file an Application for Refund pursuant to 10 CFR 205.283. Applications should provide all relevant information necessary to establish a claim, including specific documentation concerning the date, place, price, and volume of product purchased, the retention of increased costs, and the extent of any injury alleged. Detailed procedures for filing applications will be provided in a final Decision and Order. *See Vickers.* Before disposing of any of the funds received as a result of the consent order involved in this proceeding, we intend to publicize widely the distribution process an to provide and opportunity for any affected party to file a claim. In addition to publishing notice in the **Federal Register**, notice will be provided in publications in the areas in which Pennzoil marketed its products during the period covered by the consent order. As a final matter, we note that refund applications filed on behalf of groups of claimants identifying themselves as adversely affected purchasers also will be considered. Such applications will be evaluated on a case-by-case basis.

B. *Distribution of the Remainder of the Refund Amount.*

After all meritorious claimants have received the share of the settlement fund to which they are entitled, the settlement fund provided by Pennzoil pursuant to its consent order, while diminished, may not be exhausted. The remainder of the funds should be distributed during the second stage of the refund process in furtherance of the goals set forth in the DOE's enabling legislation and implementing regulations. In this decision, we are proposing several alternatives for the second-stage refund procedure. However, we wish to emphasize that any consideration of the second-stage procedure at this point in time involves a number of uncertainties. As we noted in *Coline* we would find such a step difficult to take before fully processing and analyzing the Applications for Refunds which will be filed in the first stage as we have outlined above. *See generally Coline,* 9 DOE at 85,055. As in that case, we intend to set forth a number of second-stage alternatives in this proposed decision, consider the comments received after publication in the **Federal Register**, and then issue a final Decision and Order establishing procedures for the first stage. In that decision, we will summarize and address briefly the comments received concerning the proposed second-stage procedure, and will solicit another round of comments on the distribution of the funds remaining after payment of claims in the first stage. In this way, we will have several opportunities to consider the outstanding issues before reaching a final decision on the second stage.

Since refunding money to adversely affected parties is the primary concern of Subpart V proceedings, any remaining funds should, if administratively and economically feasible, be distributed to groups of ultimate consumers who were likely to have borne a portion of the higher prices charged by Pennzoil. In view of the relatively small sums of money likely to be involved in claims by many ultimate consumers, and the improbability that members of this class will possess records sufficient to establish their claims, we anticipate that only a limited number of ultimate consumers who were actually injured by the alleged overcharges will be able to prove during the first stage of the refund process that they are entitled to refunds. *See Vickers.* The fact that claims to specific refunds may not have been proved, however, does not mean that injuries to ultimate consumers have not occurred. Rather, the absence of claims for the full amount of the settlement would tend to reflect the difficulty such parties encounter in establishing a valid claim for a portion of the consent order fund.

One alternative we propose is that after payments are made to successful claimants, additional refunds might be made in the form of lowered energy or energy-related costs in areas where the products associated with the alleged overcharges by Pennzoil were marketed. For example, in *Office of Special Counsel for Compliance*, No. DFF–0003 (March 13, 1981) (proposed decision), we proposed that the second-stage refund to consumers who were likely to have been overcharged be effected by using rate-regulated utilities to pass through the remaining funds to consumers through fuel adjustment clauses or other appropriate mechanisms. We observed that it is likely that the persons who purchased motor gasoline or heating oil in a particular area would reside there as well and would be ultimate consumers of electricity. They would therefore benefit from the proposed rate reduction. We further suggested that state governments in the affected areas also may be designated as refund recipients for the purpose of reducing energy-related expenses subject to their direct control. Although we cannot yet determine what actions we will take in the second stage, we will consider this type of restitutionary scheme as one possible alternative.

In the event that distribution schemes for the second stage prove to be inappropriate because of administrative costs or the lack of accurate information, we propose that the portion of the settlement fund which would go undistributed after the second stage be deposited in the United States Treasury. We also propose as an alterntive to the distribution scheme outlined above that any funds remaining after the first stage claims procedure be deposited directly into the United States Treasury. Subpart V regulations specifically sanction this course of action, *see* 10 CFR 205.287(c), and direct payments to the Treasury may well be appropriate in those cases where other remedies would be ineffectual or administratively burdensome. *See Citronelle-Mobile Gathering, Inc.* v. *O'Leary*, 499 F. Supp. 871 (S.D. Ala. 1980); *Golden Eagle Oil Co.*, 6 DOE ¶ 83,005 at 86,065 (1980); *cf. Chana's Auto Service Center*, 8 DOE ¶ 83,002 (1981). However, as noted above, we will not be in a position to decide what should be done with any remaining funds until after the first-stage refund procedure is completed. The amount of money available for the second stage of the refund process will be a factor that will influence the ultimate disposition of those funds.

It Is Therefore Ordered That:

The $3,000,000 refund amount supplied by the Pennzoil Company will be distributed in accordance with the foregoing Decision.

References

(1) The parties who submitted comments were the Transportation Group and the National Consumer Law Center. These parties have been included on the service list for this proceeding.

(2) The sole modification adopted by the parties was the elimination of provisions concerning Pennzoil's treatment of its banks of unrecouped product cost increases. *See* 46 FR 36927 (1981).

[FR Doc. 82-176 Filed 1-4-82; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL 2019-1, OPTS 211003]

Alpha-Chloroacetophenone; Denial of Citizen's Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Denial of Citizen's Petition.

SUMMARY: This notice announces the decision of the Administrator of the Environmental Protection Agency (EPA) to deny a citizen's petition requesting that EPA ban the manufacture, distribution, possession, or use of alpha-chloroacetophenone for use in tear gas thermal grenades or foggers.

FOR FURTHER INFORMATION CONTACT: John B. Ritch, Jr., Director, Industry Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, Rm. E–511, 401 M St., SW., Washington, D.C. 20460, Toll-free: (800–424–9065), In Washington, D.C.: (544–1404), Outside the USA: (Operator—202–554–1404).

A copy of the petition and all related information is located in Rm. E–107, Environmental Protection Agency, 401 M St., SW., Washington, D.C., 20460. It will be available for viewing and copying from 9:00 a.m. to 4:00 p.m. Monday through Friday, excluding legal holidays.

SUPPLEMENTARY INFORMATION:

I. Citizen's Petitions Under TSCA

Section 21 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2620, provides that any person may petition the Administrator of EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 6, or 8 or an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B). If the Administrator grants the petition, the Agency must promptly commence appropriate action in accordance with the petition. If the Administrator denies the petition, the reasons for doing so must be published in the **Federal Register**. The petitioner may commence a civil action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding as requested in the petition. Any such civil action shall be filed within 60 days after the Administrator's denial of the petition or, if the Administrator fails to grant or deny the petition within 90 days after filing the petition, within 60 days after the expiration of the 90-day period.

II. Summary of the Petition

On August 26, 1980, Mr. Thomas L. Rush of Oakwood Village, Ohio, submitted a petition to the Administrator to initiate action to ban the manufacture, processing, distribution in commerce, or use of alpha-chloroacetophenone (CN) for the purpose of being used as a tear gas dispersed as a thermally generated aerosol by any means (Rush, 1980). The petitioner presented three reasons for his request:

1. The primary gas produced by the discharge of a tear gas thermal grenade or compressed air fogger is phosgene, and phosgene is capable of instantaneously causing permanent pulmonary injury and, on a number of occasions, death by pulmonary edema.

2. Gas masks of any known type do not provide any protection from the effects of phosgene; only self-contained breathing respirators are effective.

3. The control of aerosol tear gas products, so as to protect innocent bystanders in buildings or urban settings, is virtually impossible.

The petitioner indicated that CN is a chemical substance that is capable of causing acute and subacute injuries and could be regulated by EPA under the Toxic Substances Control Act.

III. Evaluation of the Petitioner's Evidence and Other Information

To decide whether to grant this petition, the Agency evaluated the information and concerns presented by the petitioner, the references cited by the petitioner as evidence of risk, and numerous other references. These are all listed as part of the public record. The Agency also spoke with the petitioner, law enforcement officials, and representatives of some CN manufacturers and processors.

A. Risks and Benefits of CN-Containing Thermal Tear Gas Devices

Alpha-chloroacetophenone (CN), chemical formula $C_6H_5COCH_2Cl$, was discovered in 1869 and was used in chemical warfare in World War I. CN is still used as an active ingredient in tear gas products in the U.S.

CN is a crystalline solid that can be used as a gas, liquid, or solid. Generally, CN is found in one of three basic forms in tear gas products: large granulated crystals, pulverized fine dust, or suspended particulates in a liquid solvent.

CN can be dispersed as a tear gas by various means, depending on the specific needs of the user. The scope of the petition is limited to thermal (also called "Pyrotechnic") devices, which produce a thermally generated aerosol. Pyrotechnic devices burn and vaporize the chemical agent and release it in a smoke. They are designed only for outdoor use in riot control because their use indoors can cause fires (although one type of recently developed pyrotechnic grenade is reported to be fire-safe). Pyrotechnic devices include grenades, projectiles, and foggers.

The suitability of CN for law enforcement derives from its reversible lacrimogenic (tear-producing) and essentially noninjurious stimulatory effect on corneal nerve endings, when used in low concentrations. However, a number of severe and permanent corneal injuries have been reported from excessive eye contamination by CN, such as via close-range spraying in the face (Grant, 1974).

CN is also a dermal irritant, and some heavily exposed persons have experienced skin problems in the form of primary irritant dermatitis or allergic contact dermatitis (Penneys, 1971). Symptoms may include itching, inflammation, swelling, and, in severe cases, necrosis (death of tissue). Sensitized individuals may subsequently develop dermatitis from substances chemically related to the initial allergen.

EPA identified reports of pulmonary damage and death in at least five cases associated with the use of CN by police (Stein and Kirwan, 1964; and Gonzales, 1954). All of these cases appear to have resulted from the inappropriate use of thermal tear gas devices, such as the prolonged exposure of individuals to CN in enclosed spaces or the incidence of fire as a result of indoor use of pyrotechnic devices. Death by pulmonary edema was confirmed in at least one instance, where the concentration of CN far exceeded the concentrations which would generally occur outdoors.

References cited in the petition and other information sources reviewed by EPA do not support the petitioner's assertion that phosgene is the primary or a significant combusion product of CN-containing pyrotechnic tear gas devices. The studies cited in the petition, which include infrared spectra and gas-liquid chromatographs, concluded that CN is the predominant combustion product, accompanied by smaller quantities of other products, none of which resemble phosgene. Further, the infrared spectra from a CN grenade do not demonstrate absorption bands characteristic of phosgene (Sass et al., 1966; and Shimanouchi, 1977). If any phosgene is produced from CN in tear gas thermal grenades and foggers, it would be expected only in harmless trace amounts.

Review of the information on the effectiveness of gas masks indicates that masks designed for use with tear gas offer adequate personal protection from tear gas. Most of these masks use an activated charcoal filtering system. Although masks designed for tear gas use do not provide protection from phosgene, there does not appear to be a need for protection from that chemical because it is not expected to be produced in any significant concentration during the use of a thermally generated aerosol device.

Thermal tear gas devices containing CN are used by law enforcement agencies as an effective alternative to potentially more physically damaging measures to control civil disorders and to subdue criminals. There appears to be a significant benefit to society from the proper use of thermal tear gas devices for control of dangerous situations.

As mentioned earlier, indoor use of pyrotechnic tear gas devices has caused some reported deaths and serious injuries from excessive and prolonged exposure or fire. However, the normal, manufacturer-recommended application of these devices in outdoor situations does not appear to carry the same level of risk of fire and excessive exposure. Training in the proper use of chemical agents is available to law enforcement officials from the manufacturers of tear gas devices. Such training is generally included in the curricula of police academies; also, the International Association of Chiefs of Police has prepared a guidance manual on the proper use of chemical agents which is available to law enforcement officials (Crockett, 1969).

B. Alternatives to the Use of CN-Containing Thermal Tear Gas Devices

In deciding how to act on this petition, EPA considered the suitability of available alternatives to the use of CN-containing thermal tear gas devices.

Aerosol devices, which are not thermally activated, possess the inherent limitation of having to be hand-held for short-range use and, therefore, could result in injury to law enforcement officers. Nonthermal grenades can be thrown for long-range use but do not have the advantage possessed by thermally activated tear gas devices of being too hot to be picked up and thrown back by rioters.

Ortho-chlorobenzylidene malononitrile (CS) is a widely used substitute for CN in tear gas devices. Today, the demand for CN and CS is approximately equal in the U.S., while CS is the primary chemical agent used in Europe. The U.S. military switched from the use of CN to CS in the early 1960's. Experiments conducted by the military with volunteers exposed to CN and CS show that CS produces a more immediate and severe reaction at lower levels of exposure. The median lethal dosage for CS is approximately twice that on CN (Crockett, 1969). Although its more immediate physiological effects at lower concentrations and its higher median lethal dosage may impart an advantage to CS over CN in some situations, there is no evidence that the risks associated with the proper use of CN outweigh the benefits.

IV. References

1. Crockett, T.S. Police Chemical Agents Manual, International Association of Chiefs of Police, Inc., Washington, D.C., 1969.

2. Fisher, A.A. Dermatitis due to tear gases (lacrimators), Intern. J. Dermatology 9: 91–95, 1970.

3. Gonzales, T.A., M. Vance, M. Helpern, and C.J. Umberger. Legal Medicine, Pathology and Toxicology, Appleton-Century-Crofts, New York, p. 518, 1954.

4. Grant, W.M. Toxicology of the Eye, Charles C. Thomas, Springfield, Illinois, 1974.

5. Penneys, N.S. Contact dermatitis to chloroacetophenone. Fed. Proc. 30: 96–99, 1971.

6. Rush, T.L. Petition to Administrator of EPA to initiate action to ban the manufacture, processing, distribution in commerce, or use of alpha-chloroacetophenone, August 26, 1980.

7. Sass, S., P.M. Davis, J.J. Martin, R.J. Piffath, and T.L. Fisher. Analytical studies of some CN-pyrotechnic-mix samples and disseminates using m-DNB, DB3, UV, IR, and GLC methods. Edgewood Arsenal Technical Report, EATR 4004, July, 1966.

8. Shimanouchi, T. Tables of molecular vibrational frequencies. J. Phys. Chem. Ref. Data 6: 993–1102, 1977.
9. Stein A.A. and W.E. Kirwan. Chloroacetophenone (tear-gas) poisoning: a clinicopathologic report, J. Forensic Sci. 9: 374–382, 1964.

V. Administrator's Decision

The petition to initiate a regulatory proceeding under TSCA for control of the manufacture, processing, or distribution in commerce of CN for use as a thermally generated tear gas is denied.

Based upon the review of information available to EPA on the risks posed by CN-containing thermal tear gas devices, the Agency has concluded that the benefits of using them outweigh the small potential for serious health injuries.

(Sec. 21, 90 Stat. 2042 (15 U.S.C. 2620))

Dated: December 16, 1981.

Anne M. Gorsuch,

Administrator.

[FR Doc. 82-126 Filed 1-4-82; 8:45 am]
BILLING CODE 6560-31-M

[OPTS-42005A; TSH-FRL-1988-6]

Alkyl Phthalates and Benzyl Butyl Phthalate; Follow-up Response To The Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In a previous notice which appeared in the Federal Register of October 30, 1981 (46 FR 53775), the EPA announced a preliminary decision not to propose a section 4(a) rule to require environmental or health effects testing of alkyl phthalates or benzyl butyl phthalate. This preliminary decision was made pending review of public comment received too late for consideration prior to the statutory deadline for action. On the basis of the now completed review, the Agency finds no reason to alter its preliminary decision. Therefore, the Agency has determined not to propose, at this time, a section 4(a) rule to require environmental or health effects testing of alkyl phthalates or benzyl butyl phthalate.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, Room E–511, 401 M St., SW., Washington, D.C., 20460, Toll free: (800–424–9065), In Washington, D.C.: (554–1404), Outside the USA: (Operator–202–554–1404).

SUPPLEMENTARY INFORMATION:

I. Background

In a previous notice which appeared in the Federal Register of October 30, 1981 (46 FR 53775), the Agency announced a preliminary decision not to propose, at that time, a section 4(a) rule under the Toxic Substances Control Act (TSCA) to require environmental or health effects testing of alkyl phthalates or benzyl butyl phthalate (BBP). This decision was based on the Agency's acceptance of a comprehensive testing proposal for phthalate esters from the Chemical Manufactures Association (CMA) on behalf of the Phthalate Esters Program Panel.

Previous to that notice, a public meeting was held on September 15, 1981, to brief the public on the CMA voluntary testing proposal as an alternative to a test rule under TSCA section 4. The briefing was followed by an opportunity for discussion and comment.

At the conclusion of the meeting, and by letter of September 21, 1981, the Natural Resources Defense Council (NRDC) requested additional time to review and comment on the proposed testing scheme for the phthalates.

Although EPA believes that it had provided adequate opportunity for the public to examine the proposed testing scheme and comment upon it, because this is the first time the Agency has considered deferring testing because of a voluntary scheme, EPA agreed to accept NRDC comments up to October 21, 1981. However, because section 4(e) of TSCA requires EPA to publish a response to the ITC within one year from the date a chemical is designated by the Committee and the one year anniversary date for benzyl butyl phthalate was October 24, 1981, EPA did not have an opportunity to consider NRDC's comments so that action could be taken by that date. Instead, EPA elected to issue a preliminary decision not to proceed with development of a test rule, giving the Agency time to consider NRDC's comments before issuing a final decision on the acceptability of the CMA program.

II. EPA's Response To Public Comment

On October 21, 1981, the Agency received NRDC's comments on (1) EPA's proposed decision not to require testing of the alkyl phthalates and BBP; and (2) CMA's proposed testing scheme for those compounds. NRDC raised various concerns, both legal and scientific. Their basic concerns, along with EPA's response to each, are summarized below. More detailed responses to these legal issues and responses to all scientific issues are included in the public record.

A. Legal Concerns

(1) NRDC argues that acceptance of a negotiated testing scheme in place of issuance of a section 4 test rule is contrary to the statutory language and legislative history indicating that Congress intended EPA to issue test rules even if appropriate testing was planned or ongoing.

EPA disagrees with this contention. EPA has found that neither the statutory language nor the legislative history would support NRDC's contention that negotiated testing schemes are an inappropriate response to ITC recommendations. The Agency believes that the purpose of section 4 was to assure that adequate data are developed, that the data are developed in expeditious fashion, and that industry assumes financial responsibility for testing. Because the negotiated scheme will meet these criteria, EPA believes it is consistent with section 4.

(2) NRDC contends that negotiated schemes in general, and this scheme in particular, are not an acceptable alternative to section 4 test rules because of certain specific legal and procedural deficiencies including (1) lack of public participation in their development; (2) lack of deadlines on completion of testing (which result in getting data later than under a rule); (3) lack of public access to data from the tests; and (4) lack of legal enforceability of industry's promise to perform testing.

EPA disagrees with this comment. First, EPA believes that there was adequate opportunity for public comment on the decision to defer testing. A public meeting was held on September 15, 1981, at which the voluntary approach was discussed. A docket containing all the pertinent information was available to the public beginning August 27, 1981. In addition, the basics of the phthalate voluntary testing scheme were presented at the Scoping Workshop on the 7th ITC Report, March 12, 1981, and the NTP/IRGL Phthalate Conference on June 11, 1981. The Agency, however, will continue to work with the public to develop new and better ways of facilitating that review. Comments were requested from the public on how to facilitate this in the tentative phthalates decision (46 FR 53775).

Second, the Agency believes that the schedule of testing provided by the industry in most cases will result in initiation and completion of testing significantly earlier than would result if the Agency pursued a test rule for these

substances. CMA has submitted an approximate schedule for testing to the Agency. Testing under this schedule would begin in November 1981 for some of the tests, no later than July 1982 for the majority of the tests and by February 1983 for the remaining Phase II (environmental) tests. Due to the experimental nature of the health program, the start of long-term testing is uncertain. However, the Agency generally expects any necessary long-term health effects testing to begin by mid-1983. If EPA were to pursue issuance of a test rule on these chemicals, this rule would probably not be final until January 1983 and short-term testing would not actually begin for several months after that. Furthermore, while EPA had not determined that it would pursue a tiered testing scheme for those chemicals, such a scheme, if included in a rule, would have further delayed the start of long-term testing which would occur in the later tiers. Therefore, the Agency believes that the CMA scheme will produce results at least as fast, and in most cases faster than would be obtainable under a test rule. Third, the CMA has agreed that all data on the tests it performs will be made available to the Agency, and that it will assert no claims of confidentiality on the data when they are transmitted to EPA.

Finally, the EPA believes that while the NRDC is correct in asserting that the negotiated test scheme is not enforceable, the importance of this fact is exaggerated. EPA believes that the real issue is whether the testing will actually be done, and EPA is convinced that CMA will not retreat from its commitment. The Agency will monitor the industry's performance, and if the CMA does not follow through, EPA intends to exercise its full legal authority under section 4 to require that all necessary testing be performed.

B. Scientific Concerns

(1) NRDC was concerned that the compounds selected for testing may not be truly representative of the alkyl phthalate class of compounds, and that to assume so *a priori* and without a subsequent review of the test data would be unwise.

EPA agrees that compound selection for testing is critical throughout the course of the testing program. A thorough review of the test data in regard to its applicability to other (untested) chemicals in the class has been the Agency's and CMA's intent from the start. Scoring systems for chemical selection, as described in CMA's proposal, will not be applied uncritically but are subject to modification as deemed necessary.

(2) NRDC stated that a significant gap in the CMA testing program is that no explicit criteria are given for making decisions about which higher level or additional tests are to be performed.

Given the large number of testing endpoints, both the EPA and the CMA felt that explicit decision criteria would be exceedingly difficult to formulate. Because the EPA will be involved in making all testing decisions, the absence of explicit decision criteria is not considered by the Agency to be a problem. EPA reserves its right to require industry to perform tests it considers necessary.

(3) NRDC believes that too few tests are being proposed in the CMA program to allow for effective regulation of the phthalate esters.

EPA disagrees with this contention. As discussed in detail in the Agency's preliminary decision not to require testing of the alkyl phthalates and BBP, CMA's program is ultimately expected to satisfy all of the ITC's and the Agency's needs for additional environmental effects of concern for the alkyl phthalates and BBP. CMA's proposal calls for the testing of a wide variety of aquatic species on an acute basis and what are regarded by Agency scientists to be very sensitive species on a chronic basis. CMA's program will also address the biodegradation and bioaccumulation of the phthalates. Based on past phthalate testing, these test data are expected to provide excellent guidance for setting acceptable concentration levels in the environment. Because of the demonstrated low toxicity of the phthalate esters to mammalian, bird and terrestial plant species, and because the chemical-physical properties and (limited) monitoring data indicate very low concentrations in the terrestrial environment; terrestrial toxicity testing was not considered a priority, nor did the ITC recommend such testing. CMA's health effects testing program admittedly involves an experimental approach in an attempt to screen and prioritize the alkyl phthalates for potential long-term testing. Should the initial tests not prove sufficient to demonstrate a clear dose-response relationship, first with the reference chemicals, and then with all of the chemicals under test, the Agency has requested, and CMA has agreed, to conduct other short-term assays as required both to validate the test battery and allow structure-activity inferences to be made. CMA has also made a commitment to perform additional testing, including long-term tests, where this appears to be indicated by the initial test results.

III. Public Record

EPA has established a public record for this decision not to pursue testing under section 4, docket number OPTS-42005, which is available for inspection from 8:00 a.m. to 4:00 p.m. Monday through Friday, excluding legal holidays, in Rm. E-106, 401 M St., SW., Washington, D.C. 20460. This record includes basic information considered by the Agency in developing this decision. This record includes the following information:

(1) **Federal Register** notices containing the designation of alkyl phthalates and benzyl butyl phthalate to the Priority List.

(2) Communications:

(a) Public and intra-agency of interagency memoranda, comments and proposals.

(b) Contact reports of telephone conversations.

(c) Meetings.

(3) Public comments on the ITC reports.

(4) Reports—published and unpublished data.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601)).

Dated: December 22, 1981.

Anne M. Gorsuch,

Administrator.

[FR Doc. 82-127 Filed 1-4-82; 8:45 am]

BILLING CODE 6560-31-M

[OPTS-51374; TSH-FRL-2018-8]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in EPA statements of interim policy published in the *Federal Register* of May 15, 1979 (44 FR 28558) and November 7, 1980 (45 FR 74378). This notice announces receipt of seven PMNs and provides a summary of each.

DATES: Written comments by:

PMN 81-645, 81-646, 81-647, 81-648, 81-649, 81-650, & 81-651: February 20, 1982.

ADDRESS: Written comments, identified by the document control number "[OPTS-51374]" and the specific PMN number should be sent to:

Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-409, 401 M St., SW., Washington, CC 20460, (202-382-3532).

FOR FURTHER INFORMATION CONTACT:

David Dull, Acting Chief, Notice Review Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. A-216, 401 M St., SW., Washington, DC 20460, (202-426-2601).

SUPPLEMENTARY INFORMATION: The following are summaries of information provided by the manufacturer on the PNMs received by EPA:

PMN 81-645

Close of Review Period. March 22, 1982.

Manufacturer's Identity. Air Products and Chemicals, Inc., Allentown, PA 18105

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Organic salts of tertiary aliphatic amines.

Use. The manufacturer states that the PMN substance will by used as a urethane polymerization catalyst.

Production Estimates. Claimed confidential business information.

Physical/Chemical Properties.

pH (3% in H_2O)—7.3
Specific gravity ($H_2O=1$)—1.058
Boiling point—327°F
Flash point (SETA FLASH)—230°F
Solubility, water—99%
Vapor pressure—1.0 mm Hg @ 32°F; 2.0 mm Hg @ 70°F; 4.0 mm Hg @ 100°F; 9.0 mm Hg @ 130°F

Toxicity Data

Acute oral toxicity LD_{50} (male rats)—6500 mg/kg; (female rats)—4290 mg/kg
Acute dermal toxicity (rabbit)—2.0 g/kg
(Primary) skin irritation (rabbit)—not an irritant
(Primary) eye irritation (rabbit)—not an irritant
Acute Inhalation Toxicity—no deaths at maximally achievable concentrations of 1.0 mg/1.

Exposure. The manufacture states that during manufacture, drumming and quality control an unspecified number of workers may have dermal and eye exposure at periodic intervals and that workers will wear protective clothing and equipment. At a site not controlled by the submitter, 8-10 workers may have dermal and eye exposure periodically.

Environmental Release/Disposal. The manufacturer states that there will be no significant release to the environment, and that the ultimate fate (or disposal) of the chemical will be coincident with disposal of the polyurethane foam in which it is distributed.

PMN 81-646

Close of Review Period. March 22, 1982.

Manufacturer's Identity. Air Products and Chemicals, Inc., Allentown, PA 18105.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Organic salts of tertiary aliphatic amines.

Use. The manufacturer states that the PMN substance will be used as a urethane polymerization catalyst.

Production Estimates. Claimed confidential business information.

Physical/Chemical Properties

pH (3% in H_2O)—7.3
Specific gravity ($H_2O=1$)—1.058
Boiling point—327°F
Flash point (SETA FLASH)—230°F
Solubility, water—>99%
Vapor pressure—1.0 mm Hg @ 32°F; 2.0 mm Hg @ 70°F; 4.0 mm Hg @ 100°F; 9.0 mm Hg @ 130°F

Toxicity Data

Acute oral toxicity LD_{50} (male rats)—6500 mg/kg; (female rats)—4290 mg/kg
Acute dermal toxicity (rabbit)—>2.0 g/kg
(Primary) skin irritation (rabbit)—not an irritant
(Primary) eye irritation (rabbit)—not an irritant
Acute Inhalation Toxicity—no deaths at maximally achievable concentrations of 1.0 mg/1.

Exposure. The manufacturer states that during manufacture, drumming and quality control an unspecified number of workers may have dermal and eye exposure at periodic intervals and that workers will wear protective clothing and equipment. At a site not controlled by the submitter, 8-10 workers may have dermal and eye exposure periodically.

Environmental Release/Disposal. The manufacturer states that there will be no significant release to the environment, and that the ultimate fate (or disposal) of the chemical will be coincident with disposal of the polyurethane foam in which it is distributed.

PMN 81-647

Close of Review Period. March 22, 1982.

Manufacturer's Identity. Air Products and Chemicals, Inc., Allentown, PA 18105

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Organic salts of tertiary aliphatic amines.

Use. The manufacturer states that the PMN substance will be used as a urethane polymerization catalyst.

Production Estimates. Claimed confidential business information.

Physical/Chemical Properties

pH (3% in H_2O)—7.3
Specific gravity ($H_2O=1$)—1.058
Boiling point—327°F
Flash point (SETA FLASH)—230°F
Solubility, water—99%
Vapor pressure—1.0 mm Hg @ 32°F; 2.0 mm Hg @ 70°F; 4.0 mm Hg @ 100°F; 9.0 mm Hg @ 130°F

Toxicity Data

Acute oral toxicity LD_{50} (male rats)—6500 mg/kg; (female rats)—4290 mg/kg
Acute dermal toxicity (rabbit)>2.0 g/kg
(Primary) skin irritation (rabbit)—not an irritant
(Primary) eye irritation (rabbit)—not an irritant
Acute Inhalation Toxicity—no deaths at maximally achievable concentrations of 1.0 mg/1.

Exposure. The manufacturer states that during manufacture, drumming and quality control an unspecified number of workers may have dermal and eye exposure at periodic intervals and that workers will wear protective clothing and equipment. At a site not controlled by the submitter, 8-10 workers may have dermal and eye exposure periodically.

Environmental Release/Disposal. The manufacturer states that there will be no significant release to the environment, and that the ultimate fate (or disposal) of the chemical will be coincident with disposal of the polyurethane foam in which it is distributed.

PMN 81-648

Close of Review Period. March 22, 1982.

Manufacturer's Identity. Claimed confidential business information.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Tetrasubstituted benzenamine.

Use. The manufacturer states that the PMN substance will be used as a company-limited intermediate and that the new chemical will be used to manufacture another chemical intermediate.

PRODUCTION ESTIMATES

	Maximum (kg)
First year	5,000
Second year	6,000
Third year	7,000

Physical/Chemical Properties

Melting point—224–228°C

Toxicity Data. No data were submitted.

Exposure. The manufacturer states that during manufacture and processing 5 workers may experience dermal and inhalation exposure, up to 2 hrs/day, up to 20 days/yr during transfer and cleanup operations. The manufacturer states that average and potential maximum concentrations for those operations are expected to be 0–10 mg/m^3 and 10–30 mg/m^3 respectively. The manufacturer also states that during use of the chemical up to 20 people may have dermal and inhalation exposure for a maximum of 0.3 hour/day for up to 5 days/yr during transfer operations at similar average and potential maximum exposure levels.

Environmental Release/Disposal. The manufacturer states that no release of the new chemical to land or water is expected and that release to air will be negligible. Disposal is by incineration.

PMN 81–649

Close of Review Period. March 22, 1982.

Manufacturer's Identity. Claimed confidential business information.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Tetrasubstituted benzene.

Use. The manufacturer states that the PMN substance will be used as a site limited intermediate and that the new chemical will be used to manufacture another chemical intermediate.

PRODUCTION ESTIMATES

	Maximum (kg)
First year	6,000
Second year	7,000
Third year	8,000

Physical/Chemical Properties

Melting point—130–132°C

Toxicity Data. No data were submitted.

Exposure. The manufacturers states that during manufacture and use 5 workers may experience dermal and inhalation exposure up to 2 hrs/day, up to 20 days/yr during transfer operations. The manufacturer also states that the average and potential maximum concentrations for these operations are expected to be 0–10 mg/m^3 and 1–30 mg/m^3 respectively.

Environmental Release/Disposal. The manufacturer states that no release of the new chemical to land or water is expected and that release to air will be negligible. Disposal is by incineration.

PMN 81–650

Close of Review Period. March 22, 1982.

Manufacturer's Identity. Claimed confidential business information.

Specific Chemical Identity. Polymer of hexanediolic acid and 2,2'-iminobisethanol.

Use. The manufacturer states that the PMN substance will have a site-limited use in chemical manufacture.

PRODUCTION ESTIMATES

	Maximum (kg)
First year	1
Second year	1
Third year	1

Physical/Chemical Properties

Solubility: water—>10%

Number Average Molecular Weight—300–400

Toxicity Data. No data were submitted.

Exposure. The manufacturer states that during manufacture and use 5 workers may experience dermal and inhalation exposure up to 0.5 hrs/day, up to 2 days/yr during transfer operations. The manufacturer also states that the average and maximum concentrations during these operations is expected to be 0–1 mg/m^3.

Environmental Release/Disposal. The manufacturer states that no release of the new chemical is expected to land or air and that 0–1 kg/year is expected to be released to water. The manufacturer also states that wastes generated during use will be treated in a biological treatment system.

PMN 81–651

Close of Review Period. March 22, 1982.

Manufacturer's Identity. Claimed confidential business information.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Tetrasubstituted benzene.

Use. The manufacturer states that the PMN substance will be used as a site-limited chemical intermediate and will be used to manufacture another chemical.

PRODUCTION ESTIMATES

	Maximum (kg/yr)
First year	4,000
Second year	5,000
Third year	6,000

Physical/Chemical Properties

Melting point—150–153°C

Toxicity Data. No data were submitted.

Exposure. The manufacturer states that during manufacture and use 5 workers may experience dermal and inhalation exposure up to 2 hrs/day, up to 50 days/yr during transfer operations. The manufacturer also states that average and potential maximum concentrations during these operations are expected to be 0–10 mg/m^3 and 1–30 mg/m^3 respectively.

Environmental Release/Disposal. The manufacturer states that no release is expected to land or water and that the release to air will be negligible. Disposal is by incineration.

Dated: December 24, 1981.

Woodson W. Bercaw,

Acting Director, Management Support Division.

[FR Doc. 82–125 Filed 1–4–82; 8:45 am]

BILLING CODE 6560–31–M

[AMS–FRL–2020–6]

Fuel Economy Retrofit Devices; Supplement to Announcement of Fuel Economy Retrofit Device Evaluation for "Grancor Air Computer (Self-Modulating Air Bleed)"

AGENCY: Environmental Protection Agency (EPA).

ACTION: Revised Notice of Fuel Economy Retrofit Device Evaluation.

SUMMARY: This announcement will supplement and revise the earlier EPA evaluation of the "Grancor Air Computer (Self-Modulating Air Bleed)" which was published on July 27, 1981 (46 FR 38403). At that time, EPA concluded that there was no technical basis to support any claims for a fuel economy benefit. The inventor of this device has contended that this conclusion was inappropriate in light of the test results on 1971 and earlier models supplied with his application for evaluation. Although EPA has not actually tested the device, it has re-examined the supporting documentation. As a result, EPA agrees the device can have a positive effect on fuel economy for vehicles from 1971 and earlier model years. The benefits arise from the

enleanment of the fuel-air mixture. In those years, carburetors were typically set to run rich since the richness improved driveability. However, as exhaust emission levels and fuel economy became a greater factor in vehicle design, carburetors were recalibrated to operate much leaner. This change in calibration essentially eliminates the possibility that further enleanment could be beneficial to fuel economy in post-1971 vehicles. Moreover, an excessively lean mixture may result in unacceptable driveability and could lead to excessive emission levels and possible engine damage. EPA tests of similar air-bleed devices on vehicles more representative of the current vehicle population have not shown any significant fuel economy gains.

Based on these tests and the fact that the applicant did not submit test data to show the device is effective on recent vehicles, EPA will reaffirm its conclusion on vehicles newer than the 1971 model year.

The results of the EPA evaluation are described completely in a report entitled: "EPA Evaluation of the Grancor Air Computer (Self-Modulating Air Bleed) Device Under Section 511 of the Motor Vehicle Information and Cost Savings Act." The text has been revised to address the contentions of the applicant. This entire report is contained in two volumes. The discussions, conclusions, and list of all attachments are listed in EPA–AA–TEB–511–81–13A, which consists of 14 pages. The attachments are contained in EPA–AA–TEB–511–81–13B, which consists of 106 pages. The attachments include correspondence between the applicant and EPA and all documents submitted in support of the application.

Copies of these reports may be obtained from the National Technical Information Service by using the above report numbers. Address requests to:

National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161, Telephone: (703) 487–4650 or FTS 737–4650.

FOR FURTHER INFORMATION CONTACT:

Merrill W. Korth, Emission Control Technology Division, Office of Mobile Source Air Pollution Control, Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, Michigan 48105, 313–668–4299.

Dated: December 23, 1981.

Kathleen M. Bennett,

Assistant Administrator for Air, Noise, and Radiation.

[FR Doc. 82–119 Filed 1–4–82; 8:45 am]

BILLING CODE 6560–26–M

FEDERAL MARITIME COMMISSION

[Independent Ocean Freight Forwarder License No. 1788]

American Cargo Corp.; Order of Revocation

On December 16, 1981, American Cargo Corporation, P.O. Box M–634, 95 River Street, Hoboken, NJ 07030 requested the Commission to revoke its Independent Ocean Freight Forwarder License No. 1788.

Therefore, by virtue of authority vested in me by the Federal Maritime Commission as set forth in Manual of Orders, Commission Order No. 1 (revised), § 10.01(e) dated November 12, 1981;

It is ordered, that Independent Ocean Freight Forwarder License No. 1788 issued to American Cargo Corporation, be revoked effective December 16, 1981, without prejudice to reapplication for a license in the future.

It is further ordered, that Independent Ocean Freight Forwarder License No. 1788 issued to American Cargo Corporation be returned to the Commission for cancellation.

It is further ordered, that a copy of this Order be published in the **Federal Register** and served upon American Cargo Corporation.

Albert J. Klingel, Jr.,

Director, Bureau of Certification and Licensing.

[FR Doc. 82–181 Filed 1–4–82; 8:45 am]

BILLING CODE 6730–01–M

[Independent Ocean Freight Forwarder License No. 2190]

Middle Eastern Transport Agencies, Ltd.; Order of Revocation

On December 16, 1981, Middle Eastern Transport Agencies, Ltd., One World Trade Center, Suite 1125, New York, NY 10048 surrendered its Independent Ocean Freight Forwarder License No. 2190 for revocation.

Therefore, by virtue of authority vested in me by the Federal Maritime Commission as set forth in Manual of Orders, Commission Order No. 1 (revised), § 10.01(e) dated November 12, 1981;

It is ordered, that Independent Ocean Freight Forwarder License No. 2190 issued to Middle Eastern Transport Agencies, Ltd. be revoked effective December 16, 1981, without prejudice to reapplication for a license in the future.

It is further ordered, that a copy of this Order be published in the **Federal Register** and served upon Middle Eastern Transport Agencies, Ltd.

Albert J. Klingel, Jr.,

Director, Bureau of Certification and Licensing.

[FR Doc. 82–180 Filed 1–4–82; 8:45 am]

BILLING CODE 6730–01–M

[Docket No. 80–63]

West Coast of Italy, Sicilian and Adriatic Ports, North Atlantic Range Ports Conference—Tariff Rule No. 26; Further Order To Show Cause

On August 21, 1981, the Commission ordered the member lines of the West Coast of Italy, Sicilian and Adriatic Ports, North Atlantic Range Ports Conference (WINAC), to cancel what was then Rule 26 in their FMC Tariff No. 3. Cancellation was ordered because, among other things, Rule 26 was found to constitute an unreasonable refusal to deliver cargo within the meaning of section 17, second paragraph of the Shipping Act, 1916 (46 U.S.C. 816, second paragraph). Tariff Rule No. 26, 20 S.R.R. 1489 (1981).

WINAC has responded to this order by filing an amendment to Tariff No. 3 on September 30, 1981 which deleted Rule 26 and replaced it with a new Rule 27 dealing with the same subject. This new tariff provision does not appear to comply with the Commission's August 21, 1981 Order.[1]

The present deficiency in rule 27 lies in Paragraphs B and C, which provide, in pertinent part, that:

> B. * * * the *cargo interests* shall be liable to pay:
>
> (2) * * * a (penalty) amount equal to double such difference of freight * * * (Emphasis supplied).
>
> C. * * * the carrier shall have a lien for the amount equal to double the difference of freight if the carrier or the conference verification service:
>
> (1) First seeks to collect such amount from the shipper; and
>
> (2) Has reasonable ground to believe that the consignee is at fault.
>
> In lieu of enforcing any lien by public sale, the carrier shall release the cargo to the consignee if the consignee furnishes a bond or other financial guarantee acceptable to the conference verification service for the total amount claimed by the carrier to be due pursuant to this rule.

This procedure for enforcing carrier-imposed penalties by refusing to deliver cargo to the consignee unless the

[1] Tariff matter which does not comply with a Commission order is subject to rejection under § 536.10(d) of the Rules (46 CFR 536.10(d)). In this instance, however, Rule No. 27 was allowed to take effect to permit full review of WINAC's submission by the Commission.

penalty is paid or a bond is posted is inconsistent with the Commission's directive that cargo liens not be used to require payment—either ultimately or in the first instance—from a person not "accurately determined to be the party at fault." 20 S.R.R. at 1497, n. 29. Although the August 21, 1981 Order did not use language which expressly invalidates any possible penalty system employing a cargo lien to collect penalty amounts, the Order clearly indicated there was to be no room for error concerning the consignee's "guilt." [2]

Specifically, Rule 27 is deficient for imposing liability for penalties against the "cargo interests," permitting the carrier to withhold delivery of the cargo whenever the carrier unilaterally believes the consignee is "guilty" of misdescribing cargo, and requiring that penalty payments be sought from the shipper in all cases, including those where the consignee is believed to be the "party at fault." The August 21st Order plainly states that carrier-imposed penalties may be assessed only against the party responsible for the cargo misdescription or misdeclaration.

Accordingly, WINAC will be directed to show cause why Rule 27 of its FMC tariff should not be cancelled for noncompliance with the Commission's Order of August 21, 1981.

Therefore, it is ordered, that pursuant to section 22 of the Shipping Act, 1916 (46 US.C. 821), Docket No. 80–63 be reopened and the member lines of the West Coast of Italy, Sicilian and Adriatic Ports, North Atlantic Range Ports Conference appear before the Commission and show cause why Rule 27 of their FMC Tariff No. 3 should not be cancelled for noncompliance with the Commission's August 21, 1981 Order in this proceeding insofar as it: (1) Makes the "cargo interests" rather than the "party at fault" liable for cargo misdescription penalties (Paragraph B); and (2) attempts to collect penalty amounts by means of a lien against the cargo which could be asserted against a consignee which is not in fact "at fault." (Paragraph C); and

It is further ordered, that the Commission's Bureau of Hearings and Field Operations continue to participate in this proceeding; and

It is further ordered, that this proceeding is limited to the submission of affidavits of fact and memoranda of law and replies thereto. WINAC's affidavits and memorandum shall be filed no later than the close of business January 29, 1982 and served upon all other parties of record. The reply of Hearing Counsel shall be filed and served no later than February 12, 1982. Oral argument may be scheduled if requested by a party prior to February 19, 1982 and deemed necessary by the Commisison; and

It is further ordered, that a copy of this Order be served upon each of the respondent carriers.

By the Commission

Francis C. Hurney,

Secretary.

[FR Doc. 82–179 Filed 1–4–82; 8:45 am]

BILLING CODE 6730–01–M

[2] The Commission's intent was that an innocent consignee never be denied delivery of cargo for failing to pay a carrier-imposed penalty. This intention was expressed in relatively flexible language so as to not interfere unduly with the carriers' business judgment in fashioning penalty provisions properly directed against the "party at fault." Practically speaking, however, it is improbable that a carrier could fairly and accurately establish that a consignee is the party at fault within the time allotted for the delivery of cargo without the assessment of demurrage charges, a period which customarily does not exceed five working days. See WINAC Tariff FMC No. 3, original page 64. The burden is upon WINAC to demonstrate that any tariff rule which uses a cargo lien to collect private penalties cannot possibly deny cargo delivery to a consignee which has not been clearly proven to be the party responsible for the misdescription or misdeclaration.

[Docket No. 81–49]

Availability of Finding of No Significant Impact

Upon completion of an environmental assessment, the Federal Maritime Commission's Office of Energy and Environmental Impact has determined that the Commission's decision on Docket No. 81–49 will not constitute a major federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.*, and that preparation of an environmental impact statement is not required.

Docket No. 81–49 is an Order of Further Investigation and Hearing of Rate Agreement No. 10387. The agreement was originally conditionally disapproved by Commission Order dated February 6, 1981. On August 24, 1981, the agreement was resubmitted for the Commission's reconsideration. The agreement is between the members of the Pacific/Australia-New Zealand Conference, acting as one party, and Karlander Kangaroo Line, an independent carrier. The agreement covers the trade from U.S. and Canadian Pacific Coast ports (not including Alaska) and ports in Hawaii and inland points through ports in Australia and New Zealand. The agreement would permit the parties to discuss and agree upon rates, charges, classifications, practices, brokerage, freight forwarder compensation, equalization, absorption, transshipment and overland and/or other inland movements.

The Finding of No Significant Impact (FONSI) will become final within 20 days of publication of this Notice in the **Federal Register** unless petitions for review are filed pursuant to 46 CFR 547.6(b).

The FONSI and related environmental assessment is available for inspection on request from the Office of the Secretary, Room 11101, Federal Maritime Commission, Washington, D.C. 20573, telephone (202) 523–5725

Francis C. Hurney,

Secretary..

[FR Doc. 82–106 Filed 1–4–82; 8:45 am]

BILLING CODE 6730–01–M

[Independent Ocean Freight Forwarder License No. 2198]

Ferguson Shipping and Forwarding Co., Inc.; Order of Revocation of License

Section 44(c), Shipping Act, 1916, provides that no independent ocean freight forwarder license shall remain in force unless a valid bond is in effect and on file with the Commission. Rule 510.15(d) of Federal Maritime Commission General Order 4 further provides that a license shall be automatically revoked for failure of a licensee to maintain a valid bond on file.

The bond issued in favor of Ferguson Shipping and Forwarding Co., Inc., P.O. Box 10952, Suite 116, Houston, TX 77018 was cancelled effective November 14, 1981.

By letter dated October 26, 1981, Ferguson Shipping and Forwarding Co., Inc. was advised by the Federal Maritime Commission that Independent Ocean Freight Forwarder License No. 2198 would be automatically revoked unless a valid surety bond was filed with the Commission.

Ferguson Shipping & Forwarding Co., Inc. has failed to furnish a valid bond.

By virtue of authority vested in me by the Federal Maritime Commission as set forth in Manual of Orders, Commission Order No. 1 (revised), section 10.01(f) dated November 12, 1981;

Notice is hereby given, that Independent Ocean Freight Forwarder License No. 2198 be and is hereby revoked effective November 14, 1981.

It is ordered, that Independent Ocean Freight Forwarder License No. 2198 issued to Ferguson Shipping & Forwarding Co., Inc. be returned to the Commission for cancellation.

It is further ordered, that a copy of this Order be published in the Federal Register and served upon Ferguson Shipping and Forwarding Co., Inc.

Albert J. Kingel, Jr.,

Director, Bureau of Certification & Licensing.

[FR Doc. 82-104 Filed 1-4-82; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Ballerton Corp.; Formation of Bank Holding Company

Ballerton Corporation, N.V., Oviedo, Spain, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 50 percent or more of the voting shares of Totalbank Corporation of Florida, Miami, Florida. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Atlanta. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than January 27, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-31 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

First Colonial Bankshares Corp.; Acquisition of Bank

First Colonial Bankshares Corporation, Chicago, Illinois, has applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire 10 per cent or more of the voting shares of All American Bank of Chicago, Chicago, Illinois. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Reserve Bank to be received not later than January 23, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-33 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

First Delhi Corp.; Formation of Bank Holding Company

First Delhi Corporation, Delhi, Louisiana, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 per cent or more of the voting shares of The First National Bank of Delhi, Delhi, Louisiana. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Dallas. Any person wishing to comment on the application should submit views in writing to the Reserve Bank to be received not later than January 27, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-35 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

First Dodge City Bancshares, Inc.; Formation of Bank Holding Company

First Dodge City Bancshares, Inc., Dodge City, Kansas, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 per cent or more of the voting shares of First National Bancshares of Dodge City, Inc., Dodge City, Kansas and thereby indirectly acquire shares of First National Bank and Trust Co. in Dodge City, Dodge City, Kansas. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than January 27, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-34 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

First Mid-Illinois Bancshares, Inc.; Formation of Bank Holding Company

First Mid-Illinois Bancshares, Inc., Mattoon, Illinois, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 100 per cent of the voting shares of First National Bank, Mattoon, Illinois, Mattoon, Illinois. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than January 22, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-36 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

Fourth Financial Corp., Formation of Bank Holding Company

Fourth Financial Corporation, Wichita, Kansas, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 24.99 percent or more of the voting shares of M-L Bancshares, Inc., Wichita, Kansas. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the 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 January 26, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-37 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

M-L Bancshares, Inc.; Formation of Bank Holding Company

M-L Bancshares, Inc., Wichita, Kansas, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 96.8 percent of the voting shares of Newton Bancshares, Inc., Newton, Kansas, and, indirectly, 93.0 percent of the voting shares of The Kansas State Bank, Newton, Kansas. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the 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 January 26, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-38 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

Gaylord Bancorporation, Ltd.; Formation of Bank Holding Company

Gaylord Bancorporation, Ltd., Gaylord, Minnesota, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 96 percent or more of the voting shares of Citizens State Bank of Gaylord, Gaylord, Minnesota. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Minneapolis. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than January 27, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-39 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

Hol-Ark, Inc.; Formation of Bank Holding Company

Hol-Ark, Inc., Blytheville, Arkansas, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 50 percent or more of the voting shares of The First National Bank in Blytheville, Blytheville, Arkansas. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Hol-Ark, Inc., Blytheville, Arkansas, has also applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. section 1843(c)(8)) and 225.4(b)(2) of the Board's Regulation Y (12 CFR 225.4(b)(2)), for permission to retain and service certain notes receivable. These activities would be performed from Applicant's offices in Blytheville, Arkansas, and the geographic areas to be served are the area surrounding Blytheville, Arkansas. Such activities have been specified by the Board in § 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of § 225.4(b).

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweight possible adverse effects, such as undue concentration of resourses, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of St. Louis.

Any views or requests for hearing should be submitted in writing and received by the Reserve bank not later than January 27, 1982.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-40 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

Midwest National Bancshares, Inc.; Formation of Bank Holding Company

Midwest National Bancshares, Inc., Midwest City, Oklahoma, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 per cent or more of the voting shares of Midwest National Bank, Midwest City, Oklahoma. The factors that are considered in acting on the application

are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the 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 January 27, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-41 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

Milford, N.V.; Formation of Bank Holding Company

Milford, N.V., Oranjestad, Netherlands Antilles, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 40 percent or more of the voting shares of Totalbank Corporation of Florida, Miami, Florida. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Atlanta. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than January 27, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-32 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

NBG Atlantic International Corp.; Corporation to Do Business Under Section 25(a) of the Federal Reserve Act

An application has been submitted for the Board's approval of the organization of a corporation to do business under section 25(a) of the Federal Reserve Act ("Edge Corporation"), to be known as NBG Atlantic International Corporation, New York, New York. NBG Atlantic International Corporation would operate as a subsidiary of the National Bank of Greece, S.A., Athens, Greece, and Atlantic Bank of New York, New York, New York. The factors that are considered in acting on the application are set forth in § 211.4(a) of the Board's Regulation K (12 CFR 211.4(a)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of New York. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than January 27, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identify specifically any questions of fact that are in dispute and summarize the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-42 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

NCB, CORP; Formation of Bank Holding Company

NCB, Corp., Mansfield, Georgia, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring at least 80 percent of the voting shares of Newton County Bank, Mansfield, Georgia. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Atlanta. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than January 27, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-43 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

Shawmut Corp.; Acquisition of Bank

Shawmut Corporation, Boston, Massachusetts, has applied for the Board's approval under section 3(a)(5)) of the Bank Holding Company Act (12 U.S.C. 1842(a)(5) to merge with Worcester Bancorp, Inc., Worcester, Massachusetts. 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)).

Shawmut Corporation, Boston, Massachusetts, is also engaged in the following nonbank activities: commercial and agricultural financing activities and securities clearance and related activities. In addition to the factors considered under section 3 of the Act (banking factors), the Board will consider the proposal in the light of the company's nonbanking activities and the provisons and prohibitions in section 4 of the Act (12 U.S.C. 1843).

The application may be inspected at the offices of the Board of Governors or the Federal Reserve Bank of Boston. 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 January 27, 1982. Any comment on an application that requests a hearing include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-45 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

Shawmut Corp.; Proposed Acquisition of Worcester Bancorp, Inc.

Shawmut Corporation, Boston, Massachusetts, has applied, pursuant to section 4(c)(8) of the Bank Holding

Company Act (12 U.S.C. 1843(c)(8)) and 225.4(b)(2) of the Board's Regulation Y (12 CFR 225.4(b)(2)), for approval to merge with Worcester Bancorp, Inc., Worcester, Massachusetts ("Bancorp").

Applicant states that upon completion of the proposed merger, nonbanking subsidiaries acquired from Bancorp would continue to engage in certain nonbanking activities. Specifically, Wornat Development Corporation would continue to engage in certain portfolio liquidation activities authorized by the Federal Reserve Bank of Boston on November 28, 1980, and Wornat Insurance Agency, Inc., would continue to engage in insurance activities within the scope permitted by the Board's Regulation Y. These activities would be performed on behalf of Applicant from the offices from which they are currently being performed on behalf of Bancorp, in Worcester, Massachusetts, and the geographic areas to be served are those currently served by these subsidiaries on behalf of Bancorp. Such activities have been specified by the Board in § 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of § 225.4(b).

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Boston.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than January 27, 1982.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-44 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

Wyoming Bancorporation; Acquisition of Bank

Wyoming Bancorporation, Cheyenne, Wyoming, has applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire 100 percent of the voting shares of First Wyoming Bank, N.A.-Green River, Green River, Wyoming, a *de novo* bank. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the 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 January 26, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 28, 1981.

James McAfee,

Assistant Secretary of the Board.

[FR Doc. 82-46 Filed 1-4-82; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 81M-0402]

American Medical Products Corp.; Collastat™, Absorbable Collagen Hemostatic Sponge

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application for premarket approval under the Medical Device Amendments of 1976 of the Collastat™, Absorbable Collagen Hemostatic Sponge, sponsored by American Medical Products Corp., Freehold, NJ. After reviewing the recommendation of the General and Plastic Surgery Device Section of the Surgical and Rehabilitation Devices Panel, FDA notified the sponsor that the application was approved because the device had been shown to be safe and effective for use as recommended in the submitted labeling.

DATE: Petitions for administrative review by February 4, 1982.

ADDRESS: Requests for copies of the summary of safety and effectiveness data and petitions for administrative review may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Charles Kyper, Bureau of Medical Devices (HFK-402), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7445.

SUPPLEMENTARY INFORMATION: On May 22, 1980, American Medical Products Corp., Freehold, NJ, submitted to FDA an application for premarket approval of the Collastat™, Absorbable Collagen Hemostatic Sponge, a hemostatic agent used in surgical procedures as an adjunct to hemostasis when control of bleeding by ligatures or conventional procedures is ineffective or impractical. The application was reviewed by the General and Plastic Surgery Device Section of the Surgical and Rehabilitation Devices Panel, an FDA advisory committee, which recommended approval of the application. On December 10, 1981, FDA approved the application by a letter to the sponsor from the Acting Director of the Bureau of Medical Devices.

A summary of the safety and effectiveness data of which FDA's approval is based is on file in the Dockets Management Branch (address above) and is available upon request from that office. A copy of all approved final labeling is available for public inspection at the Bureau of Medical Devices. Contact Charles Kyper (HFK-402) at the address above. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition under section 515(g) of the act (21 U.S.C. 360(g)) for administrative review of FDA's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative

practices and procedures regulations or a review of the application and FDA's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration of FDA action under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before February 4, 1982, file with the Dockets Management Branch (address above) four copies of each petition and supporting data and information identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-13 Filed 1-4-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 81D-0230]

Effectiveness Evaluation of Bovine Anthelmintics; Availability of Guideline

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces the availability of a guideline prepared by the Bureau of Veterinary Medicine for use in developing data to establish the effectiveness of bovine anthelmintic drugs entitled "Guidelines for the Evaluation of Bovine Anthelmintics". FDA invites interested persons to submit written comments on the guideline.

ADDRESSES: The guideline is available for public examination at, and comments may be submitted to, the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Interested persons may request a single copy of the guideline from the Information Services Staff (HFV-5), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard P. Lehmann, Bureau of Veterinary Medicine (HFV-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3134.

SUPPLEMENTARY INFORMATION: The Federal Food, Drug, and Cosmetic Act (the act) requires that a new animal drug be the subject of an approved new animal drug application (NADA) before it may be marketed. Section 512(b)(1) of the act (21 U.S.C. 360b(b)(1)) requires that each NADA include full reports of investigations which show that the drug is safe and effective for use. Section 512(d) of the act (21 U.S.C. 360b(d)) describes the criteria that must be met before a new animal drug may be approved, including a requirement that a drug's effectiveness be shown by "substantial evidence" as defined in section 512(d)(3) (21 U.S.C. 360b(d)(3)).

The Bureau of Veterinary Medicine has prepared a guideline entitled "Guidelines for the Evaluation of Bovine Anthelmintics." The guideline was developed with the aid of a committee whose members represented industry, academia, and government. The guideline addressed the type of data to be included in an NADA for bovine anthelmintic drugs to establish "substantial evidence" of effectiveness for the drug.

This notice of availability is issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidelines to establish procedures of general applicability that are not legal requirements but are acceptable to the agency.

A person who follows a guideline is assured that his or her conduct will be acceptable to the agency. A person may also choose to use alternative procedures even though they are not provided for in the guideline. A person who chooses to depart from the guideline may discuss the matter further with the agency to prevent expenditure of resources for work that the agency may later determine to be unacceptable.

A copy of the guideline is on file in the Dockets Management Branch (address above). Interested persons may receive a single copy of the guideline by submitting a request to the Information Services Staff (HFV-5) (address above).

Interested persons may submit written comments on the guideline to the Dockets Management Branch. Such comments will be considered in determining whether amendments to or revisions of the guideline are warranted. Comments should be in two copies (except that individuals may submit a single copy) identified with the docket number found in brackets in the heading of this document. The guideline and received comments may be seen in the Dockets Management Branch, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 22, 1981.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-12 Filed 1-4-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 81M-0400]

Professional Pharmacal Co.; Premarket Approval of Professional Pharmacal Co. Salt Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application for premarket approval under the Medical Device Amendments of 1976 of the Professional Pharmacal Co. Salt Tablets for all hydrophilic contact lenses, sponsored by Professional Pharmacal Co., Lindenhurst, NY. After reviewing the recommendation of the Ophthalmic Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel, FDA notified the sponsor that the application was approved because the device had been shown to be safe and effective for use as recommended in the submitted labeling.

DATE: Petitions for administrative review by February 4, 1982.

ADDRESS: Requests for copies of the summary of safety and effectiveness data and petitions for administrative review may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Charles Kyper, Bureau of Medical Devices (HFK-402), Food and Drug Administration, 8757 Georgia Ave., Silver Springs, MD 20910, 301-427-7445.

SUPPLEMENTARY INFORMATION: On January 13, 1981, Professional Pharmacal Co., Lindenhurst, NY, submitted to FDA an application for premarket approval of the Professional Pharmacal Co. Salt Tablets for all hydrophilic contact lenses. The application was reviewed by the Ophthalmic Device Section of the

Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel, and FDA advisory committee, which recommended approval of the application. On December 10, 1981, FDA approved the application by a letter to the sponsor from the Acting Director of the Bureau of Medical Devices.

Before enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295, 90 Stat. 539–583), salt tablets for preparing solutions for use in heat disinfection of hydrophilic contact lenses were regulated as new drugs. Because the amendments broadened the definition of the term "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(h)), such salt tablets are now regulated as class III devices (premarket approval). The FDA explained in a notice published in the **Federal Register** of December 16, 1977 (42 FR 63472), the amendments provide transitional provisions to ensure continuation of premarket approval requirements for class III devices formerly considered new drugs. Furthermore, FDA requires, as a condition to approval, that sponsors of applications for premarket approval of soft contact lenses or the solutions prepared from salt tablets for the above use comply with the records and reports provisions of Subpart D of Part 310 (21 CFR Part 310) until these provisions are replaced by similar requirements under the amendments.

A summary of the safety and effectiveness data on which FDA's approval is based is on file in the Dockets Management Branch (address above) and is available upon request from that office. A copy of all approved final labeling is available for public inspection at the Bureau of Medical Devices. Contact Charles Kyper (HFK–402), addressed above. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

The labeling of the Professional Pharmacal Co. Salt Tablets states that the solution prepared from the salt tablets is designed for use in heat disinfection of all hydrophilic contact lenses. Sponsors of any hydrophilic contact lenses that have been approved for marketing are advised that whenever FDA publishes a notice in the **Federal Register** of the agency's approval of a new solution for use with an approved soft contact lens, the sponsor of each lens shall correct its labeling to refer to the new solution, at the next printing or at such other time as FDA prescribes by letter to the sponsor. A sponsor who fails to update the restrictive labeling may violate the misbranding provisions of section 502 of the act (21 U.S.C. 352) as well as the Federal Trade Commission Act (15 U.S.C. 41–58), as amended by the Magnuson-Moss Warranty-Federal Trade Commission Improvement Act (Pub. L. 93–637). Furthermore, failure to update the restrictive labeling to refer to new salt tablets that may be used with an approved lens may be grounds for withdrawing approval of the application for the lens under section 515(e)(1)(F) of the act (21 U.S.C. 360e(e)(1)(F)).

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of FDA's decision to approve this application. A petitioner may request either formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and FDA's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration of FDA action under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issues to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before February 4, 1982, file with the Dockets Management Branch (address above) four copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 81–37231 Filed 1–4–82; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 78N–0124]

Depo-Provera; Hearing on Proposal To Refuse Approval of Supplemental New Drug Application

AGENCY: Food and Drug Administation, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the decision of the Public Board of Inquiry to require participants to update their submissions to the Board for the hearing to be held on the agency's proposal to refuse approval of a supplemental new drug application (NDA) of the Upjohn Co. The NDA was submitted for the general marketing of Depo-Provera (medroxyprogesterone acetate) Sterile Aqueous Suspension as a contraceptive agent in humans.

DATE: Updated submissions must be received by March 8, 1982; the date, time, and location of the hearing will be announced in a later **Federal Register** notice.

ADDRESS: Updated submissions should be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Tenny P. Neprud, Jr., Regulations Policy Staff (HFC–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3480.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 27, 1979 (44 FR 44274), FDA ordered that a hearing before a Public Board of Inquiry be held to determine whether the supplemental NDA for Depo-Provera (NDA 12–541/S–004) contained reports of investigations that were adequate to show that the drug was safe for use under the conditions prescribed, recommended, or suggested in the labeling as required by section 505(d) (1), (2), and (4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d) (1), (2), and (4)), and whether that information, combined with other information about the drug, provided a sufficient basis from which FDA could determine that Depo-Provera was safe for general marketing in the United States under such conditions. The agency also ordered that, by September 25, 1979, participants in the hearing were to submit to the Dockets Management Branch (formerly the Hearing Clerk) all data and information relied on, as specified by § 13.25 (21 CFR 13.25), except for the names of witnesses required by § 13.25(a)(2) (21 CFR 13.25(a)(2)). In accordance with the procedures specified in § 13.10(c)(3) (21

CFR 13.10(c)(3)), on September 10, 1981, the Commissioner of Food and Drugs announced the creation of a Public Board of Inquiry on Depo-Provera.

More than 2 years have elapsed since the date on which participants were required to submit data and information for inclusion in the administrative record of this proceeding. Because participants were not permitted to submit additional information after that date, the record does not contain information relevant to this proceeding which became available after September 25, 1979. The Board has determined that the issues presented in this proceeding can be considered fully only if the administrative record is complete and up to date. Therefore, the Board has decided to require the participants to this hearing to supplement their previous submissions with all materials that were not known or reasonably available when the initial submissions were made. The Board is not ordering the participants to resubmit their initial submissions, but rather is seeking additional information relevant to the issues in this proceeding that did not exist or was not reasonably available in September, 1979.

Therefore, by March 8, 1982, each participant shall file with the Dockets Management Branch data and information specified in § 13.25, except the names of witnesses required by § 13.25(a)(2) and except as waived in the July 27, 1979 notice, which they have not already submitted or which is not otherwise a part of the record of this proceeding, and which did not exist or was not reasonably available at the time the initial submissions were made. To aid in reviewing the record, participants are requested to index and tab each submission using a letter prefix. Participants who have any questions regarding the submission of this material, or the letter prefix may contact the Dockets Management Branch on 301–443–1751. In accordance with § 13.20(b) (21 CFR 13.20(b)), and as provided in the Commissioner's December 21, 1979 Notice to Parties and Participants, documents other than documentary data and information are required to be served on each other participant. All submissions will be available for inspection and copying in the Dockets Management Branch pursuant to § 13.45 (21 CFR 13.45).

The time, date, and place of the first session of the Board will be announced in a subsequent notice to be published in the **Federal Register**.

Dated: December 24, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82–19 Filed 1–4–82; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 81F–0379]

TAL Chemicals Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that TAL Chemicals Co. has filed a petition proposing that the food additive regualtions be amended to provide for the safe use of sucrose fatty acid esters as components of protective coatings on fruit.

FOR FURTHER INFORMATION CONTACT: Patricia J. McLaughlin, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2A3590) has been filed by TAL Chemicals Co., 24–26 Queens Rd., Reading, Berkshire RG1 4AU, United Kingdom, proposing that the food additive regulations be amended to provide for the safe use of sucrose fatty acid esters as components of protective coatings on fruit.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulations in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: December 21, 1981.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 82–18 Filed 1–4–82; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 81N–0346; DESI Nos. 6327 etc.]

Revised Marketing Requirements for Certain Drug Products; Drugs for Human Use; Drug Efficacy Study Implementation; Followup Notice

Corrections

In FR Doc. 81–35368 appearing on page 60652 in the issue for Friday, December 11, 1981, make the following changes:

1. On page 60653, in the table, NDA 9–048, the product name should read "Oxsoralen (methoxsalen)"; and NDA 10–347, the prodjct name should read "Delalutin (hydroxyprogesterone caproate)".

BILLING CODE 1505–01–M

[Docket No. 81N–0253]

Skull X-Ray Referral Criteria Panel; Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming second meeting of the Skull X-Ray Referral Criteria Panel. FDA provides logistical support for this Panel, which is convened by the University of California at San Francisco. This notice tells how to submit written data and views to the Panel, how to participate in open sessions of the meeting, and how to review the reports of the Panel.

DATES: Open sessions: January 21, 1982, 8:30 a.m. to 10 a.m. and January 22, 1982, 8:30 a.m. to 10 a.m.; closed sessions: January 21, 1982, 10:15 a.m. to 4:30 p.m. and January 22, 1982, 10:30 a.m. to 12 p.m.

ADDRESSES: The Panel meeting will be held at the Holiday Inn, 5520 Wisconsin Ave., Chevy Chase, MD 20015, 301–656–1500. The report of the first meeting of this Panel may be reviewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. The report of the forthcoming second meeting will be placed on public display as soon as it is available.

FOR FURTHER INFORMATION CONTACT: Philip M. McClean, Bureau of Radiological Health (HFX–76), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4600.

SUPPLEMENTARY INFORMATION: Through the Bureau of Radiological Health, FDA

conducts and supports research, training, and other activities to minimize unproductive radiation exposure from diagnostic radiological examinations. One possible source of unproductive radiation exposure is radiological examinations that are not likely to affect patient management. To minimize requests for ineffective examinations, it is important that the referring physician have up-to-date information about when a given radiological study is likely to provide needed diagnostic information. This information, which can take the form of decision guides based on patient signs, symptoms, or history, is termed here "referral criteria."

Under one part of a program designed to facilitate the development and testing by the medical profession of referral criteria for diagnostic radiological examinations, FDA provides logistical support through a contractor for the convening of small panels of clinical and scientific experts to formulate draft referral criteria or statements of use. A detailed description of the x-ray referral criteria development process was published in the **Federal Register** of June 9, 1981 (46 FR 30568).

This is the second meeting of the Skull X-Ray Referral Criteria Panel. The meeting is being called to continue the assessment of the existing state of knowledge regarding the use of plain skull radiography following head trauma and to discuss modifications to the draft referral criteria statement developed at the first Panel meeting. Anyone interested in specific agenda items to be discussed in the open sessions may determine from the contact person the approximate time of discussion.

Any interested person may submit written data and views to the Panel. Anyone who wishes to request time for oral presentations during the open sessions of the meeting should inform the contact person listed above, either orally or in writing, before the meeting. Any person attending the meeting who does not in advance of the meeting request time will be permitted to make an oral presentation at the conclusion of the open sessions, if time permits, at the chairperson's discretion.

A list of committee members and the meeting agenda or the report of the first meeting of the Panel may be reviewed at the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday. The report of the second meeting of the Panel will be placed on public display at the Dockets Management Branch as soon as it is available and will contain minutes of the open sessions, copies of written data and views submitted to the Panel in the open sessions, and summaries of the closed sessions. Materials will be filed under the docket number appearing in the heading of this notice.

Dated: December 29, 1981.

William T. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-37151 Filed 12-30-81; 10:20 am]

BILLING CODE 4160-01-M

Consumer Participation; Open Meeting

Note.—This document originally appeared in the **Federal Register** for Thursday, December 31, 1981. It is reprinted in this issue to meet requirements for publication on the Tuesday/Friday schedule assigned to the Food and Drug Administration.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a forthcoming National Consumer Exchange Meeting to be chaired by the Commissioner of Food and Drugs.

DATE: The meeting will be held at 3:30 p.m., Monday, January 11, 1982.

ADDRESS: The meeting will be held at the Hubert H. Humphrey Bldg. Auditorium, 200 Independence Ave. SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Alexander Grant, Associate Commissioner for Consumer Affairs (HFE-1), Food and Drug Administration, 5600 Fishers Lane, Rm. 16-85, Rockville, MD 20857, 301-443-5006.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to exchange information between FDA officials and consumer representatives, by providing an opportunity for consumer representatives to present their views directly to the Commissioner and to the top managers of FDA, by seeking solutions to any problems agreed on during this communication, and by giving the agency an opportunity to discuss and communicate vital health and policy issues to the concerned public. Proposed discussion at the meeting will focus on the issues of standards policy for class II medical devices and the Patient Package Insert (PPI) program for prescription drugs.

Dated: December 29, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-37375 Filed 12-29-81; 12:52 pm]

BILLING CODE 4160-01-M

[Docket No. 81P-0191]

Hennepin Medical Center; Approval of Variance for a Biplane Cinefluoroscopic X-Ray System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing approval of a variance from the performance standard for diagnostic x-ray systems and their major components, permitting modification of a biplane cinefluoroscopic x-ray system located at Hennepin Medical Center thereby allowing the use of the equipment for oblique views during coronary catheterization.

DATE: The variance became effective November 5, 1981.

ADDRESS: The application and all correspondence on the application have been placed on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert A. Phillips, Bureau of Radiological Health (HFX-460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: Under § 1010.4 (21 CFR 1010.4), Hennepin Medical Center, 701 Park Ave. South, Minneapolis, MN 55415, has been granted a variance from § 1020.32(a)(1) (21 CFR 1020.32(a)(1)), of the performance standard for diagnostic x-ray systems and their major components. This regulation would otherwise require that equipment used for fluoroscopy and for the recording of images through an image intensifier have a primary protective barrier in position to intercept the entire useful beam before the x-ray tube can produce x-rays. This variance permits the system to have an override switch for the vertical centering interlocks to allow for configuration and operation in the oblique position during biplane angiography. The Director of the Bureau of Radiological Health has determined that the arguments submitted in support of the application are valid and that the alternate methods specified in the variance will ensure the radiation safety of the system. This variance applies to a single cinefluoroscopic system designated, "Phillips Cardiac Catheterization X-ray System", manufactured by Phillips Medical Systems, Shelton, CN, and located in the

coronary angiography suite of Hennepin Medical Center. Because the variance is for the assembly of one system only, a specific termination date is inappropriate, instead the variance will remain in effect until the x-ray system is substantially modified, sold or no longer used for cardiac catheterization.

The assembly will bear the variance No. 81P–0191. In accordance with § 1010.4, the application and all correspondence (including the written notice of approval) on this application have been placed on public display in the Dockets Management Branch (address above), and may be seen between 9 a.m. and 4 p.m., Monday though Friday.

Dated: December 24, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82–102 Filed 1–4–82; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Geothermal Competitive Sale Schedule for Remainder of Fiscal Year 1982

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of geothermal competitive lease sale schedule for remainder of fiscal year 1982.

SUMMARY: This notice is given to keep the public informed of the geothermal competitive lease sale schedule for the remaining period of the 1982 fiscal year. This notice will assist those interested in participating in the sales of geothermal leases in planning their activities. The precise dates of each sale will be announced in accordance with the provisions of 43 CFR 3220.3.

DATES: The schedule is as follows:

Month	State	KGRA's offered	Projected acreage per sale
February	California	Geysers-Calistoga, Glass Mt.	45,000
March	Arizona	Clifton, Gillard Hot Springs.	2,000
	California	Beckwourth Peak, Dunes, Ford Dry Lake, Little Horse Mt., Love Lady Ridge, Suprise Valley, Wendall-Amadee.	50,000
April	Utah	Cove Fort-Sulphurdale, Crater Hot Springs, Monroe-Joseph, Navahoe, Roosevelt.	16,000
May	California	Bodie, Coso Hot Springs, Geysers-Calistoga, Knoxville, Lassen, Saline Valley, Whittier Springs.	146,000
June	Oregon	Indian Heaven, McCready Hot Springs.	7,000
August	Nevada	Double Hot Springs, Gerlach NE, Soldier Meadows, Trego.	18,000
	New Mexico	Baca, Kilbourne Hole, Lightning Dock, Socorro Peak.	35,000
September	California	Mono-Long Valley, Salton Sea.	234,000
	Idaho	Castle Creek, Conda, Crane Creek, Vulcan Hot Springs.	12,000
	Oregon	Belknap-Foley, Brietenbush, Carey (Austin) Hot Springs, Kennedy, Mt. Hood, Summer Lake.	40,000
Total Acreage			610,000

FOR FURTHER INFORMATION CONTACT: Karl Duscher, Bureau of Land Management (520), 1800 C Street, N.W., Washington, D.C. 20240, (202)343–7722.

James M. Parker,

Acting Director.

December 29, 1981.

[FR Doc. 82–25 Filed 1–4–82; 8:45 am]

BILLING CODE 4310–84–M

Combined Hydrocarbon Leasing Act of 1981

AGENCY: Bureau of Land Management.

ACTION: Notice.

SUMMARY: This notice is to inform the public of provisions of the Combined Hydrocarbon Leasing Act of 1981, Pub. L. 97–78. This legislation clears up the confusion about leasing of tar sand when such deposits occur where oil or gas is or may be present by amending the Mineral Lands Leasing Act of 1920, 30 U.S.C. 181 *et seq.*

DATE: All holders of oil and gas leases issued prior to November 16, 1981, and holders of certain valid mining claims within a special tar sand area shall be entitled to convert such lease or claim to a Combined Hydrocarbon Lease by November 16, 1983.

ADDRESSES: All notices of intent to file an application for conversion of leases or valid mining claims located in a special tar sand area should be forwarded to: Bureau of Land Management, State Director of Utah, University Club Building, 136 East South Temple, Salt Lake City, Utah 84111.

FOR FURTHER INFORMATION CONTACT: Mr. Edward E. Coggs, Bureau of Land Management, Division of Coal, Tar Sands, and Oil Shale, Room 3618, open weekdays 7:45 a.m. to 4:15 p.m., 18th and C Streets, N.W. Washington, D.C. 20240, telephone (202) 343–6821. Mr. Orval Hadley and Mr. Bob Randolph, Bureau of Land Management, University Club Building, 136 East South Temple, Salt Lake City, Utah 84111, telephone (801) 524–5326 or (FTS) 588–5326.

SUPPLEMENTARY INFORMATION: Under the Mineral Lands Leasing Act (MLLA) of 1920 prior to amendment, an oil and gas lease issued under section 17 of the MLLA carried with it no rights to deposits of asphalt, bitumen or bituminous rock, including tar sands. Similarly, tar sand leases issued under section 21 of the MLLA gave no rights to deposits of oil or gas. Because of the difficulty in distinguishing between tar sand and conventional oil prior to completion of a well, tar sand leases have not been issued since 1965.

The newly enacted amendments to the MLLA provide for the development of oil and tar sand under a single lease, thereby removing these obstacles. Any oil and gas lease, issued after November 16, 1981, includes tar sand rights. The amendments allow the owner of (1) an oil and gas lease issued prior to the date of enactment of the Combined Hydrocarbon Leasing Act (CHLA) of 1981, or (2) a valid claim to any hydrocarbon resources leasable under section 21 of the MLLA based on a mineral location under the 1872 Mining Law made prior to January 21, 1926, within a "special tar sand area" *only*, shall be entitled to convert such lease or claim to a "Combined Hydrocarbon Lease" (CHL) with a primary term of 10 years upon the filing of an application to convert within 2 years from the date of enactment of the CHLA (November 16, 1981). The application for conversion must contain an acceptable plan of operation which will assure reasonable protection of the environment and diligent development of those resources requiring enhanced recovery methods of development or mining. The term "special tar sand areas" means an area designated by the Secretary of the Interior's orders of November 20, 1980 (45 FR 76800–76801) and January 21, 1981 (46 FR 6077–6078).

The Bureau of Land Management (BLM) is now in the process of preparing

regulations governing such conversions. To preserve a right to conversion, a lessee must file a notice of intent *prior* to the expiration of an oil and gas lease. The filing of a notice of intent *preserves* the right of an existing oil and gas lessee to convert the lease to a CHL even though the primary term of the oil and gas lease otherwise expires. If any oil and gas lease eligible for conversion under this act would expire after the date of the Act, (November 16, 1981) and before 6 months following the issuance of implementing regulations (approximately May 15, 1982), the lessee may perserve his/her conversion rights for a period ending 6 months after the issuance of implementing regulations (approximately October 5, 1982) by filing a notice of intent to file an application for conversion before the expiration of the oil and gas lease.

For those leases whose expiration date is during this regulatory development period, a notice of intent to convert must be filed with the BLM in order to perserve a right to conversion.

Dated: December 29, 1981.

James M. Parker,

Acting Director, Bureau of Land Management.

[FR Doc. 82-108 Filed 1-4-82; 8:45 am]

BILLING CODE 4310-84-M

National Park Service

Cape Hatteras National Seashore; Cape Hatteras Fishing Pier, Inc.; Intention to Negotiate Concession Contract

Pursuant to the provisions of section 5 of the Act of October 9, 1965, (79 Stat. 969; 16 U.S.C. 20), public notice is hereby given that on February 4, 1982, the Department of the Interior, through the Regional Director, Southeast Region, National Park Service, proposes to negotiate a concession contract with Cape Hatteras Fishing Pier, Inc., authorizing it to continue to provide fishing pier, pier house, limited merchandising and related services for the public within Cape Hatteras National Seashore, North Carolina, for a period of five (5) years from January 1, 1983, through December 31, 1987.

This contract renewal has been determined to be a categorical exclusion under the National Park Service regulations implementing the National Environmental Policy Act and no environmental document will be prepared.

The foregoing concessioner has performed its obligations to the satisfaction of the Secretary under an existing contract which expires by limitation of time on December 31, 1982, and therefore, pursuant to the Act of October 9, 1965, as cited above, is entitled to be given preference in the negotiation of a new contract. This provision, in effect, grants Cape Hatteras Fishing Pier, Inc., as the present satisfactory concessioner, the right to meet the terms of responsive proposals for the proposed new contract and a preference in the award of the contract, if thereafter, the proposal of Cape Hatteras Fishing Pier, Inc., is substantially equal to others received. In the event a responsive proposal superior to that of Cape Hatteras Fishing Pier, Inc., (as determined by the Secretary) is submitted, Cape Hatteras Fishing Pier, Inc., will be given the opportunity to meet the terms and conditions of the superior proposal the Secretary considers desirable, and, if it does so, the new contract will be negotiated with Cape Hatteras Fishing Pier, Inc. The Secretary will consider and evaluate all proposals received as a result of this notice.

Any proposal, including that of the existing concessioner, must be postmarked or hand delivered on or before February 4, 1982, to be considered and evaluated.

Interested parties should contact the Regional Director, Southeast Region, National Park Service, 75 Spring Street, S.W., Atlanta, Georgia 30303, for information as to the requirements of the proposed contract.

Dated: December 22, 1981.

Neal G. Guse,

Acting Regional Director, Southeast Region.

[FR Doc. 82-129 Filed 1-4-82; 8:45 am]

BILLING CODE 4310-70-M

Cape Hatteras National Seashore; Chicamacomico Enterprises, Inc., Intention To Negotiate Concession Contract

Pursuant to the provisions of section 5 of the Act of October 9, 1965, (79 Stat. 969; 16 U.S.C. 20), public notice is hereby given that on February 4, 1982, the Department of the Interior, through the Regional Director, Southeast Region, National Park Service, proposes to negotiate a concession contract with Chicamacomico Enterprises, Inc., authorizing it to continue to provide fishing pier, pier house, limited merchandising and related services for the public within Cape Hatteras National Seashore, North Carolina, for a period of five (5) years from January 1, 1983, through December 31, 1987.

This contract renewal has been determined to be a categorical exclusion under the National Park Service regulations implementing the National Environmental Policy Act and no environmental document will be prepared.

The foregoing concessioner has performed its obligations to the satisfaction of the Secretary under an existing contract which expires by limitation of time on December 31, 1982, and, therefore, pursuant to the Act of October 9, 1965, as cited above, is entitled to be given preference in the negotiation of a new contract. This provision, in effect, grants Chicamacomico Enterprises, Inc., as the present satisfactory concessioner, the right to meet the terms of responsive proposals for the proposed new contract and a preference in the award of the contract, if thereafter, the proposal of Chicamacomico Enterprises, Inc., is substantially equal to others received. In the event a responsive proposal superior to that of Chicamacomico Enterprises, Inc., (as determined by the Secretary) is submitted, Chicamacomico Enterprises, Inc., will be given the opportunity to meet the terms and conditions of the superior proposal the Secretary considers desirable, and, if it does so, the new contract will be negotiated with Chicamacomico Enterprises, Inc. The Secretary will consider and evaluate all proposals received as a result of this notice.

Any proposal, including that of the existing concessioner, must be postmarked or hand delivered on or before February 4, 1982, to be considered and evaluated.

Interested parties should contact the Regional Director, Southeast Region, National Park Service, 75 Spring Street, S.W., Atlanta, Georgia 30303, for information as to the requirements of the proposed contract.

Dated: December 22, 1981.

Neal G. Guse,

Acting Regional Director, Southeast Region.

[FR Doc. 82-130 Filed 1-4-82; 8:45 am]

BILLING CODE 4310-70-M

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before December 24, 1981. Pursuant to section 60.13 of 36 CFR Part 60, written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, U.S. Department of the Interior, Washington, D.C. 20243.

Written comments should be submitted by January 20, 1982.

Carol D. Shull,

Acting Keeper of the National Register.

ALABAMA

Lauderdale County

Florence, Coulter, George, House, 420 S. Pine St.

CALIFORNIA

Alameda County

Berkeley, *College Women's Club*, 2680 Bancroft Way
Berkeley, *Haviland Hall*, University of California campus
Berkeley, *Tupper and Reed Building*, 2275 Shattuck Ave.

Butte County

Chico, *St. John's Epsicopal Church*, 230 Salem St.

Napa County

St. Helena, *Taylor, Duckworth and Company Foundry Building*, 1345 Railroad Ave.

Sacramento County

Folsom, *Cohn House*, 305 Scott St.
Sacramento, *Mesick House*, 517 8th St.
Sacramento, *Ruhstaller Building*, 900 J St.
Sacramento, *Sacramento Bank Building*, 3418 Broadway

San Diego County

San Diego, *Ruiz-Alvarado Ranch Site (Rancho Penasquitos)*, Penasquitos Valley Regional Park

San Francisco County

San Francisco, *Griffing's, Frederick, Ship*, Battery St.

Santa Clara County

San Jose, *De Anza Hotel*, 233 W. Santa Clara St.
San Jose, *Roma Bakery*, 655 Almaden Ave.

Santa Cruz County

Santa Cruz, *Cope Row Houses*, 412—420 Lincoln St.

Yuba County

Marysville, *Hart Building*, 423—425 4th St.

CONNECTICUT

Fairfield County

Bridgeport, *Fairfield County Courthouse*, 172 Golden Hill St.

OKLAHOMA

Cleveland County

Norman, *Beta Theta Phi Fraternity House, The University of Oklahoma*, 800 S. Chautauqua Ave.

Oklahoma County

Oklahoma City, *Cain's Coffee Building*, 1 NW. 12th St.

Tulsa County

Tulsa, *Gillette-Tyrell Building*, 423 S. Boulder Ave.

SOUTH CAROLINA

Bamberg County

Denmark vicinity, *Voorhees College Historic District*, Voorhees College campus

Charleston County

Edisto Island vicinity, *Seaside Plantation House*, Off SC 174

Laurens County

Laurens vicinity, *Dial, Allen, House*, SR 729

WEST VIRGINIA

Calhoun County

San Ridge, *Alberts Chapel*, U.S. 119/33

Harrison County

Clarksburg vicinity, *Templemoor*, WV 20

Jefferson County

Charles Town vicinity, *Blakeley*, SR 13/3
Leetown vicinity, *Bower, The*, Warm Springs Rd.
Shenandoah Junction vicinity, *Burr, Peter, House*, Warm Springs Rd.

Kanawha County

Charleston, *Breezemont*, 915 Breezemont Dr.

Marion County

Fairmont, *High Gate (James Edwin Watson House*, 801 Fairmont Ave.

Monongalia County

Morgantown, *Willey, Waitman T., House*, 128 Wagner Rd.

Wirt County

Burning Springs vicinity, *Ruble Church*, N of Burning Springs

[FR Doc. 82-123 Filed 1-4-82; 8:45 am]

BILLING CODE 4310-07-M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 29697 (Sub. No. 1)]

Grand Trunk Western Railroad Co.; Trackage Rights Over Lines of Norfolk and Western Railway Co. and Chesapeake and Ohio Railway Co. at Detroit, MI.; Exemption

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission exempts from the requirements of prior approval under 49 U.S.C. 11343 trackage rights agreements permitting the Grand Trunk Western Railroad Company to operate over approximately 3.3 miles of lines owned by the Norfolk and Western Railway Company and the Chesapeake and Ohio Railway Company in Detroit, MI.

DATES: This exemption will become effective on February 17, 1982. Petitions for reconsideration must be filed by February 2, 1982,

ADDRESSES: Send petition for reconsideration to:

(1) Section of Finance, Room 5414, Interstate Commerce Commission, Washington, D.C. 20423 and
(2) Petitioner's representative: John C. Danielson, 131 West Lafayette Blvd., Detroit, MI 48226.

Pleadings should refer to Finance Docket No. 29697 (Sub-No. 1).

Copies of the full decision may be obtained from: Interstate Commerce Commission, Office of the Secretary, Room 2227, 12th and Constitution Avenue, NW., Washington, D.C. 20423 or by calling, Toll-free: 800–424–5403.

FOR FURTHER INFORMATION CONTACT: Richard A. Kelly, (202) 275–7564.

SUPPLEMENTARY INFORMATION: The decision served by the Commission contains further information.

Decided: December 28, 1981.

By the Commission, Chairman Taylor, Vice Chairman Clapp, Commissioners Gresham and Gilliam.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-191 Filed 1-4-82; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 29471 (Sub-No. 1)]

Little Rock and Western Railway Corp.; Purchase (Portion)-Chicago, Rock Island and Pacific Railroad Co., Debtor (William M. Gibbons, Trustee) Between North Little Rock and Perry, AR; Proceedings Scheduled

AGENCY: Interstate Commerce Commission.

ACTION: Proceedings scheduled.

SUMMARY: The Commission is setting a procedural schedule for the filing of comments and evidence.

DATES: 1. Within 10 days of this publication, verified statements supporting or opposing this proposal must be filed. 2. Within 15 days of this publication, verified statements in reply must be filed.

ADDRESSES: The original and 10 copies of each submission should be sent to: Section of Finance, Room 5414, Interstate Commerce Commission, 12th & Constitution Ave, NW., Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT: Richard A. Kelly, (202) 275–7245
or
Elaine Sehrt, (202) 275–7899.

SUPPLEMENTARY INFORMATION: By application filed September 14, 1980, the Little Rock and Western Railway Corportion (LR&W) sought approval to

purchase two connecting railroad lines, 53.7 and 4.8 miles respectively, of Chicago, Rock Island, and Pacific Railroad Company (Rock Island). As supplemented, LR&W would purchase only 44 miles between (Milepost 141.0 at Pulaski, AR, west of Little Rock, and Milepost 185.0 at Perry, AR) for $2.7 million. The LR&W will receive overhead trackage rights over another 10.5 miles of the line extending eastward from Milepost 141.0 to Milepost 130.5, to connect with the Cotton Belt in North Little Rock.

Federal financial assistance for the proposed transaction had been applied for under § 505 of the Railroad Revitalization and Regulatory Reform Act of 1976 (4R Act) and § 112 of the Rock Island Railroad Transition and Employee Assistance Act (RITEA). Consummation of the transaction is not contingent upon federal financial assistance.

By decision served December 18, 1980, the Commission determined that LR&W's application was incomplete. The Commission treated the LR&W application as a purchase offer and stated that this offer would be handled expeditiously as an application when the pertinent information was provided.

On December 3, 1981, the Rock Island Reorganization Court preliminarily approved Rock Island's and LR&W's contract of sale, and directed the Commission before February 16, 1982 to approve or disapprove LR&W's purchase application. On December 16, 1981, LR&W submitted additional information to support its application. Parties wishing to comment on the application may do so within the time outlined at the beginning of this decision.

Decided: December 28, 1981.

By the Commission, Richard A. Kelly, Acting Director, Office of Proceedings.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-190 Filed 1-4-82; 8:45 am]

BILLING CODE 7035-01-M

Long-and-Short-Haul Application for Relief (Formerly Fourth Section Application)

December 30, 1981.

This application for long-and-short-haul relief has been filed with the I.C.C.

Protests are due at the I.C.C. within 10 days from the date of publication of the notice.

No. 43948, Burlington Northern Railroad Company, (No. 1) increased unit train rate on coal, carloads, from Belle Ayr, Caballo Jct., Eagle Jct., Rawhide Jct., and Thunder Jct., WY to Sadler, MO, in Supplement 8 to its tariff ICC BN 4204, effective December 30, 1981. Grounds for relief: Additional Revenue.

By the Commission:

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-189 Filed 1-4-82; 8:45 am]

BILLING CODE 7035-01-M

[Ex Parte No. 387 (Sub-79)]

Missouri-Kansas-Texas Railroad Company, Exemption for Contract Tariff ICC-MKT-C-0119 (Supplement 1)

AGENCY: Interstate Commerce Commission.

ACTION: Notice of Provisional Exemption.

SUMMARY: Petitioner is granted a provisional exemption under 49 U.S.C. 10505 from the notice requirements of 49 U.S.C. 10713(e). The contract tariff to be filed may become effective on one day's notice. This exemption may be revoked if protests are filed within 15 days of publication in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Donald J. Shaw, Jr., or Jane F. Mackall, (202) 275-7656.

SUPPLEMENTARY INFORMATION: The Missouri-Kansas-Texas Railroad Company (MKT) filed a petition on December 22, 1981, seeking an exemption under 49 U.S.C. 10505 from the statutory notice provisions of 49 U.S.C. 10713(e). It requests that we permit its contract tariff—ICC-MKT-C-0119 (Supplement 1) to become effective by December 31, 1981. Unless this new tariff becomes effective no later than the expiration date of the present contract on December 31, 1981, rail service for this shipper must be terminated and will not be available pursuant to the terms of a new contract effective on January 1, 1982.

Under 49 U.S.C. 10713(e), contracts must be filed on not less than 30 nor more than 60 days' notice. There is no provision for waiving this requirement. Cf. former section 10762(d)(1). However, the Commission has granted relief under our section 10505 exemption authority in exceptional situations.

The petition is granted. A subsidiary of the MKT, which is the Oklahoma, Kansas, and Texas Railroad Company (OKKT), has operated portions of the former Rock Island Railroad. Together, the MKT and OKKT have served this shipper by transporting its grain (corn, grain, sorghums, soybeans, and wheat) at annual volume rates from Kansas City, MO/KS, Salina, Topeka, Wichita, and Coffeyville, KS, and Fort Worth, TX, to Galveston and Houston, TX, for export. The temporary lease to the OKKT of the Rock Island's operations, with option to buy, has resulted in unsuccessful negotiations with the Trustee for such purchase. Thus, the OKKT's temporary operations terminate on December 31, 1981. Although the OKKT serves this shipper (under former Rock Island rights) from only three of the indicated origins, while the MKT operates from the other three origins, the current contract provides that if OKKT ceases operations the entire contract of service by OKKT/MKT for this shipper is void. Therefore, MKT and the shipper have negotiated a new contract covering the service MKT can provide from Kansas City, Coffeyville, and Fort Worth, based on reduced annual volume requirements to reflect the reduction in the number of origins served. This new contract will become effective on January 1, 1982. In order to prevent termination of the MKT's rail service, it is necessary for the amended contractual tariff, which is, specifically, supplement 1 to contract tariff ICC-MKT-C-0119 (to correspond with the contract amendment, which is Amendment 1 to contract ICC-MKT-C-0119) to become effective no later than the date that the OKKT ceases operations, or by December 31, 1981. If this is accomplished, there will be effective rail service available from the three MKT origins, covered by the new/amended contract, on the date (January 1, 1982) when that contract goes into effect. Both parties will suffer financial hardship as a result of the explained cessation of operations by the OKKT, unless the effective dates of the new tariff and contract can be coordinated.

MKT's contract tariff may become effective on one day's notice. We will apply the following conditions which have been imposed in similar exemption proceedings:

> If the Commission permits the contract to become effective on one day's notice, this fact neither shall be construed to mean that this is a Commission approved contract for purposes of 49 U.S.C. 10713(g) nor shall it serve to deprive the Commission of jurisdiction to institute a proceeding on its own initiative or on complaint, to review this contract and to disapprove it.

Subject to compliance with these conditions, under 49 U.S.C. 10505(a) we find that the 30 day notice requirement in these instances is not necessary to carry out the transportation policy of 49 U.S.C. 10101a and is not needed to protect shippers from abuse of market power. Further, we will consider revoking this exemption under 49 U.S.C.

10505(c) if protests are filed within 15 days of publication in the **Federal Register**.

This action will not significantly affect the quality of the human environment or the conservation of energy resources.

(49 U.S.C. 10505)

Dated: December 29, 1981.

By the Commission, Division 1, Commissioners Clapp, Gresham, and Taylor. Commissioner Taylor did not participate.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-193 Filed 1-4-82; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 29794]

Illinois Central Gulf Railroad Co.; Purchase (Portion)—Waterloo Railroad Co.; Exemption

December 28, 1981.

The Illinois Central Gulf Railroad Company (ICG) and its wholly owned subsidiary Waterloo Railroad Company (Waterloo) have notified the Commission that ICG intends to acquire from Waterloo 7.08 miles of rail line extending between Marion and Louisa, IA, in Linn County, IA. ICG is currently conducting operations over the line under a lease from Waterloo.

This transaction is within a corporate family and comes within that class of transactions described in 49 CFR 1111.5(c)(3) which has been exempted from Commission regulation. The ICG purchase of the line will not result in changes in service levels, significant operation changes, or a change in the competitive balance with carriers outside the corporate family.

As a condition to use the exemption, any employee affected by the acquisition of the line by ICG shall be protected pursuant to *New York Dock Ry.-Control-Brooklyn Eastern Dist.*, 360 I.C.C. 60 (1979). This will satisfy the statutory requirements of 49 U.S.C. 10505(g)(2).

By the Commission, Richard A. Kelly, Acting Director, Office of Proceedings.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-192 Filed 1-4-82; 8:45 am]

BILLING CODE 7035-01-M

[Ex Parte No. 387 (Sub-No. 73)]

Pittsburgh and Lake Erie Railroad, Exemption for Contract Tariff ICC-PLE-C-04

AGENCY: Interstate Commerce Commission.

ACTION: Notice of provisional exemption.

SUMMARY: Petitioner is granted a provisional exemption under 49 U.S.C. 10505 from the notice requirements of 49 U.S.C. 10713(e). The contract tariff to be filed may become effective on one day's notice. This exemption may be revoked if protests are filed within 15 days of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Donald J. Shaw, Jr. or Jane F. Mackall (202) 275-7656.

SUPPLEMENTARY INFORMATION: The Pittsburgh and Lake Erie Railroad (PLE) filed a petition on December 10, 1981, seeking an exemption under 49 U.S.C. 10505 from the statutory notice provisions of 49 U.S.C. 10713(e). It requests that we permit its contract tariff ICC-PLE-C-04, to become effective on one day's notice. The tariff was filed on December 10, 1981 and is scheduled to become effective on January 9, 1982. The tariff provides for the movement and relocation of certain locomotives, freight cars and on-rail work equipment owned by the Monongahela Connecting Railroad Company, the Aliquippa and Southern Railway, and the Mahoning Valley Railway Company over the lines of the PLE.

Under 49 U.S.C. 10713(e), contracts must be filed on not less than 30 nor more than 60 days' notice. There is no provision for waiving this requirement. Cf. former section 10762(d)(1). However, the Commission has granted relief under our section 10505 exemption authority in exceptional situations.

The petition shall be granted. The owning carriers have an immediate need to arrange for the relocation and transfer of various types of equipment. Unless the provisional exemption is granted, intraplant operations at the various steel mills served by the owning carriers could be subject to unnecessary disruption. We find this to be the type of exceptional circumstance which warrants a provisional exemption.

PLE's contract tariff may become effective on one day's notice. We will apply the following conditions which have been imposed in similar exemption proceedings:

If the Commission permits the contract to become effective on one day's notice, this fact neither shall be construed to mean that this is a Commission approved contract for purposes of 49 U.S.C. 10713(g) nor shall it serve to deprive the Commission of jurisdiction to institute a proceeding on its own initiative or on complaint, to review this contract and to disapprove it.

Subject to compliance with these conditions, under 49 U.S.C. 10505(a) we find that the 30 day notice requirement in these instances is not necessary to carry out the transportation policy of 49 U.S.C. 10101a and is not needed to protect shippers from abuse of market power. Further, we will consider revoking this exemption under 49 U.S.C. 10505(c) if protests are filed within 15 days of publication in the **Federal Register**.

This action will not significantly affect the quality of the human environment or the conservation of energy resources.

(49 U.S.C. 10505)

Dated: December 28, 1981.

By the Commission, Division 1, Commissioners Clapp, Gresham, and Taylor. Commissioner Taylor did not participate.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-195 Filed 1-4-82; 8:45 am]

BILLING CODE 7035-01-M

[Ex Parte No. 387 (Sub-No. 77)]

Union Pacific Railroad Co., Exemption for Contract Tariff ICC-UP-C-0010

AGENCY: Interstate Commerce Commission.

ACTION: Notice of Provisional Exemption.

SUMMARY: Petitioner is granted a provisional exemption under 49 U.S.C. 10505 from the notice requirements of 49 U.S.C. 10713(e). The contract tariff to be filed may become effective on one day's notice. This exemption may be revoked if protests are filed within 15 days of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Donald J. Shaw, Jr. or Jane F. Mackall (202) 275-7656.

SUPPLEMENTARY INFORMATION: Union Pacific Railroad Company (UP) filed a petition on December 21, 1981, seeking an exemption under 49 U.S.C. 10505 from the statutory notice provisions of 49 U.S.C. 10713(e). It requests that we permit its contract tariff—ICC-UP-C-0010 to become effective by December 31, 1981. The contract tariff was filed on December 21, 1981 and would normally become effective on 30-days' statutory notice. However, the concurrently filed contract, of one year's duration, takes effect on December 31, 1981, pursuant to agreement between shipper and carrier. Therefore, the UP seeks to have its tariff's effective date advanced to coordinate it with the effective date of the contract, or, in other words, to become effective on 10 days' notice.

Under 49 U.S.C. 10713(e), contracts must be filed on not less than 30 nor more than 60 days' notice. There is no

provision for waiving this requirement. Cf. former section 10762(d)(1). However, the Commission has granted relief under our section 10505 exemption authority in exceptional situations.

The petition is granted. UP and its shipper have reached an agreement for the transportation of copper products from a Utah facility to Illinois points, where the shipments will be interchanged with another railroad for movement beyond. The traffic will be transported at an agreed upon rate, in exchange for the tender to UP of certain minimum percentages of the shipper's copper production at its Utah plant. If the tariff does not become effective on the same date as the contract, it will force a slow-down in production or the build up of a large inventory, with corresponding reduction in use of rail cars moving to the facility. Under these circumstances, a provisional exemption is warranted.

UP's contract tariff may become effective on one day's notice. We will apply the following conditions which have been imposed in similar exemption proceedings:

> If the Commission permits the contract to become effective on one day's notice, this fact neither shall be construed to mean that this is a Commission approved contract for purposes of 49 U.S.C. 10713(g) nor shall it serve to deprive the Commission of jurisdiction to institute a proceeding on its own initiative or on complaint, to review this contract and to disapprove it.

Subject to compliance with these conditions, under 49 U.S.C. 10505(a) we find that the 30 day notice requirement in these instances is not necessary to carry out the transportation policy of 49 U.S.C. 10101a and is not needed to protect shippers from abuse of market power. Further, we will consider revoking this exemption under 49 U.S.C. 10505(c) if protests are filed within 15 days of publication in the Federal Register.

This action will not significantly affect the quality of the human environment or the conservation of energy resources.

(49 U.S.C. 10505)

Dated: December 28, 1981.

By the Commission, Division 1, Commissioners Clapp, Gresham and Taylor. Commissioner Taylor did not participate.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-194 Filed 1-4-82; 8:45 am]

BILLING CODE 7035-01-M

Motor Carriers; Permanent Authority Decisions; Decision-Notice

The following applications, filed on or after February 9, 1981, are governed by Special Rule of the Commission's Rules of Practice, see 49 CFR 1100.251. Special Rule 251 was published in the **Federal Register** of December 31, 1980, at 45 FR 86771. For compliance procedures, refer to the **Federal Register** issue of December 3, 1980, at 45 FR 80109.

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.252. A copy of any application, including all supporting evidence, can be obtained from applicant's representative upon request and payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.g., unresolved common control, fitness, water carrier dual operations, or jurisdictional questions) we find, preliminarily, that each applicant has demonstrated a public need for the proposed operations and that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. This presumption shall not be deemed to exist where the application is opposed. Except where noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication, (or, if the application later becomes unopposed), appropriate authorizing documents will be issued to applicants with regulated operations (except those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued.

Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

Note.—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce over irregular routes, unless noted otherwise. Applications for motor contract carrier authority are those where service is for a named shipper "under contract".

Please direct status inquiries to the Ombudsman's Office, (202) 275-7326.

Volume No. OPY-2-252

Decided: December 23, 1981.

By the Commission, Review Board No. 1, Members Parker, Chandler, and Fortier. (Member Fortier not participating.)

MC 102223 (Sub-17), filed December 10, 1981. Applicant: FRETTE NICHOLSON TRUCK LINES, INC., P.O. Box 206, Ankeny, IA 50021. Representative: Kenneth F. Dudley, P.O. Box 279, Ottumwa, IA 52501, 515-682-8154. Transporting *food and related products* (1) between points in Crawford and Hardin Counties, IA, on the one hand, and, on the other, points in DE, IN, ME, NH, RI, VT, VA, and WV, (2) between points in Omaha, NE, Council Bluffs, IA, and Saline and Lancaster Counties, NE, on the one hand, and, on the other, points in CT, DE, IL, IN, IA, KY, ME, MD, MA, NH, NJ, NY, OH, PA, RI, VT, VA, WV, and DC, and (3) between points in Cherokee, Polk, Webster, and Woodbury Counties, IA, on the one hand, and, on the other, points in CT, DE, IL, IN, KY, ME, MD, MA, NH, NJ, NY, OH, PA, RI, VT, VA, WV, and DC.

MC 13703 (Sub-4), filed December 4, 1981. Applicant: TOTEM TRANSIT CO., 6929 N. Richmond Ave., Portland, OR 97203. Representative: Robert G. Simpson, 1200 Standard Plaza, 1100 S.W. 6th Ave., Portland, OR 97204, 503-289-6575. Transporting *lumber and wood products, clay, concrete, glass or stone products, metal products, and machinery*, between points in the U.S., under continuing contract(s) with McCormick & Baxter Creosoting Co., and Pacific Power and Light Company, both of Portland, OR.

MC 159602, filed December 4, 1981. Applicant: JOSEPHINE C. KIMBALL, d.b.a. A-B BUS SERVICE 4918½ 24th St. North, St. Petersburg, FL 33714. Representative: Morris J. Levin, Suite 701, 1050 17th St. NW, Washington, DC 20036 202-872-0005. As a *broker* at St. Petersburg, FL, in arranging for the transportation, by motor vehicle, of *passengers and their baggage*, in the same vehicle with passengers, in special and charter operations, between points in the U.S.

MC 159652, filed December 10, 1981. Applicant: BELL'S BUS SERVICE, 218 Burns Crossing Rd., Severn, MD 21144. Representative: Steven L. Weiman, Suite 145, 4 Professional Dr., Gaithersburg, MD 20879, 301–840–8565. Transporting *passengers and their baggage,* in the same vehicle with passengers, in charter and special operations, beginning and ending at Baltimore, MD and points in its commercial zone and points in Baltimore and Anne Arundel Counties, MD, and extending to points in the U.S.

MC 159653, filed December 11, 1981. Applicant: CHICAGO-NEW ENGLAND CARGO, INC., Main St. (P.O. Box 207), East Douglas, MA 01516. Representative: Robert G. Parks, 20 Walnut St., Suite 101, Wellesley Hills, MA 02181, 617–235–5571. Transporting *metal products, plastics and plastic products, and paper and paper products,* between points in CT, MA, and RI, on the one hand, and, on the other, points in OH, IL, and WI.

Volume No. OPY–2–253

Decided: December 28, 1981.

By the Commission, Review Board No. 1, Members Parker, Chandler, and Fortier.

MC 110683 (Sub-198), filed December 7, 1981. Applicant: SMITH'S TRANSFER CORPORATION, P.O. Box 1000, Staunton, VA 24401. Representative: Francis W. McInerny, 1000 16th St. NW, Washington, DC 20036, 202–783–8131. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI).

MC 142672 (Sub-187), filed December 7, 1981. Applicant: DAVID BENEUX PRODUCE AND TRUCKING, INC., P.O. Drawer F, Mulberry, AR 72947. Representative: Harry Keifer (same address as applicant), 501–997–1683. Transporting *general commodities,* between the facilities of Delaware Valley Shipper Association, Inc., at points in the U.S., on the one hand, and, on the other, points in the U.S. Condition: To the extent any certificate issued in this proceeding authorizes the transportation of classes A and B explosives, it shall be limited in point of time to a period expiring 5 years from its date of issuance.

MC 146213 (Sub-14), filed December 11, 1981. Applicant: WISCONSIN FARM LINES, LTD., P.O. Box 76, Wisconsin Dells, WI 53965. Representative: Stanley C. Olsen, Jr., 5200 Willson Rd., Suite 307, Edina, MN 55424, (612) 927–8855. Transporting *clay, concrete, glass or stone products,* between points in OH, AL, PA, and WI, on the one hand, and, on the other, points in the U.S. (except MT, ND, ID, CA, NV, AZ, NM, KS, and OK).

MC 146343 (Sub-14), filed December 8, 1981. Applicant: SOUTHERN EXPRESS CORPORATION, 505 South Ocean Blvd., Pompano Beach, FL 33062. Representative: Joe Badway, 2 Sawyer Drive, Coventry, RI 02816, 401–822–0878. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S., under continuing contract(s) with National Wholesale Lubricants, Inc., of East Greenwich, RI.

MC 150573 (Sub-6), filed December 9, 1981. Applicant: BEN KENNEDY TRUCKING COMPANY, INC., P.O. Box 13, Preston, GA 31824. Representative: C. E. Walker, P.O. Box 1085, Columbus, GA 31902, (404) 323–2416. Transporting (1) *feed and feed ingredients, phosphate, feed phosphate, and scrap fish and bone meal,* (2) *agricultural chemicals, lime, lime materials, lime granulars, landplaster, and basic slag,* (3) *food and related products, cottonseed, soybean meal and hulls, sunflower meal, cottonseed meal, and citrus pulp,* and (4) *gravel, crushed granite, and crushed limestome,* between points in AL, FL, GA, SC, and NC.

MC 158093, filed December 11, 1981. Applicant: H & H DISTRIBUTING CO., INC., 304 S. Vine, West Union, IA 52175. Representative: Richard D. Howe, 600 Hubbell Bldg., Des Moines, IA 50309, (515) 244–2329. Transporting *canned goods,* between points in Franklin and Polk Counties, IA, and Columbia County, WI, on the one hand, and, on the other, points in Jackson, Clay, Cass, and Platte Counties, MO, and Wyandotte, Johnson, and Leavenworth Counties, KS.

MC 158563, filed December 7, 1981. Applicant: TOW LEASING CORPORATION, 218 South Victory Drive, Mankato, MN 56001. Representative: Stanley C. Olsen, Jr., 5200 Willson Rd., Suite 307, Edina, MN 55424, 612–927–8855. Transporting *food and related products,* between points in Douglas, Martin, Blue Earth, Mower, Olmsted and Winona Counties, MN, and Minneapolis and St. Paul, MN, on the one hand, and, on the other, points in CA, and those points in the U.S., in and east of WI, IA, MO, OK, and TX.

MC 158612, filed December 7, 1981. Applicant: C.M. McNEELY d.b.a. C.M.N. EXPRESS, Rte. 2, Box 68, Humansville, MO 65674. Representative: Herman W. Huber, 101 East High St., Jefferson City, MO 65101, 314–636–9131. Transporting (1) *chemical,* (a) between points in NY, on the one hand, and, on the other, points in PA and CA, and (b) between points in CA, on the one hand, and, on the other, points in AZ, IL, NV, and TX, and (2) *grape juice, grape byproducts, alcoholic beverages, and wine,* between points in CA, on the one hand, and, on the other, points in AR.

Volume No OPY–2–255

Decided: December 29, 1981.

By the Commission, Review Board No. 1, Members Parker, Chandler, and Fortier.

MC 1222 (Sub-54), filed December 14, 1981. Applicant: THE REINHARDT TRANSFER COMPANY, 1410 Tenth St., Portsmouth, OH 45662. Representative: Robert H. Kinker, 314 West Main St., P.O. Box 464, Frankfort, KY 40602, (502) 223–8244. Transporting *chemicals and related products, rubber and plastic products, and metal products,* between points in Will County, IL, Mason County, MI, and Hancock, Licking, and Lawrence Counties, OH, on the one hand, and, on the other, points in PA.

MC 69322 (Sub-11), filed December 14, 1981. Applicant: DOBSON CARTAGE AND STORAGE COMPANY, 5024 South Garfield Rd., Auburn, MI 48611. Representative: Robert J. Gallagher, 1000 Connecticut Ave., NW, Suite 1200, Washington, DC 20036, (202) 785–0024. Transporting *household goods,* between points in MI, IL, IN, NY, OH, PA, WI, NJ, IA, MO, KY, NC, TN, AR, OK, NM, AZ, CA, TX, MS, AL, GA, SC, LA, and FL.

MC 77202 (Sub-5), filed December 14, 1981. Applicant: CAPITOL TRANSIT & STORAGE CO., INC., 420 Ledyard St., Hartford, CT 06114. Representative: Richard G. Gagon (same address as applicant), (203) 525–5681. Transporting *household goods,* between points, in CT and MA, on the one hand, and, on the other, points in MA, CT, VT, ME, NH, RI, NY, NJ, PA, OH, WV, DE, MD, and DC.

MC 92633 (Sub-35), filed December 15, 1981. Applicant: ZIRBEL TRANSPORT, INC., P.O. Box 933, Lewiston, ID 83501. Representative: William Seehafer (same address as applicant), (208) 743–6588. Transporting *general commodities* (except classes A and B explosives and household goods), between points, in AZ, CA, CO, ID, MT, NM, NV, OR, UT, WA, and WY.

MC 139483 (Sub-7F), filed December 7, 1981. Applicant: ALLEN MITCHEK, P.O. Box 512, Sterling, CO 80751. Representative: Jack B. Wolfe, 665 Capitol Life Center, 1600 Sherman St., Denver, CO 80203, (303) 839–5856. Transporting *commodities in bulk,* between points, in the U.S., under continuing contract(s) with Ralston Purina Company, of St. Louis, MO.

MC 140763 (Sub-11), filed December 15, 1981. Applicant: ONEIDA-COLUMBUS EXPRESS COMPANY, P.O. Box 356, Oneida, TN 37841. Representative: Marshall Kragen, 1919 Pennsylvania Ave. NW, Suite 300, Washington, DC 20006, (202) 466–3778. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with Hydro Hose Corporation, of Tupelo, MS.

MC 143483 (Sub-5), filed December 14, 1981. Applicant: QUIK HAUL, INC., 307 West Dumble, P.O. Drawer D, Alvin, TX 77511. Representative: Fred R. Lindsey, 1001 West Shaw, Pasadena, TX 77506, (713) 472–8628. Transporting *Mercer commodities,* between points in TX, on the one hand, and, on the other, points in MS.

MC 146293 (Sub-87F), filed December 11, 1981. Applicant: REGAL TRUCKING CO., INC., P.O. Box 829, Lawrenceville, GA 30246. Representative: Richard M. Tettelbaum, P.O. Box 720434, Atlanta, GA 30328, (404) 256–4320. Transporting *General commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S.

MC 146442 (Sub-3), filed December 14, 1981. Applicant: CLEARFIELD TRANSPORTATION COMPANY, INC., P.O. Box 313, Clinton, MO 64735. Representative: Mark J. Andrews, Suite 1100, 1660 L St., NW, Washington, DC 20036, (202) 452–7400. Transporting *food and related products,* between points in the U.S., under continuing contract(s) with H.P. Hood, Inc., of Boston, MA, and its affiliates.

MC 148142 (Sub-2F), filed December 11, 1981. Applicant: GORDON PRIEST, INC., 10 Quarry Rd., Acton, MA 01720. Representative: Robert G. Parks, 20 Walnut St., Suite 101, Wellesley Hills, MA 02181, (617) 235–5571. Transporting *food and related products,* between points in the U.S., under continuing contract(s) with New England Apple Products, Inc., of Littleton, MA.

MC 148832 (Sub-5F), filed December 10, 1981. Applicant: DELTA MOTOR FREIGHT, INC., 1616 Rowe Blvd., Poplar Bluff, MO 63901. Representative: Ronald D. Dodds (same address as applicant), (314) 785–1490. Transporting *general commodities* (except classes A and B explosives) between points in Cape Girardeau County, MO, on the one hand, and on the other, points in the U.S.

Note.—Applicant intends to tack this authority with its existing authority.

MC 151392 (Sub-4), filed December 15, 1981. Applicant: ALPHA MOTOR WAYS, INC., 25 County Ave., Secaucus, NJ 07094. Representative: Harold L. Reckson, 33–28 Halsey Rd., Fair Lawn, NJ 07410, (201) 791–2270. Transporting *electric and electronic appliances and equipment,* between points in the U.S., under continuing contract(s) with Sony Corporation, of Moonachie, NJ.

MC 152082 (Sub-10), filed December 14, 1981. Applicant: R. C. SERVICE, INC., P.O. Box 823, Bensenville, IL 60106. Representative: Daniel C. Sullivan, 10 S. LaSalle St., Suite 1600, Chicago, IL 60603, (312) 263–1600. Transporting *such commodities* as are dealt in or used by printers and distributors of printed matter, between points in the U.S., under continuing contract(s) with Conde'Nast Publishing Co., Inc., of New York, NY.

MC 153883 (Sub-5), filed December 14, 1981. Applicant: HARNIC TRUCKING, INC., 3340 Calumet Ave., Hammond, IN 46320. Representative: Kenneth F. Dudley, P.O. Box 279, Ottumwa, IA 52501, (515) 682–8154. Transporting *vacuum cleaners, and vacuum cleaner parts, attachments, and accessories,* between points in the U.S., under continuing contract(s) with Electrolux Corp., of Bristol, VA, Div. of Consolidated Foods Corp.

MC 154103 (Sub-4), filed December 14, 1981. Applicant: MID SOUTH FREIGHT, INC., P.O. Box 446, Hendersonville, TN 37075. Representative: John M. Nader, 1600 Citizens Plaza, Louisville, KY 40202, (502) 589–5400. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in TN, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 156032 (Sub-3), filed December 14, 1981. Applicant: ROY LEATHAM TRANSPORT, INC., 5217 S.E. Aldercrest Rd., Milwaukie, OR 97222. Representative: David R. Benson, 3170 N.W. Parkview Dr., Beaverton, OR 97006, (503) 228–3996. Transporting *general commodities* (except classes A and B explosives), between points in the U.S., under continuing contract(s) with Deseret Transportation, of Salt Lake City, UT.

MC 156362, filed December 14, 1981. Applicant: JAMES B. WOODS, d.b.a. J. B. WOODS TRUCKING, 2444 Middle Ridge Rd., Amherst, OH 44001. Representative: Anthony E. Young, 29 South LaSalle St., Suite 350, Chicago, IL 60603, (312) 782–8880. Transporting *metal products,* between points in Lorain County, OH, on the one hand, and, on the other, those points in the U.S., in and east of ND, SD, NE, KS, OK, and TX.

MC 159592F, filed December 7, 1981. Applicant: INDIANA MOBILE HOME TRANSPORT, INC., R.R. 1, Box 100, Springport, IN 47386. Representative: Walter F. Jones, Jr., Indianapolis, IN 46220, (317) 257–4066. Transporting *mobile homes,* between points in IN, IL, KY, OH, MI, and FL.

MC 159593, filed December 7, 1981. Applicant: LYLE BICKNELL, d.b.a. MID-CONTINENT SYSTEMS, 14705 "Y" Circle, Omaha, NE 68137. Representative: Marshall D. Becker, Suite 610, 7171 Mercy Rd., Omaha, NE, 68106, 402–392–1220. Transporting *floor coverings, and equipment, materials and supplies used to install and maintain floor coverings* between Omaha, NE, on the one hand, and, on the other, points in Lancaster County, PA and Kankakee County, IL.

MC 159702, filed December 14, 1981. Applicant: GEORGE W. OWEN, d.b.a. ASSOCIATED DISTRIBUTION COMPANY, Route 1 Highway 77 South, Ashland, AL 36251. Representative: George M. Boles, 727 Frank Nelson Bldg., Birmingham, AL 35203, (205) 251–5223. Transporting *lumber and wood products, and furniture and fixtures,* between points in the U.S., under continuing contract(s) with (a) Wellburn Cabinet, Inc., and (b) Wellborn Forest Products, Inc., both of Ashland, AL.

MC 159703, filed December 14, 1981. Applicant: ECKS STEVE DIXON, SR., d.b.a. DIXON BUS RENTAL, 2510 Woodberry St., Hyattsville, MD 20782. Representative: Ecks Steve Dixon, Sr. (same address as applicant) (301) 422–8070. Transporting *passengers and their baggage,* in the same vehicle with passengers, in charter operations, beginning and ending at points in MD, VA, and DC, and extending to points in the U.S.

MC 159712, filed December 14, 1981. Applicant: PETROLEUM TRANSPORTATION, INC., 107 E. Court St., P.O. Box 226, Doylestown, PA 18901. Representative: Robert L. Lansberry (same address as applicant) (215) 348–2636. Transporting *petroleum and petroleum products,* between points in the U.S., under continuing, contract(s) with Brinker's Fuels, Inc., of Doylestown, PA.

MC 159713, filed December 14, 1981. Applicant: LEE INDUSTRIES, INC., Ryan Ave., P.O. Box 5, Westville, NJ 08093. Representative: Martin S. Ettin, 499 Cooper Landing Rd., Cherry Hill, NJ 08002, (609) 667–6000. Transporting *plastic and plastic products,* between points in the U.S., under continuing contract(s) with (a) M.A. Industry, of

Peachtree City, GA, and (b) Plastic Recycling, of Pittsburgh, PA.

MC 159722, filed December 14, 1981. Applicant: GEM TOURS, INC., P.O. Box 483, Grayslake, IL 60030. Representative: Thomas A. Morris, Jr., 110 North West St., Waukegan, IL 60085, (312) 249–0300. As a *broker* at Grayslake, IL, in arranging for the transportation of *passengers and their baggage*, between points in the U.S.

Volume No. OPY–3–235

Decided: December 28, 1981.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.

MC 9914 (Sub-19), filed December 14, 1981. Applicant: WARREN TRUCKING CO., INC., P.O. Box 5224, Martinsville, VA 24112. Representative: D. R. Beeler, P.O. Box 482, Franklin, TN 37064, (615) 790–2510. Transporting *furniture and fixtures*, between points in VA, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 14955 (Sub-1), filed December 15, 1981. Applicant: GEIGER TRANSFER & STORAGE COMPANY, INC., 401 Northwest Second St., Evansville, IN 47708. Representative: Timothy J. Hubert, 220 Northwest Fourth St., P.O. Box 3261, Evansville, IN 47731, (812) 423–4433. Transporting *general commodities* (except classes A and B explosives), between points in IL, IN, KY, and MO, on the one hand, and, on the other, points in AR, IL, IN, KY, LA, MI, MS, MO, OH, OK, PA, TN, and WI.

MC 20824 (Sub-50), filed December 10, 1981. Applicant: COMMERCIAL MOTOR FREIGHT INC. OF INDIANA, 2141 South High School Rd., Indianapolis, IN 46241. Representative: C. C. Boyd (same address as applicant), (317) 243–8521. Over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment). Serving points in the lower peninsula of Michigan as off-route points in connection with carrier's otherwise-authorized regular-route operations.

Note.—Applicant intents to tack and interline this requested authority.

MC 26825 (Sub-68), filed December 14, 1981. Applicant: ANDREWS VAN LINES, INC., Seventh St., and Park Ave., P.O. Box 1609, Norfolk, NE 68701. Representative: Jack L. Shultz, P.O. Box 82028, Lincoln, NE 68501, (402) 475–6761. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in NE, on the one hand, and, on the other, points in the U.S.

MC 89684 (Sub-120), filed December 15, 1981. Applicant: WYCOFF COMPANY INCORPORATED, P.O. Box 366, Salt Lake City, UT 84110. Representative: John J. Morrell, P.O. Box 366, Salt Lake City, UT 84110, (801) 972–9500. Transporting *general commodities* (except classes A and B explosives, commodities in bulk, commodities requiring special equipment, and household goods), between points in AZ, CA, CO, ID, MT, NM, NV, OR, UT, WA, and WY, restricted (1) to the transportation of packages or articles weighing not more than 100 pounds in weight, and (2) against the transportation of shipments of packages or articles weighing in the aggregate more than 500 pounds.

Note.—Applicant intends to tack this authority with its existing authority.

MC 95864 (Sub-2), filed December 15, 1981. Applicant: PENN HIGHWAY TRANSIT COMPANY, a Corporation, 825 East Chestnut St., Lancaster, PA 17604 Representative: Jeremy Kahn, Suite 733 Investment Bldg., 1511 K St., N.W., Washington, DC 20005, (202) 783–3525. Transporting *passengers and their baggage*, in the same vehicles with passengers, in charter operations, between points in the U.S., under continuing contract(s) with Conestoga Tours, Inc., of Lancaster, PA.

MC 98154 (Sub-22), filed December 16, 1981. Applicant: BRUCE CARTAGE, INCORPORATED, 3460 E. Washington Rd., Saginaw, MI 48601. Representative: Karl L. Gotting, 1200 Bank of Lansing Bldg., Lansing, MI 48933, (517) 482–2400. Transporting *such commodities* as are dealt in by retail department stores, between the facilities of Montgomery Ward & Co., Inc., in MI, IL, IN, and OH, on the one hand, and, on the other, points in MI, IL, IN, and OH.

MC 106074 (Sub-188), filed December 14, 1981. Applicant: B AND P MOTOR LINES, INC., Shiloh Rd. and U.S. Hwy. 221, S., Forest City, NC 28043. Representative: John J. Capo, 5299 Roswell Rd., N.E., Suite 212, P.O. Box 720434, Atlanta, GA 30328. Transporting *food and related products*, between points in IA, NE, SD, and WI, on the one hand, and, on the other, points in KY, VA, TN, AR, LA, MS, AL, SC, GA, and FL.

MC 114015 (Sub-37), filed December 14, 1981. Applicant: HUSS, INCORPORATED, Hwy 47 W, P.O. Box 666, Chase City, VA 23924. Representative: Morton E. Kiel, Suite 1832, Two World Trade Center, New York, NY 10048–0640, (212) 466–0220. Transporting *metal products*, between points in the U.S., under continuing contract(s) with Baldwin Steel Company of Jersey City, NJ.

MC 120364 (Sub-42), filed December 15, 1981. Applicant: A & B FREIGHT LINE, INC., 4805 Sandy Hollow Rd., Rockford, IL 61109. Representative: Michael J. Wyngaard, 150 E. Gilman St., Madison, WI 53703, (608) 256–7444. Transporting *general commodities* (except classes A and B explosives), between points in IL, IN, MO and WI, on the one hand, and, on the other, points in the U.S.

MC 126775 (Sub-1), filed December 14, 1981. Applicant: COSBY TRANSFER AND STORAGE CORPORATION, d.b.a. W. G. COSBY TRANSFER & STORAGE, 2910 N. Boulevard, Richmond, VA 23230. Representative: Carroll B. Jackson, 1810 Vincennes Rd., Richmond, VA 23229, (804) 282–3809. Transporting *household goods, furniture and fixtures*, between points in AL, CT, DE, FL, GA, IL, IN, KY, MA, MD, ME, MI, MS, NC, NH, NJ, NY, OH, PA, RI, SC, TN, VA, VT, WI, WV, and DC.

MC 133805 (Sub-66), filed December 15, 1981. Applicant: LONE STAR CARRIERS, INC., Route 1 Box 48, Tolar, TX 76476. Representative: Don Garrison, P.O. Box 1065, Fayetteville, AR 72702, (501) 521–8121.Transporting *general commodities* (except classes A and B explosives and household goods), between points in the U.S.

MC 134134 (Sub-103), filed December 14, 1981. Applicant: MAINLINER MOTOR EXPRESS, INC., 4202 Dahlman Ave., Omaha, NE 68107. Representative: James F. Crosby, 7363 Pacific St., Suite 210B, Omaha, NE 68114, (402) 397–9900. Transporting *such commodities* as are dealt in or used by manufacturers and distributors of tile and floor coverings, between points in NY, NJ, PA, OH, IL and IA, on the one hand, and, on the other, points in IA, NE, OH, IL and SD.

MC 135435 (Sub-5), filed December 11, 1981. Applicant: SMART CARRIERS, INC., 4950 Fannett Road, Beaumont, TX 77705. Representative: James R. Boyd, 1000 Perry Brooks Building, Austin, TX 78701, (512) 476–8066. Transporting *Mercer commodities, machinery and metal products*, (1) between points in LA, MS, OK and TX, and (2) between points in LA, MS, OK and TX, on the one hand, and, on the other, points in the U.S.

MC 140174 (Sub-8), filed December 11, 1981. Applicant: BROOKS TRUCKING, INC., E. North St., P.O. Box 187, Vanlue, OH 45890. Representative: Richard H. Brandon, 220 W. Bridge St., P.O. Box 97, Dublin, OH 43017. Transporting *general commodities* (except classes A and B

explosives), between the facilities of Beck Concrete Corporation, Duwe Concrete Industries, Inc., and Copperweld Corporation, their division and subsidiaries at points in the U.S., on the one hand, and, on the other, points in the U.S.

MC 146464 (Sub-12), filed December 14, 1981. Applicant: NEVADA GENERAL TRANSPORTATION, INC., 11560 So. State, Draper, UT 84020. Representative: Carl I. Sundeaus (same address as applicant), (801) 572–4440. Transporting *general commodities* (except classes A and B explosives, and household goods), between points in the U.S., under continuing contract(s) with Anaconda Copper Co., of Denver, CO, Bergandi Manufacturing Co., Inc., of El Monte, CA, North Pacific Lumber Co., of Portland, OR, Roscoe Steel and Culvert Inc., of Billings, MT, and Terra Aqua Conservation, a division of Bakaert Steel Wire Corp., of Reno, NV.

MC 147655 (Sub-6), filed December 15, 1981. Applicant: PAYNE, INC., P.O. Box 112, Brandy Station VA 22714. Representative: Daniel B. Johnson, 4304 East-West Hwy, Bethesda, MD 20814, (301) 654–2240. Transporting (1) *coal*, between points in VA, OH, WV, MD, PA, and KY, on the one hand, and, on the other, points in VA, NC, NY, MD, and DC; (2) *non-metallic minerals*, between points in Louisa and Albermerle Counties, VA, on the one hand, and, on the other, those points in the U.S. in and east of ND, SD, NE, KS, OK and TX; and (3) *recyclable materials*, between those points in the U.S. in and east of ND, SD, NE, KS, OK, and TX.

MC 147915 (Sub-8), filed December 11, 1981. Applicant: RUSSO MOTOR EXPRESS, INC., P.O. Box 21, Burlington, NJ 08016. Representative: Robert R. Harris, 1730 M Street NW., Suite 501, Washington, DC 20036, (202) 296–2900. Transporting *general commodities* (except classes A and B explosives, commodities in bulk and household goods), between Boston, MA, New York, NY, Philadelphia, PA, Baltimore, MD, Norfolk, VA, Charleston, SC, Savannah, GA, New Orleans, LA, Houston, TX and Los Angeles and San Francisco, CA, on the one hand, and, on the other, points in the U.S.

MC 148434 (Sub-3), filed December 11, 1981. Applicant: SECURITY INCORPORATED, 711 Franklin Sq., P.O. Box 274, Michigan City, IN 46360. Representative: Richard A. Huser, 1301 Merchants Plaza, Indianapolis, IN 46204, (317) 638–1301. Transporting *coin, currency and negotiable items*, between Chicago, IL, Detroit, MI, and points in Lake, Porter, LaPorte, St. Joseph, Elkhart, LaGrange and Noble Counties, IN, Berrien, Cass, St. Joseph, Branch, Kalamazoo, Calhoun, Jackson, and Washtenaw Counties, MI.

MC 149525 (Sub-2), filed December 7, 1981. Applicant: REYNOLDS L. MIARER, 4577 W. State Rte. 12, Kansas, OH 44841. Representative: Richard H. Brandon, 220 W. Bridge St., P.O. Box 97, Dublin, OH 43017, (614) 889–2531. Transporting *general commodities* (except classes A and B explosives), between points in the U.S., under continuing contract(s) with Ohio Farmers Grain and Supply Association, of Fostoria, OH.

MC 150214 (Sub-4), filed December 14, 1981. Applicant: J. N. CARR TRANSPORT, INC., 351 Market St., Espy, PA 17815. Representative: James H. Sweeney, P.O. Box 9023, Lester, PA 19113, (215) 365–5141. Transporting *food and related products*, between points in Will County, IL, Hillsborough County, FL and Polk County, GA, on the one hand, and, on the other, points in the U.S.

MC 151905 (Sub-1), filed December 15, 1981. Applicant: FREHNER WHOLESALE d.b.a. FREHNER TRANSPORTATION, 1208 Taylor, North Las Vegas, NV 89030. Representative: Robert G. Harrison, 4299 James Dr., Carson City, NV 89701, (702) 882–5649. Transporting *lumber and wood products, metal products, construction materials and supplies, and waste or scrap materials not identified by industry producing*, between points in OR, WA, ID, CA, NV, UT, CO and AZ.

MC 152594 (Sub-2), filed December 15, 1981. Applicant: MIDLANTIC TRANSFER, LTD., 1061 Carlisle St., P.O. Box 92, Hanover, PA 17331. Representative: John P. Fonte, 1333 New Hampshire Ave., NW., Suite 400, Washington, DC 20036, (202) 887–4090. Transporting *pulp, paper, and related products*, between points in the U.S., under continuing contract(s) with Domtar, Inc., of Montreal, Canada.

MC 153075, filed December 14, 1981. Applicant: SHERMAN HANSON, d.b.a. HANSON TRUCKING, 402 Center St., Box 256, Boyceville, WI 54725. Representative: William J. Gambucci, 525 Lumber Exchange Bldg., Minneapolis, MN 55402, (612) 340–0808. Transporting (1) *machinery* and *metal products*, between points in the U.S., under continuing contract(s) with Hedlund Manufacturing Co., Inc., of Boyceville, WI; (2) *metal products*, and *such commodities* as are dealt in or used by foundries, between points in the U.S., under continuing contract(s) with Badger Iron Works, Inc., of Menomonie, WI, and Scott-Atwater Foundry Co., of Minneapolis, MN; and (3) *cleaning compounds* and *chemicals and related products*, between points in the U.S., under continuing contract(s) with Jennico, Inc., of Eau Claire, WI.

MC 155344 (Sub-1), filed December 11, 1981. Applicant: B & M TRUCKING, INC., 103 3rd Street, Gwinner, ND 58040. Representative: William J. Gambucci, 525 Lumber Exchange Bldg., Minneapolis, MN 55402, (612) 340–0808. Transporting *machinery and metal products*, between points in the U.S., under continuing contract(s) with Loegering Manufacturing, Inc., of Casselton, ND.

MC 155595 (Sub-3), filed December 10, 1981. Applicant: WTR TRANSPORTATION, INC., 3023, Herbert St., Dallas, TX 75215. Representative: Daniel C. Sullivan, 10 S. LaSalle St., Chicago, IL 60603, (312) 263–1600. Transporting *such commodities* as are dealt in or used by (1) farm home improvement and appliance centers, (2) wholesale hardware distributors, and (3) manufacturers of furniture and fixtures, between points in AL, AR, CT, DE, FL, GA, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, NE, NH, NJ, NY, NC, ND, OH, OK, PA, RI, SC, SD, TN, TX, VT, VA, WV, WI, and DC.

MC 155934, filed December 15, 1981. Applicant: C. J.'S TRUCKING AND HOTSHOT, a division of C. J.'S WELDING, INC., P.O. Box 1031, Evanston, WY 82930. Representative: C. J. Reece (same address as applicant), (307) 789–9812. Transporting *Mercer commodities*, between points in UT, ID, NV, CO, TX, ND, MT, NM, AZ, OK, SD, LA, and WY.

MC 156564, filed December 11, 1981. Applicant: WINTERGREEN TRANSPORT CORP., LTD., 92 St. Michel Blvd., C.P. 38, Joliette, Quebec, Canada J6E–3Z3. Representative: Mel P. Booker, Jr., P.O. Box 1281, Old Town Station, Alexandria, VA 22313, (703) 836–6115. Transporting *general commodities* (except classes A and B explosives and household goods), between points in the U.S., under continuing contract(s) with Independent Cement Corp., of Albany, NY.

MC 157755 (Sub-1), filed December 10, 1981. Applicant: MICHIANA NEWS SERVICE, INC., 2232 S. Eleventh St., Niles, MI 49120. Representative: Edward Malinzak, 900 Old Kent Bldg., Grant Rapids, MI 49503. Transporting *general commodities* (except commodities in bulk, classes A and B explosives, and household goods), between Cincinnati, OH, on the one hand, and, on the other, points in IN.

MC 157995, filed December 14, 1981. Applicant: ONONDAGA ENVIRONMENTAL SYSTEMS, INC., 4439 James St., East Syracuse, NY 13057. Representative: Sidney L. Manes, 507 East Fayette St., Syracuse, NY 13202, (315) 476–2121. Transporting (1) *Industrial, chemical, and hazardous wastes,* between Syracuse and Niagara Falls, NY, Philadelphia, PA, Williamsburg, OH, Emelelle and Ft. Payne, AL, and Chattanooga, TN, and (2) *equipment,* used for industrial, chemical and hazardous wastes, between Syracuse and Niagara Falls, NY, Philadelphia, and Coatesville, PA, Williamsburg, OH, Emelelle and Ft. Payne, AL, and Chattanooga, TN.

MC 157224, filed December 16, 1981. Applicant: DEAN CHARLES PUTNAM, SR., d.b.a. PUTNAM TRUCKING, 2615 Avenue L, Council Bluffs, IA 51501. Representative: James F. Crosby, 7363 Pacific St., Suite 210B, Omaha, NE 68114, (402) 397–9900. Transporting *such commodities* as are dealt in or used by distributors of sand and gravel, between points in Douglas, Sarpy, and Cass Counties, NE, on the one hand, and, on the other, points in IA, KS, and SD.

MC 158784, filed December 14, 1981. Applicant: RONALD E. BALIK, d.b.a. BALIK TRUCKING, R. R.#2, Fort Atkinson, IA 52144. Representative: Richard D. Howe, 600 Hubbell Bldg., Des Moines, IA 50309, (515) 244–2329. Transporting *beer,* between points in Shelby County, TN, on the one hand, and, on the other, points in Winneshiek County, IA.

MC 158795, filed December 10, 1981. Applicant: SAM BUCCI TRUCKING, 21714 Royalton Road, Columbia Station, OH 44028. Representative: Lynn R. Delnoce, 10219 Brecksville Road, Brecksville, OH 44141, (216) 526–2718 Transporting *motor parts and components,* betwen points in the U.S., under continuing contract(s) with Kirkwood Industries, Inc., of Cleveland, OH.

MC 159644, filed December 10, 1981. Applicant: GOODMAN'S AUTOMOTIVE SERVICE, INC., 497 Broadway, Malden, MA 02148. Representative: Marshall Goodman (same address as applicant), (617) 324–2713. Transporting (a) *wrecked or disabled vehicles* and (b) *Air compressors, containers, fork lift trucks and mobile office trailers,* between points in CT, MA, ME, NH, NJ, NY, PA, RI and VT.

MC 159665, filed December 11, 1981. Applicant: ESCORT CARRIERS, INC., 22226 Ecorse Rd., Taylor, MI 48180. Representative: Robert E. McFarland, 2855 Coolidge, Suite 201A, Troy, MI 48084, (313) 649–6650. Transporting *food and related products,* between those points in the U.S. in and east of MN, IA, MO, AR, and LA.

MC 159695, filed December 16, 1981. Applicant: FRED HINSON AND DALE WELDY, d.b.a. H. & W. Leasing, 2903 Burke St., Jacksonville, FL 32205. Representative: Fred Hinson (same address as applicant), (904) 387–5571. Transporting *general commodities* (except classes A and B explosives), between points in the U.S., under continuing contract(s) with (1) Crown Insulation Inc., (2) H H & W Chemical Inc., and (3) Thermex Inc., all of Jacksonville, FL.

MC 159714, filed December 14, 1981. Applicant: DONALD W. WROUGHTON, d.b.a. WROUGHTON TRUCK LINE, P.O. Box 156, Nelson, NE 68961. Representative: Bradford E. Kistler, P.O. Box 82028, Lincoln, NE 68501, (402) 475–6761. Transporting *anhydrous ammonia,* between points in Adams County, NE, on the one hand, and, on the other, points in CO and KS.

MC 159715, filed December 14, 1981. Applicant: G. & R. G., INC., 501 West 6th St., Odessa, TX 79762. Representative: James R. Boyd, 1000 Perry Brooks Bldg., Austin, TX 78701, (512) 475–8066. Transporting *Mercer commodities,* between points in AZ, CO, ID, LA, MT, NM, OK, TX, UT, and WY.

MC 159664, filed December 11, 1981. Applicant: TERRY LEE JONES, d.b.a. JONES BUS CO., P.O. Box 1018, Goldsboro, NC 27530. Representative: J. G. Dail, Jr., P.O. Box LL, McLean, VA 22101, (703) 893–3050. Transporting *passengers and their baggage,* in charter operations beginning and ending at points in Duplin, Greene, Lenoir, Pitt, and Wayne Counties, NC, and extending to points in CT, DE, FL, GA, ME, MD, MA, NH, NJ, NY, PA, RI, SC, TN, VT, VA, WV and DC.

MC 159724, filed December 15, 1981. Applicant: DALE A. RILEY, d.b.a. DALE A. RILEY EXPRESS, R.D. #1, Box 477, Gibsonia, PA 15044. Representative: William J. Lavelle, 2310 Grant Bldg., Pittsburgh, PA 15219, (412) 471–1800. Transporting *general commodities* (except classes A and B explosives), between points in the U.S., under continuing contract(s) with Graybar Electic Company, Inc., of Pittsburgh, PA.

MC 159725, filed December 15, 1981. Applicant: TESKEY TRANSPORTATION CO., 501 S. Stimson Ave., City of Industry, CA 91745. Representative: Patricia M. Schnegg, 707 Wilshire Blvd., Suite 1800, Los Angeles, CA 90017. Transporting *such commodities* as are dealt in or used by grocery and food business houses, hardware, discount, drug, variety and department stores, between points in AZ, CA, CO, ID, MT, NM, NV, OR, UT, WA, and WY.

Volume No. OPY–3–238

Decided: December 29, 1981.

By the Commission, Review Board No. 2, Members Carleton, Werner, and Williams.

MC 142114 (Sub-15), filed December 17, 1981. Applicant: RETAIL EXPRESS, INC., 9 Stuart Road, Chelmsford, MA 01824. Representative: Frank M. Cushman, 36 South Main Street, Sharon, MA 02067, (617) 784–6041. Transporting *glass lamps, glass lamp bases, electric lamps,* and *lamp shades,* between points in the U.S., under continuing contract(s) with C. N. Burman Company, of Paterson, NJ.

MC 142114 (Sub-16), filed December 17, 1981. Applicant: RETAIL EXPRESS, INC., 9 Stuart Road, Chelmsford, MA 01824. Representative: Frank M. Cushman, 36 South Main Street, Sharon, MA 02067, (617) 784–6041. Transporting *such commodities* as are dealt in by retail department stores (except commodities in bulk and frozen foodstuffs), between points in the U.S., under continuing contract(s) with Action Industries, Inc., Cheswick, PA.

MC 142114 (Sub-17), filed December 17, 1981. Applicant: RETAIL EXPRESS, INC., 9 Stuart Road, Chelmsford, MA 01824. Representative: Frank M. Cushman, 36 South Main Street, Sharon, MA 02067, (617) 784–6041. Transporting *games and toys,* between points in the U.S., under continuing contract(s) with Mattel Toy Company, Division of Mattel, Inc., of Edison, NJ.

MC 151204 (Sub-3), filed December 17, 1981. Applicant: 321 EQUIPMENT LEASING CO., 712 West Airline Ave., Gastonia, NC 28052. Representative: Rebecca P. Dalton (same address as applicant), (704) 867–2317. Transporting *general commodities* (except classes A and B explosives), between points in AL, AZ, AR, CA, CO, CT, DE, FL, NC, GA, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, NE, NH, NJ, NM, NY, OH, OK, PA, RI, SC, TN, TX, VT, VA, WV, WI, and DC.

MC 152005 (Sub-2), filed December 18, 1981. Applicant: TRANSCONTINENTAL FREIGHT SYSTEMS, INC., 2559 South Archer Ave., Chicago, IL 60608. Representative: Rex Eames, 900 Guardian Blvd., Detroit, MI 48226, (313) 963–3750. Transporting *general commodities* (except classes A and B explosives, and household goods, and commodities in bulk), between points in the U.S., under continuing contract(s)

with Federal Mogul Corporation, of Detroit, MI.

MC 152115 (Sub-2), filed December 15, 1981. Applicant: GEORGE KUIPHOFF, d.b.a. G.K. DISTRIBUTING CO., 13924 Maryton Ave., Santa Fe Springs, CA 90670. Representative: George Kuiphoff (same address as applicant), (213) 921–3030. Transporting *general commodities* (except classes A and B explosives and used household goods), between points in AZ, CA, NV, NM, OR, UT and WA.

MC 153914 (Sub-2), filed December 17, 1981. Applicant: NEWMAN BROTHERS TRUCKING, INC., Highway 96, Belk, AL 35545. Representative: Gerald D. Colvin, Jr., 603 Frank Nelson Bldg., Birmingham, AL 35203, (205) 251–2881. Transporting *metal products,* between points in Fayette, Marion and Lamar Counties, AL, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 159745, filed December 15, 1981. Applicant: TRAVEL MASTERS, LTD., 38 Carolina Mall, Concord, NC 28025. Representative: Elisabeth D. von Dietrich, (same address as applicant), (704) 786–8150. As a *broker* at Concord, NC, in arranging for the transportation by motor vehicle, of *passengers and their baggage,* between points in NC, on the one hand, and, on the other, points in the U.S.

MC 159755, filed December 17, 1981. Applicant: CANOGA FREIGHT LINES, 7357 Deering Ave., Canoga Park, CA 91303. Representative: Edward F. Seibold, (same address as applicant), (213) 340–7243. Transporting *general commodities* (except classes A and B explosives, and household goods), between points in CA, AZ, and NV.

MC 159764, filed December 17, 1981. Applicant: WILLIAM'S, INC., 4908 N. 40th St., Sheboygan, WI 53081. Representative: Wayne W. Wilson, 150 E. Gilman St., Madison, WI 53703, (608) 256–7444. Transporting *food and related products,* between points in the U.S., under continuing contract(s) with Galloway Company, of Neenah, WI.

MC 159765, filed December 17, 1981. Applicant: DEAN SCHROEDER, d.b.a. UNIQUE TRUCKING, Rt. #1, Caledonia, MN 55921. Representative: Charles J. Lee, 114 N. Leonard St., West Salem, WI 54669, (608) 786–0060. Transporting *general commodities* (except classes A and B explosives), between those points in the U.S. in and west of WI, IL, MO, AR, and LA.

Volume No. OPY–5–231

Decided: December 22, 1981.

By the Commission, Review Board No. 3, Members Krock, Joyce, and Dowell.

MC 157489, filed December 22, 1981. Applicant: BANI SERVICES, INC., d.b.a. TEXAS PONY EXPRESS, 5503 Lancaster St., P.O. Box 26603, Houston, TX 77207. Representative: N. W. Sims, (same address as applicant) 713–643–1424. Transporting *general commodities* (except classes A and B explosives, household goods as defined by the Commission, and commodities in bulk), between points in TX, NM, CO, KS, OK, MO, AR, LA, TN, MS, AL, NC, SC, GA, and FL.

MC 158809 (Sub-1), filed December 10, 1981. Applicant: JEWELL IMPLEMENT COMPANY, INC., 105 South Custer, Jewel, KS 66949. Representative: B. J. Loomis, (same address as applicant) 913–428–3261. Transporting *farm equipment,* between points in the U.S. under continuing contract(s) with Center Eq. Co., of Smith Center, KS, Cawker City Eq. of Cawker City, KS and Moritz Imp. Co., of Beloit, KS.

MC 159668, filed December 11, 1981. Applicant: KER-JO CORPORATION, 994 S. State St., Provo, UT 84601. Representative: Irene Marr, 311 S. State St., Ste 280, Salt Lake City, UT 84111, 801–531–1300. Transporting *metal products,* between points in the U.S. under continuing contract(s) with Brown-Strauss, Division of Azcon Corporation of Pleasant Grove, UT.

MC 159669, filed December 11, 1981. Applicant: AMIL BRUNEAU, d.b.a. AMIL'S TRUCKING SERVICE, 50 Maple St., P.O. Box 447, Branford, CT 06405. Representative: William J. Meuser, 86 Cherry St., P.O. Box 507, Milford, CT 06460. Transporting *metal products,* between points in the U.S. under continuing contract(s) with Primary Steel, Inc., of New Haven, CT.

MC 159678, filed December 14, 1981. Applicant: D.A.T., INC., Rural Route 1, Princeton, KS 66078. Representative: Donald J. Quinn, Commerce Bank Bldg., Suite 232–8901 State Line, Kansas City, MO 64114, 816–444–7474. Transporting *food and related products,* between points in the U.S., under continuing contract(s) with Dubuque Packing Company, of Mankato, KS.

MC 159699 filed December 15, 1981. Applicant: JOANN THIELEN, d.b.a. JACOBSEN T TRAVEL AGENCY, 806 East 7th, Atlantic, IA 50022. Representative: JoAnn Thielen (same address as applicant) 712–243–4452. To operate as a *broker* at Atlantic, IA, in arranging the transportation by motor vehicle of *passengers and their bassage,* in the same vehicle with passengers, in special and charter operations, beginning and ending at points in Cass County, IA, and extending to points in the U.S.

MC 159738, filed December 16, 1981. Applicant: SUPREME BUS COMPANY, INC., 2609 Evergreen Road, Odenton, MD 21113. Representative: Walter T. Evans, 7961 Eastern Ave., Silver Spring, MD 20910, 301–587–8656. Transporting: *passengers and their baggage* in the same vehicle with passengers, in special and charter operations, beginning and ending at points in the Washington, DC commercial zone and extending to points in the U.S.

MC 159748, filed December 17, 1981. Applicant: DOMKE DISTRIBUTORS LTD., 21583 58th Ave., Langley, B.C., Canada V3A 4R5. Representative: George R. LaBissoniere, 15 S. Grady Way, Suite 233, Renton, WA 98055, (206) 228–3807. Transporting: *general commodities* (except classes A and B explosives), between points in the U.S., under continuing contract(s) with Shar-Mac Industrial Ltd., and Domke Terminals, Inc., both of Langley, B.C., Canada.

Volume No. OPY–5–232.

Decided: December 22, 1981.

By the Commission, Review Board No. 3, Members Krock, Joyce, and Dowell.

MC 8768 (Sub-39), filed December 16, 1981. Applicant: SECURITY VAN LINES, INC., P.O. Box 830, 100 W. Airline Hwy., Kenner, LA 70063. Representative: Marshall Kragen, 1919 Pennsylvania Ave. NW., Suite 300, Washington, DC 20006, 202–466–3778. Transporting: *general commodities* (except classes A and B explosives, commodities in bulk,) between points in the U.S. under continuing contract(s) with Security Household Goods Forwarding, Inc. of Kenner, LA.

MC 105269 (Sub-109), filed December 14, 1981. Applicant: GRAFF TRUCKING COMPANY, INC., 2110 Lake St., P.O. Box 986, Kalamazoo, MI 49005. Representative: Edward Malinzak, 900 Old Kent Bldg., Grand Rapids, MI 49503, (616) 459–6121. Transporting: *paper and paper products,* between points in IA, IL, IN, KY, MI, MN, MO, NY, OH, PA, WI, and WV.

MC 112989 (Sub-154), filed December 10, 1981. Applicant: WEST COAST TRUCK LINES, INC., 85647 Highway 99 South, Eugene, OR 97405. Representative: John T. Morgans (same address as applicant) (503) 747–1283. Transporting: *urethane foam products,* between points of entry on the international boundary line between the U.S. and Canada located in WA, on the one hand, and; on the other, points in CA, ID, MT, NV, OR, UT, and, WA.

MC 133119 (Sub-191), filed December 7, 1981. Applicant: HEYL TRUCK LINES, INC., P.O. Box 206, Akron, IA 51001. Representative: A. J. Swanson, P.O. Box 1103, Sioux Falls, SD 57101–1103, (605) 335–1777. Transporting *machinery, metal products, farm equipment and supplies, and transportation equipment, parts and supplies,* between points in AL, CO, FL, GA, IA, IL, KS, LA, MA, MD, MN, MO, NE, OH, OR, PA, TX, and WI, on the one hand, and, on the other, points in IA, SD, and NE.

MC 136098 (Sub-4), filed December 14, 1981. Applicant: LOBDELL TRANSPORTATION, INC., Box 368, Lena, IL 61048. Representative: Michael W. O'Hara, 300 Reisch Bldg., Springfield, IL 62701, 217–544–5468. Transporting *fertilizer and anhydrous ammonia,* between points in IL, IA, IN, KY, MO, MN and WI.

MC 139858 (Sub-44), filed December 16, 1981. Applicant: AMSTAN TRUCKING, INC., 1255 Corwin Ave., Hamilton, OH 45015. Representative: Chandler L. Van Orman, 1729 H Street N.W., Washington, DC 20006, 202–337–6500. Transporting *general commodities* (except classes A and B explosives, household goods as defined by the Commission, and commodities in bulk), between points in the U.S. (except AK & HI), under continuing contract(s) with Gold Circle, a Division of Federated Department Stores, Inc. of Worthington, OH.

MC 143308 (Sub-2), filed December 17, 1981. Applicant: GENERAL TRUCKING SERVICE, INC., 3700 Park East Dr., Cleveland, OH 44122. Representative: J. A. Kundtz, 1100 National City Bank Bldg., Cleveland, OH 44114, 216–566–5639. Transporting *general commodities* (except classes A and B explosives), between points in the U.S. under continuing contract(s) with Goodyear Tire and Rubber Co. of Akron, OH.

MC 144989 (Sub-25), filed November 27, 1981. Applicant: BLUE RIDGE MOUNTAIN CONTRACT CARRIER, INC., P.O. Box 1965, Dalton, GA 30720. Representative: S. H. Rich, 1600 Cromwell Court, Charlotte, NC 28205, (704) 847–6961, Ext. 317. Transporting (1) *such commodities* as are dealt in or used by textile manufacturers, under continuing contact(s) with Carpets of Dalton, of Dalton, GA, Carpet Supply, Inc., of Tukwila, WA, Professional Marketing Services of Napa, CA, Tuftco Corp.-Tufting Machine Division, Tuftco International, and Gowin-Card, Inc., both of Dalton, GA, and (2) *machinery, machinery parts and accessories,* under continuing contract(s) with Clarklift of Dalton, GA, between points in the U.S.

MC 145088 (Sub-15), filed December 14, 1981. Applicant: S & T TRUCKLOAD, INC., P.O. Box 4408, Fort Worth, TX 76106. Representative: Billy R. Reid, 1721 Carl St., Fort Worth, TX 76103, (817) 332–4718. Transporting *rubber, plastic and metal products,* between points in Johnson County, TX, on the one hand, and, on the other, points in the U.S.

MC 145179 (Sub-7), filed December 4, 1981. Applicant: J & J CONTRACT CARRIER, INC., 60 South State Ave. Representative: Donald W. Smith, P.O. Box 40248, Indianapolis, IN 46240, (317) 846–6655. Transporting *general commodities,* between points in the U.S. under continuing contact(s) with J & J Distributors, Inc., of Indianapolis, IN.

MC 145858 (Sub-6,), filed December 14, 1981. Applicant: B & G SUPPLY COMPANY, INC., P.O. Box 748, Albertville, AL 35950. RePresentative: John R. Frawley, Jr., Suite 200, 120 Summit Pkwy., Birmingham, AL 35209, 205–942–9116. Transporting *general commodities,* (except classes A and B explosives), between points in Marshall County, AL on the one hand, and, on the other, points in the U.S.

MC 146449 (Sub-4), filed December 17, 1981. Applicant: ALL CITIES TRANSFER, INC., 1567 East Hamilton Ave., East Point, GA 30344. Representative: William J. McCann (same address as applicant), 404–768–7780. Transporting *carbonated beverages,* between points in Vandenburg County, IN and Buncombe County, NC on the one hand, and, on the other, points in AL, FL, GA, MS, NC, SC, and TN.

MC 149308 (Sub-18), filed December 16, 1981. Applicant: VICTORY FREIGHTWAYS SYSTEM, INC., P.O. Box P, Sellersburg, IN 47172. Representative: William P. Jackson, Jr., P.O. Box 1240, Arlington, VA 22210, 703–525–4050. Transporting *metal products,* and *waste or scrap materials,* between Dallas, TX; Indianapolis, IN; and points in Orange County, NY; Los Angeles County, CA and King County, WA on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 150168 (Sub-3), filed December 14, 1981. Applicant: AJ & COMPANY, 423 Amelia St., Plymouth, MI 48170. Representative: John Allman (same address as applicant), (313) 459–1000. Transporting *Chemicals* between points in the U.S., under continuing contract(s) with Celex Corporation of Plymouth, MI.

MC 151419 (Sub-3), filed December 11, 1981. Applicant: GORDON JOHNSON, P.O. Box 252, Fredericktown, OH 43019. Representative: Lewis S. Witherspoon, 2455 North Star Road, Columbus, OH 43221, (614) 486–0448. Transporting (1) *lawn and garden tools,* and *farm implements,* between points in Franklin County, OH on the one hand, and, on the other, points in IL and IN, (2) *glass containers,* between points in Knox County, OH, on the one hand, and, on the other, points in the U.S., and (3) *paper and paper products,* between points in Morrow and Marion Counties, OH, on the one hand, and, on the other, points in the U.S.

MC 153938 (Sub-6), filed December 11, 1981. Applicant: ENERGY EXPRESS, INC., P.O. Box 27605, Salt Lake City, UT 84127. Representative: Norval Millsap (same address as applicant), 801–364–4532. Transporting *petroleum, natural gas and their products,* between points in the U.S. under continuing contract(s) with Enterprise Products Company of Houston, TX.

MC 154648 (Sub-1), filed December 14, 1981. Applicant: WAYNE PHILLIPS, INCORPORATED, P.O. Box 648, Pharr, TX 78577. Representative: Harry F. Horak, Suite 115, 5001 Brentwood Stair Road, Ft. Worth, TX, (817) 457–0804. Transporting *food and related products,* between points in the U.S., under continuing contract(s) with Tremar Import-Export Co., Inc., of Weslaco, TX, Randolph Slaughter Co., of Laredo, TX, C. H. Belt & Associates, of Irving, CA, Land O'Frost of Arkansas, Inc., of Searcy, AR, and Sales Pak, Inc., of Atlanta, GA.

MC 156088 (Sub-2), filed December 15, 1981. Applicant: R & S TRUCk LEASING, INC., 1651 Walker Road, Muskegon, MI 49442. Representative: D. Richard Black, Jr., 7610 Cottonwood Drive, P.O. Box 294, Jenison, MI 49428, (616) 457–9290. Transporting *plastic products,* between points in the U.S., under continuing contract(s) with Rogers City Industries a division of Cadillac Products, of Rogers City, MI.

MC 156499, filed December 14, 1981. Applicant: CIRCLE C TRUCKING, INC., P.O. Box 865, Grand Island, NE 69802. Representative: Robert D. Eklund, 175 W. Apple Ave., Muskegon, MI 49443–0786, 616–722–1621. Transporting *general commodities* (except classes A and B explosives), between points in the U.S. (except AK and HI) under continuing contract(s) with County Home Bakery, Inc. of Bridgeport, CT; Readi-Bake, Inc. of Grand Rapids, MI; Jesse Lord, Inc. of Los Angeles, CA; Borck County Home Bakeries, Inc. of Atlanta, GA; Michigan Fruit Canners, Division of Curtice-Burns, Inc. of Coloma, MI; Shaw Walker Company of Muskegon, MI; Hi Life Packing Company of Hamilton, MI; and

Lehigh Products, Inc. of Coopersville, MI.

MC 156858 (Sub-1), filed December 7, 1981. Applicant: D J & R TRUCKING, INC. 60 Leonard St., Metuchen, NJ 08840. Representative: Phil Torrisi (same address as applicant), (201) 548–5010. Transporting *agricultural chemicals and product applicators,* between points in the U.S., under continuing contract(s) with Chevron Chemical Company, of Perth Amboy, NJ.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–141 Filed 1–4–82; 8:45 am]

BILLING CODE 7035–01–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importation of Controlled Substances; Application

Pursuant to Section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(h)), the Attorney General shall, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in Schedule I or II, and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with § 1311.42 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on September 17, 1981, Sterling Drug Inc., 1776 North Centennial Drive, McPherson, Kansas 67460, made application to the Drug Enforcement Administration to be registered as an importer of Buprenorphine (9064), a basic class controlled substance in Schedule II.

As to the basic class of controlled substance listed above for which application for registration has been made, any other applicant therefor, and any existing bulk manufacturer registered therefor, may file written comments on or objections to the issuance of such registration and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.54 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Acting Administrator, Drug Enforcement Administration, United States Department of Justice, 1405 I Street, NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative (Room 1203), and must be filed no later than February 8, 1982.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1311.43(b), (c), (d), (e) and (f). As noted in a previous notice at 40 FR 43745–46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Acting Administrator of the Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.42(a), (b), (c), (d), (e) and (f) are satisfied.

Dated: December 28, 1981.

Francis M. Mullen, Jr.,

Acting Administrator, Drug Enforcement Administration.

[FR Doc. 82–211 Filed 1–4–82; 8:45 am]

BILLING CODE 4410–09–M

Importation of Controlled Substances; Application

Pursuant to Section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(h)), the Attorney General shall, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in Schedule I or II, and prior to issuing a regulation under Section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with § 1311.42 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on September 1, 1981, Sigma Chemical Company, 3500 Dekalb Street, St. Louis, Missouri 63118, made application to the Drug Enforcement Administration to be registered as an importer of marihuana (7360), a basic class controlled substance in Schedule I.

As to the basic class of controlled substance listed above for which application for registration has been made, any other applicant therefor, and any existing bulk manufacturer registered therefor, may file written comments on or objections to the issuance of such registration and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.54 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Acting Administrator, Drug Enforcement Administration, U.S. Department of Justice, 1405 I Street NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative (Room 1203), and must be filed no later than February 8, 1982.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1311.42 (b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745–46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Acting Administrator of the Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.42 (a), (b), (c), (d), (e), and (f) are satisfied.

Dated: December 28, 1981.

Francis M. Mullen, Jr.,

Acting Administrator, Drug Enforcement Administration.

[FR Doc. 82–212 Filed 1–4–82; 8:45 am]

BILLING CODE 4410–09–M

Manufacturer of Controlled Substances; Withdrawal

On August 21, 1981, the Drug Enforcement Administration published a Notice of Application in the **Federal Register** (Vol. 46, No. 162, p. 42541) stating that Mallinckrodt, Inc., Dept. CB, Mallinckrodt and Second Street, St. Louis, Missouri 63147, had submitted an application for registration as a bulk manufacturer of hydromorphone (9150), a basic class of controlled substance in Schedule II.

On December 7, 1981, the Drug Enforcement Administration was advised that Mallinckrodt, Inc., Dept. CB, Mallinckrodt and Second Street, St. Louis, Missouri 63147, wishes to withdraw its application for registration as a bulk manufacturer of hydromorphone (9150).

The application having been withdrawn, any proceedings relating to the application have been terminated and the publication withdrawn. This pertains only to hydromorphone (9150).

Dated: December 28, 1981.

Francis M. Mullen, Jr.,

Acting Administrator, Drug Enforcement Administration.

[FR Doc. 82–209 Filed 1–4–82; 8:45 am]

BILLING CODE 4410–09–M

Manufacturer of Controlled Substances; Application

Pursuant to § 1301.43(a) of Title 21 of the Code of Federal Regulations (CFR),

this is notice that on July 8, 1981, Syncates Associates, Inc., 9307–M Harwin, Houston, Texas 77036, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the Schedule II controlled substance pentobarbital.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substance, may file comments or objections to the issuance of the above application and may also file a written request for a hearing thereon in accordance with 21 CFR 1301.54 and in the form prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Acting Administrator, Drug Enforcement Administration, United States Department of Justice, 1405 I Street, NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative (Room 1203), and must be filed no later than February 8, 1982.

Francis M. Mullen, Jr.,

Acting Administrator, Drug Enforcement Administration.

[FR Doc. 82–210 Filed 1–4–82; 8:45 am]

BILLING CODE 4410–09–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Humanities Panel; Cancellation and Rescheduling of Meetings

Notice is hereby given that the meetings of the Humanities Panel scheduled to be held at 806 15th Street, NW., Washington, DC 20506.

In room 314 from 9:00 a.m. to 5:30 p.m. on January 9, 1982 has been canceled the new date is January 13, 1982 in room 314 from 9:00 a.m. to 5:30 p.m.

In room 314 from 9:00 a.m. to 5:30 p.m. on January 13, 1982 has been changed to January 12, 1982 in room 314 from 9:00 a.m. to 5:30 p.m.

In room 1023 from 9:00 a.m. to 5:30 p.m. on January 15, 1982 has been changed to room 1134 from 9:00 a.m. to 5:30 p.m. on January 15, 1982.

These meetings were announced in the Federal Register on Thursday, December 24, 1981 at page 62569.

Joseph Bruns,

Acting Advisory Committee Management Officer.

[FR Doc. 82–182 Filed 1–4–82; 8:45 am]

BILLING CODE 7536–01–M

NATIONAL SCIENCE FOUNDATION

Committee Management; Extension of Advisory Committees

The Foundation is conducting a review of its Advisory Committee structure. Because of this review, the Advisory Committees listed below, which were due to expire December 31, 1981, or as otherwise indicated, are being extended until February 15, 1982.

This extension follows consultation with the Committee Management Secretariat, General Services Administration.

The Advisory Committees being extended are:

Advisory Committee for Astronomical Sciences
Advisory Committee for Atmospheric Sciences
Advisory Committee for Behavioral and Neural Sciences
Advisory Committee for Chemistry
Advisory Committee for Earth Sciences
Advisory Committee for Engineering and Applied Science
Advisory Committee for Environmental Biology
Advisory Committee for International Programs (1/3/82)
Advisory Committee for Materials Research
Advisory Committee for Mathematical and Computer Sciences
Advisory Committee for Ocean Sciences
Advisory Committee for Physics
Advisory Committee for Physiology, Cellular, and Molecular Biology
Advisory Committee for Polar Programs
Advisory Committee for Policy Research and Analysis and Science Resources Studies (1/20/82)
Advisory Committee for Social and Economic Science

Fred K. Murakami,

Committee Management Officer.

December 28, 1981.

[FR Doc. 82–60 Filed 1–4–82; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–249]

Commonwealth Edison Co.; Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 57 to Facility Operating License No. DPR–25, issued to Commonwealth Edison Company, which revised the Technical Specifications for operation of the Dresden Nuclear Power Station, Unit No. 3 located in Grundy County, Illinois. The amendment became effective November 23, 1981.

The amendment authorizes deletion of the requirment to demonstrate the operability of the automatic pressure relief valves daily during the period beginning November 23, 1981 through November 29, 1981 while the High Pressure Coolant Injection System is inoperable.

The application for amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Ch. I, which are set forth in the license amendment. Prior public notice of the amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of the amendment.

For further details with respect to this action, see (1) the application for amendment dated November 23, 1981, (2) the Commission's letter to the licensee dated November 24, 1981, (3) Amendment No. 57 to Facility Operating License No. DPR–25, and (4) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., and at the Morris Public Library, 604 Liberty Street, Morris, Illinois. A copy of items (2), (3) and (4) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Md., this 23rd day of December 1981.

For the Nuclear Regulatory Commission.

Thomas A. Ippolito,

Chief, Operating Reactors Branch No. 2, Division of Licensing.

[FR Doc. 82–131 Filed 1–4–82; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–265]

Commonwealth Edison Co. and Iowa-Illinois Gas and Electric Co.; Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 69 to Facility Operating License DPR–30 issued to

Commonwealth Edision Company and Iowa-Illinois Gas and Electric Company, which revised the Technical Specifications for operation of the Quad Cities Nuclear Power Station, Unit No. 2, located in Rock Island County, Illinois. The amendment becomes effective as of the date of issuance.

The amendment (1) authorizes operation in Cycle 6 using 224 assemblies of prepressurized 8 × 8R fuel, including 144 bundles of GE barrier fuel, (2) incorporates revised Minimum Critical Power Ratio (MCPR) limits in response to plant specific analyses for Cycle 6, (3) incorporates new Maximum Average Planar Linear Heat Generation Rate (MAPLHGR) limits for the barrier fuel, (4) deletes MCPR, MAPLHGR and Linear Heat Generation Rate (LHGR) operating limits for all 7×7 fuel (none to remain in the core), and (5) changes the pressure safety limits due to the recently installed Anticipated Transients Without Scram Recirculation Pump Trip.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Ch. I, which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of the amendment.

For further details with respect to this action, see (1) the application for amendment dated July 27, 1981, as supplemented August 21, 1981, and December 3, 1981, (2) Amendment No. 69 to License No. DPR–30, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document, Room 1717 H Street, NW., Washington, D.C., and at the Moline Public Library, 504—17th Street, Moline, Illinois. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Md, this 23rd day of December 1981.

For the Nuclear Regulatory Commission.

Thomas A. Ippolito,

Chief, Operating Reactors Branch No. 2, Division of Licensing.

[FR Doc. 81-132 Filed 1-4-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-315 and 50-316]

Indiana and Michigan Electric Co.; Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 51 to Facility Operating License No. DPR–58, and Amendment No. 36 to Facility Operating License No. DPR–74 issued to Indiana and Michigan Electric Company (the licensee), which revised Technical Specifications for operation of Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2 (the facilities) located in Berrien County, Michigan. The amendments are effective as of the date of issuance.

The amendments revise the Technical Specifications to provide for limiting conditions for operation of the alternate reserve A. C. power source (69 kv source).

The applications for the amendments comply with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Ch. I, which are set forth in the license amendments. Prior public notice of these amendments was not required since the amendments do not involve a significant hazards consideration.

The Commission has determined that the issuance of these amendments will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of these amendments.

For further details with respect to this action, see (1) the applications for amendments dated December 17, 1979 and May 28, 1980 (as supplemented January 27, 1981), (2) Amendment Nos. 51 and 36 to License Nos. DPR–58 and DPR–74, and (3) the Commission's related letter dated December 28, 1981. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and the Maude Reston Memorial Library, 500 Market Street, St. Joseph, Michigan 49085. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Md., this 28th day of December, 1981.

For The Nuclear Regulatory Commission.

Steven A. Varga,

Chief, Operating Reactors Branch No. 1, Division of Licensing.

[FR Doc. 82-133 Filed 1-4-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-220]

Niagara Mohawk Power Corp.; Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 47 to Facility Operating License No. DPR–63 to Niagara Mohawk Power Corporation (the licensee) which revised the Technical Specifications for operation of the Nine Mile Point Nuclear Station, Unit No. 1 (the facility) located in Oswego County, New York. The amendment is effective as of its date of issuance.

The amendment revises the Technical Specifications to modify the Maximum Average Planar Linear Heat Generation Rate.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Ch. I which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) the application for amendment dated October 26, 1981, (2) Amendment No. 47 to License No. DPR–63, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. and at the Oswego County Office

Building, 46 E. Bridge Street, Oswego, New York 13126. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Md., this 24th day of December 1981.

For the Nuclear Regulatory Commission.

Thomas A. Ippolito,

Chief, Operating Reactors Branch No. 2, Division of Licensing.

[FR Doc. 82-134 Filed 1-4-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-336]

Northeast Nuclear Energy Co., et al.; Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 71 to Facility Operating License No. DPR-65 issued to the Northeast Nuclear Energy Company, the Connecticut Light and Power Company, the Hartford Electric Light Company, and the Western Massachusetts Electric Company (the licensee), which revised Technical Specifications for operation of the Millstone Nuclear Power Station, Unit No. 2 (the facility) located in the Town of Waterford, Connecticut. The amendment is effective as of its date of issuance.

The amendment changes the Technical Specification to modify the operability requirements for two independent shutdown cooling loops.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Ch. I, which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) the applications for amendment dated December 2 and 18, 1981, (2) Amendment No. 71 to License No. DPR-65, and (3) the Commission's letter dated December 18, 1981. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., and at the Waterford Public Library, Rope Ferry Road, Waterford, Connecticut. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Md., this 18th day of December 1981.

For the Nuclear Regulatory Commission.

Robert A. Clark,

Chief, Operating Reactors Branch No. 3, Division of Licensing

[FR Doc. 82-135 Filed 1-4-82; 8:45 am]

BILLING CODE 7590-01-M

[Dockets Nos. 50-277 and 50-278]

Philadelphia Electric Co., et al.; Issuance of Amendments to Facility Operating Licenses

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendments Nos. 82 and 81 to Facility Operating Licenses Nos. DPR-44 and DPR-56, issued to Philadelphia Electric Company, Public Service Electric and Gas Company, Delmarva Power and Light Company, and Atlantic City Electric Company, which revised Technical Specifications for operation of the Peach Bottom Atomic Power Station, Units Nos. 2 and 3 (the facility) located in York County, Pennsylvania. The amendments are effective as of the date of issuance.

These amendments permit an increase in the main steam line tunnel exhaust temperature setpoint from 200°F to 250°F for up to 30 minutes during reactor building ventilation system startups to avoid inadvertent and unnecessary main steam line isolations and reactor trips.

The application for the amendments complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Ch. I, which are set forth in the license amendments. Prior public notice of these amendments was not required since the amendments do not involve a significant hazards consideration.

The Commission has determined that the issuance of these amendments will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of these amendments.

For further details with respect to this action, see (1) the application for amendments dated June 29, 1981, (2) Amendment No. 82 to License No. DPR-44 and Amendment No. 81 to License No. DPR-56 and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. and at the Government Publications Section, State Library of Pennsylvania, Education Building, Commonwealth and Walnut Street, Harrisburg, Pennsylvania. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Md., this 16th day of December 1981.

For the Nuclear Regulatory Commission.

John F. Stolz,

Chief, Operating Reactors Branch No. 4, Division of Licensing.

[FR Doc. 82-136 Filed 1-4-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-346]

Toledo Edison Co. and Cleveland Electric Illuminating Co.; Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 42 to Facility Operating License No. NPF-3, issued to The Toledo Edison Company and The Cleveland Electric Illuminating Company (the licensees), which revised Technical Specifications (TSs) for operation of the Davis-Besse Nuclear Power Station, Unit No. 1 (the facility) located in Ottawa County, Ohio. The amendment is effective as of its date of issuance.

This amendment modifies the TSs concerning regulating rod group position limits, axial power shaping rod group position limits, and axial power imbalance limits. It also modifies (1) the corrective action required by the TSs in the event axial power imbalance limits are exceeded and (2) the surveillance requirement applicable to the axial power shaping rod group position. These modifications will accommodate an extension of the present core cycle length.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Ch. I, which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with the issuance of this amendment.

For further details with respect to this action, see (1) the application for amendment dated November 5, 1981, (2) Amendment No. 42 to License No. NPF–3 and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, and at the University of Toledo Library Documents Department, 2801 West Bancroft Avenue, Toledo, Ohio 43606. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Md., this 23rd day of December 1981.

For the Nuclear Regulatory Commission.

John F. Stolz,

Chief, Operating Reactors Branch No. 4, Division of Licensing.

[FR Doc. 82–137 Filed 1–4–82; 8:45 am]

BILLING CODE 7590–01–M

DEPARTMENT OF THE TREASURY

Fiscal Service

Renegotiation Board Interest Rate

The Renegotiation Board previously published the rate of interest determined by the Secretary of the Treasury pursuant to section 105(b) (2) of the Renegotiation Act of 1951, as amended. Since the Renegotiation Board is no longer in existence, the Department of the Treasury is publishing the current rate of interest.

Therefore, notice is hereby given that, pursuant to section 105(b) (2) of the Renegotiation Act of 1951, as amended, (50 U.S.C. App. Sec. 1215(b) (2)) the Secretary of the Treasury has determined that the rate of interest applicable, for the purposes of said section 105(b) (2) and section 108 of such Act, to the period beginning January 1, 1982 and ending on June 30, 1982, is 14-¾ per centum per annum.

Dated: December 28, 1981.

Gerald Murphy,

Deputy Fiscal Assistant Secretary.

[FR Doc. 82–107 Filed 1–4–82; 8:45 am]

BILLING CODE 4810–35–M

Office of Foreign Assets Control

Account Parties with Standby Letters of Credit in Favor of an Iranian Entity

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: This notice calls to the attention of account parties who have standby letters of credit in favor of an Iranian entity, including instruments against which no demand has been made, relevant factors concerning the purposes of certain sections of the Iranian Assets Control Regulations and the approach of the January 19, 1982, deadline for filing claims with the Iran-United States Claims Tribunal.

FOR FURTHER INFORMATION CONTACT: Dennis M. O'Connell, Director, Office of Foreign Assets Control, Department of the Treasury, Washington, D.C. 20220, Tel: (202) 376–0396.

Pursuant to the agreements of January 19, 1981, between the Governments of the United States and the Islamic Republic of Iran ("the Agreements"), §§ 535.212–535.215 of the Iranian Assets Control Regulations, 31 CFR Part 535 ("the Regulations"), direct the transfer of property in which Iran or an Iranian entity has an interest. However, § 535.438 provides that the transfer directives contained in §§ 535.212 through 535.214 do not apply to obligations under standby letters of credit as to which a blocked account has been established under § 535.568 of the Regulations or as to which payment is prohibited under an injunction obtained by the account party. Section 535.333 excludes obligations under standby letters of credit, including accounts established pursuant to § 535.568, from the definition of Iranian properties subject to transfer under § 535.215.

Under § 535.568 of the Regulations, U.S. banks which have issued or confirmed standby letters of credit in favor of an Iranian entity are required to give notice to the account party when a demand for payment under such letter of credit has been received. Section 535.568(b) permits the account party to obtain a specific license from the Office of Foreign Assets Control authorizing it to establish a blocked account on its books in the name of the Iranian entity for the amount payable under the credit, in lieu of payment by the issuing or confirming bank into a blocked account and reimbursement by the account party. The Regulations provide that none of the transfer directives or other provisions added after conclusion of the Agreements modify the application of the prohibitions and procedures contained in §§ 535.201 and 535.568 to transactions involving standby letters of credit. See §§535.333, 535.438, and 535.579(b).

When adopted, § 535.568 was intended as a temporary measure to protect United States account parties from demands against standby letters of credit during the hostage crisis. After conclusion of the Agreements, § 535.568 was continued in force to allow the account parties and Iran to negotiate disputes concerning the standby letters of credit, as well as disputes concerning the contracts underlying these instruments, where relevant. In the event that such disputes could not be resolved, the Iran-United States Claims Tribunal ("the Tribunal") would be expected to handle standby letter of credit issues with underlying contract claims of U.S. nationals and any Iranian counterclaims arising out of the same transactions.

It has come to the attention of the United States Government that a number of account parties have been unable to resolve their disputes with Iran but have not filed claims with the Tribunal. The United States draws the attention of account parties having standby letters of credit in favor of an Iranian entity, including any such instruments against which no demand has been made, to the fact that the deadline for filing with the Tribunal is January 19, 1982. Account parties should give careful consideration to filing a claim by that time.

Account parties with questions concerning the procedures for filing statements of claim with the Tribunal are directed to notices published by the Department of State at 46 FR 58631 (Dec. 2, 1981), 46 FR 55468 (Nov. 9, 1981), 46 FR 49695 (Oct. 7, 1981), 46 FR 45057 (Sept. 9, 1981), and 46 FR 37418 (July 20, 1981). Account parties requiring further information should contact David P. Stewart, Administrator for Iranian Claims, Office of the Legal Adviser, Department of State, Washington, D.C. 20520; tel.: (202) 632–5040.

The United States notes that it could determine at some future time that it

would be appropriate to modify the current policy concerning standby letters of credit. In that event, modification or revocation of sections pertaining to those instruments could take place. Sections which might be affected in whole or in part include §§ 535.218, 535.222, 535.438, 535.568, and 535.579.

The United States Government reserves the right to require that account parties provide adequate assurances of indemnification to the United States against liability in the Tribunal if it is decided to continue the policies and procedures established in § 535.568 of the Regulations.

Dated: December 31, 1981.

Dennis M. O'Connell,

Director, Office of Foreign Assets Control.

[FR Doc. 81-37480 Filed 12-31-81; 2:12 pm]

BILLING CODE 4810-25-M

VETERANS ADMINISTRATION

Privacy Act of 1974; Amendment of Systems Notices; Revised Systems of Records

1. Notice is hereby given that the VA (Veterans Administration) is considering changing two systems of records entitled, "Veterans and Beneficiary Indentification and Records Locator System-VA" (38VA28), and "Veterans Assistance Discharge System-VA" (45VA28), respectively set forth on page 44739 of the **Federal Register** of March 23, 1979; and page 49751 of the **Federal Register** of December 2, 1977. These two systems are being completely revised as part of an overall Agency effort to administratively update its Privacy Act systems of records. The notices of the systems of records are being rewritten in a clearer, more concise manner, in order to better identify to the public the types of individuals covered by the systems of records, the types of records being maintained by the VA, and the types of routine use disclosures currently being made from the systems. The routine use statements are being separated, reformatted, and/or rewritten in order to be more concise and to conform with the requirements of the VA confidentiality statutes. Also, for the purpose of simplifying usage, the sequence of listing the routine use statements is being changed.

In VA system of records 38VA28, current routine use numbers 11 and 12 are being deleted. In the revised system notice proposed routine use numbers 4, 15, and 16 are being added. Routine use number 4 concerns the release of information to a Federal agency in order to obtain information relevant to the issuance of a benefit under title 38 U.S.C. Routine use number 15 concerns the release of information to the Federal Parent Locator Service in accordance with Pub. L. No. 93-647, which requires disclosure of this information in order to locate missing parents. Routine use number 16 concerns the release of information to a third party requestor who is seeking the current address of a veteran, in order to refer the requestor to the VA regional office where the veteran's folder is located and to assist the regional office in conducting a blind mailing in accordance with 38 CFR 1.518(c).

In VA system of records 45VA28, current routine use numbers 1 and 9 are being deleted. In the revised system notice proposed routine use numbers 4, 10, and 12 are being added. Routine use number 4 concerns the release of information to a Federal agency in order for the VA to obtain information relevant to the issuance of a benefit under title 38 U.S.C. Routine use number 10 concerns the release of information to accredited service organization representatives, VA-approved claims agents and attorneys acting under a declaration of representation so that these individuals can aid veterans in the preparation, presentation, and prosecution of claims under the laws administered by the VA. Routine use number 12 concerns the release of information to the Department of Defense Manpower Data Center for statistical compilation of information contained on the separation documents issued by the Department of Defense.

2. Notice is hereby given that the Veterans Administration is considering changing a system of records entitled, "TARGET-Compensation, Pension, Education and Rehabilitation Records-VA" (58VA21/22), set forth on page 44743 of the **Federal Register** of March 23, 1979. The term "TARGET" has been deleted from the system name, since it is a means of access to information in the system and not the title of the system. The remainder of the system notice has been revised similar to the aforementioned systems. In the current VA system of records 58VA21/22, routine use number 30 has been deleted. In the revised system notice proposed routine use numbers 30, 31, 32, 38, 39, and 41, are being added. Routine use numbers 30 and 31 concern the release of information pursuant to a subpoena from a Federal, State, or municipal grand jury; a Federal, State or municipal court of a party in litigation; a Federal agency or party to an administrative proceeding being conducted by a Federal agency; or to a State or municipal administrative agency functioning in a quasi-judicial capacity or a party to a proceeding being conducted by such agency, in order for the VA to respond to and comply with the issuance of the subpoena. Routine use number 32 concerns the release of information to the ED (Department of Education), or contractor thereof, for specific use by the ED to validate information regarding entitlement to VA benefits which is submitted by applicants who request educational assistance grants from the ED. Routine use number 38 concerns the release of information relating to a veteran's or beneficiary's incarceration in a penal institution, and regarding a dependent's right to a special apportionment of the incarcerated individual's VA benefit payment, to those dependents who may be eligible for entitlement to such apportionment in accordance with 38 U.S.C. 504, 1682, 1780, and 3113. Routine use number 39 concerns the release of information to penal institutions or to correctional authorities in order to verify information concerning the veteran's or beneficiary's incarceration status. Routine use number 39 is necessary in order to determine an incarcerated veteran's or beneficiary's continuing eligibility for benefits. Routine use number 41 concerns the release of information to the Department of Agriculture for the purpose of a matching program designated USDA/OIG-6 for verification by the Department of Agriculture of applicants' eligibility for food stamps, to reduce unauthorized payments in the food stamp program, and to collect debts owed to the United States Government. This anti-fraud matching program is being performed pursuant to the Department of Agriculture's Inspector General authority under Pub. L. No. 95-452, section 4(a), to detect and prevent fraud and abuse.

3. Notice is hereby given that the Veterans Administration is considering deleting two systems of records entitled, "Veterans, Dependents and Beneficiary Compensation and Pension Records-VA" (49VA21), and "Veterans, Dependents, Beneficiaries and Armed Forces Personnel Education and Rehabilitation Records-VA" (50VA22), respectively set forth on pages 44740 and 44741 of the **Federal Register** of March 23, 1979. In 1978 when Target, the VA's automated record system for locating claims folders and determining claims status, was implemented, it was believed to be a significant computer system accessing records requiring Privacy Act protection. Based upon this belief the current system 58VA21/22 was established with the basic intent of

deleting systems 49VA21 and 50VA22. The Department of Veterans Benefits has recently completed a review of its Privacy Act systems of records. This review reemphasized the lack of need to maintain three separate systems of records (49VA21, 50VA22, and 58VA21/22) for the same VA records. Therefore, the three current systems have been consolidated into a proposed system entitled "Compensation, Pension, Education Rehabilitation Records-VA" (58VA21/22/28). The proposed 58VA21/22/28 has been revised to be clearer, more concise, and consistent with the VA confidentiality statutes (38 U.S.C. 3301 and 4132). Therefore, to avoid conflicts and confusion, it is necessary that the current 49VA21 and 50VA22 be deleted at the same time the proposed 58VA21/22/28 is published.

In accordance with 5 U.S.C. 552a(b)(3), the Veterans Administration has adopted and published routine uses for its systems of records. A routine use allows the agency to disclose Privacy Act records/information without the written consent of the individual to whom the record pertains. Within the VA, routine uses are principally used to permit disclosure of information from a Privacy Act system of records to a third party to enable the VA to carry out its programs in the most expeditious manner possible. Generally, a routine use identified in a VA system of records will either specifically identify information, or in the alternative, the general subject matter (i.e., a major group of information such as "identifying information" and "medical information") which is being disclosed. In those instances where a routine use identifies disclosure of a general subject matter, the general subject matter will be specifically described in the "Categories of records in the system" section of the system of records. Routine uses may be used in conjunction with one another. Each VA system of records contains the routine uses which are applicable for that system.

For purposes of these VA systems of records, the subsequent definitional terms or concepts are used as follows:

a. Veteran—A person who served in the active military, naval or air service, and who was discharged or released therefrom under conditions other than dishonorable and whose name and address and other information is maintained by the VA by virtue of the administration of veterans benefits under title 38, United States Code. For purposes of these system notices (unless specifically stated otherwise in the "Categories of individuals covered by this system" section of a system of records) the term "veteran" will also include the dependents of a veteran and any other individual who has been granted veteran status by virtue of a specific statutory authority. The name, address and other information regarding a veteran is protected by 38 U.S.C. sections 3301 and 4132 in addition to the Privacy Act. Accordingly, any disclosures of information concerning a veteran made from these Privacy Act system of records under a routine use or other Privacy Act authority shall be consistent with the provisions of 38 U.S.C. sections 3301 and 4132.

b. Claimant—Any individual making a claim for a benefit under title 38, United States Code, e.g., veteran, nonveteran life insurance beneficiaries.

C. Record—Any item, collection or grouping of information about an individual that is maintained by the agency. It is noted that the term "record" may be used with regard to as little as one descriptive item about an individual.

d. Information v. Data—"Information" is individually identifiable (e.g., record includes an individual's name or address or other identifying information) whereas "data" is not individually identifiable.

e. Subsidiary records—Subsidiary records contain information which is part of a more comprehensive, published VA system of records. Subsidiary records may be physically located separate and apart from the rest of the system of records. Any subsidiary records are maintained for the same general purposes as a published system of records and, therefore, are considered to be part of that published system of records. (OMB Circular A-108.)

f. Disclosures Made "At the Request of the Veteran"—In a few routine use notices, for purposes of section 3301 of title 38, United States Code, the VA has identified situations when the disclosure of a veteran's name and address by the VA to a third party is being made "at the request of the veteran." In these instances, an express or implied consent to disclose a veteran's name or address may be inferred by the VA when a veteran has submitted a claim for VA benefits, inquired into benefits provided by the VA, or has sought assistance from the VA in obtaining any other benefits (e.g., employment, State or local agency benefits programs) to which the veteran might be entitled and referral of the name and address of the veteran by the VA to a third party will reasonably be required for the VA to act on the request of the veteran for assistance.

Interested persons are invited to submit written comments, suggestions, or objections regarding the proposed systems of records to the Administrator of Veterans Affairs (271A), Veterans Administration, 810 Vermont Avenue NW., Washington, D.C. 20420. All relevant material received before February 1, 1982 will be considered. All written comments received will be available for public inspection at the above address only between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays) until February 16, 1982. Any person visiting Central Office for the purpose of inspecting any such comments will be received by the Central Office Veterans Services Unit in room 132. Visitors to any VA field station will be informed that the records are available only in Central Office and furnished the above address and room number.

If no public comment is received during the 30-day review period allowed for public comment or unless otherwise published in the **Federal Register** by the Veterans Administration, the revised systems of records are effective December 24, 1981.

Approved: December 24, 1981.

Francis D. DeGeorge,

Acting Administrator.

Notice of System of Records

1. The system identified as 38VA28, "Veterans and Beneficiaries Identification and Records Locator System—VA", appearing at 43 FR 44739 is revised as follows:

38VA23

SYSTEM NAME:

Veterans and Beneficiaries Identification and Records Location Subsystem—VA

SYSTEM LOCATION:

Records are maintained at the VA Data Processing Center, 1615 East Woodward Street, Austin, Texas 78772; VA Central Office, 810 Vermont Ave., N.W., Washington, D.C. 20420; the VA Records Processing Center, P.O. Box 5020, St. Louis, Missouri 63115 and at Neosho, Missouri.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The following categories of individuals will be covered by the system: (1) Veterans who applied for VA benefits (e.g., compensation, pension,, rehabilitation and education, U.S. Government life insurance, National Service life insurance, and medical and dental care); (2) veterans discharged from military service since March 1973; (3) veterans because of whose military

service benefits have been sought by others (e.g., beneficiaries (spouse, children or parents) who have applied for or who are receiving or have received VA benefits (i.e., insurance awards, education, burial benefits)); (4) Medal of Honor recipients; and (5) service members who have established accounts from which future applications for VA educational benefits under title 38, United States Code, Chapter 32 may be used.

CATEGORIES OF RECORDS IN THE SYSTEM:

The record, or information contained in the record may include (1) identifying information, (2) military discharge information, (3) date of death, (4) VA claims and insurance file numbers, (5) records location and (6) cross-references to beneficiaries of a veteran and to other names used by the veteran. Identifying information may include the following concerning the veteran: full name, social security number, service number, date of birth, entry and release from active duty, character of service, and branch of service. Military discharge information may include sex, total amount of active service, the dollar amount of readjustment or severance pay, number of nonpaydays, pay grade, narrative reason for separation and information on whether the veteran was discharged with a disability, served during the Vietnam Conflict, reenlisted in the military service, or received a Purple Heart award.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 38, United States Code, Chapter 3, section 210(c)(1)

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USES AND THE PURPOSES OF SUCH USES:

1. The record of an individual who is covered by this system may be disclosed to a member of Congress or staff person acting for the member when the member or staff person requests the record on behalf of and at the request of that individual.

2. Any information in this system may be disclosed to a Federal agency, upon its official request, to the extent that it is relevant and necessary to that agency's decision regarding: the hiring, retention or transfer of an employee; the issuance of a security clearance, the letting of a contract, or the issuance or continuance of a license, grant or other benefit given by that agency. However, in accordance with an agreement with the U.S. Postal Service, disclosures to the U.S. Postal Service for decisions concerning the employment of veterans will only be made with the veteran's prior written consent.

3. Any information in this system may be disclosed to a State or local agency, upon its official request, to the extent that it is relevant and necessary to that agency's decision on: the hiring, transfer or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance or continuance of a license, grant or other benefit by that agency; *Provided,* that if the information pertains to a veteran, the name of the veteran will not be disclosed unless the name is provided first by the requesting State or local agency.

4. Any information in this system, except for the name of a veteran, may be disclosed to a Federal agency in order for the VA to obtain information relevant to the issuance of a benefit under title 38, United States Code. The name of a veteran may be disclosed to a Federal agency under this routine use if the name is required by the Federal agency to respond to the VA inquiry.

5. Any information in this system, except for the name of a veteran, which is relevant to a suspected violation or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, may be disclosed to a Federal, State, local or foreign agency charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, rule, regulation or order issued pursuant thereto.

6. The name of a veteran, which is relevant to a suspected violation or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, may be disclosed to a Federal agency charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto, in response to its official request.

7. The name of a veteran, which is relevant to a suspected violation, or reasonably imminent violation of law concerning public health or safety, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, may be disclosed to any foreign, State or local governmental agency or instrumentality charged under applicable law with the protection of the public health or safety if a qualified representative of such organization, agency or instrumentality has made a written request that the name be provided for a purpose authorized by law.

8. Any information, including the name of a veteran, may be disclosed to any nonprofit organization if the release is directly connected with the conduct of programs and the utilization of benefits under title 38 U.S.C. (such disclosures include computerized lists of names).

9. The file number and folder location may be disclosed to the Railroad Retirement Board (RRB) pursuant to its standing request. This information is used by the RRB to obtain information from VA compensation, pension, or education records in accordance with the Railroad Retirement Act of 1937, § 228.1(i).

10. Any information in this system may be disclosed to components of the Armed Forces such as the National Personnel Record Center (NPRC) and the U.S. Army Reserve Components Personnel and Administration Center (RCPAC) in accordance with its standing request. This information is used to aid in rebuilding lost military service records and to upgrade the character of discharge or to correct or complete military records.

11. Identifying information, the claims file number and folder location may be disclosed to the National Research Council, National Academy of Sciences, in accordance with its standing request. This information is used in medical studies for the VA or another Federal agency as approved by the Chief Medical Director.

12. Identifying information, the claims file number and folder location may be disclosed to the U.S. Treasury upon its official request. This information is used to obtain the necessary information to return U.S. savings bonds to veterans which are currently in the safekeeping of the U.S. Treasury.

13. A veteran's claims or insurance file number and folder location may be disclosed to accredited service organization representatives, VA-approved claims agents and attorneys acting under a declaration of representation so that these individuals can aid veterans in the preparation, presentation, and prosecution of claims under the laws administered by the VA.

14. Identifying information, the claims file number and folder locaton may be disclosed to research facilities provided the name of the veteran is furnished by the requestor. The purpose of this disclosure is for such research facilities to obtain information necessary to assist in the medical studies of the veterans. These studies must be approved by the VA Chief Medical Director.

15. Identifying information, the claims file number and folder location may be diclosed to the Federal Parent Locator Service (PLS) of the Department of Health and Human Services upon its official request in accordance with Public Law No. 93–647, which requires disclosure of this information in order to locate missing parents.

16. The claims file number and the folder location may be disclosed to a third party requestor who is seeking the current address of the veteran, in order to refer the requestor to the VA regional office where the veteran's folder is located and to assist the regional office in conducting a blind mailing in accordance with 38 CFR 1.518(c).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Th basic file is on magnetic disks with backup copies of the information on magnetic tape at Neosho, Missouri. An adjunct file (at the Records Processing Center in St. Louis, Missouri) contains microfilm and paper documents of former manual Central Index claims numbers registers, partial files of pensioners with service prior to 1930, personnel with service between 1940 and 1948 with VA insurance, and partial lists of other Armed Forces personnel indexed by service number. A duplicate of the microfilm is also located at VA Central Office.

RETRIEABILITY:

Information can be retrieved by the use of name only, name and one or more number (service, social security, VA claims file and VA insurance file number), name and one or more criteria (i.e., dates of birth, death and service), number only, or initials or first five letters of last name with incorrect file number.

SAFEGUARDS:

Access to the basic file in the Austin DPC (Data Processinng Center) is restricted to authorized VA employees and vendors. Access to the computer room where the basic file is maintained within the DPC is further restricted to authorized VA employees and vendor personnel on a "need to know" basis and is protected from unauthorized access by an alarm system, the Federal Protective Service, and VA security personnel. Information in the system may be accessed from authorized terminals via a multi-Federal telecommunications network maintained by the General Services Administration known as the Advanced Records System (ARS) or it may be accessed from a VA telecommunications network known as Target (see Compensation, Pension, Education and Rehabilitation Records—58VA21/22/28). The ARS system terminals are teletype only (i.e., do not have visual screens). The ARS system recognizes only authorized users. As to access to Target terminals, see Safeguards, Compensation, Pension, Education, and Rehabilitation Records—58VA21/22/28. Currently, authorized ARS terminals are located only at VA regional offices. VA medical facilities, VA Central Office, New York Long Island National Cemetery, Railroad Retirement Board, the National Records Personnel Center and the U.S. Army Reserve Components Personnel and Administration Center at St. Louis, Missouri. The adjunct file is accessible for official use only by personnel assigned to Administrative Service (23), VA Central Office, Washington, D.C., and the BIRLS Support Division VA Records Processing Center, St. Louis, Missouri.

RETENTION AND DISPOSAL:

Records are maintained on magnetic tape, disks, microfilm or paper documents and are retained and disposed of in accordance with disposition authorization approved by the Archivist of the United States.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Administrative Service (23), VA Central Office, 810 Vermont Avenue, NW., Washington, D.C. 20420.

NOTIFICATION PROCEDURE:

Any individual who wishes to determine whether a record is being maintained in this system under his or her name or other personal identifier, or wants to determine the contents of such record should submit a written request or apply in person to the nearest VA regional office or center. Addresses for these offices may be found in VA Appendix 1 at the end of this document. Inquires should include the individual's full name and VA claims file number. If the VA claims file number is not available, then as much of the following information concerning the service person as possible should be furnished: social security number, service number, branch of service, dates of service, date of birth or date of death.

RECORD ACCESS PROCEDURES:

Individuals seeking information regarding access to and contesting of VA records in this system may write, call or visit the nearest VA regional office.

CONTESTING RECORD PROCEDURES:

(See Record access procedures above.)

RECORD SOURCE CATEGORIES:

Information contained in the records is obtained from veterans' military separation documents, veterans, VA records, the Railroad Retirement Board and other Federal agencies.

2. The system identified as 45VA28, "Veterans Assistance Discharge System—VA", appearing at 42 FR 49751 is revised as follows:

45VA23

SYSTEM NAME:

Veterans Assistance Discharge System (VADS)–VA

SYSTEM LOCATION:

Records are maintained at the VA Data Processing Center, 1615 East Woodward Street, Austin, Texas 78772.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals (veterans only) released from active military service from March, 1973, for whom separation documents (i.e., DD Form 214, 215) were received in the Data Processing Center, Austin, Texas.

CATEGORIES OF RECORDS IN THE SYSTEM:

The record, or information contained in the record may include identifying information and military discharge information. Identifying information may include the following concerning the veteran: full name, social security number, service number, dates of birth. Military discharge information generally includes the primary military occupational specialty number, entry and release from active duty, character of service, branch of service, and mailing address at the time of discharge, amount of education (e.g., high school graduate or equivalent or *not* high school graduate or equivalent), sex, total amount of active service, the dollar amount of readjustment or severance pay, number of nonpaydays, pay grade, narrative reason for separation and whether the veteran was discharged with a disability, served in the Vietnam Conflict, reenlisted in the military service or received a military decoration such as a Purple Heart.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 38, United States Code, Chapter 3, section 210(c).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USES AND THE PURPOSES OF SUCH USES:

1. The record of an individual who is covered by this system may be disclosed to a member of Congress or staff person acting for the member when the member or staff person requests the record on behalf of and at the request of that individual.

2. Any information in this system may be disclosed to a Federal agency, upon its official request, to the extent that it is relevant and necessary to that agency's decision regarding: the hiring, retention or transfer of an employee; the issuance of a security clearance, the letting of a contract, or the issuance or continuance of a license, grant or other benefit given by that agency. However, in accordance with an agreement with the U.S. Postal Service, disclosures to the U.S. Postal Service for decisions concerning the employment of veterans will only be made with the veteran's prior written consent.

3. Any information in this system may be diclosed to a State or local agency, upon its official request, to the extent that it is relevant and necessary to that agency's decision on: the hiring, transfer or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance or continuance of a license, grant or other benefit by that agency; Provided, that if the information pertains to a veteran, the name and address of the veteran will not be disclosed unless the name and address is provided first by the requesting State or local agency.

4. Any information in this system may be disclosed to a Federal agency, except for the name and address of a veteran, in order for the VA to obtain information relevant to the issuance of a benefit under title 38 U.S.C. The name and address of a veteran may be disclosed to a Federal agency under this routine use if they are required by the Federal agency to respond to the VA inquiry.

5. Any information in this system, except for the name and address of a veteran, which is relevant to a suspected violation or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, may be disclosed to a Federal, State, local or foreign agency charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, rule, regulation or order issued pursuant thereto.

6. The name and address of a veteran, which is relevant to a suspected violation or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, may be disclosed to a Federal agency charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto, in response to its official request.

7. The name and address of a veteran, which is relevant to a suspected violation or reasonably imminent violation of law concerning public health or safety, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, may be disclosed to any foreign State or local governmental agency or instrumentality charged under applicable law with the protection of the public health or safety if a qualified representative of such organization, agency or instrumentality has made a written request that such name and address be provided for a purpose authorized by law.

8. Any information, including name and address of a veteran, may be disclosed to any nonprofit organization if the release is directly connected with the conduct of programs and the utilization of benefits under title 38 U.S.C. (such disclosures include computerized lists of names and addresses).

9. A listing of names and addresses of educationally disadvantaged veterans residing in a specific geographic area may be disclosed to VA-approved nonprofit educational facilities in order to aid these facilities in VA outreach programs by permitting direct contact with the educationally disadvantaged veteran.

10. Identifying information may be disclosed at the request of the veteran to accredited service organization representatives, VA-approved claims agents and attorneys acting under a declaration of representation so that these individuals can aid veterans in the preparation, presentation, and prosecution of claims under the laws administered by the VA. The name and address of a veteran will not, however, be disclosed to these individuals if the veteran has not requested the assistance of an accredited service organization, claims agent or an attorney.

11. The names and addresses and military discharge information (e.g., job-related information regarding veterans with a certain primary occupational specialty number) may be disclosed upon official request to the Departments of Justice, Labor and to the Department of Health and Human Services, Operation MEDIHC (Military Experience Directed Into Health Careers) State coordinators. These disclosures help veterans who were trained in health and other skills while in the military to learn of career opportunities.

12. Any information in this system of records may be disclosed to the Department of Defense Manpower Data Center, upon its official request, for statistical compilation of information contained on the separation documents issued by the Department of Defense.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on magnetic tape.

RETRIEVABILITY:

Records are retrievable by use of the social security number and the first five letters of the last name.

SAFEGUARDS:

Access to the basic file in the Austin DPC (Data Processing Center) is restricted to authorized VA employees and vendors. Access to the computer room where the magnetic tape is located within the DPC is further restricted to specifically authorized employees and is protected by an alarm system, the Federal Protective Service, and other VA security personnel.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with disposition authorization approved by the Archivist of the United States.

SYSTEM MANAGER(S) AND ADDRESSES:

Director, Administrative Service (23), VA Central Office, 810 Vermont Avenue NW., Washington, D.C. 20420.

NOTIFICATION PROCEDURES:

An individual who wishes to determine whether a record is being maintained in this system under his or her name or other personal identifier, or wants to determine the contents of such record, should submit a written request or apply in person to the Director, Administrative Service (23), VA Central Office, 810 Vermont Avenue NW., Washington, D.C. 20420. Inquiries should include the individual's full name and social security number.

RECORD ACCESS PROCEDURES:

Interested persons seeking information regarding access to and contesting of VA records may write, call or visit the Director, Administrative Service (23), VA Central Office, 810 Vermont Avenue, NW., Washington, D.C. 20420.

CONTESTING RECORD PROCEDURES:

(See Record access procedures above.)

RECORD SOURCE CATEGORIES:

The Department of Defense which provides copies to VA of DD Form 214, Certificate of Release or Discharge from Active Duty, DD Form 215, Correction to DD Form 214, U.S. Public Health Service which provides copies to the VA of PHS–1867, Statement of Service—Verification of Status of Commissioned Officers of the U.S. PHS, and the National Oceanic and Atmospheric Administration which provides the VA with copies of ESSA Form 56–16, report of separation, discharge.

3. The system identified as 58VA21/22, "TARGET-Compensation, Pension, Education and Rehabilitation Records", appearing at 43 FR 44743 is revised as follows:

58VA21/22/28

SYSTEM NAME:

Compensation, Pension, Education and Rehabilitation Records-VA.

SYSTEM LOCATION:

Records are maintained at the VA regional offices, the VA Records Processing Center, St. Louis, Missouri, and the Data Processing Center at Hines, Illinois, with subsidiary accounts receivable records located at the Data Processing Center, St. Paul, Minnesota. Active records are generally maintained by the regional office having jurisdiction over the domicile of the claimant. Address locations are listed in VA Appendix 1 at the end of this document.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The following categories of individuals will be covered by the system:

(1) Veterans who have applied for compensation for service-connected disability under 38 U.S.C. Chapter 11.

(2) Veterans who have applied for nonservice-connected disability, under 38 U.S.C. Chapter 23.

(3) Veterans entitled to burial benefits under 38 U.S.C. Chapter 15.

(4) Surviving spouses and children who have claimed pension based on nonservice-connected death of a veteran under 38 U.S.C. Chapter 15.

(5) Surviving spouses and children who have claimed pension based on service-connected death of a veteran under 38 U.S.C. Chapter 11.

(6) Surviving spouses and children who have claimed dependency and indemnity compensation for service-connected death of a veteran under 38 U.S.C. Chapter 13.

(7) Parents who have applied for death compensation based on service-connected death of a veteran under 38 U.S.C. Chapter 11.

(8) Parents who have applied for dependency and indemnity compensation for service-connected death of a veteran under 38 U.S.C. Chapter 13.

(9) Veterans who have applied for VA educational benefits under 38 U.S.C. Chapters 31, 32 and 34.

(10) Spouses, surviving spouses and children of veterans who have applied for VA educational benefits under 38 U.S.C. Chapter 35.

(10) Spouses, surviving spouses and children of veterans who have applied for VA educational benefits under 38 U.S.C. Chapter 35.

(11) Servicemembers who have applied for educational benefits under 38 U.S.C. chapter 34 and 35.

(12) Servicemembers who have contributed money from their military pay to the post-Vietnam Era veterans Education Account under 38 U.S.C. Chapter 32.

CATEGORIES OF RECORDS IN THE SYSTEM:

The record, or information contained in the record, may include indentifying information (e.g., name, address, social security number); military service and active duty separation information (e.g., name, service number, date of birth, rank, sex, total amount of active service, branch of service, character of service, pay grade, assigned separation reason, whether veteran was discharged with a disability, served in Vietnam Conflict, reenlisted, received a Purple Heart of other military decoration); payment information (e.g., veteran payee name, address, dollar amount of readjustment service pay, amount of disability or pension payments number of nonpaydays, any amount of indebtedness (accounts receivable) arising from title 38 U.S.C. benefits and which are owed to the VA); medical information (e.g., medical and dental treatment in the Armed Forces including type of service-connected disabilty, medical facilities or by VA health care personnel or received from private hospitals and health care personnel relating to a claim for VA disability benefits or medical or dental treatment); personal information (e.g., martial status, name and address of dependents, occupation, amount of education of a veteran or a dependent, dependent's relationship to veteran); education benefit information (e.g., information arising from utilization or training benefits such as a veteran trainee's induction, reentrance or dismissal from a program or progress and attendance in an education or training program); applications for compensation, pension, education and rehabilitation benefits and training which may contain identifying information, military service and active duty separation information, payment information, medical and dental information, personal and education benefit information relating to a veteran or beneficiary's incarceration in a penal institution (e.g., name of incarcerated veteran or beneficiary, claims file number, name and address of penal institution, date of commitment, type of offense, scheduled release date, vetreran's date of birth, beneficiary relationship to veteran and whether veteran or beneficiary is in a work release or half way house program, on parole or has been released from incarceration).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 38, United States Code, Chapter 3, section 210(c) and Chapters 11, 13, 15, 23, 31, 32, 34, 35, and 36.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. The record of an individual who is covered by this system may be disclosed to a member of Congress or staff person acting for the member when the member or staff person requests the record on behalf of and at the request of that individual.

2. Any information in this system may be disclosed to a Federal agency, upon its official request, to the extent that it is relevant and necessary to that agency's decision regarding: the hiring, retention or transfer of an employee; the issuance of a security clearance, the letting of a contract, or the issuance or continuance of a license, grant or other benefit given by that agency. However, in accordance with an agreement with the U.S. Postal Service, disclosures to the U.S. Postal Service for decisions concerning the employment of veterans will only be made with the veteran's prior written consent.

3. Any written information in this system may be disclosed to a State or local agency, upon official request, to the extent that it is relevant and necessary to that agency's decision on:

the hiring, retention or transfer of an employee, the issuance of a security clearance, the letting of a contract, or the issuance or continuance of a license, grant or other benefit by that agency; Provided, that if the information pertains to a veteran, the name and address of the veteran will not be disclosed unless the name and address is provided first by the requesting State or local agency.

4. Any information in this system, except for the name and address of a veteran, which is relevant to a suspected violation or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, may be disclosed to a Federal, State, local or foreign agency charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, rule, regulation or order issued pursuant thereto.

5. The name and address of a veteran, which is relevant to a suspected violation or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, may be disclosed to a Federal agency charged with the responsibility of investigation or prosecuting such violation or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto, in response to its official request.

6. The name and address of a veteran, which is relevant to a suspected violation or reasonably imminent violation of law concerning public health or safety, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, may be disclosed to any foreign, State or local governmental agency or instrumentality charged under applicable law with the protection of the public health or safety if a qualified representative of such organization, agency or instrumentality has made a written request that such name and address be provided for a purpose authorized by law.

7. The name and address of a veteran may be disclosed to any nonprofit organization if the release is directly connected with the conduct of programs and the utilization of benefits under title 38 U.S.C. (such disclosures include computerized lists of names and addresses).

8. Any information in this system, except for the name and address of a veteran, may be disclosed to a Federal agency in order for the VA to obtain information relevant to the issuance of a benefit under title 38 U.S.C. The name and address of a veteran may be disclosed to a Federal agency under this routine use if they are required by the Federal agency to respond to the VA inquiry.

9. Any information in this system may be disclosed in connection with any proceeding for the collection of an amount owed to the United States by virtue of a person's participation in any benefit program administered by the Veterans Administration when in the judgment of the Administrator, or official generally delegated such authority under standard agency delegation of authority rules (38 CFR 2.6), such disclosure is deemed necessary and proper, in accordance with 38 U.S.C. 3301(b)(6).

10. The name and address of a veteran, and other information as is reasonably necessary to identify such veteran, may be disclosed to a consumer reporting agency for the purpose of locating the veteran, or, obtaining a consumer report to determine the ability of the veteran to repay an indebtedness to the United States arising by virtue of the veteran's participation in a benefits program administered by the VA, provided that the requirements of 38 U.S.C. 3301(g)(2) have been met.

11. The name and address of a veteran, other information as is reasonably necessary to identify such veteran, and any information concerning the veteran's indebtedness to the United States by virtue of the person's participation in a benefits program administered by the VA may be disclosed to a consumer reporting agency for purposes of assisting in the collection of such indebtedness, provided that the provisions of 38 U.S.C. 3301(g)(4) have been met.

12. Any information in this system, including available identifying information regarding the debtor, such as name of debtor, last known address or debtor, VA insurance number, VA loan number, VA claim number, place of birth, date of birth of debtor, name and address of debtor's employer or firm and dates of employment may be disclosed, under this routine use, except to consumer reporting agencies, to a third party in order to obtain current name, address, locator, and credit report in connection with any proceeding for the collection of an amount owed to the United States by virtue of a person's participation in any VA benefit program when in the judgment of the Administrator such disclosure is deemed necessary and proper. This purpose is consistent with the Federal Claims Collection Act of 1966 (Public Law No. 89-508, 37 U.S.C. 951-953 and 4 CFR 101-105 and 38 U.S.C. 3301(b)(6).

13. Any information in this system, including the nature and amount of a financial obligation, may be disclosed to a debtor's employing agency or commanding officer so that the debtor-employee may be counseled by his or her Federal employer or commanding officer and to assist in the collection of unpaid financial obligations owed the VA. This purpose is consistent with 5 U.S.C. 5514, 4 CFR 102.5, and section 206 of Executive Order 11222 of May 8, 1965 (30 FR 6469).

14. Payment information may be disclosed to the Department of the Treasury, in accordance with its official request, to permit delivery of benefit checks to veteran-payees.

15. Military service and active duty separation information, and identifying information may be disclosed to a State unemployment compensation agency to the extent required to determine eligibility for its benefits, provided the name and address of the individual to whom the record pertains are provided by the State agency. The purpose for this disclosure is consistent with 5 U.S.C. 8523.

16. Medical information may be disclosed in response to a request from the superintendent of a State hospital for psychotic patients, a commissioner or head of a State department of mental hygiene, or a head of a State, county or city health department or any fee basis physician or sharing institution in direct connection with authorized treatment for a veteran provided the name of the individual to whom the record pertains is given and the information will be treated as confidential, as is customary in civilian professional medical practice.

17. The name, branch of service, effective date of compensation, current and historical benefit pay amounts for disability or pension and the amount and type of education contribution made under title 38, United States Code, Chapter 32, may be disclosed to the following agencies upon their official request: Department of the Army, Navy, and Air Force; Department of Defense; Defense Manpower Data Center, Marine Corps; Department of Transportation (Coast Guard); Department of Health and Human Services; Department of Education; PHS (Public Health Service), NOAA (National Oceanic and Atmospheric Administration), Commissioned Officer Corps in order for these departments and agencies and the VA to reconcile the amount and/or waiver of service, department and retired pay.

18. The amount of pension, compensation, dependency and indemnity compensation, educational assistance allowance, retirement pay and subsistence allowance of any veteran identified to the VA may be disclosed to any person who applies for such information.

19. Identifying, personal, payment and medical information may be disclosed to a Federal, State, or local government agency at the request of a veteran in order to assist the veteran and insure that all of the title 38 U.S.C. or other benefits to which the veteran is entitled are received. This information may also be disclosed without a request from the veteran, to a Federal agency, upon its official request or to a State or local agency provided the name and address of the veteran is given beforehand by the State or local agency in order to assist the veteran in obtaining a non-title 38 U.S.C. benefit to which the veteran is entitled.

20. Any information in this system which directly affects payment or potential payment of benefits to contesting claimants, including parties claiming an apportioned share of benefits, may be coequally disclosed to each affected claimant upon request from that claimant in conjunction with the claim for benefits sought or received.

21. Any information in this system such as identifying information, nature of a claim, amount of benefit payments, percentage of disability and personal information, may be disclosed to the Social Security Administration, Bureau of Supplemental Security Income, upon its official request, in order for that agency to determine eligibility regarding amounts of social security benefits, or to verify other information with respect thereto.

22. Identifying information in this system may be disclosed at the request of a veteran to a third party having information relevant to a claim, such as an employer or school, in order to obtain information from the third party to the extent necessary to develop a veteran's claim for VA benefits.

23. Medical data (excluding the name and address of a veteran unless the name and address are furnished by the requestor) may be disclosed to epidemiological and other research facilities approved by the Chief Medical Director to obtain data from those facilities necessary to assist in medical studies on veterans for the Veterans Administration or for any research purposes determined to be necessary and proper by the Chief Medical Director.

24. The name(s) and address(es) of a veteran may be disclosed to another Federal agency or to a contractor of that agency, at the written request of the head of that agency or designee of the head of that agency for the purpose of conducting government research necessary to accomplish a statutory purpose of that agency.

25. Any information in this system relevant to a veteran's claim such as the name, address, the basis and nature of a claim, amount of benefit payment information, medical information and military service and active duty separation information may be disclosed at the request of the veteran to accredited service organizations, VA-approved claims agents and attorneys acting under a declaration of representation so that these individuals can aid veterans in the preparation, presentation and prosecution of claims under the laws administered by the VA. The name and address of a veteran will not, however, be disclosed to these individuals under this routine use if the veteran has not requested the assistance of an accredited service organization, claims agent or an attorney.

26. Identifying and payment information may be disclosed, upon the request of a Federal agency, to a State or local government agency, in order for that State or local government agency to determine a veteran's eligibility under programs provided for under Federal legislation and for which the requesting Federal agency has responsibility.

27. Any information in this system such as the amount of benefit or disability payments and medical information may be disclosed in the course of presenting evidence to a court, magistrate, or administrative authority, in matters of guardianship, inquests, and commitments, to private attorneys representing veterans rated incompetent in conjunction with issuance of Certificates of Incompetency, and to probation and parole officers in connection with court-required duties.

28. Any information in this system including medical information, the basis and nature of claim, the amount of benefits and personal information may be disclosed to a VA Federal fiduciary or a guardian ad litem in relation to his or her representation of a veteran only to the extent necessary to fulfill the duties of the VA Federal fiduciary or the guardian ad litem.

29. Any information in this system may be disclosed to the United States Department of Justice or United States Attorneys in order for the foregoing parties to prosecute or defend litigation involving or pertaining to the United States.

30. Any information in this system may be disclosed to a Federal grand jury, a Federal court or a party in litigation, or a Federal agency or party to an administrative proceeding being conducted by a Federal agency, in order for the VA to respond to and comply with the issuance of a Federal subpoena.

31. Any information in this system may be disclosed to a State or municipal grand jury, a State or municipal court or a party in litigation, or to a State or municipal administrative agency functioning in a quasi-judicial capacity or a party to a proceeding being conducted by such agency, in order for the VA to respond to and comply with the issuance of a State or municipal subpoena; provided, that any disclosure of claimant information made under this routine use must comply with the provisions of 38 CFR 1.511.

32. Any information in this system including the name, social security number, date of birth, delimiting date and remaining entitlement of VA educational benefits, may be disclosed to the ED (Department of Education), upon its official request, or contractor thereof, for specific use by the ED to validate information regarding entitlement to VA benefits which is submitted by applicants who request educational assistance grants from the ED. Such information will not be used for any other purpose by the ED or contractor thereof.

33. VA educational forms and letters which contain identifying information about a veteran may be disclosed at the request of the veteran to a VA-approved education or training establishment to assist the veteran in the completion of claims forms or for the VA to obtain further information from the educational or training establishments as may be necessary for the VA to properly process the veteran trainee's claim or to monitor the trainee's progress.

34. Identifying and payment information may be disclosed to a VA-approved educational or training establishment at the request of the veteran in order for the VA to obtain sufficient information necessary to pay the veteran or the educational or training establishment the correct monetary amounts in an expeditious manner. However, this information will not be provided under this routine use to an educational or training establishment when the request is clearly an attempt by that establishment to seek assistance in collection attempts against the veteran.

35. Identifying information and information regarding the induction, reentrance and dismissal of a disabled veteran from a vocational rehabilitation program may be disclosed at the request of the veteran to a VA-approved vocational rehabilitation training establishment to insure that the trainee receives the maximum benefit from training.

36. Identifying information and information regarding the extent and nature of a veteran's disabilities with respect to any limitations to be imposed on the veteran's vocational programs may be disclosed at the request of the veteran to a VA–approved vocational rehabilitation training establishment to insure that the trainee receives the maximum benefit from training.

37. Information regarding the type and amount of training/education received, and the name and address of a veteran, may be disclosed at the request of a veteran to local and State agencies and to prospective employers in order to assist the veteran in obtaining employment or further training.

38. The name, claims file number and any other information relating to a veteran's or beneficiary's incarceration in a penal institution and information regarding a dependent's right to a special apportionment of the incarcerated individual's VA benefit payment may be disclosed to those dependents who may be eligible for entitlement to such apportionment in accordance with 38 U.S.C. 504, 1682, 1780, and 3113.

39. The name, claims file number and any other information relating to a veteran or beneficiary who may be incarcerated in a penal institution may, pursuant to an arrangement, be disclosed to penal institutions or to correctional authorities in order to verify information concerning the veteran's or beneficiary's incarceration status. The disclosure of this information is necessary to determine that individual's continuing eligibility as authorized under 38 U.S.C. 504, 1682, 1780 and 3113.

40. Names and addresses, and other identifying data including the Social Security number, of surviving spouses, children and parents of decreased veterans may be released from this system of records to the Department of Defense (DOD) upon its official request in order for DOD to identify individuals eligible for health care benefits administered by the DOD, or to collect or verify information necessary for DOD facility planning, personnel studies, capitalization budgeting and post exchange, commissary and housing studies.

41. Identifying infomation including names and addresses, entitlement code, payee social security number, file number, payee number, regional office number, income for VA pension-determination purposes and pension net award may be released to the Department of Agriculture upon its official request for the purpose of a matching program designated USDA/OIG–6 for verification by the Department of Agriculture of applicants' eligibility for food stamps to reduce unauthorized payments in the food stamp program, and to collect debts owed to the United States Government. This anti-fraud matching program is being performed pursuant to the Department of Agriculture's Inspector General authority under Public Law No. 95–452, section 4(a), to detect and prevent fraud and abuse.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records (or information contained in records) are maintained on paper documents in claims file folders (e.g., "C" file folders, educational file folders and vocational rehabilitation file folders) and on automated storage media (e.g., microfilm, microfiche, magnetic tape and magnetic disks). Critical eligibility information regarding VA benefits is maintained on various automated storage media. Such information may be accessed through a data telecommunications terminal system denominated the Target System. Target terminal locations include VA Central Office, regional offices, and on a pilot basis some VA medical health care facilities. Information relating to receivable accounts owed to the VA, denominated the Centralized Accounts Receivable System (CARS), is maintained on magnetic tape and microfiche and microfilm. CARS is accessed through a data telecommunications terminal system at St. Paul, Minnesota.

RETRIEVABILITY:

Claims file folders are indexed by name of the veteran and VA file number. Automated records are indexed by named, VA file number, payee name and type of benefit.

SAFEGUARDS:

1. Physical Security: (a) access to working spaces and claims folder file storage areas in VA regional offices and centers is restricted to VA employees on a need-to-know basis. Generally, file areas are locked after normal duty hours and the offices and centers are protected from outside access by the Federal Protective Service or other security personnel. Employee claims file records and claims file records of public figures are stored in separate locked files. Strict control measures are enforced to ensure that access to and disclosure from these claims file records are limited to a need-to-know basis.

(b) Access to Target data telecommunications terminals is by authorization controlled by the site security officer. The security officer is assigned responsibility for privacy-security measures, especially for review of violations logs, information logs and control of password and badge distribution.

(c) Access to data processing centers is generally restricted to center employees, custodial personnel, Federal Protective Service and other security personnel. Access to computer rooms is restricted to authorized operational personnal through electronic locking devices. All other persons gaining access to computer rooms are escorted.

2. Target System Security: (a) Usage of the Target terminal equipment is protected by key locks, magnetic badge readers and audible alarms. Electronic keyboard locks are activated on security errors.

(b) At the data processing centers, identification of magnetic tape and disks containing data is rigidly enforced using labeling techniques. Automated storage media which are not in use are stored in tape libraries which are secured in locked rooms. Access to programs is controlled at three levels: programming, auditing and operations.

RETENTION AND DISPOSAL:

Individual claims file folders and the compensation, pension, rehabilitation and education claims records contained therein are retained at the servicing regional office for the life of the veteran. At the death of the veteran, these records are sent to the Federal Records Center (FRC), maintained by the FRC for 75 years and thereafter destroyed. Rehabilitation and education counseling records are maintained until the exhaustion of a veteran's maximum entitlement or upon the exceeding of a veteran's delimiting date of eligibility (generally, ten or twelve years from discharge or release from active duty), whichever occurs first, and then destroyed. Automated storage media containing temporary working information are retained until a claim is processed to determination. All other automated storage media is retained and disposed of in accordance with disposition authorization approved by the Archivist of the United States.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Compenation and Pension Service (21), Director, Education Service (22), Director, Vocational Rehabilitation and Counseling Service (28), VA Central Office, Washington, D.C. 20420.

NOTIFICATION PROCEDURE:

An individual who wishes to determine whether a record is being maintained in this system under his or her name or other personal identifier, or wants to determine the contents of such record, should submit a written request or apply in person to the nearest Veterans Administration regional office or center. Address locations are listed in VA Appendix 1 at the end of this document.

RECORD ACCESS PROCEDURES:

Individuals seeking information regarding access to and contesting of VA records may write, call or visit the nearest Veterans Administration regional office. Address locations are listed in VA Appendix 1 at the end of this document.

CONTESTING RECORD PROCEDURES:

(See Record access procedures above.)

RECORD SOURCE CATEGORIES:

The veteran, dependents and other beneficiaries of the veteran, accredited service organizations, VA-supervised fiduciaries (i.e., VA Federal fiduciaries, court-appointed fiduciaries), military service departments, VA medical facilities and physicians, private medical facilities and physicians, education and rehabilitation training establishments, State and local agencies, other Federal agencies, State, local and county courts and clerks, Federal, State and local penal institutions and correctional facilities, other third parties and other VA records.

[FR Doc. 82-27 Filed 1-4-82; 8:45 am]
BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register
Vol. 47, No. 2
Tuesday, January 5, 1982

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94–409) 5 U.S.C. 552b(e)(3).

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1

FEDERAL RESERVE SYSTEM

Board of Governors

TIME AND DATE: 10 a.m., Monday, January 11, 1982.

PLACE: 20th Street and Constitution Avenue, NW., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Request by the General Accounting Office for Board comment on a draft report regarding check clearing operations.
2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board (202) 452–3204.

Dated: December 31, 1981.

James McAfee,

Assistant Secretary of the Board.

[S–1956–81 Filed 12–31–81; 1:46 pm]

BILLING CODE 6210–01–M

2

UNITED STATES INTERNATIONAL TRADE COMMISSION

[USITC SE–81–41C]

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 46 FR 62998, December 29, 1981.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 2 p.m., Monday, January 4, 1982.

CHANGES IN THE MEETING: Emergency action to close a portion of the meeting originally announced as open to the public.

Pursuant to the specific exemptions of 5 U.S.C. 552b(c)(4) and in conformity with 19 CFR 201.36(b)(4). Commissioners Alberger, Calhoun, Stern, Eckes, and Frank voted by action jacket GC–81–181 to hold a portion of the discussion with respect to item No. 7 [Investigation 337–TA–105 (Certain Audio-Visual Games II)—briefing and vote on request for temporary exclusion order] in closed session.

Commissioners Alberger, Calhoun, Stern, Eckes, and Frank determined, pursuant to 19 CFR 201.37(b) that Commission business requires the change in the determination of the Commission to open or close this portion of the meeting and directed the issuance of this notice at the earliest practicable time.

PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary (202) 523–0161.

[S–1957–81 Filed 12–31–81; 3:03 pm]

BILLING CODE 7020–02–M

3

LEGAL SERVICES CORPORATION

TIME AND DATE: 3 p.m., December 31, 1981.

PLACE: The meeting will be held by teleconference but may be monitored by the public via amplification at the Federal Bar Building, William Howard Taft Room, 1815 H Street, N.W., Washington, D.C.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: Election of Chairman, 1982 grant and contract procedures.

CONTACT PERSON FOR MORE INFORMATION: William J. Olson, Acting Chairman; 202/223–9066.

[S–1955–81 Filed 12–31–81; 1:27 am]

BILLING CODE 6820–35–M

4

NUCLEAR REGULATORY COMMISSION

DATE: Week of January 4, 1982.

PLACE: Commissioners' Conference Room, 1717 H Street, NW., Washington, D.C.

STATUS: Open/closed.

MATTERS TO BE CONSIDERED:

Tuesday, January 5:
- 10 a.m.: Discussion of Management-Organization and Internal Personnel Matters (closed meeting)

Wednesday, January 6:
- 10 a.m. Briefing on Status and Plan for Severe Accident Rulemaking (public meeting)

Thursday, January 7:
- 3 p.m.: Affirmation/Discussion Session (public meeting) Items to be affirmed and/or discussed:
  - a. Proposed Rulemaking, "Environmental Qualification of Electric Equipment for Nuclear Power Plants" (POSTPONED FROM 12/22/81)
  - b. Final Rule on Intransit Physical Protection of Special Nuclear Material of Moderate Strategic Significance
  - c. Amendment to 10 CFR Part 110: Export of IAEA Safeguards Samples
  - d. Reconsideration of 10 CFR 2.700a (Exception from Procedural Rules for Adjudications Involving Conduct of Military or Foreign Affairs Functions) and Application to Pending Proceedings

ADDITIONAL INFORMATION: By a vote of 5–0 on December 22, the Commission determined pursuant to 5 U.S.C. 552b(e) and § 9.107a of the Commission's Rules that Commission business required that the affirmations of Clinch River Exemption Order and Order in TMI–1 Restart (held in closed session), held that day, be held on less than one week's notice to the public.

AUTOMATIC TELEPHONE ANSWERING SERVICE FOR SCHEDULE UPDATE: (202) 634–1498. Those planning to attend a meeting should reverify the status on the day of the meeting.

CONTACT PERSON FOR MORE INFORMATION: Walter Magee (202) 634–1410.

Dated: December 29, 1981.

Walter Magee,

Office of the Secretary.

[S–1954–81 Filed 12–30–81; 4:54 pm]

BILLING CODE 7590–01–M

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Federal Register

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Tuesday, January 5, 1982

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AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday). This is a voluntary program. (See OFR NOTICE 41 FR 32914, August 6, 1976.)

Monday	Tuesday	Wednesday	Thursday	Friday
DOT/SECRETARY	USDA/ASCS		DOT/SECRETARY	USDA/ASCS
DOT/COAST GUARD	USDA/FNS		DOT/COAST GUARD	USDA/FNS
DOT/FAA	USDA/REA		DOT/FAA	USDA/REA
DOT/FHWA	USDA/SCS		DOT/FHWA	USDA/SCS
DOT/FRA	MSPB/OPM		DOT/FRA	MSPB/OPM
DOT/MA	LABOR		DOT/MA	LABOR
DOT/NHTSA	HHS/FDA		DOT/NHTSA	HHS/FDA
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DOT/SLSDC			DOT/SLSDC	
DOT/UMTA			DOT/UMTA	

Documents normally scheduled for publication 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.

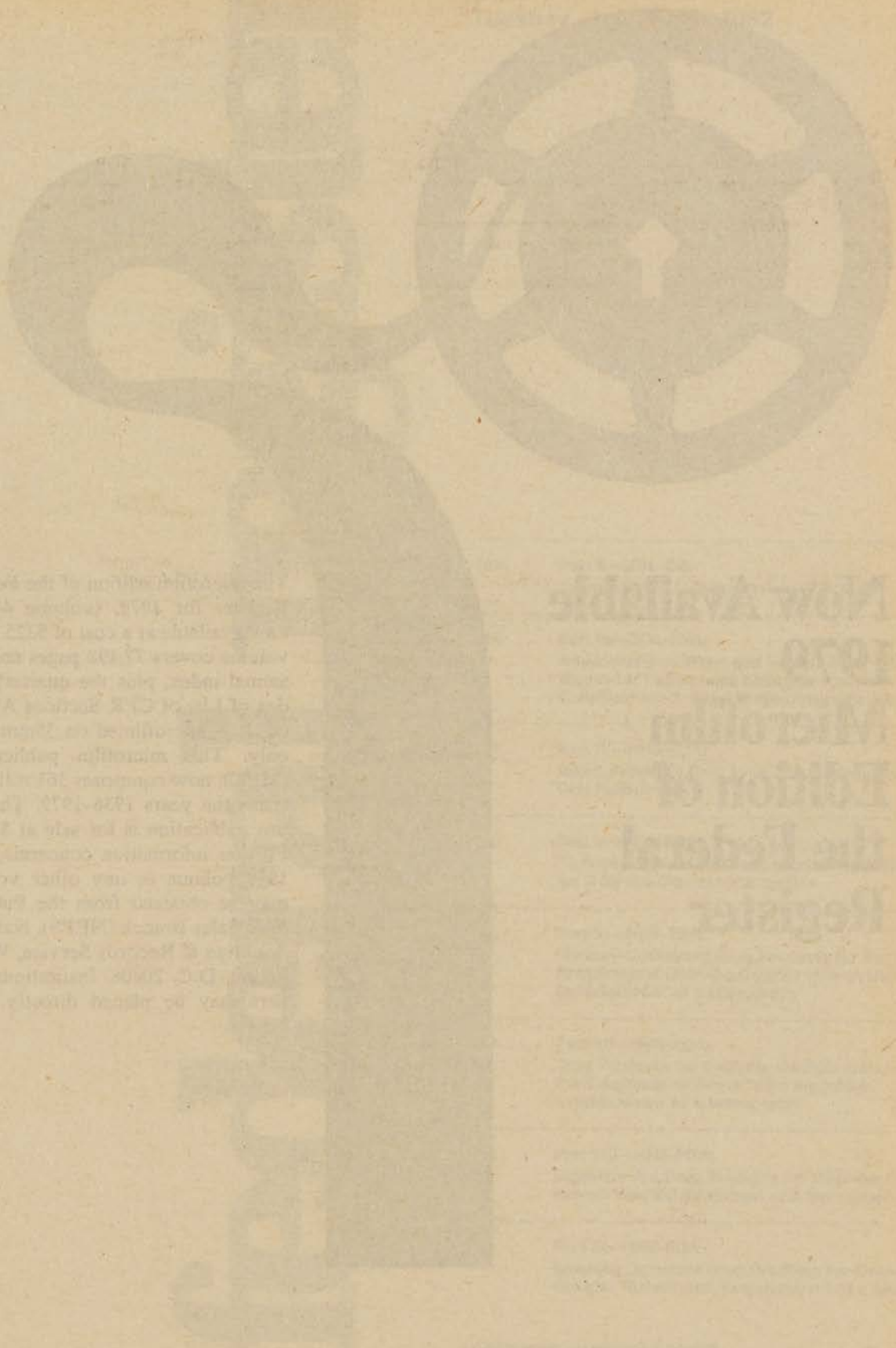
Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408.

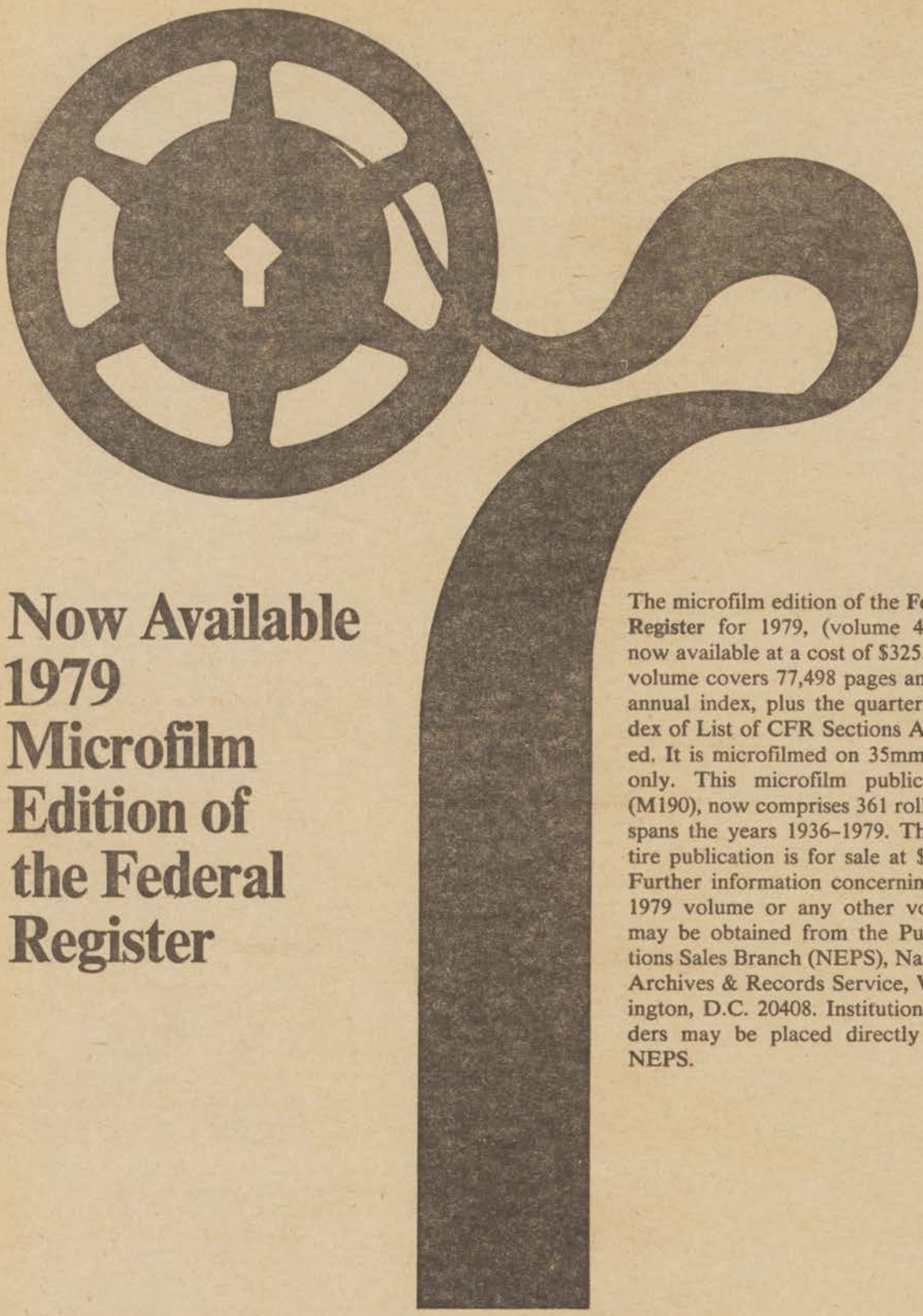
REMINDERS

List of Public Laws

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's List of Public Laws.

Last Listing December 30, 1981





Now Available 1979 Microfilm Edition of the Federal Register

The microfilm edition of the **Federal Register** for 1979, (volume 44), is now available at a cost of $325. This volume covers 77,498 pages and the annual index, plus the quarterly index of List of CFR Sections Affected. It is microfilmed on 35mm rolls only. This microfilm publication, (M190), now comprises 361 rolls and spans the years 1936–1979. The entire publication is for sale at $4693. Further information concerning the 1979 volume or any other volume may be obtained from the Publications Sales Branch (NEPS), National Archives & Records Service, Washington, D.C. 20408. Institutional orders may be placed directly with NEPS.

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federal register

Tuesday
January 5, 1982

Part II

Department of Labor

Office of the Secretary

Twelve-Month List for Review of Rules

DEPARTMENT OF LABOR

Office of the Secretary

20 CFR Chs. I, V, and VI

29 CFR Subtitle A and Chs. V, XVII, and XXV

30 CFR Ch. I

41 CFR Ch. 60

Twelve-Month List for Review of Rules

AGENCY: Department of Labor.

ACTION: Twelve-month listing for review of rules.

SUMMARY: This Notice sets forth the Department's twelve-month listing for review of existing regulations pursuant to the Regulatory Flexibility Act.

DATES: This schedule includes all regulations which will be under review between now and the succeeding twelve months.

FOR FURTHER INFORMATION CONTACT: Seth D. Zinman, Associate Solicitor for Legislation and Legal Counsel, Office of the Solicitor, Department of Labor, Room N2428, 200 Constitution Avenue, NW., Washington, D.C. 20210, 202–523–8201.

SUPPLEMENTARY INFORMATION: The Regulatory Flexibility Act requires that by July 1, 1981, each agency publish a 10-year schedule for the review of all agency rules that are in existence on the effective date of the Act (January 1, 1981), that have or will have a significant economic impact on a substantial number of small entities. The Department published its 10-year schedule on June 30, 1981 (see 46 FR 33536).

The Regulatory Flexibility Act also requires that each year agencies publish in the **Federal Register** a list of the rules to be reviewed during the succeeding twelve months which have a significant economic impact on a substantial number of small entities. The list must include a brief description of each rule, the need for and legal basis of each rule, and must invite public comment.

The twelve-month review list for the Department of Labor is listed below and public comment is invited on the listing. Concurrently with its review of each of the rules listed below, the Department intends to consider the following factors: (1) the continued need for the rule; (2) the nature of complaints or comments received concerning the rule from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

Twelve-Month Review List

I. Mine Safety and Health Administration

1. 30 CFR Part 100—Civil Penalties

Description: The existing rule, published on May 30, 1978 (45 FR 23514), set forth procedures for proposing and assessing civil penalties for violations of the Federal Mine Safety and Health Act of 1977 (Mine Act), standards and regulations. Basically, the rule established a "formula system" for determining most proposed penalties and included for the first time the metal and nonmetal mining industries in the assessment process. MSHA reviewed the existing regulation in 1979 and decided that revisions were necessary. On November 7, 1980 (45 FR 74444), MSHA published a proposal for restructuring the civil penalty system to provide increased incentives for mine operators to comply with the Mine Act, its standards and regulations. Public hearings would be the next step in the rulemaking process. This project is one of MSHA's highest priorities and the need for a regulatory impact analysis is under study.

Need and Legal Basis: This rule is necessary because it will implement the penalty provision in the Mine Act. This proposal is authorized under sections 105, 110, and 508 of the Mine Act.

2. 30 CFR Parts 55, 56 and 57—Review of Standards

Description: The existing safety and health standards applicable to metal and nonmetal mines have generally been in effect for over ten years. They cover all aspects of metal and nonmetal mining activity, e.g. ground control, electrical, explosives, fire prevention, health, and loading, hauling and dumping. MSHA is reviewing the standards to (1) eliminate unnecessary standards, (2) clarify and update existing standards, (3) incorporate technological advances and (4) reduce recordkeeping burdens on the industry. This project is one of MSHA's highest priorities and the need for a regulatory impact analysis is under study. MSHA anticipates holding open conferences on selected high priority sections during the Spring of 1982.

Need and Legal Basis: This rule is necessary to improve the existing metal and nonmetal safety and health standards, many of which are outdated, unnecessary, duplicative, or ambiguous. This project is authorized under Section 101 of the Mine Act which provides for the development, revision and promulgation of new and improved mandatory safety and health standards.

3. 30 CFR Part 23—Telephones and Signaling Devices

Description: The existing rule sets forth the requirements and conditions for MSHA approval of battery-operated telephones and signaling devices for uses in mines. The proposed amendment would modify the definition of "signaling device" to permit the approval of devices and telephones that are equipped with a standby power source, as well as those that are battery-operated. It would conform the existing rule to advances in technology. A regulatory impact analysis is not required. MSHA expects to publish the final rule by the end of 1981.

Need and Legal Basis: This regulation is necessary because it would remove outdated restrictions related to the design and approval of telephones and signaling devices in mines. It is issued pursuant to Section 101 of the Mine Act, which provides for the promulgation of improved safety and health standards.

4. 30 CFR Part 36—Electrical Components and Headlights for Mobile Diesel-powered Transportation Equipment

Description: The existing rule prohibits the use of all electrical devices except self-contained, battery-operated headlights on permissible mobile diesel-powered transportation equipment for use in gassy metal and nonmetal mines. The proposed amendment would modify the requirements and conditions for approval of such equipment by removing current design restrictions. The amendment would not affect currently approved equipment, but it would allow operators of gassy mines to use improved equipment which incorporates advanced technology. A regulatory impact analysis is not required. MSHA anticipates that the final rule will be published by the end of 1981.

Need and Legal Basis: This regulation is necessary because it would improve the existing standards by removing outdated design restrictions. It is authorized under Section 101 of the Mine Act which provides for new and improved safety and health standards.

5. 30 CFR Part 19—Electric Cap Lamps

Description: The existing rule sets forth procedures for the approval of electric cap lamps in underground

mines. The amendment would allow MSHA to test and approve cap lamps which incorporate advances in technology. The proposal would not affect currently approved cap lamps, nor would it affect testing and evaluation of any cap lamp design which can be approved under the existing procedures. A regulatory impact analysis is not required. MSHA expects to publish the final rule by the end of 1981.

Need and Legal Basis: This regulation is necessary because it would improve the existing standard by removing outdated design restrictions. MSHA believes miners would be afforded greater safety and health protection by amending Part 19. The proposal is authorized under Section 101 of the Mine Act which provides for new and improved safety and health standards.

6. 30 CFR Parts 75 and 77—Wire Rope Standards

Description: MSHA's current coal mine wire rope standards incorporate by reference the American National Standards Institute (ANSI) standard M.11.1 on wire ropes in mines. The proposal would revise the standards to include specific requirements for the selection, installation, use, inspection, maintenance, and removal of wire ropes used in underground and surface coal mines. A regulatory impact analysis is not required. MSHA expects to publish a proposed rule by the Spring of 1982.

Need and Legal Basis: In a recent decision, the Federal Mine Safety and Health Review Commission held that MSHA's coal mine wire rope standards are not mandatory. The proposal is necessary to correct any ambiguity in the existing method. It is authorized under Section 101 of the Mine Act which provides for new and improved safety and health standards.

5. 30 CFR Parts 55, 56, 57, 75 and 77—Revisions to Mandatory Safety Standards for Coal and Metal and Nonmetal Mines Based on Affirmative Decisions on Petitions for Modification of the Application of Standards

Description: Under Section 101(c) of the Mine Act, MSHA has granted many petitions for modification of the application of standards (variances) based on mine operators' implementation of alternative methods which reflect advances in technology. MSHA intends to review the standards for which modifications have been granted and determine which standards could be revised to allow the use of improved and alternative methods which provide adequate protection for miners. A regulatory impact analysis is not required. MSHA anticipates publishing an advanced notice of proposed rulemaking by the Spring of 1982.

Need and Legal Basis: This regulation is necessary so that MSHA can revise its standards, as appropriate, to reflect technological advancements. This proposal is authorized under Section 101 of the Mine Act which provides for the promulgation of improved mandatory safety and health standards.

II. Labor-Management Services Administration, The Pension and Welfare Benefits Program

1. 29 CFR 2510.3–37—Multiemployer Plan

Description: Multiemployer employee benefit plans under ERISA must meet different rules and requirements than other employee benefif plans. Section 3(37) of ERISA defines, subject to regulations of the Secretary, when an employee benefit plan is a multiemployer plan. The existing regulation specifying the requirements that an employee benefit plan must meet in order to be a multiemployer plan under ERISA was published in both temporary and proposed form on November 7, 1975 (40 FR 52008). Different standards were set forth for plans in existence prior to the effective date of ERISA (September 2, 1974) and those not in existence at that time. The regulation was never finalized. In addition, the Multiemployer Pension Plan Amendments Act of 1980, Pub. L. 96–364, amended the definition of multiemployer plan.

Need and Legal Basis: Section 3(37)(A)(iii) of ERISA provides that a plan is multiemployer plan if, among other things, it "satisfies such other requirements as the Secretary may prescribe by regulation." In addition, the Secretary is given general authority in Section 505 to promulgate necessary and appropriate regulations. In light of the new law and the fact that the temporary regulation was never finalized, this regulation has been designated for review.

2. 29 CFR 2550.412–1—Bonding Requirements

Description: Section 412 of ERISA provides that, with certain exceptions, every fiduciary of an employee benefit plan and every person who handles funds or other property shall be bonded. The statute also provides that the Secretary shall prescribe regulations necessary to carry out this section, including exemptions from the bonding requirement in certain specified instances. On January 10, 1975 (40 FR 2203), the Department published temporary regulations that were to be effective pending the issuance of permanent regulations. The temporary regulations in general, adopted the bonding requirements that were applicable under Section 13 of the Welfare and Pension Plans Disclosure Act Prior to ERISA.

Need and Legal Basis: Section 412(e) provides for the promulgation of regulations by the Secretary. In addition general authority exists under Section 505. Since this temporary regulation has never been finalized and a number of requests have been received for advisory opinions in this area, this regulation has been designated for review.

III. Occupational Safety and Health Administration

1. 29 CFR 1910.1001—Occupational Exposure to Asbestos

Description: OSHA's 1972 standard for asbestos established an 8-hour time-weighted (TWA) exposure limit of 5 fibers (longer than 5 micrometers) per cubic centimeter of air (5 f/cc), with a ceiling limitation against any exposure in excess of 10 fibers per cubic centimeter of air (10 f/cc). Under the 1972 standard, and effective as of 1976, that 8-hour TWA was reduced to 2 fibers per cubic centimeter of air (2 f/cc). On October 9, 1975 (40 FR 47652), OSHA issued a notice of proposed rulemaking to further lower the permissible exposure level (PEL) to 0.5 fibers per cubic centimeter of air (0.5 f/cc). In 1976, OSHA requested the National Institute for Occupational Safety and Health (NIOSH) to reevaluate information on asbestos and to advise OSHA of the findings. NIOSH recommended to OSHA that the PEL be lowered to 0.1 fibers per cubic centimeter of air (0.1 f/cc). A technological feasibility assessment and an economic impact analysis were prepared in September 1977 and 1978. In April 1980, OSHA announced that it would begin work on a proposed revision to the present standard. This decision was based on recommendations of an OSHA/NIOSH committee formed in 1979 to review scientific information on asbestos-related disease and to assess the adequacy of the current OSHA occupational health standard. A draft regulatory analysis was prepared in 1980 to address the proposed PELs of 0.5 f/cc of air and 0.1 f/cc of air. OSHA will continue to review the current asbestos standard during the next year, both under the standards set by Executive

Order 12291 and the Regulatory Flexibility Act.

Need and Legal Basis: This rule is needed because asbestos is a hazard to which many thousands of American workers are exposed. New research on the health hazards of asbestos, particularly its role as a cause of occupationally related cancer, and concern for the adequacy of the current standard have prompted Agency review of the PEL for asbestos. Recent epidemiologic evidence indicates that asbestos-related disease may be induced at very low levels of exposure, and experimental data in animals suggest that all forms of asbestos present a health hazard. The asbestos standard was promulgated pursuant to section 6 of the Occupational Safety and Health Act (hereinafter 29 U.S.C. 655).

2. 29 CFR 1910.20—Access to Employee Exposure and Medical Records

Description: The standard on access to employee exposure and medical records was published in the **Federal Register** on May 21, 1980 (45 FR 35212). The standard went into effect on August 21, 1980. The standard requires employers to: (1) preserve and maintain exposure and medical records pertinent to an employee's occupational exposure to toxic substances and harmful physical agents; (2) assure access to pertinent exposure records by the exposed employee, similarly exposed employees, designated employee, representatives, and OSHA; (3) assure access to medical records by the employee who is the subject of the records and to OSHA; and (4) inform employees annually of their rights under the standard and of the requisite procedures for exercising those rights. On August 7, 1981, OSHA announced in the **Federal Register** (46 FR 40492) that the Agency has requested a six-month deferral of the briefing schedule from U.S. Court of Appeals for the District of Columbia in the consolidated challenges to the records access standard, *Industrial Union Department, AFL-CIO* v. *Marshall, No. 80–1550 et al.*, to permit the Agency an opportunity to decide whether and to what extent to repropose a modified records access standard.

Need and Legal Basis: This rule is needed because employee exposure and medical records are critically important to the detection, treatment, and prevention of occupational disease. OSHA believes that workers and their representatives need direct access to this information. Representatives of OSHA also need access to this information to fulfill responsibilities under the Occupational Safety and Health Act. The legal basis for this rule is under Sections 6(b), 3(8), 2(b)(3), 2(b)(9), 8(c)(i) and 8(g)(2) of the Occupational Safety and Health Act.

3. 29 CFR 1910.1043—Occupational Exposure to Cotton Dust

Description: On March 31, 1981 (46 FR 19501), the Occupational Safety and Health Administration (OSHA) published an advance notice of proposed rulemaking to reevaluate and reconsider the occupational health standard regulating exposure to cotton dust. This standard prescribes levels of exposure from 0.2 to 0.75 milligrams per cubic meter of air (0.2–0.75 mg/m^3) for different types of operations involving exposure to cotton dust. The purpose of the current proceeding is to review the economic consequences of the regulation and the cost-effectiveness of the standard. Public comments, suggestions, and information were invited and requested to be submitted by May 15, 1981. On June 17, 1981, the U.S. Supreme Court held that cost-benefit analysis in promulgating a standard under Section 6(b)(5) is not required by the OSH Act because feasibility analysis is required.

Need and Legal Basis: This rule is needed because cotton dust exposure presents a severe risk of debilitating respiratory disease, especially among cotton textile workers. The legal basis for this rule is 29 U.S.C. 655.

4. 29 CFR 1990—Identification, Classification and Regulation of Potential Occupational Carcinogens

Description: OSHA plans to reevaluate and reconsider the current standard for the identification, classification and regulation of potential occupational carcinogens. As a result of a July 1980 Supreme Court decision on OSHA's benzene standard, the Agency deleted portions of the current regulations to reflect the Court's finding that consideration must be given to the significance of risk in the issuance of carcinogen standards. The deletions were published on January 19, 1981 (46 FR 4889). Amendments to conform the carcinogen regulations to the Supreme Court's decision were proposed on January 23, 1981 (46 FR 7402) but were withdrawn on March 27, 1981 (46 FR 19000) to permit the Agency to address alternatives that had not been fully considered. The Agency plans to publish an advance notice of proposed rulemaking and request for comments in January 1982.

Need and Legal Basis: This rule is needed because OSHA needs to have a consistent method of dealing with the specific identification, classification and regulation of toxic substances for which there is reported to be evidence of a carcinogenic potential to humans. The rule attempts to deal with the exposure of workers to toxic substances that may be potential carcinogens. The legal basis for this rule is 29 U.S.C 655.

5. 29 CFR 1910.1018—Occupational Exposure to Inorganic Arsenic

Description: The Occupational Safety and Health Administration (OSHA) will publish a limited notice of rulemaking on the risk assessment of inorganic arsenic in December 1981. This notice will provide the scientific data and an analysis of the degree of risk due to exposure to inorganic arsenic as well as the scientific basis for justifying the current standard of 10 micrograms of arsenic per cubic meter of air (10 $\mu g/m^3$). The notice will provide for public comment on the risk assessment. A hearing may be scheduled if requested. The Regulatory Flexibility Act review will be conducted in conjunction with the agency's over-all review.

Need and Legal Basis: This rule is needed because worker exposure to arsenic can result in the development of cancer. The legal basis for this rule is 29 U.S.C. 655.

6. 29 CFR 1910.1025—Occupational Exposure to Lead

Description: On April 21, 1981 (46 FR 22764), the Occupational Safety and Health Administration (OSHA) published an advance notice of proposed rulemaking to reevaluate and reconsider the occupational health standard regulating exposure to lead. The proposal provides for a permissible exposure limit (PEL) of 50 micrograms of lead per cubic meter of air (50 $\mu g/m^3$) averaged over an 8-hour day, for control strategies for reducing lead exposures, and for medical removal protection. The purpose of this proceeding is to review and analyze the technological and economic feasibility of complying with the standard and to evaluate the feasibility and utility of relying on cost-benefit analysis in setting occupational health standards. Public comments, suggestions, and information were required to be received by June 1, 1981. On June 29, 1981, the U.S. Supreme Court upheld the lead standard for primary and secondary lead smelters, ink, paint, coatings and wallpaper manufacturers, and for electronic component and battery manufacturers. During the next year, OSHA will continue to review the feasibility and cost-effectiveness of the standard for lead industries, and will conduct a Regulatory Flexibility Act review in conjunction with its over-all review.

Need and Legal Basis: This rule is needed because exposure to lead presents severe health hazards to workers. The legal basis for this rule is 29 U.S.C. 655.

7. 29 CFR 1910.95—Occupational Exposure to Noise

Description: In 1974, the Occupational Safety and Health Administration (OSHA) proposed standards governing occupational noise exposure, which included a permissible exposure limit (PEL) of 90 dB, as an 8-hour time-weighted average (TWA), and requirements for establishing hearing conservation programs. Public hearings were held during 1975 and 1976. On January 16, 1981 (46 FR 4078), OSHA published a final hearing conservation amendment as a final rule and a regulatory impact analysis of the amendment. This amendment was directed toward establishing hearing conservation programs for employees to prevent occupational hearing loss. Since January, the Agency received numerous petitions for an administrative stay and reconsideration of the hearing conservation amendment. In order to evaluate those petitions and to comply with Executive Order 12291, the Agency delayed the effective date from April 15 to June 1, 1981; from June 1 to August 1, 1981; and from August 1 to August 22, 1981. A regulatory impact and regulatory flexibility analysis was performed and published on August 21, 1981 (46 FR 42622). OSHA will continue to evaluate and study those stayed requirements of the amendment that did not go into effect on August 22, 1981.

Need and Legal Basis: This rule is needed because there are over 900,000 Americans who suffer a moderate to severe hearing loss due to exposure to occupational noise. Epidemiological and laboratory evidence indicates that protracted noise exposures above 90 dB cause hearing loss in a substantial portion of the exposed population and that more susceptible individuals will incur hearing loss at levels below 90 dB. Noise-induced hearing loss is an irreversible condition that progresses with increased exposure and with age. Because hearing is essential for communication, hearing loss can lead to serious social and psychological handicaps. The legal basis for this rule is 29 U.S.C. 655.

8. 29 CFR 1910.134; 1926.103; 1915.82; 1916.82; 1917.82, and 1918.102—Respiratory Protection

Description: On May 19, 1981 (46 FR 27358), OSHA proposed to permit specific methods of qualitative fit testing in lieu of the quantitative fit testing procedures currently required by the lead standard (29 CFR 1910.1025(f)(3)(ii)). Quantitative fit testing requires special equipment to assign a numerical value to the protection afforded the wearer; qualitative fit testing relies on the subjective reaction of a wearer to an irritant fume or other test substance. The agency invited public comment on its proposal and received several requests for a public hearing, which was held in September 1981. In addition, OSHA is building a public record to ascertain what changes should be made to present regulations for respiratory protection in general. A Regulatory Flexibility Act review will be conducted in conjunction with the overall review of the present regulations.

Need and Legal Basis: This rule is needed because respirators are effective for protecting workers only when they are properly fitted to the wearer, properly used, and properly maintained. These rules help employers provide adequate respiratory protection for employees. The legal basis for this rule is 29 U.S.C. 655.

9. 29 CFR Part 1910, Subpart H—Hazardous Materials Description: The current standards address the hazards associated with compressed gases, flammable and combustible liquids, including those used in spray finishing or dip tank operations, explosives and blasting agents, liquified petroleum gases and anhydrous ammonia. These standards were originally promulgated in 1971 based on the then existing national consensus standards.

Need and Legal Basis: This rule is needed because of the hazards associated with workers handling of substances such as compressed gases, flammable and combustible liquids, and explosives. The legal basis for the rule is 29 U.S.C. 655.

10. 29 CFR Part 1926, Subpart Q—Concrete, Concrete Forms and Shoring

Description: Present standards set forth safe work practices for the erection of concrete and masonry buildings and structures.

Need and Legal Basis: This rule is needed because of the number of building collapses an other structure collapses. The legal basis for this rule is 29 U.S.C. 655.

11. 29 CFR Part 1910, Subpart N—Materials Handling and Storage

Description: Present standards address safe design and safe work practices for storage and handling of materials. The standards also address the safe design, maintenance, and use of motorized materials handling equipment.

Need and Legal Basis: This rule is needed because of the occupational hazards related to improper handling and storage of materials and failures of material handling equipment. The legal basis for this rule is 29 U.S.C. 655.

12. 29 CFR 1910.177—Servicing Multi-Piece Rim Wheels

Description: Present standards set forth safe work practices design for servicing tires on multi-piece rim wheels. The standard sets training requirements for those who service multi-piece rim wheels.

Need and Legal Basis: This rule is needed because of worker accidents and injuries resulting from the servicing of multiple and single piece rim wheels. The legal for this rule is 29 U.S.C. 655.

13. 29 CFR Part 1926, Subpart L—Ladders and Scaffolding

Description: Present standards address safe work practices for employees who use portable and fixed ladders and scaffolds. The standard sets forth design load criteria and care and use of equipment. These standards were originally promulgated in 1971 under in the Construction Safety Act.

Need and Legal Basis: This rule is needed because of the numerous occupational injuries and deaths from accidents and falls associated with unsafe ladders and scaffolding in the general industry and in construction. The legal basis for this rule is 29 U.S.C. 655.

14. 29 CFR Part 1910, Subpart D—Walking-Working Surfaces

Description: Present standards address the design, maintenance and use of walking-working surfaces. These standards set forth fall protection measures for walking-working surfaces and address fall hazards on the same level, as well as falls to different levels. These standards were originally promulgated in 1971 based on the then existing national consensus standards.

Need and Legal Basis: This rule is needed because of the number of occupational injuries and deaths due to accidents and falls associated with unsafe walking and working surfaces in the general industry and in construction. The legal basis for this rule is 29 U.S.C. 655.

15. 29 CFR Part 1926, Subpart K—Electrical

Description: Present standards address safe design and installation for electrical wiring and electrically

energized equipment. The standard sets forth design criteria for temporary and permanent electrical installations.

Need and Legal Basis: This rule is needed because of the injuries and fatalities associated with temporary and permanent electrical installation used on the jobsite. The legal basis for this rule is 29 U.S.C. 655.

16. 29 CFR Part 1910, Subpart T—Commercial Diving Operations

Description: The current standards specify safe work practices for commercial diving operations as well as requirements for equipment and maintenance and recordkeeping and reporting. These standards were originally promulgated in 1977.

Need and Legal Basis: This rule is needed because of the safety and health hazards associated with commercial diving operations. The legal basis for this rule is 29 U.S.C. 655.

17. 29 CFR Part 1926, Subpart M—Floor and Wall Openings

Description: These standards address safety hazards associated with the danger of employees or materials falling through or from floors, roofs or wall openings or from stairways and other points of access. These standards were originally promulgated in 1971 under the Construction Safety Act.

Need and Legal Basis: This rule is needed because of the occupational injuries and deaths resulting from accidents and falls associated with unsafe floor and wall openings in the general industry and in construction. The legal basis for this rule is 29 U.S.C. 655.

18. 29 CFR Part 1926, Subpart S—Tunnels and Shafts, Caissons, Cofferdams and Compressed Air

Description: Present standards address construction activities underground and under water areas in cofferdams and similar areas. The present standards address safe conditions and work practices for structures and employees within these work areas. These standards were originally promulgated under the Construction Safety Act in 1971.

Need and Legal Basis: This rule is needed because of the safety and health hazards associated with work performed in tunnels and shafts, caissons and coffer-dams, and with compressed air. The legal basis for this rule is 29 U.S.C. 655.

19. 29 CFR Part 1910, Subpart O—Machinery and Machine Guarding

Description: Present standards address safe design, maintenance, care and use of machinery. These standards also set forth machine guarding criteria for power transmission and point-of-operation guarding of fixed machinery. These standards were originally promulgated in 1971 based on the then existing national consensus standards with some more recent changes.

Need and Legal Basis: This rule is needed because of the occupationally related injuries and deaths associated wih unguarded and poorly maintained machinery. The legal basis for this rule is 29 U.S.C. 655.

20. 29 CFR Part 1926, Subpart P—Excavation, Trenching and Shoring

Description: Subpart P, Excavation, Trenching and Shoring, is comprised of four sections, §§ 1926.650 through 1926.653. Section titles are: General protection requirements; Specific excavation requirements; Specific trenching requirements; and Definitions applicable to the subpart. Basically, the subpart requires that all trenches and/or excavations over five feet in depth be shored or the sidewalls sloped.

Need and Legal Basis: This rule is needed because of trench and excavation sidewall failures that have resulted in death and injury to workers. The percentage of such failures is unknown, but deaths resulting from these accidents exceed 100 each year. The changes, additions, and clarifications in the standard will provide a flexibility to the user that will allow for the use of more advanced technological solutions to the problems of shoring trenches and excavations. The legal basis for this rule is 29 U.S.C. 655.

IV. Employment and Training Administration

1. 20 CFR Part 615—Extended Benefits

Description: The regulation implements the Federal-State Extended Unemployment Compensation Act of 1970, and amendments thereto. The act requires States to provide for payment of Extended Benefits during periods of high unemployment to persons who have exhausted their regular benefits.

Need and Legal Basis: The regulations are necessary to clarify many terms and effective dates in the law. The legal basis for the rule is the Federal-State Extended Unemployment Compensation Act of 1980, which was Title II of Pub. L. 91–373, and amendments thereto.

2. 20 CFR Part 616—Combined Wage Claims

Description: Implementing regulations were promulgated on December 28, 1971 (36 FR 24991), and amended periodically. They approve and implement an arrangement between the States to combine all employment and wages in all States for an individual who worked in more than one State. All changes in the arrangement are developed jointly by the Secretary of Labor and the participating State agencies, as needed to meet operating problems.

Need and Legal Basis: The rule is needed to establish the basic policies that are binding upon the Federal and State partners. The legal basis for the rule is section 3304(9)(B) of the Internal Revenue Code of 1954.

3. 20 CFR Part 618—Federal Supplemental Benefits

Description: Implementing regulations were promulgated February 6, 1975 (40 FR 5498), and amended March 23, 1976 (41 FR 12152). A notice to be published in the **Federal Register** will serve to officially cancel the enabling regulations for this program.

Need and Legal Basis: The Emergency Unemployment Compensation Act of 1974 was Pub. L. 93–572 (88 Stat. 1869). It created a temporary program to pay extended benefits during periods of high unemployment to individuals who were unemployed and had exhausted all other regular and extended unemployment compensation. The program operated from January 1, 1975 to March 31, 1977. All benefit payment processes have been completed.

4. 20 CFR Part 619—Special Unemployment Assistance

Description: Implementing regulations were promulgated February 6, 1975 (40 FR 5502), and subsequently amended March 23, 1976 (41 FR 12162). A notice to be published in the **Federal Register** will serve to officially cancel the enabling regulations for this program.

Need and Legal Basis: Title II of the "Emergency Jobs and Unemployment Assistance Act of 1974" contained in Pub. L. 93–567 and amended Pub. L. 94–32 and Pub. L. 94–45, created a temporary program of Special Unemployment Assistance (SUA) for individuals who were unemployed during a period of aggravated unemployment and were not otherwise eligible for unemployment compensation under any other State or Federal Law. The program was operational commencing with the week beginning December 22, 1974. No further benefits were payable for any week of unemployment ending after June 30, 1977, thus terminating the program. All benefit payment and appellate processes have been completed.

5. 20 CFR Part 640—Benefit Payment Promptness Standard

Description: These regulations were promulgated March 5, 1976 (41 CFR 9559), and amended by July 28, 1978 (43 CFR 33224). They established a standard to assure that payment of unemployment compensation will be made as promptly as administratively feasible. The standard distinguishes between intrastate and interstate claims and between States which require a waiting period for benefits and those which do not. The regulation provides for review of compliance and enforcement.

Need for Legal Basis: Section 303(a)(1) of the Social Security Act requires that States pay unemployment benefits "when due" and provides that administrative operating costs will not be reimbursed if a State fails to provide adequate methods of administration. The regulations are needed to interpret what "when due" means and to set out arithmetic standards for measurement of each State's compliance. They provide for administrative actions when a State falls below those standards.

6. 20 CFR Part 650—Standard for Appeals Promptness—Unemployment Compensation

Description: The existing regulation was promulgated August 11, 1972 (37 FR 16173), and amended February 13, 1976 (41 FR 6756). It establishes a standard to assure that administrative appeals affecting unemployment compensation benefit rights are heard and decided with the greatest promptness that is administratively feasible. In this regulation the Secretary of Labor considers as substantial compliance the issuance of minimum percentages of first level benefit appeal decisions for calendar year 1975 and ensuing years of at least 60 percent of appeal decisions within 30 days of the date of appeal, and at lest 80 percent within 45 days.

Need and Legal Basis: This regulation was required by mandate of the U.S. Supreme Court in the case of *California Department of Human Resources* v. *JAVA*, 402 U.S. 121 (1971), and other courts, which have expressed concern with delay in the disposition of appeals on unemployment insurance benefit claims. It is in compliance with the commitment made by the Secretary of Labor in the brief filed with the Supreme Court on the *Java* case.

7. 29 CFR Part 26—Exemplary Rehabilitation Certificate for Ex-Servicemen

Description: These regulations, cover the processes by which the Secretary of Labor issues certificates to individuals released or discharged from military service under conditions other than honorable. Such certificates are awarded to individuals who have provided evidence of exemplary character, conduct, and activities within at least the three-year period prior to application. The receipt of an exemplary rehabilitation certificate does not change in any way the character of the individual's military discharge, nor does it entitle the person to any special benefits.

Need and Legal Basis: These regulations were issued pursuant to 10 U.S.C. 1571 *et seq.*, and are needed to carry out the statutory mandate of providing for a rehabilitation process for servicemen discharged from the service under conditions other than honorable.

8. 20 CFR Part 680—Comprehensive Employment and Training Act; Amendments to Title IV Youth Programs

Description: Implementing regulations were promulgated May 20, 1980 (45 CFR 33846), and subsequently amended September 4, 1981, (46 FR 44730). Part 680 establishes the requirements for governing youth programs under Title IV, Part A and C of CETA, providing career opportunities for young persons, especially disadvantaged youth, to enable them to secure unsubsidized employment in the public and private sectors of the economy.

Youth programs authorized include: The Youth Incentive Entitlement Pilot Projects (YIEPP), designed to test the effect of a guaranteed year-round structured work experience to encourage school completion; the Youth Community Conservation and Improvement Projects (YCCIP), designed to provide jobs and employment experience in community betterment projects; the Youth Employment and Training Programs (YETP), designed to make available a broad range of employment and training services adopted to local needs; and the Summer Youth Employment Program (SYEP), designed to provide eligible youth with useful work opportunities during the summer months to assist youth in developing their maximum occupational potential.

Need and Legal Basis: The Comprehensive Employment and Training Act (CETA) Amendments of 1978, Pub. L. 95–524, October 27, 1978, and the statutory changes to CETA contained in the Omnibus Budget Reconciliation Act of 1981, Pub. L. 97–35, August 13, 1981, establish employment and training programs for State and local jurisdication in the employment of economically disadvantaged and eligible participants. Part 680 is needed to regulate the implementation of prime sponsor youth programs under Title IV of CETA. The current CETA regulations of May 20, 1980, and September 4, 1981, promulgated under the Act will remain in effect to govern youth programs through the extension of the programs for fiscal year 1982.

9. 20 CFR Part 655, Labor Certification Process for the Temporary Employment of Aliens in the United States, and Part 656, Labor Certification Process for the Permanent Employment of Aliens in the United States

Description: Parts 655 and 656 set forth the Department of Labor responsibilities for the certification of aliens for employment within the United States on a temporary or permanent basis. Part 655 establishes the procedures and standards for the temporary employment of aliens. Included among these provisions are the content of job offers, assurances to be given by employers, recruitment of workers, and reviews or adjudication of DOL findings or detetrminations. Within 655 the subparts cover particular occupations or localities.

Part 656 establishes procedures and standards for the regulation of permanent employment of aliens. Subparts within 656 deal with occupational labor certifications, the certification process and the determination of prevailing wages.

Constant shifts in the labor market and occupations make frequent modifications to Parts 655 and 656 necessary.

Need and Legal Basis: Part 655 is needed to establish the standards and procedures for the temporary employment of aliens. At issue in the certification of aliens for employment in the United States are the availability of willing, qualified U.S. workers and any possible adverse effect that the admission of immigrant and non-immigrant aliens into the U.S. will have upon the wages or working conditions of U.S. workers similarly employed. The legal basis for these regulations is the Immigration and Nationality Act, 8 U.S.C. 1104 and 1184 *et seq.*

10. 29 CFR Part 75, Department of Labor Review and Certification Procedures and Rural Industrialization Loan and Grant Programs Under the Consolidated Farm and Rural Development Act of 1972

Description: Part 75 establishes standards for the review of loan applications to finance industrial and

business activities as well as pollution control and abatement projects in rural areas. The United States Employment Service responsibilities include the gathering and assessment of certain required information in the loan/grant process. This part was last amended in 1975 and will be reviewed during fiscal year 1982 in order to update references, terms, required forms and reporting instructions.

Need and Legal Basis: This part is needed to establish a specific review process for rural development loans made under the Act. The Department of Agriculture has the primary responsibility for reviewing and granting these loans. The procedures in Part 75 have been established in consultation with the Department of Agriculture for the timely issuance of labor certifications required as a condition of any loan/grant. The legal basis for these regulations is the Consolidated Farm and Rural Development Act of 1972, as amended (Pub. L. 95–334, August 4, 1978).

11. 20 CFR Part 604, Policies of the United States Employment Service

Description: Part 604 has in recent years served a double purpose in codifying the policies of the employment service. First, this part established basic policies binding on both the Federal and State partners in the employment service system. Secondly, during the conversion from Employment Security Manual (ESM) to regulatory requirements, Part 604 serves as a consistent statement of policies. As the ESM is replaced by regulations, many of the general policy statements will be removed from Part 604; for instance, publication of the basic services regulations during the last year made possible the removal of a number of the policies listed in Part 604. Because Part 604 contains basic policies of the employment service, its content will be reviewed each time new responsibilities or regulations for the employment service are issued. No date has been established for publication as amendments to Part 604 will be incorporated into other regulations for publication.

Need and Legal Basis: Part 604 is needed to establish the basic policies that are binding upon the Federal and State partners. When published as a part of the employment service regulations, they are a clear, consistent, public statement of policy. The legal basis for these regulations is the Wagner-Peyser Act of 1933, as amended, 29 U.S.C. 49 *et seq.*

12. 20 CFR Part 651—General Provisions Governing the Federal-State Employment Service System

Description: Part 651 sets forth the basic structure of the employment service system under the Wagner-Peyser Act. This part contains: Primary federal statutes governing the employment service; Executive Orders; definitions of terms used in Parts 651–658; and a format of the Federal regulations affecting the system. New statutory and regulatory requirements have been instituted since this part was last reviewed; an update is needed. No specific date has been established for publication of an updated Part 651.

Need and Legal Basis: Part 651, otherwise known as the "General Provisions" is needed to describe the basic provisions and requirements for the operation of the employment service system. By providing legislative and Executive Order citations as well as the format for regulations governing the system, all parties—the State agencies, the public and other interested parties—have in one place all necessary information on how the system is governed. The legal basis for these regulations is the Wagner-Peyser Act of 1933, as amended, 29 U.S.C. 49 *et seq.*

13. 20 CFR Part 653, Services of the Employment Service System; Subpart A—Basic Services and Subpart C—Services for Veterans

Description: The regulations issued or under development for 20 CFR Parts 651–658 provide Federal policy and requirements which must be adhered to by State employment service agencies.

The employment service performs essentially a labor exchange function, i.e., it provides no-fee employment services to applicants seeking employment and to employers seeking applicants.

Subpart A—Basic Services—establishes standards for most services to applicants and employers. Among the services provided applicants are: job information; referral to job openings listed with the employment service; employment counseling; employment testing; job development; and referral to training. Among the services provided employers are: referral of qualified applicants to job openings listed with the employment service system; labor market information; and assistance in meeting affirmative action obligations under legislation, court order, consent decree, government contracts, or other fair employment practice authority rulings.

Subpart C—Services to Veterans—establishes standards for services to veterans. In addition to describing the services to veterans under the Wagner-Peyser Act, this subpart implements many employment services responsibilities under a number of legislative initiatives for veterans.

Clarifying and technical amendments to the 20 CFR Part 653, Subpart A—Basic Services—regulations will be proposed early in fiscal year 1982. These amendments correct errors which appeared in the final rules of January 23, 1981 (46 FR 7764), and also reflect necessary changes that are the result of developments during the last few months. As Subpart A is basic and essential to the employment service system, its contents are constantly and thoroughly scrutinized and amendments are often considered. Also Subpart C—Services for Veterans—will be amended during the 1982 fiscal year. In addition to instituting the new requirements of the Veterans Rehabilitation Amendments of 1980 (Pub. L. 96–466), the amendments will clarify and consolidate the numerous mandates for specific services to veterans.

Need and Legal Basis: The Wagner-Peyser Act of 1933, as amended, 29 U.S.C. 49 *et seq.*, established a Federal-State employment service system of public employment offices to provide employment services to workers and employers. Subpart A—Basic Services—is needed to establish the standards for the basic services that must be provided (see description above). Subpart C is needed to establish the standards for services to veterans. The legal basis for these regulations is established by a number of statutory mandates.

Veterans services are specifically mentioned in the Wagner-Peyser Act. In addition, a number of laws mandate services to be provided to veterans by the employment service. For example, 38 U.S.C. 2001–2008 (Chapter 41), requires referral of veterans to employment and training opportunities; 38 U.S.C. 2012(a) requires referral of veterans on a priority basis to job openings listed by certain Federal contractors; Section 104 of the Emergency Jobs and Unemployment Assistance Act of 1974 (Pub. L. 93–567) requires the Department to provide (in conjunction with other designated agencies) outreach to veterans for employment and training opportunities; section 2012, 38 U.S.C. (Chapter 42), prescribes performance standards for State agencies' services to veterans; and the Veterans Rehabilitation Amendments of 1980 (Pub. L. 96–466) contain the most recent requirements for vetrans' services.

V. The Employment Standards Administration

1. 20 CFR Part 1—Performance of Functions under this Chapter (Office of Worker's Compensation Programs (OWCP) Organization and Procedures)

Description: This regulation sets forth the organizational background and information concerning the Office of Workers' Compensation, the assignment of functions to OWCP and regulatory responsibilities of the OWCP.

Need and Legal Basis: The regulation is needed to identify duties assigned to the Secretary by nine different statutes which have been delegated to OWCP for their implementation and to specify the location of the detailed regulations for the implementation of each of those statutes. It is based on Secretary's Order 13–71 and Employment Standards Administration Order 2–74.

2. 20 CFR Part 10—Claims for Compensation under the Federal Employee's Compensation Act, as amended

Description: This regulation sets forth the regulations applicable to the filing, processing and payment of claims for workers' compensation benefits under the provisions of the Federal Employees' Compensation Act, as amended.

Need and Legal Basis: The regulation is needed to provide detailed guidance and assistance to persons seeking compensation benefits under the Act, as well as to personnel within the Department of Labor and other agencies of the United States who are required to perform some function with respect to its administration. The legal basis for the regulation is the Federal Employees' Compensation Act (5 U.S.C. 8101 *et seq.*).

3. 20 CFR Part 25—Compensation for Disability of Noncitizen Federal Employees Outside the United States

Description: These regulations define benefit levels for injured or killed noncitizen Federal employees working outside the U.S. and govern methods for awarding such Federal employees workers' compensation benefits.

Need and Legal Basis: The regulations are necessary to define the relationships between the FECA and local law for certain groups of noncitizen Federal employees injured outside the United States. The legal basis for these regulations is 5 U.S.C. 8137, 8145, and 8149.

4. 20 CFR Part 701—General, Administering Agency; Definitions and Use of Terms (Longshoremen's and Harbor Workers' Compensation Act and Related Acts)

Description: This part of the regulations governing the administration of the Longshoremen's and Harbor Workers' Compensation Act (LHWCA), Workmen's Compensation Act, the Outer Continental Shelf Lands Act and the Nonappropriated Fund Instrumentalities Act, provides a general description of the regulations contained in 20 CFR Parts 701 through 704, information as to persons and agencies within the Department of Labor authorized by the Secretary of Labor to administer the Longshoremen's and Harbor Workers' Compensation Act and its extensions and the regulations, and guidance as to the meaning and use of specific terms in the regulations.

Need and Legal Basis: This part identifies the various statutes which incorporate substantive provisions of the LHWCA and provides uniform definitions for the regulations implementing those laws in Parts 701 through 704. The legal basis for these regulations is 33 U.S.C. 939.

5. 20 CFR Part 702—Administration and Procedures (Longshoremen's and Harbor Workers' Compensation Act and Related Statutes)

Description: This part of the regulations governing the administration of the Longshoremen's and Harbor Workers' Compensation Act and related statutes contains the general administrative regulations governing claims filed under the Act, and the procedures for the adjudication of such claims and the provision of medical and vocational rehabilitation services under the Act.

Need and Legal Basis: These regulations are necessary to provide detailed procedures for the implementation of the LHWCA and the adjudication of rights and duties established by it. The Longshoremen's and Harbor Workers' Compensation Act is codified at 33 U.S.C. 901 through 950.

6. 20 CFR Part 703—Insurance Regulations (Longshoremen's and Harbor Workers' Compensation Act and Related Statutes)

Description: This Part of the regulations governing the administration of the Longshoremen's and Harbor Workers' Compensation Act and related statutes contains regulations governing authorization of insurance carriers, authorization of self-insurers, and issuance of certificates of compliance with the insurance regulations.

Need and Legal Basis: These regulations are necessary to provide detailed procedures defining the means used to secure the payment of compensation and other benefits provided under the LHWCA. Their legal basis is 33 U.S.C. 932, 937, and 939.

7. 20 CFR Part 704—Special Provisions for Longshoremen's and Harbor Workers' Compensation Act Extensions

Description: This part of the regulations governing the administration of the Longshoremen's and Harbor Workers' Compensation Act and related statutes contains the exceptions to the general applicability of Parts 702 and 703 for the Defense Base Act, the District of Columbia Compensation Act, the Outer Continental Shelf Lands Act and the Nonappropriated Fund Instrumentalities Act.

Need and Legal Basis: These regulations are needed to provide detailed procedures for the implementation of the provisions of the extensions of the LHWCA which differ from the provisions of the basic statute. They are based on legal provisions in 33 U.S.C. 939, 42 U.S.C. 1651 *et seq.*, 36 District of Columbia Code 501 *et seq.*, 43 U.S.C. 1331, 5 U.S.C. 8171 *et seq.*

8. 20 CFR Part 722—Criteria for Determining Whether State Workmen's Compensation Laws Provide Adequate Coverage for Pneumoconiosis and Listing of Approved State laws

Description: These regulations establish procedures and standards to be applied by the Secretary of Labor in determining whether a State workmen's compensation law provides adequate coverage for death or disability due to pneumoconiosis.

Need and Legal Basis: The Black Lung Benefits Act requires the Secretary to establish criteria by which the adequacy of State laws which provide benefits for disability or death due to pneumoconiosis are to be determined. The legal basis for this regulation is 30 U.S.C. 931 and 936.

9. 20 CFR Part 725—Claims for Benefits under Part C of Title IV of the Federal Mine Safety and Health Act, as amended

Description: These regulations define the procedures for the adjudication and payment of benefits on claims for total disability due to Black Lung disease.

Need and Legal Basis: The Black Lung Benefits Act provides broad authority to the Secretary to establish specific and detailed procedures for the adjudication

of claims and the payment of benefits under the Act. These detailed procedures are necessary for the orderly administration of the Act. Their legal basis in contained in 30 U.S.C. 901 through 945 and 33 U.S.C. 901 through 950.

10. 20 CFR Part 726—Black Lung Benefits, Requirements for Coal Mine Operators' Insurance

Description: These rules governing the manner by which a coal mine operator shall fulfill its insurance obligations under the Black Lung Benefits Act, either by qualification as a self-insurer or by contracting with a commercial insurance company.

Need and Legal Basis: These regulations are necessary to provide detailed procedures defining the means used to secure the payment of benefits under the Black Lung Benefits Act. The legal basis for this regulation is 30 U.S.C. 931, 933, 936 and 33 U.S.C. 901 *et seq.*

11. 41 CFR Chapter 60—Office of Federal Contract Compliance Programs (OFCCP), Equal Employment Opportunity, Department of Labor (Except 41 CFR Part 60–3, Guidelines on Employee Selection Procedures)

Description: This group of regulations contains OFCCP's rules covering obligations of Federal contractors and under E.O. 11246 (41 CFR Part 60–1); affirmative action program requirements under E.O. 11246 (41 CFR Part 60–2); construction contractors' affirmative action requirements under E.O. 11246 (41 CFR Part 60–4); sex discrimination guidelines under E.O. 11246 (41 CFR Part 60–20); administrative hearing rules under E.O. 11246, section 402 of the Vietnam Era Veterans' Readjustment Assistance Act and section 503 of the Rehabilitation Act of 1973 (41 CFR Part 60–30); religion and national origin discrimination guidelines under E.O. 11246 (41 CFR Part 60–50); nonconstruction contractor evaluation procedures under E.O. 11246 (41 CFR Part 60–60); affirmative action requirements and enforcement provisions under Section 402 of the Vietnam Era Veterans' Readjustment Assistance Act (41 CFR Part 60–250); and affirmative action requirements and enforcement provisions under section 503 of the Rehabilitation Act of 1973 (41 CFR Part 60–741); and examination and copying of OFCCP documents (41 CFR Part 60–40).

Need and Legal Basis: These regulations implement E.O. 11246, as amended by E.O. 11375 and E.O. 12086, Section 402 of the Vietnam Era Veterans' Readjustment Act of 1974, as amended, and Section 503 of the Vocational Rehabilitation Act of 1973, as amended.

12. 29 CFR Parts 1 and 5—Labor Standards Provisions, Davis-Bacon and Related Acts

Description: These provisions contain regulations governing the issuance of prevailing wage determinations and the administration and enforcement of labor standards required to be included in federally-funded or assisted construction contracts under the Davis-Bacon Act, the Contract Work Hours and Safety Standards Act, and responsibilities under the Copeland Anti-Kickback Act.

Need and Legal Basis: These regulations are necessary to set forth the procedures for making and applying determinations of prevailing wage rates and fringe benefits under the Davis-Bacon and related Acts, to coordinate the administration and enforcement of the labor standards provisions of the Davis-Bacon and related Acts, the Contract Work Hours and Safety Act and the Copeland Act by Federal agencies responsible for their administration, and to codify the Department's policies for administering the Acts. They are issued pursuant to the Secretary of Labor's authority under 40 U.S.C. 276a and 276c Reorganization Plan No. 14 of 1950.

13. 29 CFR Part 4—Labor Standards for Federal Service Contracts

Description: The Service Contract Act requires most Federal service contractors and subcontractors to pay their service employees not less than the minimum wages and fringe benefits which the Secretary of Labor finds to be prevailing in the locality. These regulations govern the administration of the Service Contract Act and set forth official rulings and interpretations with respect to the application of the Act for the guidance of Government contracting agencies, Government contractors and subcontractors, and the employees who perform work under such contracts.

Need and Legal Basis: These regulations are necessary to implement the requirements of the Service Contract Act. They are issued pursuant to statutory authority under 41 U.S.C. 351, *et seq.*, 41 U.S.C. 38 and 39, and 5 U.S.C. 301.

14. 29 CFR Part 6—Rules of Practice for Administrative Proceedings Enforcing Labor Standards in Federal Service Contracts

Description: This regulation provides the rules of practice for administrative proceedings relating to the enforcement of labor standards under the Service Contract Act of 1965.

Need and Legal Basis: This regulation is necessary to advise contractors of the procedures for administrative proceedings and to assure the orderly conduct of such proceedings. It is issued pursuant to 41 U.S.C. 351 *et seq.*, 41 U.S.C. 38 and 39, and 5 U.S.C. 301.

15. 29 CFR Part 505—Labor Standards on Projects or Productions Assisted by Grants from the National Endowment for the Arts

Description: This regulation sets forth procedures to carry out the provisions of Section 5(j) of the National Foundation on the Arts and Humanites Act of 1965 relating to labor standards requirements on projects or productions assisted by grants from the National Endowment for the Arts.

Need and Legal Basis: Section 5(j) of the National Foundation on the Arts and Humanties Act requires grant recipients to furnish adequate assurances to pay not less than the minimum compensation to their professional employees and related or supporting professional personnel *as determined by the Secretary of Labor* to be the prevailing minimum compensation for persons employed in similar activities.

16. 29 CFR Part 516—Records to be Kept by Employers

Description: This regulation contains the recordkeeping requirements applicable to all employers whose employees are covered by the Fair Labor Standards Act (FLSA).

Need and Legal Basis: This regulation is needed to set forth employer recordkeeping requirements under the FLSA necessary to the law's enforcement. Section 11(c) of the FLSA authorizes the Secretary to prescribe the records which employers subject to the FLSA must maintain.

17. 29 CFR Part 525—Employment of Handicapped Clients in Sheltered Workshops

Description: This regulation sets forth the conditions under which certificates may be issued under the Fair Labor Standards Act authorizing special minimum wage rates for handicapped clients in sheltered workshops.

Need and Legal Basis: Section 14(c) of the Fair Labor Standards Act (29 U.S.C. 214) requires the Secretary of Labor to, "by regulation or order provide for the employment under special certificates of individuals * * * whose earning or productive capacity is impaired by age or physical or mental deficiency or injury, at wages which are lower than

the minimum wage applicable under section 6 of the Act."

18. 29 CFR Part 530—Employment of Homeworkers in Certain Industries

Description: This regulation sets forth the conditions under which certificates can be issued authorizing the employment of individuals as homeworkers in certain industries.

Need and Legal Basis: Section 11(d) of the Fair Labor Standards Act authorizes the Secretary to regulate, restrict or prohibit industrial homework to the extent necessary to safeguard the minimum wage.

19. 29 CFR Part 541—Defining the Terms "Executive," "Administrative," "Professional," and "Outside Salesman"

Description: These regulations set forth criteria for determining the application of the Fair Labor Standards Act (FLSA) exemption for "executive," "administrative," "professional," and "outside sales" employees from the minimum wage and overtime requirements of the Act.

Need and Legal Basis: These regulations delineate the duties, responsibilities, and minimum salary levels which must be met in order for employees to qualify for the minimum wage and overtime exemption contained in section 13(a)(1) of the FLSA. Section 13(a)(1) gives the Secretary of Labor the responsibility to define and delimit the terms "bona fide executive, administrative or professional capacity, or in the capacity of an outside salesman."

20. 29 CFR Part 570, Subpart C—Employment of Minors Between 14 and 16 Years of Age (Child Labor Regulation 3)

Description: This regulation sets standards for the employment of 14 and 15-year-old minors that will not interfere with their schooling, health or well-being.

Need and Legal Basis: Section 3(1) of the Fair Labor Standards Act requires the Secretary to "provide by regulation or order that the employment of employees between the ages of fourteen and sixteen years in occupations other than manufacturing and mining shall not be deemed to constitute oppressive child labor if and to the extent that the Secretary of Labor determines that such employment is confined to periods which will not interfere with their schooling and to conditions which will not interfere with their health and well-being."

21. 29 CFR 570.52—Motor Vehicle Driver and Outside Helper (Child Labor Hazardous Order No. 2 under the FLSA)

Description: Child Labor Hazardous Order No. 2 prohibits the employment of minors 16 and 17 years of age in the occupations of motor vehicle operator and outside helper on any public road, highway, in or about any mine (including open pit mine or quarry), place where logging or sawmill operations are in progress, or in any excavation identified under Hazardous Occupations Order No. 17 (29 CFR 570.68) as hazardous for the employment of such minors.

Need and Legal Basis: Section 3(1) of the Fair Labor Standards Act defines "oppressive child labor" which is prohibited under the Act. It designates as hazardous occupations those the Secretary of Labor "shall find and by order declare to be particularly hazardous" for the employment of children between the ages of 16 and 18 or detrimental to their health of well-being. This regulation implements that statutory authority.

22. 29 CFR 570.61—Occupations Involving Slaughtering, Meat Packing or Processing, or Rendering (Child Labor Hazardous Order No. 10 under the FLSA)

Description: This regulation defines specific meat-processing and allied occupations which have been found to be particularly hazardous for the employment of minors between 16 and 18 years of age.

Need and Legal Basis: Section 3(1) of the Fair Labor Standards Act defines "oppressive child labor" which is prohibited under the Act. It designates as hazardous occupations those the Secretary of Labor "shall find and by order declare to be particularly hazardous" for the employment of children between the ages of 16 and 18 or detrimental to their health or well-being. This regulation implements that statutory authority.

23. 29 CFR 570.62—Occupations Involving the Operation of Power-driven Bakery Machines (Child Labor Hazardous Order No. 11 under the FLSA)

Description: Child Labor Hazardous Order No. 11 prohibits the employment of minors 16 and 17 years of age in occupations involving the operation of various power-driven bakery machines.

Need and Legal Basis: Section 3(1) of the Fair Labor Standards Act defines "oppressive child labor" which is prohibited under the Act. It designates as hazardous occupations those the Secretary of Labor "shall find and by order declare to be particularly hazardous" for the employment of children between the ages of 16 and 18 or detrimental to their health or well-being. This regulation implements that statutory authority.

Signed this 21st day of December, 1981 at Washington, D.C.

Raymond J. Donovan,

Secretary of Labor.

[FR Doc. 82-1 Filed 1-4-82; 8:45 am]

BILLING CODE 9510-23-M

federal register

Tuesday
January 5, 1982

Part III

Department of Labor

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

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 on construction projects 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 Secretary of Labor's Order No. 24–70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's Orders 12–71 and 15–71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination 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 subsequent to its publication date shall be made a part of 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.

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 Secretary of Labor's Order No. 24–70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's orders 13–71 and 15–71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing general wage determination decisions, as hereby modified, and/or superseded 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.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Office of Government Contract Wage Standards, Division of Government Contract Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Determination Decision.

Modifications to General Wage Determination Decisions

The numbers of the decisions being modified and their dates of publication in the **Federal Register** are listed with each State.

Connecticut: CT81-3032	May 15, 1981.
Iowa:	
IA81-4088	Nov. 13, 1981.
IA81-4090	Dec. 11, 1981.
IA81-4091	Nov. 13, 1981.
IA81-4092	Nov. 27, 1981.
IA81-4093	Nov. 27, 1981.
IA81-4094	Nov. 27, 1981.
IA81-4095	Nov. 27, 1981.
IA81-4097	Nov. 27, 1981.
IA81-4101	Dec. 11, 1981.
Louisiana:	
LA81-4084	Nov. 6, 1981.
LA81-4085	Nov. 6, 1981.
LA81-4086	Nov. 6, 1981.
Pennsylvania:	
PA81-3041	July 6, 1981.
PA81-3044	Aug. 7, 1981.
Texas:	
TX81-4044	June 26, 1981.
TX81-4052	July 10, 1981.
TX81-4074	Oct. 2, 1981.
TX81-4075	Oct. 2, 1981.
TX81-4076	Oct. 2, 1981.
TX81-4077	Oct. 2, 1981.
TX81-4078	Oct. 2, 1981.
TX81-4079	Oct. 2, 1981.
TX81-4083	Nov. 6, 1981.
Virginia: VA81-3092	Dec. 18, 1981.

Signed at Washington, D.C., this 24th day of December 1981.

Dorothy P. Come,

Assistant Administrator, Wage and Hour Division.

BILLING CODE 4510-27-M

DECISION NO. CT81-3032 - MOD. #7 (46 FR 27040 - May 15, 1981) HARTFORD, MIDDLESEX, NEW HAVEN, NEW LONDON AND TOLLAND COUNTIES, CONNECTICUT	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
BOILERMAKERS	16.53	1.275	10%		.04
BRICKLAYERS; CEMENT MASONS; FINISHERS; MARBLE MASONS; PLASTERERS; STONEMASONS; TERRAZZO WORKERS AND TILE SETTERS:					
Building Construction:					
Area 2	13.50	.75	1.00		
Area 7	13.50	.75	1.00		
ELECTRICIANS:					
Area 3	13.10	1.22	3%+.60		1/8%
GLAZIERS:					
Area 2	13.16	.84	2.65	.35+i	
LINE CONSTRUCTION:					
Linemen, Cable Splicers, & Dynamite Man	15.15	.70	3%+1.00	1	
Heavy Equipment Operator	13.79	.70	3%+1.00	1	
Equipment Operator, Tractor Trailer Driver, Field Mechanic	13.01	.70	3%+1.00	1	
Material Man	12.79	.70	3%+1.00	1	
Groundman Truck Driver	11.69	.70	3%+1.00	1	
Groundman	10.34	.70	3%+1.00	1	
PAINTERS:					
Area 2:					
Brush; Tapers	12.85	1.20	1.25		.03
Paperhangers	13.35	1.20	1.25		.03
Riding Steel; Steam-cleaning; Sandblasting Tank; Towers; and Hazardous Work	13.43	1.20	1.25		.03
Spray	15.85	1.20	1.25		.03
PLUMBERS; STEAMFITTERS:					
Area 4	16.00	.75	1.40	q	.07
SPRINKLER FITTERS	15.80	.95	1.40		.08
STEAMFITTERS					
Area 1	15.08	1.16	2.00		.13
TILE, MARBLE AND TERRAZZO FINISHERS	10.65	.50	1.00		

DECISION NO. IA81-4088 - MOD. #2 (46 FR 56121 - November 13, 1981) Black Hawk County, Iowa	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
Building, Water Treatment Plants & Sewage Disposal Plants Construction:					
Sheet metal workers	$15.56	1.00	.60		.06
Power Equipment Ops.:					
Group 1	13.12	1.00	1.00		.10
Group 2	12.865	1.00	1.00		.10
Group 3	11.47	1.00	1.00		.10
Group 4	10.645	1.00	1.00		.10
DECISION NO. IA81-4090 - MOD. #1 (46 FR 60752 - December 11, 1981) Des Moines County, Iowa					
CHANGE:					
Building, Water Treatment Plants & Sewage Disposal Plants Construction:					
Cement masons	16.15				
Plasterers	15.78				
DECISION NO. IA81-4091 - MOD. #2 (46 FR 56123 - November 13, 1981) Dubuque County, Iowa					
CHANGE:					
Building, Water Treatment Plants & Sewage Disposal Plants Construction:					
Power Equipment Ops.:					
Group 1	13.12	1.00	1.00		.10
Group 2	12.865	1.00	1.00		.10
Group 3	11.47	1.00	1.00		.10
Group 4	10.645	1.00	1.00		.10

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and or Appr. Tr.
DECISION NO. IA81-4092 - MOD. #1 (46 FR 58025 - November 27, 1981) Johnson County, Iowa					
CHANGE: Building, Water Treatment Plants & Sewage Disposal Plants Construction:					
Power Equipment Ops.:					
Group 1	$13.12	1.00	1.00		.10
Group 2	12.865	1.00	1.00		.10
Group 3	11.47	1.00	1.00		.10
Group 4	10.645	1.00	1.00		.10
DECISION NO. IA81-4093 - MOD. #1 (46 FR 58018 - November 27, 1981) Linn County, Iowa					
CHANGE: Building, Water Treatment Plants & Sewage Disposal Plants Construction:					
Tile setters	13.93		.80		
Power Equipment Ops.					
Group 1	13.12	1.00	1.00		.10
Group 2	12.865	1.00	1.00		.10
Group 3	11.47	1.00	1.00		.10
Group 4	10.645	1.00	1.00		.10
DECISION NO. IA81-4094 - MOD. #3 (46 FR 58019 - November 27, 1981) Polk County, Iowa					
ADD: Building, Water Treatment Plants & Sewage Disposal Plants Construction:					
Plasterers	13.355		.90		
CHANGE: Building, Water Treatment Plants & Sewage Disposal Plants Construction:					
Cement masons	13.28		.90		.04
Power Equipment Ops.:					
Group 1	13.12	1.00	1.00		.10
Group 2	12.865	1.00	1.00		.10
Group 3	11.47	1.00	1.00		.10
Group 4	10.645	1.00	1.00		.10

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION NO. IA81-4095 - MOD. #2 (46 FR 58022 - November 27, 1981) Webster County, Iowa					
CHANGE: Building, Water Treatment Plants & Sewage Disposal Plants Construction:					
Power Equipment Ops.:					
Group 1	$13.12	1.00	1.00		.10
Group 2	12.865	1.00	1.00		.10
Group 3	11.47	1.00	1.00		.10
Group 4	10.645	1.00	1.00		.10
DECISION NO. IA81-4097 - MOD. #2 (46 FR 58016 - November 27, 1981) Cerro Gordo County, Iowa					
CHANGE: Building, Water Treatment Plants & Sewage Disposal Plants Construction:					
Power Equipment Ops.:					
Group 1	13.12	1.00	1.00		.10
Group 2	12.865	1.00	1.00		.10
Group 3	11.47	1.00	1.00		.10
Group 4	10.645	1.00	1.00		.10
DECISION NO. IA81-4101 - MOD. #1 (46 FR 60754 - December 11, 1981) Pottawattamie County, Iowa					
CHANGE: Power Equipment Ops.:					
Group 1	13.12	1.00	1.00		.10
Group 2	12.865	1.00	1.00		.10
Group 3	11.47	1.00	1.00		.10
Group 4	10.645	1.00	1.00		.10

DECISION NO. LA81-4084 - MOD. #4 (46 FR 55203 - November 6, 1981) Bossier, Caddo & Calcasieu Parishes, Louisiana	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and or Appr. Tr.
CHANGE:					
Painters:					
Calcasieu Parish:					
Group 1	$14.745		.30		
Group 2	14.945		.30		
Group 3	15.09		.30		
Roofers:					
Bossier & Caddo Parishes:					
Roofers	12.86		.20		.04
Kettlemen	8.90		.20		.04
Tile setters:					
Calcasieu Parish	11.07	.68	1.00		.02

DECISION NO. LA81-4085 - MOD. #3 (46 FR 55206 - November 6, 1981) Allen, Beauregard, Bossier, Caddo, Calcasieu, Cameron, Jefferson, Jefferson Davis Orleans, Plaquemines, St. Bernard & St. Charles Parishes, Louisiana	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
Carpenters & piledrivermen					
Zone 2	13.20	.90	.90		.06
Zone 3	13.08	.85	.48		.07
Zone 4	10.40	.85	.48		.07
Zone 5	9.90	.85	.48		.07
Cement masons:					
Zone 1	12.57	.79	.60		.09
Zone 3	13.40				
Zone 4	11.80				
Zone 5	11.30				
Ironworkers:					
Zone 1	13.56	.93	.65		.08
Zone 2	13.50	.60	.65		.05
Zone 3	11.80	.60	1.65		.06
Zone 4 - Cameron & Jefferson Davis Parishes	10.50	.60	.65		.05
Zone 4 - Allen & Beauregard Parishes	10.00	.60	.65		.05

DECISION NO. LA81-4085 - MOD. #3 (CONT'D)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Laborers:					
Zone 1 - Group 1	$ 9.23	.30	.27		.05
Group 2	9.33	.30	.27		.05
Group 3	9.78	.30	.27		.05
Group 4	10.03	.30	.27		.05
Zone 3 - Group 1	9.28	.25	.27		.05
Group 2	9.38	.25	.27		.05
Group 3	9.83	.25	.27		.05
Group 4	10.08	.25	.27		.05
Zone 4 - Group 1	7.48	.25	.27		.05
Group 2	7.58	.25	.27		.05
Group 3	8.03	.25	.27		.05
Group 4	8.23	.25	.27		.05
Zone 5 - Group 1	7.28	.25	.27		.05
Group 2	7.38	.25	.27		.05
Group 3	7.83	.25	.27		.05
Group 4	8.03	.25	.27		.05
Painters:					
Zone 1 - Group 1	14.745		.30		
Group 2	15.09		.30		
Group 3	16.535		.30		
Power equipment ops.:					
Zone 1 - Group 1	13.36	.65	1.20		.10
Group 2	13.61	.65	1.20		.10
Group 3	13.11	.65	1.20		.10
Group 4	11.54	.65	1.20		.10
Group 5	11.09	.65	1.20		.10
Group 6	9.81	.65	1.20		.10
Group 7	8.38	.65	1.20		.10
Group 8	11.14	.65	1.20		.10
Group 9	11.39	.65	1.20		.10
Group 10	8.63	.65	1.20		.10
Zone 3 - Group 1	13.01	.65	1.20		.10
Group 2	13.26	.65	1.20		.10
Group 3	12.76	.65	1.20		.10
Group 4	11.22	.65	1.20		.10
Group 5	10.51	.65	1.20		.10
Group 6	9.23	.65	1.20		.10
Group 7	7.77	.65	1.20		.10
Group 8	10.82	.65	1.20		.10
Group 9	11.07	.65	1.20		.10
Group 10	8.02	.65	1.20		.10

DECISION NO. LA81-4085 - MOD. #3 (CONT'D)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Power Equipment ops. (Cont'd):					
Zone 4 - Group 1	$ 9.95	.65	1.20		.10
Group 2	10.20	.65	1.20		.10
Group 3	9.70	.65	1.20		.10
Group 4	8.52	.65	1.20		.10
Group 5	7.94	.65	1.20		.10
Group 6	6.77	.65	1.20		.10
Group 7	6.21	.65	1.20		.10
Group 8	8.21	.65	1.20		.10
Group 9	8.46	.65	1.20		.10
Group 10	6.46	.65	1.20		.10
Zone 5 - Group 1	9.45	.65	1.20		.10
Group 2	9.70	.65	1.20		.10
Group 3	9.20	.65	1.20		.10
Group 4	8.02	.65	1.20		.10
Group 5	7.44	.65	1.20		.10
Group 6	6.27	.65	1.20		.10
Group 7	5.71	.65	1.20		.10
Group 8	7.71	.65	1.20		.10
Group 9	7.96	.65	1.20		.10
Group 10	5.96	.65	1.20		.10
Truck drivers:					
Zone 1 - Group 1	9.33	.70			
Group 2	9.46	.70			
Group 3	9.52	.70			
Group 4	9.60	.70			
Group 5	9.79	.70			
Zone 3 - Group 1	9.49	.70			
Group 2	9.62	.70			
Group 3	9.68	.70			
Group 4	9.75	.70			
Group 5	9.94	.70			
Zone 4 - Group 1	7.27	.70			
Group 2	7.40	.70			
Group 3	7.46	.70			
Group 4	7.53	.70			
Group 5	7.73	.70			
Zone 5 - Group 1	7.37	.70			
Group 2	7.50	.70			
Group 3	7.56	.70			
Group 4	7.63	.70			
Group 5	7.82	.70			

DECISION NO. LA81-4086 - MOD. #4
(46 FR 55189 - November 6, 1981)
Statewide Louisiana

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
Asbestos workers-Zone 4	$13.29	.84	.50		.02
Carpenters:					
Zone 7:					
Carpenters & soft floor layers	12.55				
Millwrights	13.30				
Piledrivermen	13.05				
Zone 9:					
Carpenters & soft floor layers	12.05	.80	.85		.10
Millwrights	12.95	.80	.85		.10
Piledrivermen	12.55	.80	.85		.10
Glaziers - Zone 2	11.25				.01
Lathers - Zone 9	12.55				
Zone 10	12.05	.80	.85		.10
Marble, tile & terrazzo workers & finishers:					
Zone 2 - Tile setters	11.07	.68	1.00		.02
Painters:					
Zone 1 - Group 1	14.745		.30		
Group 2	14.945		.30		
Group 3	15.09		.30		
Group 4	16.535		.30		
Plasterers - Zone 2	12.25				.01
Roofers:					
Zone 3 - Roofers	10.98	.75	.95		.04
Zone 4 - Roofers	10.50		.30		
Kettlemen	8.80		.30		
Zone 5 - Roofers	12.86		.20		.04
Kettlemen	8.90		.20		.04
OMIT:					
Plumbers & pipefitters					
Zone 3	13.10	1.05	1.20		.10

Avoyelles, Caldwell, Catahoula, Concordia, East Carroll, Evangeline, Franklin, Grant, Jackson, LaSalle, Lincoln, Madison, Morehouse, Natchitoches (south of Hwys. 84 & 86 from Winnfield to Natchitoches & southeast from Natchitoches to Anacoco through Bellwood), Ouachita, Rapides, Richland, Tensas, Union, Vernon (northeast of Hwy. 10), West Carroll & Winn Parishes

DECISION NO. LA81-4086 - MOD. #4 (CONT'D)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ADD:					
Plumbers & pipefitters:					
Zone 3	$13.10	1.05	1.20		.10
Zone 6	14.05	.75	.80		.10

ZONE 3 - Avoyelles, Catahoula, Concordia, Evangeline Grant, LaSalle, Natchitoches (south of Hwys. 84 & 86 from Winnfield to Natchitoches & southeast from Natchitoches to Anacoco through Bellwood), Rapides, Vernon (northeast of Hwy. 10) & Winn (south of Hwy. 84) Parishes

ZONE 6 - Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union & Winn (north of Hwy. 84) Parishes

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION NO. PA81-3041					
MOD. NO. 4					
(46 FR 34934 - July 6, 1981)					
Allegheny, Armstrong, Beaver, Bedford, Blair, Butler, Cambria, Cameron, Centre, Clarion, Clearfield, Clinton, Crawford, Elk, Erie, Fayette, Forest, Franklin, Fulton, Greene, Huntingdon, Indiana, Jefferson, Mercer, Lawrence, McKean, Mifflin, Potter, Somerset, Venango, Warren, Washington, Westmoreland Counties, Pa.					
CHANGE:					
HEAVY & HIGHWAY CONSTRUCTION					
Carpenters					
Zone I	$13.57	7%	9%	10%	
Zone II	13.37	7%	9%	10%	
Carpenter - Welder					
Zone I	13.97	7%	9%	10%	
Zone II	13.77	7%	9%	10%	
Carpenter - Burner					
Zone I	13.77	7%	9%	10%	
Zone II	13.57	7%	9%	10%	
Cement Masons	13.90	7%	16%		
Piledrivermen	15.04	6%	10%		
Piledrivermen - Welder	15.29	6%	10%		
LABORERS					
CLASS I					
ZONE I	11.18	10%	10%		
ZONE II	11.06	10%	10%		
CLASS II					
ZONE I	11.34	10%	10%		
ZONE II	11.25	10%	10%		
CLASS III					
ZONE I	11.76	10%	10%		
ZONE II	11.76	10%	10%		
CLASS IV					
ZONE I	12.72	10%	10%		
ZONE II	12.72	10%	10%		

DECISION NO. PA81-3041
MOD. NO. 4, CONT'D

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS: HEAVY & HIGHWAY CONSTRUCTION					
CLASS I					
ZONE I	$15.18	7.5%	8.25%		1%
ZONE II	14.93	7.5%	8.25%		1%
CLASS II					
ZONE I	14.96	7.5%	8.25%		1%
ZONE II	14.69	7.5%	8.25%		1%
CLASS III					
ZONE I	12.16	7.5%	8.25%		1%
ZONE II	11.92	7.5%	8.25%		1%
CLASS IV					
ZONE I	11.78	7.5%	8.25%		1%
ZONE II	11.49	7.5%	8.25%		1%
CLASS V					
ZONE I	11.56	7.5%	8.25%		1%
ZONE II	11.32	7.5%	8.25%		1%

DECISION NO. PA 81-3041

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
TRUCK DRIVERS: HEAVY & HIGHWAY CONSTRUCTION					
CLASS I					
ZONE 1	$11.95	8.5%	9.5%		
ZONE 2	11.72	8.5%	9.5%		
CLASS 2					
ZONE 1	12.08	8.5%	9.5%		
ZONE 2	11.90	8.5%	9.5%		
CLASS 3					
ZONE 1	12.16	8.5%	9.5%		
ZONE 2	12.00	8.5%	9.5%		
CLASS 4					
ZONE 1	12.16	8.5%	9.5%		
ZONE 2	12.00	8.5%	9.5%		
CLASS 5					
ZONE 1	12.25	8.5%	9.5%		
ZONE 2	12.08	8.5%	9.5%		
CLASS 6					
ZONE 1	12.25	8.5%	9.5%		
ZONE 2	12.08	8.5%	9.5%		
CLASS 7					
ZONE 1	12.24	8.5%	9.5%		
ZONE 2	12.05	8.5%	9.5%		
CLASS 8					
ZONE 1	11.99	8.5%	9.5%		
ZONE 2	11.75	8.5%	9.5%		
CLASS 9					
ZONE 1	12.08	8.5%	9.5%		
ZONE 2	11.86	8.5%	9.5%		
CLASS 10					
ZONE 1	12.16	8.5%	9.5%		
ZONE 2	12.00	8.5%	9.5%		
CLASS 11					
ZONE 1	12.08	8.5%	9.5%		
ZONE 2	11.90	8.5%	9.5%		
CLASS 12					
ZONE 1	12.04	8.5%	9.5%		
ZONE 2	11.86	8.5%	9.5%		

DECISION NO. PA81-3044 MOD. NO. 6 (46 FR 40477- August 7, 1981) Bedford, Cambria, Cameron, Clarion, Clearfield, Jefferson, Crawford, and Venango Counties, Pennsylvania	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ADD:					
Elevator Constructors	$14.95	1.345	1.085	j+k	.035
Elevator Constructors Helpers	10.465	1.345	1.085	j+k	.035
Elevator Constructors Helpers (Prob.)	7.475				

FOOTNOTES:

j. Employer contributes 6% of basic hourly rate for 5 years or more of service or 8% hourly rate for 6 months to 5 years of service as Vacation Pay Credit.

k. Paid Holidays: New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day and Christmas Day.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION NO. TX81-4044 - MOD. #4 (46 FR 33194 - June 26, 1981) Bowie County, Texas					
CHANGE:					
Plumbers & pipefitters:					
Within a 25 mile radius of Texarkana	$13.98	.80	.75		.05
Outside a 25 mile radius of Texarkana	14.38	.80	.75		.05
DECISION NO. TX81-4052 - MOD. #3 (46 FR 35903 - July 10, 1981) Cameron, Hidalgo, Starr & Willacy Counties, Texas					
CHANGE:					
Asbestos workers	14.99	.70	1.00		.04
DECISION NO. TX81-4074 - MOD. #5 (46 FR 48861 - October 2, 1981) Travis County, Texas					
CHANGE:					
Glaziers	12.06		.50		.02
Painters - Group 1	11.50				
Group 2	12.00				
DECISION NO. TX81-4075 - MOD. #4 (46 FR 48863 - October 2, 1981) Galveston & Harris Cos., Texas					
CHANGE:					
Plasterers	15.20	.92	.75		.02
DECISION NO. TX81-4076 - MOD. #4 (46 FR 48857 - October 2, 1981) Brazos County, Texas					
CHANGE:					
Plasterers	15.20	.92	.75		.02

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and or Appr. Tr.
DECISION NO. TX81-4077 - MOD. #3 (46 FR 48859 - October 2, 1981) Jefferson & Orange Cos., Texas					
CHANGE:					
Carpenters:					
Carpenters - Residential construction of not more than 2 units & condominium townhouses of not more than 10 units excluding all apartment construction & multiple buildings for rental purposes	$13.59	.85	.60		.065
Plasterers	15.20	.92	.75		.02
DECISION NO. TX81-4078 - MOD. #2 (46 FR 48865 - October 2, 1981) Bexar County, Texas					
CHANGE:					
Electricians:					
Electricians	14.29	.60	5%		1%
Cable splicers	14.54	.60	5%		1%
Painters:					
Brush; paperhangers; taper & floater; hand roller	10.65		.60		.05
Brush on all structural steel; spray on any other surface other than steel	10.90		.60		.05
DECISION NO. TX81-4079 - MOD. #3 (46 FR 48867 - October 2, 1981) Bell, Bosque, Coryell, Falls, Hill & McLennan Cos., Texas					
CHANGE:					
Building Construction:					
Bricklayers	13.45	.70	.55		.03

[FR Doc. 82-11-Filed 1-4-82; 8:45 am]

BILLING CODE 4510-27-C

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and or Appr. Tr.
DECISION NO. TX81-4083 - MOD. #3 (46 FR 55213 - November 6, 1981) Collin, Dallas, Denton, Ellis, Grayson, Hood, Hunt, Johnson, Kaufman, Palo Pinto, Rockwall, Tarrant & Wise Counties, Texas					
CHANGE:					
Carpenters:					
Zone 2 - Millwrights	$14.51	.85	1.35		.08
Laborers:					
Zone 2 - Group 1	9.13	.30	.50		.05
Group 2	9.28	.30	.50		.05
Group 3	9.38	.30	.50		.05
Group 4	9.53	.30	.50		.05
DECISION NO. VA81-3092-Mod. #1 (46 FR 61819-December 18, 1981) AMELIA, BRUNSWICK, CHARLES CITY, CHESTERFIELD, DINWIDDIE, GOOCHLAND, HANOVER, HENRICO, LUNENBURG, MECKLENBURG, NEW KENT, NOTTOWAY, POWHATAN, PRINCE GEORGE COUNTIES, and the City of RICHMOND					
CHANGE:					
Supersedes Decision No. VA80-3092 dated September 5, 1980 in 45 FR 59108 to read: Supersedes Decision No. VA80-3051 dated September 5, 1980 in 45 FR 59108					
MOTOR GRADER OPERATOR(FINE GRADE)	6.21				
MOTOR GRADER OPERATOR(ROUGH GRADE)	6.21				

federal register

Tuesday
January 5, 1982

Part IV

Department of Health and Human Services

Food and Drug Administration

Insect Repellent Drug Products for Over-the-Counter Oral Human Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 81N-0040]

Insect Repellent Drug Products for Over-the-Counter Oral Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of proposed rulemaking that would classify insect repellent drug products for over-the-counter (OTC) oral human use as not generally recognized as safe and effective and as being misbranded. This notice is based on the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by April 5, 1982, and reply comments by May 5, 1982.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's Office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on June 7, 1980 a report on insect repellent drug products for oral use from the Advisory Review Panel on OTC Miscellaneous Internal Drug Products. FDA regulations (21 CFR 330.10(a)(6)) provide that the agency issue in the **Federal Register** a proposed order containing: (1) The monograph recommended by the Panel, which establishes conditions under which OTC insect repellent drug products for oral use are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs' not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify such conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

The Panel's recommendations on OTC insect repellent drug products for oral use contain no Category I or Category III conditions, and FDA is issuing the Panel's recommendations proposing Category II classification of OTC insect repellent drug products for oral use.

The unaltered conclusions and recommendations of the Panel are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The report has been prepared independently of FDA, and the agency has not yet fully evaluated the report. This document represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it. The Panel's findings appear in this document to obtain public comment before the agency reaches any decision on the Panel's recommendations that the ingredients in insect repellent drug products for oral use be classified as Category II. If the agency proposes to adopt the Panel's recommendations, a regulation declaring these products to be new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)) will be proposed for inclusion in Part 310, Subpart E (21 CFR Part 310, Subpart E). The agency is including, in this advance notice of proposed rulemaking, a regulation based upon the Panel's recommendations in order to obtain full public comment at this time.

After reviewing all comments submitted in response to this document, FDA will publish in the **Federal Register** a notice of proposed rulemaking on OTC insect repellent drug products for oral use. The agency's position on OTC oral insect repellent drug products will be stated initially when that notice of proposed rulemaking is published in the **Federal Register.** In the notice of proposed rulemaking, the agency also will announce its intitial determination whether the proposed rule is a major rule under Executive Order 12291 and will consider the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). The present notice is referred to as an advance notice of proposed rulemaking to reflect its actual status and to clarify that the requirements of the Executive Order and the Regulatory Flexibility Act will be considered when the notice of proposed rulemaking is published. At that time FDA also will consider whether the proposed rule has a significant impact on the human environment under 21 CFR Part 25 (proposed in the **Federal Register** of December 11, 1979, 44 FR 71742).

The agency invites public comment regarding any impact that this rulemaking would have on OTC oral insect repellent drug products. Types of impact may include, but are not limited to, the following: Increased costs due to relabeling, repackaging, or reformulating; removal of unsafe or ineffective products from the OTC market; and testing, if any. Comments regarding the impact of this rulemaking on OTC oral insect repellent drug products should be accompanied by appropriate documentation.

If FDA proposes to adopt the Panel's recommendations, the agency will propose that insect repellent drug products for oral use be eliminated from the OTC market, effective 6 months after the date of publication of a final rule in the **Federal Register**, regardless of whether further testing is undertaken to justify their future use.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC miscellaneous internal drug products was issued in the **Federal Register** of November 16, 1973 (38 FR 31696). (In making their categorizations with respect to "active" and "inactive" ingredients, the advisory review panels relied on their expertise and understanding of these terms. FDA has defined "active ingredient" in its current good manufacturing practice regulations (§ 210.3(b)(7), (21 CFR 210.3(b)(7))), as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." An "inactive ingredient" is defined in § 210.3(b)(8) as "any component other than an 'active ingredient.' ") In the **Federal Register** of August 27, 1975 (40 FR 38179) a notice supplemented the initial notice with a detailed, but not necessarily all-inclusive, list of active ingredients in miscellaneous internal

drug products to be considered in the OTC drug review. The list, which did not include oral insect repellent ingredients, was provided to give guidance on the kinds of active ingredients for which data should be submitted. The notices of November 16, 1973, and August 27, 1975, informed OTC drug product manufacturers of their opportunity to submit data to the review at that time and of the applicability of the monographs from the OTC review to all OTC drug products.

Under § 330.10(a) (1) and (5), the Commissioner of Food and Drugs appointed the following Panel to review the data and information submitted and to prepare a report on the safety, effectiveness, and labeling of the active ingredients in these OTC miscellaneous internal drug products:

James L. Tullis, M.D., Chairman (appointed December 1979)
John W. Norcross, M.D., Chairman (resigned March 1979)
Diana F. Rodriguez-Calvert, Pharm. D. (appointed July 1976)
Ruth Eleanor Brown, R.Ph. (resigned May 1976)
Elizabeth C. Giblin, M.N., Ed. D.
Richard D. Harshfield, M.D.
Theodore L. Hyde, M.D.
Claus A. Rohweder, D.O. (deceased April 13, 1979)
Samuel O. Thier, M.D. (resigned November 1975)
William R. Arrowsmith, M.D. (appointed March 1976)

Representatives of consumer and industry interests served as nonvoting members of the Panel. Eileen Hoates, nominated by the Consumer Federation of America, served as the consumer liaison until September 1975, followed by Michael Schulman, J.D., Francis J. Hailey, M.D., served as the industry liaison, and in his absence John Parker, Pharm. D., served. Dr. Hailey served until June 1975, followed by James M. Holbert, Sr., Ph. D. All industry liaison members are nominated by the Proprietary Association.

The following FDA employees assisted the Panel: Armond M. Welch, R.Ph., served as the Panel Administrator until July 1979, followed by John R. Short, R.Ph., Enrique Fefer, Ph. D., served as the Executive Secretary until July 1976, followed by George W. James, Ph. D., until October 1976, followed by Natalia Morgenstern until May 1977, followed by Arthur Auer until October 1978. Roger Gregorio served as the liaison for the Office of New Drug Evaluation beginning November 1978. Joseph Hussion, R.Ph., served as the Drug Information Analyst until July 1976, followed by Anne Eggers, R.Ph., M.S., until October 1977, followed by John R. Short, R.Ph., until July 1979.

In order to expand its scientific base, the Panel called upon Ralph B. D'Agostino, Ph. D., for advice in statistics.

The Advisory Review Panel on OTC Miscellaneous Internal Drug Products was charged with the review of many categories of drugs, but due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents its conclusions and recommendations for oral insect repellent drug products in this document. The review of all other categories of miscellaneous internal drug products is being continued by the Panel, and its findings are being published periodically in the **Federal Register.**

The Panel was first convened on January 13, 1975, in an organizational meeting. Working meetings which dealt with OTC insect repellent drug products for oral use were held on the following dates: February 23 and 24, April 18 and 19, and June 6 and 7, 1980.

The minutes of the Panel meetings are on public display in the Dockets Management Branch (FHA–305), Food and Drug Administration (address above).

No person requested an opportunity to appear before the Panel to express his or her views on oral insect repellent drug products.

No submissions were made for oral insect repellent drug products; however, the Panel has thoroughly reviewed all available literature and has considered all pertinent data and information through June 7, 1980 in arriving at its conclusions and recommendations for these OTC drug products.

In accordance with the OTC drug review regulations (21 CFR 330.10), the Panel considered OTC oral insect repellent drug products with respect to the following three categories:

Category I. Conditions under which OTC oral insect repellent drug products are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which OTC oral insect repellent drug 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 reviewed one oral insect repellent drug product active ingredient and classified this ingredient in Category II.

A. Submission of Data and Information.

Although oral insect repellents were not listed in the notices published in the **Federal Register** of November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179), these requests for submission of data and information were for all OTC miscellaneous internal drug products. No submissions for oral insect repellents were made pursuant to these notices, but the Panel was made aware (by FDA's Bureau of Drugs' Office of Compliance) of oral insect repellent drug products being marketed as follows:

Firms and Marketed Products

Thompson Enterprises, Middleport, NY 14105—E–Z Mosquito Repellent, tablets.
Cordova Laboratories, Sylmar, CA 91342—E–Z Oral Mosquito Bite Relief, tablets.

It appears from the labeling available to the Panel that thiamine hydrochloride is the active ingredient in these products; therefore, this is the only ingredient discussed in this document.

B. General Discussion.

Since antiquity, mosquitos, fleas, and other biting insects have been a source of great annoyance. Within the past century it has been shown that insects are also carriers of many diseases which affect humans and animals. Transmission of malaria and yellow fever by mosquitos are the best known instances of insect-borne disease, and control of the above diseases by mosquito abatement is common knowledge. Nevertheless, these and other insect-transmitted diseases continue to be a problem throughout much of the populated area of the world. In addition to transmission of disease, biting insects are a problem to many people in many areas of the world because of localized reaction and general annoyance. These problems have plagued troops in the field, and the military has been particularly interested in methods of protecting personnel against biting insects.

Numerous efforts have been made to identify the properties or substances which attract mosquitos to humans. Among those studied have been body heat and moisture and the various components of sweat. In a review of this problem, Maibach et al. (Ref. *1*) noted that odor appeared to be more important in attracting the mosquitos from a distance but that heat and moisture were probably more important in determining the site of the bite once the mosquito was in close proximity to the individual. These investigators studied the composition of sweat and separated various components. It appeared that lipid components of sweat had some

repellent effect on mosquitos and that sweat was more attractive to them when the lipids had been removed from it. Despite this and other studies, the precise explanation of what attracts mosquitos to humans and what might repeal them is still not clear.

Several substances for application to the skin to repeal insects are available and are claimed to be effective. This Panel did not review topical insect repellents, but is cognizant of the fact that these substances tend to be washed away rapidly by perspiration or other moisture. For several decades, studies have been performed directed at identifying substances which could be taken internally and would have prolonged effectiveness in repealing biting insects. In the United States, these studies have been limited almost entirely to mosquito repellents.

Ideally, an oral insect repellent should be nontoxic and should be inactivated or eliminated slowly from the body so that ingestion once or twice daily would be effective against specific insects (e.g., mosquitos, fleas, and tsetse flies), or, better yet, against a wide variety of biting insects. Of the substances studied, only thiamine hydrochloride (vitamin B–1) has shown enough promise to have been evaluated to any significant degree. During its review, the Panel found different terminology, i.e., thiamine hydrochloride, thiamine chloride, and thiamin chloride, used to describe this vitamin B–1 preparation. The Panel concludes that each of these terms refers to thiamine hydrochloride, which is the correct name of this ingredient (Ref. *2*).

In 1943, Shannon (Ref. *3*) reported that thiamin chloride, administered by mouth or by injection, appeared to have a repellent effect on the mosquitos. This has led to further investigation of thiamine hydrochloride as an oral insect repellent, as well as its promotion for that purpose. This Panel has limited its review to drug products which are claimed to repeal mosquitos. However, some of these products had labeling and promotional material which also incorporated claims regarding the drug's ability to allevite symptoms due to the bite. Although the Panel knows of no conclusive data to substantiate "bite relief" claims, a review of these claims is beyond the scope of this document.

References

(*1*) Miabach, H. I., et al., "Human Skin in Relationship to Mosquito Attraction and Repulsion," *Connecticut Medicine*, 33:23–28, 1969.

(*2*) "The United States Pharmacopeia XIX," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 502, 1975.

(*3*) Shannon, W. R., "Thiamin Chloride—An Aid in the Solution of the Mosquito Problem," *Minnesota Medicine*, 26:799–802, 1943.

C. Category II Active Ingredient.

The Panel has classified the following oral insect repellent active ingredient as not generally recognized as safe and effective or as being misbranded for OTC use:

Thiamine hydrochloride. The Panel concludes that thiamine hydrochloride, also known as vitamin B–1, is safe in the dose noted below, but is not an effective oral insect repellent, nor is it generally recognized as such.

1. *Safety.* Thiamine hydrochloride occurs naturally in many foods of plant and animal origin. Because thiamine hydrochloride is not made or stored in the body to any significant degree, daily ingestion is required to maintain good heatlh. This daily requirement is approximately 1 milligram (mg) in the average adult, but varies somewhat depending on age, weight, and type of diet consumed. It is easily met by persons consuming a well-balanced diet.

Absorption of thiamine hydrochloride from the gastrointestinal tract is limited to a maximum of about 15 mg per day, which can be satisfied by the oral administration of 40 mg in divided doeses with food. Any excess beyond bodily requirements is rapidly excreted in the urine either as pyrimidine or thiamine (Ref. *1*).

The Panel, therefore, concludes that thiamine hydrochloride is generally recongized as safe when taken orally in doses up to 40 mg daily. The Panel does not think that dose in excess of 40 mg are unsafe, but it is inappropriate to administer more than is necessary to provide for maximum absorption.

2. *Effectiveness.* In 1943, Shannon (Ref. *2*) reported that thiamin chloride decreased the number of mosquito bites in nine patients including adults, children, and infants. All showed severe reaction to mosquito bites. In another study in 1945 Eder (Ref. *3*) reported thiamin chloride to be effective for preventing flea bites in adults, children, and infants. The species of mosquitos or fleas involved were unidentified, and no control was used in either of the above studies. A later study by Ruiz-Maldonado and Tamayo (Ref. *4*), also uncontrolled, using 200 to 300 mg thiamine chloride daily for up to 6 months in children being treated for papular urticaria (palpable hives presumably caused by insect bites) "* * * suggests that thiamine chloride is a preventive agent for insect prurigo" (papular urticaria). The significance of these results is difficult to determine because one-third of the subjects did not return for evaluation.

Strauss, Maibach, and Khan (Ref. *5*) screened 114 drugs given systemically using an objective measure (probing activity of the *Aedes aegypti* mosquito) and found no significant effect for any of the drugs, including vitamin B–1, in reducing probing activity. Probing activity referes to a test devised by Khan et al. (Ref. *6*) in which a nylon net cage containing six mosquitos is held 1 centimeter above the skin, and the time it takes for three mosquitos to start probing toward the skin is measured. Vitamin B–1 and vitamin B–6 were also tested by Strauss, Maibach, and Khan (Ref. *5*) for their effectiveness in reducing the biting activity of these mosquitos, but no signficant effect was demonstrated.

In a double-blind, placebo-controlled study performed by Khan et al. (Ref. *7*), 200 mg thiamine chloride was given three times daily for 2 days to volunteers. On the third day, after receiving a 200-mg dose of thiamine chloride the subjects were enclosed in a room containing mosquitos (*Aedes aegypti*). No significant difference was found between the number of bites received by the placebo group and the number received by the thiamine chloride-treated group.

In another controlled study, Wilson et al. (Ref. *8*) administered 120 mg of thiamin chloride per day for three days (30 mg four times daily) to three individuals. Repellency tests, using *Aedes aegypti* mosquitos, were started on the second day of treatment. Neither the rate of biting nor the subjects' reactions to the bites differed materially from the three individuals who served as controls.

An unpublished report (Ref. *9*) has indicated no protective effect of thiamine hydrochloride in doses up to 1 gram (g) per day against *Aedes aegypti* mosquitoes.

The Panel, therefore, concludes that thiamine hydrochloride is not an effective oral insect repellent, nor is it generally recognized as such.

3. *Evaluation.* The Panel concludes that thiamine hydrochloride is safe for OTC use, but the available evidence does not indicate that it is effective as an oral insect repellent, nor is it generally recognized as such. The Panel concludes that there are no ingredients that are safe and effective when used as an oral insect repellent.

References

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(3) Eder, H. L., "Flea Bites—Prevention and Treatment with Thiamin Chloride," *Archives of Pediatrics*, 62:300–301, 1945.

(4) Ruiz-Maldonado, R., and L. Tamayo, "Treatment of 100 Children with Papular Urticaria with Thiamine Chloride," *International Journal of Dermatology*, 12:258–260, 1973.

(5) Strauss, W. G., H. I. Maibach, and A. A. Khan, "Drugs ad Disease as Mosquito Repellents in Man," *The American Journal of Tropical Medicine and Hygiene*, 17:461–464, 1968.

(6) Khan, A. A., et al., "Screening Humans for Degrees of Attractiveness to Mosquitos," *Journal of Economic Entomology*, 58:694–697, 1965.

(7) Khan, A. A., et al., "Vitamin B_1 is not a Systemic Mosquito Repellent in Man," *Transactions of the St. John's Hospital Dermatological Society*, 55:99–102, 1969.

(8) Wilson, C. S., D. R. Mathieson, and L. A. Jachowski, "Ingested Thiamin Chloride as a Mosquito Repellent," *Science*, 100:147, 1944.

(9) OTC Volume 170174 (report of tests performed at the USDA Orlando Laboratory contained in a letter dated July 31, 1959 from Colonel Ralph W. Bunn to Captain John W. Goodner).

D. Category II Labeling.

The Panel concludes that since there are no Category I or Category III ingredients, any labeling which claims insect repellency for an orally administered drug product is considered to be Category II and may not be used.

PART 310—NEW DRUGS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under 21 CFR 5.11 (see 46 FR 26052; May 11, 1981), the agency advises in this advance notice of proposed rulemaking that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations would be amended in Part 310 by adding to Subpart E new § 310.529, to read as follows:

§ 310.529 Drug products containing active ingredients offered over-the-counter (OTC) for oral use as insect repellents.

(a) Thiamine hydrochloride (vitamin B–1) has been marketed as an ingredient in over-the-counter (OTC) drug products for internal use as an insect repellent (an orally administered drug product intended to keep insects away). There is a lack of adequate data to establish the effectiveness of this, or any other, ingredient for OTC internal use as an insect repellent. Labeling claims for OTC orally administered insect repellent drug products are either false, misleading, or unsupported by scientific data. The following claims are examples of some that have been made for orally administered OTC insect repellent drug products: "Oral mosquito repellent," "Mosquitos avoid you," "bugs stay away," "keep mosquitos away for 12 to 24 hours," and "the newest way to fight mosquitos." Therefore, any drug product containing ingredients offered for internal use as an insect repellent cannot be generally recognized as safe and effective.

(b) Any OTC drug product that is labeled, represented, or promoted for internal use as an insect repellent is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act and is regarded as a new drug within the meaning of section 201(p) of the act for which an approved new drug application under section 505 of the act and Part 314 of this chapter is required for marketing.

(c) A completed and signed "Notice of Claimed Investigational Exemption for a New Drug" (Form FD–1571) as set forth in § 312.1 of this chapter, is required to cover clinical investigations designed to obtain evidence that any drug product labeled, represented, or promoted OTC as an insect repellent for internal use is safe and effective for the purpose intended.

(d) After the effective date of the final regulation any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

Interested persons may, on or before April 5, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this advance notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments replying to comments may also be submitted on or before May 5, 1982. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 23, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: December 17, 1981.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-9 Filed 1-4-82; 8:45 am]

BILLING CODE 4160-01-M

federal register

Tuesday
January 5, 1982

Part V

Department of Health and Human Services

Food and Drug Administration

Topically Applied Hormone-Containing Drug Products for Over-the-Counter Human Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 310

[Docket No. 81N-0144]

Topically Applied Hormone-Containing Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of proposed rulemaking that would classify hormone-containing drug products for over-the-counter (OTC) oral human use as not generally recognized as safe and effective and as being misbranded. This notice is based on the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products and is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by April 5, 1982, and reply comments by May 5, 1982.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's Office) (HFA-305) Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on December 15, 1980 a report on OTC topically applied hormone-containing drug products from the Advisory Review Panel on OTC Miscellaneous External Drug Products. FDA regulations (21 CFR 330.10(a)(6) provide that the agency issue in the **Federal Register** a proposed order containing: (1) The monograph recommended by the Panel, which establishes conditions under which OTC topically applied hormone-containing drug products are generally recognized as safe and effective and not misbranded: (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs' not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify such conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

The Panel's recommendations on topically applied hormone-containing drug products for OTC use contain no Category I or Category III conditions, and FDA is issuing the Panel's recommendations proposing Category II classification of topically applied hormone-containing drug products for OTC use.

The unaltered conclusions and recommendations of the Panel are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The report has been prepared independently of FDA, and the agency has not yet fully evaluated the report. This document represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it. The Panel's findings appear in this document to obtain public comment before the agency reaches any decision on the Panel's recommendations that the ingredients in topically applied hormone-containing drug products for OTC use be classified as Category II. If the agency proposes to adopt the Panel's recommendations, a regulation declaring these products to be new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)) will be proposed for inclusion in Part 310, Subpart E (21 CFR 310, Subpart E). The agency is including, in this advance notice of proposed rulemaking, a regulation based upon the Panel's recommendations in order to obtain full public comment at this time.

After reviewing all comments submitted in response to this document, FDA will publish in the **Federal Register** a notice of proposed rulemaking on topically applied hormone-containing drug products for OTC use. The agency's position on OTC topically applied hormone-containing drug products will be stated initially when that notice of proposed rulemaking is published in the **Federal Register**. In the notice of proposed rulemaking, the agency also will announce its initial determination whether the proposed rule is a major rule under Executive Order 12291 and will consider the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). The present notice is referred to as an advance notice of proposed rulemaking to reflect its actual status and to clarify that the requirements of the Executive Order and the Regulatory Flexibility Act will be considered when the notice of proposed rulemaking is published. At that time FDA also will consider whether the proposed rule has a significant impact on the human environment under 21 CFR Part 25 (proposed in the **Federal Register** of December 11, 1979, 44 FR 71742).

The agency invites public comment regarding any impact that this rulemaking would have on OTC topically applied hormone-containing drug products. Types of impact may include, but are not limited to, the following: Increased costs due to relabeling, repackaging, or reformulating; removal of unsafe or ineffective products from the OTC market; and testing, if any. Comments regarding the impact of this rulemaking on OTC topically applied hormone-containing drug products should be accompanied by appropriate documentation.

If FDA proposes to adopt the Panel's recommendations, the agency will propose that topically applied hormone-containing drug products be eliminated from the OTC market, effective 6 months after the date of publication of a final rule in the **Federal Register**, regardless of whether further testing is undertaken to justify their future use.

In accordance with § 330.10(a)(2), the Panel and FDA have held as confidential all information concerning topically applied hormone-containing drug products for OTC use submitted for consideration by the Panel. All this information will be put on public display in the Dockets Management Branch, Food and Drug Administration, after February 4, 1982, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs (HFD-510) (address above).

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC miscellaneous external drug products was issued in the **Federal Register** of November 16, 1973 (38 FR 31697). (In making their categorizations with respect to "active" and "inactive" ingredients, the advisory review panels relied on their expertise and

understanding of these terms. FDA has defined "active ingredient" in its current good manufacturing practice regulations (§ 210.3(b)(7), (21 CFR 210.3(b)(7))), as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or preventation of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." An "inactive ingredient" is defined in § 210.3(b)(8) as "any component other than an 'active ingredient.' ") In the **Federal Register** of August 27, 1975 (40 FR 38179) a notice supplemented the initial notice with a detailed, but not necessarily all-inclusive, list of active ingredients in miscellaneous external drug products to be considered in the OTC drug review. The list, which included hormone cream active ingredients, was provided to give guidance on the kinds of active ingredients for which data should be submitted. The notices of November 16, 1973, and August 27, 1975, informed OTC drug product manufacturers of the opportunity to submit data to the review at that time and of the applicability of the monographs from the OTC review to all OTC drug products.

Under § 330.10(a)(1) and (5), the Commissioner appointed the following Panel to review the information submitted and to prepare a report on the safety, effectivenss, and labeling of the active ingredients in these miscellaneous external drug products:

William E. Lotterhos, M.D., Chairman
Rose Dagirmanjian, Ph. D.
Vincent J. Derbes, M.D. (resigned July 1976)
George C. Cypress, M.D. (resigned November 1978)
Yelva L. Lynfield, M.D. (appointed October 1977)
Harry E. Morton, Sc. D.
Marianne N. O'Donohue, M.D.
Chester L. Rossi, D.P.M.
J. Robert Hewson, M.D. (appointed September 1978)

Representatives of consumer and industry interests served as nonvoting members of the Panel. Marvin M. Lipman, M.D., of Consumers Union, served as the consumer liaison. Gavin Hildick-Smith, M.D., served as industry liaison from January until August 1975, followed by Bruce Semple, M.D., until February 1978. Both were nominated by the Proprietary Association. Saul A. Bell, Pharm. D., nominated by the Cosmetic, Toiletry, and Fragrance Association, also served as an industry liaison since June 1975.

Two nonvoting consultants, Albert A. Belmonte, Ph. D., and Jon J. Tanja, R.Ph., M.S., have provided assistance to the Panel since February 1977.

The following FDA employees assisted the Panel: John M. Davitt served as Executive Secretary until August 1977, followed by Arthur Auer until September 1978, followed by John T. McElroy, J.D. Thomas D. DeCillis, R.Ph., served as Panel Administrator until April 1976, followed by Michael D. Kennedy until January 1978, followed by John T. McElroy, J.D. Joseph Hussion, R.Ph., served as Drug Information Analyst until April 1976, followed by Victor H. Lindmark, Pharm. D., until March 1978, followed by Thomas J. McGinnis, R.Ph.

The Advisory Review Panel on OTC Miscellaneous External Drug Products was charged with the review of many categories of drugs. Due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents its conclusions and recommendations for topically applied hormone-containing drug products for OTC use in this document. The Panel's findings on other categories of miscellaneous external drug products are being published periodically in the **Federal Register.**

The Panel was first convened on January 13, 1975 in an organizational meeting. Working meetings which dealt with the topic in this document were held on: January 28 and 29, 1978; November 7 and 8, and December 14 and 15, 1980.

The minutes of the Panel meetings are on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration (address above).

No individuals requested to appear before the Panel to discuss topically applied hormone-containing drug products for OTC use, nor was any individual requested to appear by the Panel.

The Panel has thoroughly reviewed the literature and data submissions, and has considered all pertinent information submitted through December 15, 1980 in arriving at its conclusions and recommendations.

In accordance with the OTC drug review regulations in § 330.10, the Panel reviewed topically applied hormone-containing drug products for OTC use with respect to the following three categories:

Category I. Conditions under which topically applied hormone-containing drug products for OTC use are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which topically applied hormone-containing drug products for OTC use 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 reviewed three active ingredients in topically applied hormone-containing drug products and classified no ingredients in Category I, three ingredients in Category II, and no ingredients in Category III.

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients, recognized either through historical use or use in marketed products, of hormone active ingredients contained in topically applied products (hormone creams). Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC hormone cream drug products.

A. Submissions of Data and Information

Pursuant to the above notices, the following submissions were received:

Firms and Products

Helena Rubinstein, New York, NY 10022—Ultra Feminine Cream with Natural Estrogen and Progesterone, Ultra Feminine Beauty Oil with Natural Estrogen and Progesterone.

Sterling Drug, Inc., New York, NY 10016—Satura Moisture Cream with Hormones, Satura Moisture Lotion with Hormones, Moisturing Hormone Hand Cream, Cellogen Moisturizing Hormone Cream with Protein Hydrolysate.

USV Pharmaceutical Corporation, Tuckahoe, NY 10707—Hormonex Beauty Serum, Hormonex in Cream, Hormonex Hair and Scalp Serum.

In addition, FDA's Bureau of Drugs' Office of Compliance provided information to the Panel regarding potential hazards of topical skin and hair preparations containing various hormones (OTC Volune 160195). (See paragraph D. below—Referenced OTC Volumes.)

B. Ingredients Reviewed by the Panel

1. *Labeled ingredients contained in marketed products submitted to the Panel.*

Estrone

Lanolin
Natural estrogenic hormones
Natural estrogens
Progesterone
Sesame oil
Vitamin A

2. *Other ingredients reviewed by the Panel.*

Estradiol
Estrogenic hormones
Estrogen
Pregnenolone acetate

C. Classification of Ingredients

1. *Active ingredients.*

Estrogens (estrogen, natural estrogens, estrogenic hormones, natural estrogenic hormones, estradiol, estrone)
Progesterone

2. *Inactive ingredients.*

Lanolin
Sesame oil
Vitamin A

3. *Other ingredient.* The Panel was not able to locate nor is it aware of any data demonstrating the safety and effectiveness of pregnenolone acetate, or any other ingredient, when used in topically applied hormone-containing drug products for OTC use. The Panel, therefore, classifies all such ingredients as Category II for this use, and they will not be discussed further in this document.

D. Referenced OTC Volumes

The "OTC Volumes" cited throughout this document include submissions made by interested persons in response to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179). All of the information included in these volumes, except for those deletions which are made in accordance with the confidentiality provisions set forth in § 330.10(a)(2), will be put on public display after February 4, 1982, in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

E. General Discussion

The Panel has discussed topically applied hormone-containing drug products as a therapeutic class, as well as the two groups of active ingredients, the estrogens and progesterone, that are generally used in these products. The medical literature indicates that the topical application of hormone-containing drug products may affect the cellular structure of the skin but that these changes are observable only through a microscope.

Estrogenic hormones are responsible for the development of secondary sex characteristics in women at puberty. These hormones cause maturation of the internal and external genitals, enlargement of the breasts, and growth of pubic and axillary hair. Estrogens alone can produce proliferation of the uterine lining sufficient to cause menstrual bleeding; the normal ovulatory menstrual cycle results from the synergistic action of estrogens and progesterone. Pregnancy is associated with a large increase in levels of estrogens and progesterone. At the menopause, with declining levels of these hormones, menstrual cycles become irregular and then cease. Estrogen deficiency causes vasomotor disturbances (hot flashes) and atrophic vaginitis (Ref. *1*).

The ovary is the principal site of estrogen production in the nonpregnant premenopausal woman, and it secretes chiefly estradiol-17B (estradiol) and estrone. During pregnancy, the placenta produces more estrogens, primarily estradiol, than does the ovary. Estradiol is readily oxidized in the body to estrone, which in turn can be hydrated to estriol. These transformations take place mainly in the liver, where estrogens are also conjugated with sulfate of glucuronic acid. The conjugated estrogens are excreted by the kidney.

Natural estrogens for medicinal use are extracted from the urine of horses. A pregnant mare excrets over 100 milligrams (mg) of conjugated estrogens daily, more than any other mammal except a stallion.

Synthetic estrogens are often used therapeutically instead of natural estrogens. Alkylation of estradiol at the C17 position produces the orally potent estrogenic substances ethinyl estradiol and mestranol. Diethylstilbestrol and similar compounds have potent estrogenic activity although they do not have the steroidal configuration that estrogens have.

Progesterone is the ovarian hormone which changes the estrogen-primed lining of the womb into the secretory state necessary for pregnancy. In the mature menstrual cycle, a mature ovum is released; if it is not fertilized, a decline in the level of progesterone causes the lining of the womb to be shed—a change visible as menstrual bleeding. The activity of progesterone is determined by studying the cytology of vaginal smears and by measuring urinary pregnanediol, a metabolite of progesterone. Daily secretion of progesterone in a young woman ranges from a few milligrams during the early phase of the menstrual cycle to 10 to 20 mg in the latter half of the cycle to several hundred milligrams during the latter part of pregnancy, when progesterone is produced by the placenta as well as the ovary (Ref. *1*).

1. *Safety.* Estrogens are readily absorbed through the skin and mucous membranes, and systemic effects may result from topical application. In factory workers, gynecomastia (male breast development) followed the handling of diethylstilbestrol.

Masters (Ref. *2*) demonstrated an increased estrogen level in the urine and an estrogen-induced vaginal keratinization when two healthy postmenopausal women applied various estrogen creams topically. Five cream formulations were tested on each of the two women: Cream alone, cream plus 1 milligram per ounce (mg/oz) estrogen, cream plus 2 mg/oz estrogen, cream plus 4 mg/oz estrogen, and cream plus 1 mg/oz estrogen and 5 mg/oz progesterone. Haznam, Mahesh, and Greenblatt (Ref. *3*) reported similar vaginal keratinization effects in a 67-year-old woman from cutaneous application of estrogen creams containing 10,000 International Units per ounce (I.U./oz) and 50,000 I.U./oz estrogen. Greenblatt (Ref. *4*) treated an 18-year-old girl with Turner's Syndrome with an estrogen cream containing 10,000 I.U./oz estrone and 5 mg/oz progesterone. She developed vaginal keratinization, breast enlargement, and an increase in pubic hair. After applying radioactive estrogen under plastic or aluminum foil to women's backs, radioactive metabolites were promptly detected in their urine (Refs. *5* and *6*).

The Panel received three submissions for creams and oils claiming to improve the appearance of skin and hair (Refs. *7*, *8*, and *9*). These creams and oils contained 5,000 to 33,000 I.U./oz natural estrogen; in addition, one product contained progesterone 5 mg/oz.

Using 10,000 I.U./oz as an example for making calculations, and assuming for the calculation that the estrogen is estrone, the Panel calculated the concentration of estrogen in the reviewed OTC products as approximately 1 mg per 30 grams (g) or 0.003 percent, because 0.1 microgram (ug) of crystalline estrone is equivalent to 1 I.U. (Ref. *10*). One submission stated that the natural estrogen in its hormone cream is obtained from pregnant mares' urine and consists of 95 percent estrone with 17-estradiol and 5 percent miscellaneous female hormones (Ref. *9*). Bioassay is a better way of expressing estrogenic potency than weight because equal weights of chemically different estrogens differ markedly in their biologic effect. The estrogenic potency of estradiol is 12 times that of estrone

and 80 times that of estriol (Ref. *11*). Nevertheless, recent publications give estrogen content by weight.

The concentration of 10,000 I.U./oz estrogen was selected to achieve local cutaneous effects without significant systemic effects. The lack of systemic effects of this concentration is well documented in studies by Masters (Ref. *2*), Haznam, Mahesh, and Greenblatt (Ref.*3*), Karnaky (Ref. *12*), and Greenblatt (Ref. *13*). In the 30 years that these preparations have been marketed, only 3 cases of uterine bleeding (Ref. *14*) may be ascribed to their use (Ref. *15*). Adverse effects of systemic estrogen therapy, such as thrombotic disorders, nausea, edema, and breast tenderness and enlargement, have been reported from external use, due to the fact that when these products are purchased OTC it is possible for the user to disregard the instructions and apply far larger quantities than recommended (Ref. *16*). The incidence of irritation and allergic contact dermatitis using 10,000 I.U./oz is low. The Panel recognized that the data submitted are relatively old and concludes that there are inadequate data to establish that the use of estrogen is safe when used in amounts up to 2 oz/month in cream or oil. Therefore, the Panel recommends that estrogens in topically applied estrogen-containing OTC drug products be placed in Category III for safety.

Progesterone applied to the skin in concentrations similar to estrogen concentrations in marketed OTC cream and oil products seems free of systemic effects. Goldzieher and Baker (Ref. *5*), using a combination of estrogren 10,000 I.U./oz and progesterone 25 mg/oz, demonstrated no detectable increase in urinary pregnanediol. Karnaky (Ref. *12*) found no change in vaginal smears from the once-a-day use of cream containing estrogen 10,000 I.U. and progesterone 5 mg/oz. The Panel concludes that the topical OTC daily use of progesterone in a concentration up to 5 mg/oz is safe.

2. *Effectiveness.* The Panel was not presented any evidence or photographs showing any gross change, such as more even pigmentation or less wrinkling, to demonstrate that local application of estrogens improve the appearance of the skin. The only changes demonstrated have been histologic (microscopic review of sections of tissue) (Ref. *16*).

Goldzieher (Ref. *17*) biopsied the thighs and forearms of five elderly women before and after topical application of estrogen 10,000 I.U./oz. He found upon microscopic examination that the thin, senile epidermis thickened, both because of an increased number of cell layers and also because of the increased size of individual epidermal cells, and that the dermal-epidermal junction (rete ridges) returned to normal. A similar study using estrogen 5,000 to 15,000 I.U./oz on 28 elderly women, 6 elderly men, and 4 young women showed similar changes in the elderly people of both sexes but no change in the young women (Ref. *18*). Microscopic improvement was first evident histologically 10 days after starting treatment, and by the thirtieth day of treatment the epidermis has doubled in thickness and was better differentiated. Eller and Eller (Ref. *19*) did serial biopsies on 36 adults of both sexes and various ages treated with estrogen cream containing 7,500 and 15,000 I.U./oz and reached the same conclusion. Brown (Ref. *20*) instructed women aged 30 to 75 to apply estrogen cream to one side of their faces and the cream base alone to the other side for 45 days. The cream contained either 10,000 I.U. estrogen with 5 mg progesterone per ounce or 50,000 I.U./oz estrogen. Twenty-six post-treatment facial biopsies were submitted to expert dermatopathologists, who could not detect any histologic difference between the estrogen-treated and cream base-treated sides. In this study, Brown (Ref. *20*) noted a clinical (visual) impression of moderate improvement in appearance and wrinkling on the estrogen-treated side. This was also noted by Spoor (Ref. *21*) in double-blind half-face studies on eight women aged 22 to 64 treated for 30 days with cream containing 10,000 I.U./oz estrogen and 5 mg/oz progesterone.

Peck (Ref. *22*) performed a modified McClure-Aldrich test by injecting 0.05 milliliter (mL) of normal saline intradermally and measuring the time required for the visible and palpable wheal to disappear. This test measures the ability of the dermis to absorb additional fluid and therefore the saturation of the dermis which fluid prior to the injection. Peck (Ref. *22*) tested the cheeks of 4 women who used 10,000 I.U./oz estrogen cream daily. He found that the absorption time of the saline was increased in every case after 6 weeks of treatment. He did not report McClure-Aldrich tests after using the cream base alone. The Panel believes that it is possible that the mild dermal edema, which was difficult to demonstrate histologically, may be produced equally well by a moisturizing cream which does not contain hormones.

The use of progesterone on the skin is thought to increase skin surface oil by stimulating sebaceous glands. Animal experiments have shown that progesterone increased the size and rate of secretion of sebaceous glands in castrated male and female rats (Ref. *23*). A qualitative study by Spoor (Ref. *21*) using osmic acid staining of surface fat was interpreted as showing an increase in sebum production from local application of progesterone. However, quantitative gravimetric and histologic studies by Pochi and Strauss (Ref. *24*) demonstrated no effect on sebaceous gland secretion or size from the intramuscular administration of 50 mg/day progesterone in prepubertal girls and boys, young adult women, and aged women.

The physiologic stimulus to sebaceous gland growth and secretion is testosterone (Ref. *24*). In 1961, Strauss (Ref. *25*) demonstrated an appreciable increase in sebum production in aged females after the daily administration of 100 mg of methyltestosterone orally. Accordingly, Strauss (Ref. *25*) believed that some of the synthetic progestational agents, such as 17-*alpha*-ethynyl-nortestosterone, have and rogenic activity and stimulate sebaceous glands. However, more recent medical opinion (1975 to 1980) is that progesterone has no effect on human sebaceous glands (Refs. *16* and *26*).

The Panel notes that estrogen and progesterone hormones are often included in products that make cosmetic claims only. The Panel recognizes that evidence submitted demonstrating safety of estrogens not exceeding 10,000 I.U./oz and progesterone not exceeding 5 mg/oz is relatively old data. Additionally, the Panel knows of no objective data that show these levels are effective. The Panel believes that inclusion of estrogen and progesterone in these products misleads the consumer into believing that using the ingredient will give the user a more youthful appearance when in fact the changes that occur cannot be seen with the naked eye.

3. *Evaluation.* The Panel concludes that there are inadequate data to establish the safety of topically applied estrogens in the concentration reviewed, up to 10,000 I.U./oz, and that progesterone, in a concentration up to 5 mg/oz, is safe when used on the skin daily in a quantity not exceeding 2 oz/month. These amounts of topical estrogens and progesterone do not produce systemic effects and have a low incidence of irritation or allergic local effects. Higher concentrations of topical estrogens produce systemic effects and should not be available OTC. Higher concentrations of progesterone have not been tested for safety for OTC use.

The Panel further concludes that there is no evidence that using a hormone-containing drug product at the levels which are safe for OTC use will do

anything more than using the cream vehicle alone. Therefore, the Panel concludes that these products are ineffective for OTC drug use. Further, the Panel recognizes an inherent fallacy in marketing a cosmetic product which contains a medication regardless of the nonmedical intention of the label claim. If the medication affects the structure or function of the skin, then the purported cosmetic is, in fact, a medication. If the medication is present in such small amounts that neither the structure or function of the skin is altered, then its presence in the cosmetic is misleading because of lack of effectiveness, and the product should be considered misbranded.

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PART 310—NEW DRUGS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under 21 CFR 5.11 (see 46 FR 26052; May 11, 1981), the agency advises in this advance notice of proposed rulemaking that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations would be amended in Part 310 by adding to Subpart E new § 310.530, to read as follows:

§ 310.530 Topically applied hormone-containing drug products for over-the-counter (OTC) human use.

(a) Estrogens and progesterone have been present as ingredients in over-the-counter (OTC) drug products marketed for topical use as hormone cream. There is a lack of adequate data to establish the safety and effectiveness of these ingredients as OTC topically applied hormones. Data on any other ingredients intended for use as a topically applied hormone in OTC drug products have not been submitted to the Food and Drug Administration for review for safety and effectiveness. Therefore, any OTC drug product containing an ingredient offered for use as a topically applied hormone cannot be considered generally recognized as safe and effective for its intended use.

(b) Any OTC drug product labeled, represented, or promoted for use as a topically applied hormone-containing drug product is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act and is regarded as a new drug within the meaning of section 201(p) of the act for which an approved new drug application under section 505 of the act and Part 314 of this chapter is required for marketing.

(c) A completed and signed "Notice of Claimed Investigational Exemption for a New Drug" (Form FD–1571), as set forth in § 312.1 of this chapter, is required to cover clinical investigations designed to obtain evidence that any drug product labeled, represented, or promoted for use as a topically applied hormone-containing drug product is safe and effective for the purpose intended.

(d) After the effective date of the final regulation, any such drug product introduced in interstate commerce that is not in compliance with this section is subject to regulatory action.

Interested persons may, on or before April 5, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this advance notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments replying to comments may also be submitted on or before May 5, 1982. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 23, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: December 17, 1981.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-6 Filed 1-4-82; 8:45 am]

BILLING CODE 4160-01-M

federal register

Tuesday
January 5, 1982

Part VI

Department of Health and Human Services

Food and Drug Administration

Mercury-Containing Drug Products for Topical Antimicrobial Over-the-Counter Human Use; Establishment of a Monograph

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 333

[Docket No. 75N-0183]

Mercury-Containing Drug Products for Topical Antimicrobial Over-the-Counter Human Use; Establishment of a Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of a proposed rulemaking that would classify over-the-counter (OTC) mercury-containing drug products for topical antimicrobial use as not generally recognized as safe and effective and as being misbranded. This notice related to the development of a monograph for topical antimicrobial drug products in general, which is part of the ongoing review of OTC drug products conducted by FDA. This notice also reopens the administrative record for OTC topical antimicrobial drug products to allow for consideration of recommendations on mercury-containing drug products that have been received from the Advisory Review Panel on OTC Miscellaneous External Drug Products.

DATES: Written comments by April 5, 1982, and reply comments by May 5, 1982.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's Office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on October 6, 1980 a report on OTC mercury-containing drug products for topical antimicrobial use from the Advisory Review Panel on OTC Miscellaneous External Drug Products. FDA regulations (21 CFR 330.10(a)(6)) provide that the agency issue in the **Federal Register** a proposed rule containing (1) the monograph recommended by the Panel, which established conditions under which OTC mercury-containing drug products for topical antimicrobial use are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs' not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

Because mercurial ingredients are marketed in OTC drug products for topical antimicrobial use, FDA has determined that the Miscellaneous External Panel's recommendations on OTC mercury-containing drug products should be included as part of the proposed rulemaking for topical antimicrobial drug products. Development of this rulemaking has been ongoing for some time.

In the **Federal Register** of September 13, 1974 (39 FR 33103), FDA issued an advance notice of proposed rulemaking to establish the monograph for OTC topical antimicrobial drug products. In the **Federal Register** of January 6, 1978 (43 FR 1210), FDA issued a tentative final monograph (notice of proposed rulemaking) for OTC topical antimicrobial drug products. In the **Federal Register** of March 9, 1979 (44 FR 13041) FDA reopened the administrative record and announced its intent to publish an updated (amended) tentative final monograph (amended notice of proposed rulemaking) for OTC topical antimicrobial drug products. FDA advises that it is again reopening the administrative record for OTC topical antimicrobial drug products in order to allow for the consideration of the Miscellaneous External Panel's recommendations on mercury-containing drug products. An amended tentative final monograph (amended notice of proposed rulemaking) will be published in a future issue of the **Federal Register**. At that time, comments received on this advance notice of proposed rulemaking concerning mercury-containing drug products will be addressed. Also, the proceeding to develop a monograph for mercury-containing drug products will be merged with the general proceeding to establish a monograph for OTC topical antimicrobial drug products. Because the Panel has recommended that mercury-containing drug products be classified in Category II, no new sections to Part 333 are being included in this advance notice of proposed rulemaking.

The unaltered conclusions and recommendations of the Panel relating to OTC mercury-containing drug products for topical antimicrobial use are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The statement has been prepared independently of FDA, and the agency has not yet fully evaluated the Panel's recommendations. The Panel's findings appear in this document to obtain public comment before the agency reaches any decision on the Panel's recommendations. This document represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it.

After reviewing all comments submitted in response to this document, FDA will issue in the **Federal Register** an amended tentative final monograph for OTC topical antimicrobial drug products, including mercury-containing drug products, as an amended notice of proposed rulemaking. Under the OTC drug review procedures, the agency's position and proposal are first stated in the tentative final monograph, which has the status of a proposed rule. Final agency action occurs in the final monograph, which has the status of a final rule.

The agency's position on OTC topical antimicrobial drug products will be restated when the amended tentative final monograph is published in the **Federal Register** as an amended notice of proposed rulemaking. In that amended notice of proposed rulemaking, the agency also will announce its initial determination whether the proposed rule is a major rule under Executive Order 12291 and will consider the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). The present notice is referred to as an advance notice of proposed rulemaking to reflect its actual status and to clarify that the requirements of the Executive Order and the Regulatory Flexibility Act will be considered in the amended notice of proposed rulemaking. At that time FDA also will consider whether the proposed rule has a significant impact on the human environment under 21 CFR Part (proposed in the **Federal Register** of December 11, 1979; 44 FR 71742).

The agency invites public comment regarding any impact that this rulemaking would have on OTC mercury-containing drug products for topical antimicrobial use. Types of impact may include, but are not limited to, the following: Increased costs due to relabeling, repackaging, or

reformulating; removal of unsafe or ineffective products form the OTC market; and testing necessary, if any, to elevate Category III conditions to Category I. Comments regarding the impact of this rulemaking on OTC mercury-containing drug products for topical antimicrobial use should be accompanied by appropriate documentation. Comments will not be accepted at this time on any portion of the OTC topical antimicrobial rulemaking other than that relating to mercury-containing drug products.

In accordance with § 330.10(a)(2), the Panel and FDA have held as confidential all information concerning OTC mercury-containing drug products for topical antimicrobial use submitted for consideration by the Panel. All the submitted information will be put on public display in the Dockets Management Branch, Food and Drug Administration, after February 4, 1982, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs (HFD–510) (address above).

FDA published in the **Federal Register** of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The Court in *Cutler* held that the OTC drug review regulations (21 CFR 330.10) were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph has been established. Accordingly, this provision is now deleted from the regulations. The regulations now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph.

Although it was not required to do so under *Cutler*, FDA will no longer use the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and II). This document retains the concepts of Categories I, II, and III because that was the framework in which the Panel conducted its evaluation of the data.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 6 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions which would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce. Further, any OTC drug products subjects to this monograph which are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

Statement of the Advisory Review Panel on OTC Miscellaneous External Drug Products on Mercury-Containing Drug Products for Topical Antimicrobial Use.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC miscellaneous external drug products was issued in the **Federal Register** on November 16, 1973 (38 FR 31697). (In making their categorizations with respect to "active" and "inactive" ingredients, the advisory review panels relied on their expertise and understanding of these terms. FDA has defined "active ingredient" in its current good manufacturing practice regulations (§ 210.3(b)(7), (21 CFR 210.3(b)(7))) , as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure of any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." An "inactive ingredient" is defined in § 210.3(b)(8) as "any component other than an 'active ingredient.' ") In the **Federal Register** of August 27, 1975 (40 FR 38179) a notice supplemented the original notice with a detailed, but not necessarily all inclusive, list of ingredients in miscellaneous external drug products to be considered in the OTC drug review. The list, which included ingredients described as "mercurials," was provided to give guidance on the kinds of active ingredients for which data should be submitted. The notices of November 16, 1973, and August 27, 1975, informed OTC drug product manufacturers of their opportunity to submit data to the review at that time and of the applicability of the monographs from the OTC drug review to all OTC drug products.

Under § 330.10(a)(1) and (5) the Commissioner of Food and Drugs appointed the following Panel to review the information submitted and to prepare a report on the safety, effectiveness, and labeling of the active ingredients in these OTC miscellaneous external drug products:

William E. Lotterhos, M.D., Chairman

Rose Dagirmanjian, Ph. D.

Vincent J. Derbes, M.D. (resigned July 1976)

George C. Cypress, M.D. (resigned November 1978)

Yelva L. Lynfield, M.D. (appointed October 1977)

Harry E. Morton, Sc. D.

Marianne N. O'Donoghue, M.D.

Chester L. Rossi, D.P.M.

J. Robert Hewson, M.D. (appointed September 1978)

Representatives of consumer and industry interests served as nonvoting members of the Panel. Marvin M. Lipman, M.D., of Consumers Union served as the consumer liaison. Gavin Hildick-Smith, M.D., served as industry liaison from January until August 1975, followed by Bruce Semple, M.D., until February 1978. Both were nominate by the Proprietary Association. Saul A. Bell, Pharm. D., nominated by the Cosmetic, Toiletry, and Fragrance Association, also served as an industry liaison since June 1975.

Two nonvoting consultants, Albert A. Belmonte, Ph. D., and Jon J. Tanja, R.Ph., M.S., have provided assistance to the Panel since February 1977.

The following FDA employees assisted the Panel: John M. Davitt served as Executive Secretary until August 1977, followed by Arthur Auer until September 1978, followed by John T. McElroy, J.D. Thomas D. DeCillis, R.Ph., served as Panel Administrator until April 1976, followed by Michael D. Kennedy until January 1978, followed by

John T. McElroy, J.D. Joseph Hussion, R. Ph., served as Drug Information Analyst until April 1976, followed by Victor H. Lindmark, Pharm. D., until March 1978, followed by Thomas J. McGinnis, R.Ph.

The Advisory Review Panel on OTC Miscellaneous External Drug Products was charged with the review of many categories of drugs. Due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents in this document its conclusions and recommendations on OTC mercury-containing drug products for topical antimicrobial use. The Panel's findings on other categories of miscellaneous external drug products are being published periodically in the **Federal Register.**

The Panel was first convened on January 13, 1975 in an organizational meeting. Working meetings which dealt with the topic in this document were held on: January 27 and 28, March 7 and 8, April 20 and 21, June 22 and 23, August 3 and 4, and October 5 and 6, 1980.

The minutes of the Panel meetings are on public display in the Dockets Management Branch (HFA–305) Food and Drug Administration (address above).

No individuals requested to appear before the Panel to discuss mercury-containing drug products for topical antimicrobial use, nor was any individual requested to appear by the Panel.

The Panel has thoroughly reviewed the literature and data submissions, and has considered all pertinent information submitted through October 6, 1980 in arriving at its conclusions and recommendations.

In accordance with the OTC drug review regulations set forth in § 330.10, the Panel reviewed OTC mercury-containing drug products for topical antimicrobial use with respect to the following three categories:

Category I. Conditions under which OTC mercury-containing drug products for topical antimicrobial use are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which OTC mercury-containing drug products for topical antimicrobial use 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 reviewed 18 active ingredients in OTC mercury-containing drug products for topical antimicrobial use and classified all 18 in Category II.

I. Submissions of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or in marketed products, as mercurial active ingredients. Fourteen ingredients were identified as follows: Ammoniated mercury, bichloride of mercury, calomel, mercuric salicylate, mercuric sulfide, mercurochrome, mercury, mercury chloride, mercury oleate, nitromersol, *para*-chloromercuriphenol, vitromersol, yellow mercuric oxide, and zyloxin. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC mercurial drug products. In addition, in the **Federal Register** of September 13, 1974 (39 FR 33103), the following ingredients were deferred from the OTC Antimicrobial I Panel to the Miscellaneous Topical Panel (later renamed the Advisory Review Panel on OTC Miscellaneous External Drug Products) for review: mercuric chloride (also included in the call-for-data as bichloride of mercury), *ortho*-chloromercuriphenol, and *ortho*-hydroxyphenylmercuric chloride.

A. Submissions.

Pursuant to the above notices, the following submissions were received:

Firms and Marketed Products

Becton, Dickinson and Co., Rochelle Park, NJ 07662—Mercurochrome.

Bowman Pharmaceuticals, Inc., Canton, OH 44702—Merphol, Mercuronate, Ointment.

Corona Manufacturing Co., Atlanta, GA 30301—Corona Ointment.

Eli Lilly and Co., Indianapolis, IN 46206—Merthiolate.

Marion Health and Safety, Inc., Rockford, IL 61101—Kip Ointment, Merthiolate Swabs, Mercurochrome Swabs.

Whitehall Laboratories, New York, NY 10017—Sperti.

B. Ingredients Reviewed by the Panel.

1. *Labeled ingredients contained in marketed products submitted to the Panel.*

Ammoniated mercury
Merbromin
Orthohydroxyphenylmercuric chloride
Phenylmercuric nitrate
Thimerosal

2. *Other ingredients reviewed by the Panel.*

Calomel (mercurous chloride)
Mercuric chloride (bichloride of mercury)
Mercuric salicylate
Mercuric sulfide
Mercury
Mercury chloride
Mercury oleate
Nitromersol
Ortho-chloromercuriphenol
Para-chloromercuriphenol
Vitromersol
Yellow mercuric oxide
Zyloxin

C. Classification of Ingredients.

1. *Active ingredients.*

Calomel (mercurous chloride)
Merbromin
Mercuric chloride (bichloride of mercury)
Mercury, ammoniated (ammoniated mercury)
Ortho-hydroxyphenylmercuric chloride
Phenylmercuric nitrate
Thimerosal

2. *Inactive ingredients.*

None.

3. *Other ingredients.* Mercury oleate was submitted to this Panel for the treatment of psoriasis only and will be included in the Panel's recommendations on dandruff, seborrheic dermatitis, and psoriasis drug products to be published in a future issue of the **Federal Register.**

Mercuric oxide, yellow (yellow mercuric oxide) was reviewed as an ophthalmic anti-infective by the Advisory Review Panel on OTC Ophthalmic Drug Products in its report published in the **Federal Register** of May 6, 1980 (45 FR 30002).

The Panel was not able to locate nor is it aware of data demonstrating the safety and effectiveness of the following ingredients when used as OTC mercurial topical antimicrobial active ingredients. The Panel, therefore, classifies these ingredients as Category II, not generally recognized as safe and effective for this use, and they will not be discussed further in this document.

Mercuric oxide, yellow (yellow mercuric oxide)
Mercuric salicylate
Mercuric sulfide, red (mercuric sulfide)
Mercury
Mercury chloride
Mercury oleate
Nitromersol
Ortho-chloromercuriphenol
Para-chloromercuriphenol
Vitromersol
Zyloxin

D. Referenced OTC Volumes.

The "OTC Volumes" cited in this document include submissions made by interested persons in response to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179). All of the information included in

these volumes, except for those deletions which are made in accordance with the confidentiality provisions set forth in § 330.10(a)(2), will be put on public display after February 4, 1982, in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

II. General Discussion

Mercury is a silver-white, heavy, liquid metal with an atomic weight of 200.59. It forms alloys with most metals except iron and combines with sulfur at ordinary temperatures.

Mercury has been known to humans perhaps longer than any other metal, and humans have used it in various ways for treating illness. With the advent of the science of chemistry, new compounds of mercury were developed and used in treatment of different pathological conditions. With the advent of the science of bacteriology, mercury compounds were among the preparations chosen for antimicrobial therapy.

It has been the general course of events that, whenever a mercury compound has been tried for a particular therapeutic function, it has been used enthusiastically at first, only to be replaced eventually by a safer or more effective drug.

Elemental mercury, especially when vaporized, is toxic and readily absorbed through intact skin, the respiratory tract, and the gastrointestinal tract (Ref. *1*). The mercury compounds exhibit varying degrees of toxicity, and sensitivity to these compounds is not unusual. The literature includes a number of cases of sensitivity to mercury-containing preparations ranging from topical salves and solutions to amalgam tooth fillings (Refs. *2* and *3*). Both organic and inorganic mercury compounds produce allergic contact dermatitis, and cross-sensitivity has been noted (Ref. *3*).

The decline in the importance of mercury in antimicrobial therapy since midcentury can be attributed more to the discovery of its lack of effectiveness for this purpose than lack of safety, however. Work done in the field of enzyme chemistry clarifying the mode of action of mercury against bacterial and fungal cells has shown that mercury compounds as a class are of dubious value for antimicrobial use (Ref. *4*).

Mercuric ions combine with free sulfhydryl groups in the bacterial cells and thus deprive the cells of these sulfhydryl groups which are necessary to insure that metabolism and growth take place. The action of mercury is primarily bacteriostatic, but it may act slowly as a bactericide (Ref. *5*). That is to say, mercury inhibits the growth of bacteria, but does not act swiftly to kill them (Ref. *6*).

In late 1939 and early 1940, important discoveries were made showing that the bacteriostatic action of mercury can be reversed by many types of sulfur-containing compounds. Brewer (Refs. *7* and *8*) formulated a culture medium, thioglycollate, which allowed the growth of anaerobic microorganisms by the use of aerobic techniques. Marshall, Gunnison, and Luxen (Ref. *9*) demonstrated that the thioglycollate medium was capable of inactivating the bacteriostatic action of thimerosal and supported the growth of contaminants. Morton, North, and Engley (Refs. *10* and *11*) demonstrated that inhibited bacteria are not completely killed by mercury-containing compounds. When these inhibited bacteria are cultured in sodium thioglycollate solution, growth resumes because the solution chemically removes the mercury and eliminates any residual bacteriostatic activity (Ref. *12*). Intraperitoneal injections of the sodium thioglycollate culture proved fatal to mice and hemolytic streptococci were isolated from the heart's blood after death of the mice (Ref. *11*). These discoveries made it necessary to reexamine all previous reports in the literature claiming a killing activity for mercurial compounds.

It has been found that, if mercury is first allowed to combine with the sulfhydryl groups in bacterial cells, growth is inhibited, but the introduction of additional sulfhydryl groups to the cell-mercury complex neutralizes this action, and growth again takes place (Ref. *6*). Brewer (Ref. *13*) examined a hospital's stock of sutures, some of which had been stored for up to 10 years. Some of the sutures were nonsterile even though they had been stored in a solution containing a high concentration of mercury. Viable *Staphylococcus aureus* were recovered from sodium thioglycollate solution after exposure to a phenylmercuric nitrate preparation for 24 hours (Ref. *14*).

The presence of serum has also been shown to reduce the antibacterial action of mercury compounds. Three hundred times more mercuric chloride, 800 times more merbromin, and 14,000 times more thimerosal were required to inactivate half the *Salmonella typhosa* cells suspended in 10 mL of an 80-percent serum solution than were required to achieve comparable results in the same period of time when the microorganisms were suspended in a salt solution (Ref. *15*). Thus, the activity of mercury preparations as topical antimicrobial agents would be markedly affected if the microorganisms on the skin or the surface of a wound were in contact with serum, pus, or other body fluids.

In 1933 Birkhaug (Ref. *16*) calculated extremely high phenol coefficients (measurements of the killing power of a compound compared to that of phenol) for mercury compounds. The method of measurement, however, was imprecise so that one could not distinguish between the bacteriostatic and bactericidal activity. Today, measurement techniques for bactericidal activity have demonstrated that the phenol coefficient for OTC mercury-containing topical antimicrobial preparations is nonexistent when their bacteriostatic action is neutralized. This has been demonstrated by Morton, North, and Engley (Ref. *11*) in studies demonstrating the effect of merbromin and thimerosal on *Streptococcus pyogenes* and by Engley (Ref. *17*) in additional studies of the effect of mercuric chloride, phenylmercuric borate, and other mercurial compounds on this strain of bacteria.

After reviewing all data and information submitted on mercury-containing products for which topical antimicrobial activity is claimed, and after a careful review of the literature, the Panel concludes that some mercury-containing preparations are not effective and others are not safe and effective for OTC topical antimicrobial use. A bacteriostatic action that is capable of being reversed by contact with body fluids and other organic matter does not constitute an effective topical antimicrobial action, and the Panel has therefore placed all mercury compounds in Category II for topical antimicrobial use.

References

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III. Categorization of Data

A. Category I Conditions.

These are conditions under which active ingredients used as OTC mercury-containing drug products for topical antimicrobial use are generally recognized as safe and effective and are not misbranded. This document contains no Category I conditions.

B. Category II Conditions.

These are conditions under which active ingredients used as OTC mercury-containing drug products for topical antimicrobial use are not generally recognized as safe and effective or are misbranded.

1. *Category II ingredients.*

Inorganic mercury compounds:
Calomel
Mercuric chloride
Mercury, ammoniated
Organic mercury compounds:
Merbromin
Thimerosal
Ortho-hydroxyphenylmercuric chloride
Phenylmercuric nitrate

a. *Inorganic mercury compounds*—(i) *Calomel.* Calomel (mercurous chloride) is practically insoluble in water and therefore relatively nonpoisonous for humans unless it remains in the body for a long enough time to be oxidized. Once oxidized to mercuric chloride, it is highly toxic (Ref. *1*). It has been used in the past by inunction (rubbing into the skin) as a prophylactic against venereal disease and internally as a cathartic. The Panel concludes calomel may be safe as a topical antimicrobial agent, but is not effective for this purpose.

(ii) *Mercuric chloride.* Mercuric chloride (bichloride of mercury) is a bivalent mercury salt that exhibits a high toxicity for tissue cells, a low lethal action for microorganisms, and an inability to protect against infection (Ref. *1*). The Panel concludes that mercuric chloride is not safe and not effective as a topical antimicrobial agent.

(iii) *Mercury, ammoniated.* Ammoniated mercury is insoluble in water and alcohol, but readily soluble in warm hydrochloric, nitric, and acetic acids. If ingested, it causes epigastric pain, nausea, and purging.

Ammoniated mercury has been used topically in the treatment of impetigo, ringworm, psoriasis, pruritus ani, pinworm, and infestations with pubic lice (Refs. *2* and *3*). Prolonged use may cause chronic mercury poisoning, local pigmentation of skin and eyelids (Ref. *4*), and/or hypersensitivity to mercury (Ref. *5*).

Of 70 patients treated for psoriasis with ammoniated mercury, 33 showed signs of mercury poisoning (Ref. *6*). The Panel concludes that ammoniated mercury is not safe for use as a topical antimicrobial agent.

b. *Organic mercury compounds.* Organic mercury compounds were first synthesized in an attempt to decrease the toxicity of the mercuric ion. That the attempt was not wholly successful is shown by the fact that, while merbromin and phenylmercuric nitrate have been found to be less toxic than bichloride of mercury for human epithelial cells in vitro, thimerosal was found to be more toxic (Ref. *7*). The toxicities of these compounds were not in proportion to their mercury content.

Some microorganisms have exhibited a tolerance to organic mercury compounds. For example, a strain of *Penicillium roqueforti* resistant to phenylmercuric acetate was shown to incorporate mercury in its hyphae, thus reducing the amount of biologically active mercury in its environment and permitting other microorganisms to grow that would have been inhibited by the mercury (Ref. *8*).

(i) *Merbromin.* Merbromin is soluble in water and alcohol but practically insoluble in acetone, chloroform, and ether. This compound produces a carmine red solution that stains the skin a deep red, not a desirable property for an antimicrobial agent, as this can mask inflammation, and inflammation is a warning sign of infection.

In a 1928 study Simmons (Ref. *9*) pointed out that most of the killing action of merbromin in an alcohol-acetone vehicle was due to the vehicle. Aqueous merbromin, 2 percent, failed to kill two strains of *Staphylococcus aureus* in an exposure of 10 minutes and one strain of hemolytic streptococci in an exposure of 5 minutes. The cultures were killed under similar conditions by merbromin, 2 percent, in an alcohol-acetone vehicle and by the alcohol-acetone vehicle alone, which was included as a control. It was shown in 1942 that a 1:20 dilution of merbromin failed to kill *Staphylococcus aureus* and *Escherichia coli* during an exposure of 10 minutes at room temperature (Ref. *10*). A 1:20 dilution is two and one-half times more concentrated than the 2-percent aqueous solution of merbromin that is marketed OTC for topical antimicrobial use.

The Panel concludes that merbromin is safe for topical use but lacks a bactericidal action and is not an effective topical antimicrobial active ingredient.

(ii) *Thimerosal.* Thimerosal is a cream-colored crystalline powder that is stable in air, but not in sunlight. One gram (g) is soluble in approximately 1 milliliter (mL) water and in 8 mL alcohol, but is practically insoluble in ether and benzene. At the cellular level, thimerosal has been found to be more toxic for human epithelial cells in vitro than mercuric chloride, phenylmercuric nitrate, and merbromin (Ref. *7*). It was found to be 35.3 times more toxic for embryonic chick heart tissue than for *Staphylococcus aureus* (Ref. *11*).

Moller and Trofast (Ref. *12*) demonstrated that 10 of 20 guinea pigs sensitized to thimerosal developed a delayed hypersensitivity. This production of a hypersensitivity condition in 50 percent of laboratory animals demonstrates that the substance is very allergenic and it is reasonable to expect that thimerosal will act similarly in humans.

In Sweden, where thimerosal is used mainly as a preservative in vaccines and test materials and is not sold as an OTC skin disinfectant, Moller (Ref. *13*) reported a mean frequency of thimerosal allergy of 3.7 percent among dermatologic patients throughout a 5-year period during which 600 to 800 patients were treated for contact allergy each year. Moller classified thimerosal a medium stong allergen in comparison to nickel and balsam of Peru, which showed an incidence of reactions of 9 percent and 7 percent, respectively. Moller also found that among healthy subjects 10 percent of school children, 16 percent of military recruits, 18 percent of twins, and 26 percent of medical students had hypersensitivity to thimerosal. He concluded that the periodic tuberculin testing of individuals in Sweden with vaccines containing thimerosal as a preservative affords an opportunity for the development of delayed hypersensitivity to thimerosal in this population.

Underwood et al. (Ref. *14*) patch tested over 400 patients in which 160 patients (40 percent) showed a positive reaction to one or more of the remedies which had been applied before an initial visit to a dermatologist. Of the 160 patients, 56 (35 percent) reacted to a mercury compound, and thimerosal was responsible for 90 percent of these reactions. The North American Contact Dermatitis Group (Ref. *15*) tested 1,200 subjects with 16 allergens. Thimerosal produced an incidence of 8 percent reactions and ranked third highest of the 16 allergens. Epstein, Rees, and Maibach (Ref. *16*) tested a group of private dermatological patients in the western United States with 26 substances. Thimerosal had a 13.4-percent incidence of sensitivity, which was the third highest incidence of sensitivity.

It has been suggested that hypersensitivity to thimerosal may be due to the thiosalicylate portion of the molecule and not the mercury (Ref. *5*); however, this has not been confirmed. Based on the above data, the Panel concludes that thimerosal is very allergenic.

A comprehensive study of several mercury compounds in 1950 (Ref. *1*) showed that these compounds were bacteriostatic rather than bactericidal and that thimerosal was no better than water in protecting mice from potential fatal streptococcal infection under the conditions of the study. The streptococcal culture was added to the various mercury antimicrobial preparations; the mixture held at the temperature of skin (32° to 34° C) for 10 minutes; subcultured into dextrose broth, dextrose broth with 0.1 percent thioglycollate, and dextrose broth with 10 percent blood serum; and then injected intraperitoneally into mice. The latter two culture media neutralized the bacteriostatic action of the mercury compounds (Ref. *1*).

The Panel concludes that thimersal is not safe for OTC topical use because of its potential for cell damage if applied to broken skin and its allergy potential. It is not effective as a topical antimicrobial because its bacteriostatic action can be reversed.

(iii) *Ortho-hydroxyphenylmercuric chloride.* Ortho-hydroxyphenylmercuric chloride occurs as white to faint pink feathery crystals that are soluble in water, alcohol, and benzene (Ref. *2*). It is used in burn preparations. The Panel concludes that this compound is safe for topical use in the concentration marketed for OTC use (0.056 percent). However, as a topical antimicrobial, this compound is not effective because its action is bacteriostatic rather than bactericidal (Ref. *17*).

(iv) *Phenylmercuric nitrate.* Phenylmercuric nitrate occurs as pearly, lustrous scales that are soluble in water (1 part to about 1,250 parts water) and slightly soluble in alcohol. Against human epithelial cells in vitro, phenylmercuric nitrate was found to be less toxic than bichloride of mercury and thimerosal, but it was still very toxic (Ref. *7*). Solutions of phenylmercuric salts in concentrations of 1:1,500 and greater tend to cause blistering of human skin and may act as primary skin irritants and allergens (Ref. *18*). The Panel finds phenylmercuric nitrate in the concentration submitted (1:10,000) (Ref. *19*) safe for topical application, but there is no evidence that this compound is an effective topical antimicrobial at this concentration.

2. *Category II labeling.* The Panel concludes that labeling of any OTC mercury-containing product for topical antimicrobial use is Category II because all mercury ingredients are placed in Category II.

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C. Category III Conditions.

These are conditions for which the available data are insufficient to permit final classification at this time. This document contains no Category III conditions.

Interested persons may, on or before April 5, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this advance

notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments replying to comments may also be submitted on or before May 5, 1982. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 23, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: December 17, 1981.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-7 Filed 1-4-82; 8:45 am]

BILLING CODE 4160-01-M

federal register

Tuesday
January 5, 1982

Part VII

Department of Health and Human Services

Food and Drug Administration

Drug Products for Over-the-Counter Human Use for the Treatment of Acute Toxic Ingestion; Establishment of a Monograph

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 357

[Docket No. 81N-0050]

Drug Products for Over-the-Counter Human Use for the Treatment of Acute Toxic Ingestion; Establishment of a Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of proposed rulemaking that would establish conditions under which over-the-counter (OTC) drug products used for the treatment of acute toxic ingestion are generally recognized as safe and effective and not misbranded. This notice is based on the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by April 5, 1982, and reply comments by May 5, 1982.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's Office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on June 24, 1978 a report of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products. FDA regulations (21 CFR 330.10(a)(6))provide that the agency issue in the **Federal Register** a proposed order containing: (1) The monograph recommended by the Panel, which establishes conditions under which OTC drug products for the treatment of acute toxic ingestion are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs' not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

The unaltered conclusions and recommendations of the Panel are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The report has been prepared independently of FDA, and the agency has not yet fully evaluated the report. The Panel's findings appear in this document to obtain public comment before the agency reaches any decision on the Panel's recommendations. This document represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it.

After reviewing all comments submitted in response to this document, FDA will issue in the **Federal Register** a tentative final monograph for OTC drug products used for the treatment of acute toxic ingestion as a notice of proposed rulemaking. Under the OTC drug review procedures, the agency's position and proposal are first stated in the tentative final monograph, which has the status of a proposed rule. Final agency action occurs in the final monograph, which has the status of a final rule.

The agency notes that the Panel has included in its report a series of labeling recommendations for the use of ipecac syrup as an emetic. (See part III. paragraph A.1.b. below—Ipecac Syrup.) The Panel was aware that ipecac syrup had already been reviewed by the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products and requested that its recommendations regarding ipecac syrup be incorporated in the tentative final monograph (notice of proposed rulemaking) for emetic drug products rather than in the advance notice of proposed rulemaking for drug products for the treatment of acute toxic ingestion which is included in this document. Unfortunately, the report of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products was received too late for the recommendations to be considered in the development of the emetic tentative final monograph (notice of proposed rulemaking) which was published in the **Federal Register** on September 5, 1978 (43 FR 39544). Therefore, FDA will consider that portion of this document which deals with ipecac syrup in promulgating the final rule for emetic drug products.

Ipecac syrup is frequently an integral part of acute toxic ingestion therapy. Additionally, ipecac syrup is marketed with activated charcoal in a kit for acute toxic ingestion. The Panel's recommendations regarding the labeling of ipecac syrup by itself are not incorporated into this advance notice of proposed rulemaking. Rather, this advance notice of proposed rulemaking refers to the tentative final monograph (notice of proposed rulemaking) for OTC emetic drug products (43 FR 39544) for required labeling of ipecac syrup. This advance notice of proposed rulemaking will deal with ipecac syrup only to the extent that it is used in conjunction with other drug products for the treatment of acute toxic ingestion.

The agency's position on OTC drug products for the treatment of acute toxic ingestion will be stated initially when the tentative final monograph is published in the **Federal Register** as a notice of proposed rulemaking. In that notice of proposed rulemaking, the agency also will announce its initial determination whether the proposed rule is a major rule under Executive Order 12291 and will consider the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). The present notice is referred to as an advance notice of proposed rulemaking to reflect its actual status and to clarify that the requirements of the Executive Order and the Regulatory Flexibility Act will be considered when the notice of proposed rulemaking is published. At that time FDA also will consider whether the proposed rule has a significant impact on the human environment under 21 CFR Part 25 (proposed in the **Federal Register** of December 11, 1979, 44 FR 71742).

The agency invites public comment regarding any impact that this rulemaking would have on OTC drug products for the treatment of acute toxic ingestion. Types of impact may include, but are not limited to, the following: Increased costs due to relabeling, repackaging, or reformulating; removal of unsafe or ineffective products from the OTC market; and testing necessary, if any. Comments regarding the impact of this rulemaking on OTC drug products for the treatment of acute toxic ingestion should be accompanied by appropriate documentation.

In accordance with § 330.10(a)(2), the Panel and FDA have held as confidential all information concerning OTC drug products used in the treatment of acute toxic ingestion submitted for consideration by the Panel. All the submitted information will be put on public display in the Dockets Management Branch, Food and Drug Administration, after February 4, 1982, except to the extent that the person

submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs (HFD–510) (address above).

FDA published in the **Federal Register** of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The Court in *Cutler* held that the OTC drug review regulations (21 CFR 330.10) were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision is now deleted from the regulations. The regulations now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process, before the establishment of a final monograph.

Although it was not required to do so under *Cutler*, FDA will no longer use the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III because that was the framework in which the Panel conducted its evaluation of the data.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 6 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions which would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce. Further, any OTC drug products subject to this monograph which are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to voluntarily comply with the monograph at the earliest possible date.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC miscellaneous internal drug products was issued in the **Federal Register** of November 16, 1973 (38 FR 31696). (In making their categorizations with respect to "active" and "inactive" ingredients, the advisory review panels relied on their expertise and understanding of these terms. FDA has defined "active ingredient" in its current good manufacturing practice regulations (§ 210.3(b)(7), (21 CFR 210.3(b)(7))), as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." An "inactive ingredient" is defined in § 210.3(b)(8) as "any component other than an 'active ingredient.' ") In the **Federal Register** of August 27, 1975 (40 FR 38179) a further notice supplemented the initial notice with a detailed, but not necessarily all-inclusive, list of active ingredients in miscellaneous internal drug products to be considered in the OTC drug review. The list, which included ingredients for the treatment of acute toxic ingestion described as "universal antidotes," was provided to give guidance on the kinds of active ingredients for which data should be submitted. The notices of November 16, 1973, and August 27, 1975, informed OTC drug product manufacturers of their opportunity to submit data to the review at that time and of the applicability of the monographs from the OTC review to all OTC drug products.

Under § 330.10(a) (1) and (5), the Commissioner of Food and Drugs appointed the following Panel to review the information submitted and to prepare a report on the safety, effectiveness, and labeling of the active ingredients in these OTC miscellaneous internal drug products:

John W. Norcross, M.D., Chairman
Ruth Eleanor Brown, R.Ph. (resigned May 1976)
Elizabeth C. Giblin, M.N., Ed. D.
Richard D. Harshfield, M.D.
Theodore L. Hyde, M.D.
Claus A. Rohweder, D.O.
Samuel O. Thier, M.D. (resigned November 1975)
William R. Arrowsmith, M.D. (appointed March 1976)
Diana F. Rodriguez-Calvert, Pharm. D. (appointed July 1976)

Representatives of consumer and industry interests served as nonvoting members of the Panel. Eileen Hoates, nominated by the Consumer Federation of America, served as the consumer liaison until September 1975, followed by Michael Schulman, J.D. Francis J. Hailey, M.D., served as the industry liaison, and in his absence John Parker, Pharm. D., served. Dr. Hailey served until June 1975, followed by James M. Holbert, Sr., Ph. D. All industry liaison members were nominated by the Proprietary Association.

The following FDA employees assisted the Panel: Armond M. Welch, R.Ph., served as the Panel Administrator. Enrique Fefer, Ph. D., served as the Executive Secretary until July 1976, followed by George W. James, Ph. D., until October 1976, followed by Natalia Morgenstern until May 1977, followed by Arthur Auer. Joseph Hussion, R.Ph., served as the Drug Information Analyst unitl July 1976, followed by Anne Eggers, R.Ph., M.S., until October 1977, followed by John R. Short, R. Ph.

To expand its medical and scientific base, the Panel called upon the following consultants for advice in areas which required particular expertise:

Carol R. Angle, M.D. (pediatrics)
Jay M. Arena, M.D. (pediatrics)
William A. MacColl, M.D. (pediatrics)
Lynn R. Brady, Ph. D. (pharmacognosy)
Arthur E. Schwarting, Ph. D. (pharmacognosy)
Ralph B. D'Agostino, Ph. D. (statistics)

The Advisory Review Panel on OTC Miscellaneous Internal Drug Products was charged with the review of many categories of drugs; but due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for each drug category. The Panel presents its conclusions and recommendations for drug products used for the treatment of acute toxic ingestion in this document. The review of other categories of miscellaneous internal drug products is being continued by the Panel, and its findings are being published periodically in the **Federal Register.**

The Panel was first convened on January 13, 1975 in an organizational meeting. Meetings at which drug products used for the treatment of acute toxic ingestion were discussed were held on the following dates: March 23 and 24, April 27 and 28, September 21 and 22, November 16 and 17, 1975; March 7 and 8, October 10 and 11, 1976; May 15 and 16, July 9, 10, and 11, 1977; January 28, 29, and 30, March 10, 11, and 12, May 5, 6, and 7, and June 23 and 24, 1978.

The minutes of the Panel meetings are on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration (address above).

John B. Johnson requested, and was given, an opportunity to appear before the Panel to express his views on activated charcoal used for the treatment of acute toxic ingestion. No other person requested an opportunity to appear before the Panel.

The Panel has thoroughly reviewed the literature and submitted data, has listened to additional testimony from an interested person, and has considered all pertinent data and information submitted through June 24, 1978 in arriving at its conclusions and recommendation for OTC drug products used for the treatment of acute toxic ingestion.

In accordance with the OTC drug review regulations (21 CFR 330.10), the Panel considered OTC drug products for the treatment of acute toxic ingestion with respect to the following three categories:

Category I. Conditions under which OTC drug products used for the treatment of acute toxic ingestion are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which OTC drug products used for the treatment of acute toxic ingestion 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 reviewed six active ingredients in drug products for the treatment of acute toxic ingestion and classified two ingredients in Category I, four ingredients in Category II, and no ingredients in Category III.

I. Submission of Data and Information

A. Submission by Firm

Pursuant to the notices published in the Federal Register of November 16, 1973 (39 FR 31696) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on OTC miscellaneous internal drug products, the following firm made a submission for a drug product used for the treatment of acute toxic ingestion.

Firm and marketed product

Bowman Pharmaceuticals, Inc., Canton, OH 44702—Poison antidote kit.

B. Labeled Ingredients Contained in Marketed Products

1. *Ingredients in products submitted to the Panel for review.*

Charcoal, activated
Ipecac syrup

2. *Other ingredients reviewed by the Panel.* In addition to those ingredients included in the product submitted to the Panel, the following ingredients were listed in the Federal Register notice of August 27, 1975 (40 FR 38179).

Alcohol
Magnesium hydroxide
Potassium arsenite
Tannic acid

C. Classification of Ingredients

1. *Active ingredients.*

Charcoal, activated
Ipecac syrup

2. *Inactive ingredients.* None.

3. *Other ingredients.* No submissions were received for the following ingredients. The Panel has not been able to locate, nor is it aware as a group of experts, of any data, published or unpublished, demonstrated the safety and effectiveness of these ingredients for OTC use in the treatment of acute toxic ingestion. The Panel therefore classifies these ingredients as Category II for this use, and they will not be reviewed in this document.

Alcohol
Magnesium hydroxide
Potassium arsenite
Tannic acid

D. Referenced OTC Volumes

The "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the Federal Register of November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179). All of the submitted information is included in one volume which, except for those deletions which are made in accordance with the confidentiality provisions set forth in § 330.10(a)(2), will be put on public display after February 4, 1982, in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

II. General Statements and Recommendations

A. Definitions of Terms

For the purpose of this document, the Panel agreed upon the following definitions:

1. *Acute toxic ingestion.* An ingestion, within a brief time, of a substance in amounts that could threaten the survival or well-being of an individual.

2. *Adjunct.* An accessory, auxiliary agent, or measure.

3. *Adsorption.* Adhesion of the molecules of a gas, liquid, or dissolved substance to a surface.

4. *Antidote.* A substance used to counteract a poison.

5. *Aspiration.* Inhalation of a foreign substance into the lungs.

6. *Emesis.* Vomiting.

7. *Emetic.* An agent that causes vomiting.

8. *Poison.* A substance ingested within a brief time in amounts that could threaten the survival or well-being of an individual.

9. *Toxic substance.* A poison.

B. General Discussion.

An estimated 2 million accidental poisonings occur in the United States each year (Ref. *1*), and about 60 percent of these poisonings involve children under 5 years of age (Ref. *2*). Therefore, it is obvious that extensive preventive measures are needed to reduce the incidence of accidental poisoning. When ingestion of a toxic substance occurs, means should be available to handle the situation until the patient can be treated by a physician.

The Panel is aware of the current OTC labeling regulation dealing with warning statements (21 CFR 330.1(g)). The Panel concurs with the warning, "Keep this and all drugs out of the reach of children," and believes that it should be incorporated in the labeling for digestive aid products. However, the Panel recommends that the other warning statement required by § 330.1(g). "In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately" be revised to read as follows: "In case of accidental overdose, contact a Poison Control Center, emergency medical facility, or physician immediately for advice." The Panel believes that this revision will be more informative to the consumer.

With the exception of corrosives such as strong acids and alkalies, the emergency treatment of poisoning is aimed at minimizing the absorption of the poison. This can be accomplished by interfering with the absorption of the

poison by the gastrointestinal tract or by removing the poison from the body as quickly as possible.

Upon discovering that a toxic substance has been ingested, a Poison Control Center, emergency medical facility, or physician should be called at once for advice. If medical consultation cannot be obtained immediately, the following procedure should be carried out:

1. The patient should be transported to the medical facility as soon as possible.

2. In most cases the poison should be removed from the patient's stomach immediately by inducing vomiting. However, vomiting should not be induced if the patient: (a) Is semiconscious or unconscious; (b) is having convulsions; (c) has swallowed strychnine, unless advised otherwise by a Poison Control Center, emergency medical facility, or physician; (d) has swallowed petroleum distillates such as kerosene, gasoline, paint thinner, or cleaning fluids, unless advised otherwise by a Poison Control Center, emergency medical facility, or physician; or (e) has swallowed a corrosive poison such as alkali (lye) or strong acid, unless advised otherwise by a physician or emergency treatment facility.

Vomiting may be induced by gently irritating the back of the patient's throat with the blunt end of a spoon or a finger or by using an emetic such as ipecac syrup. In the former method, before the vomiting reflex (gagging) is stimulated, the patient should drink one or two glasses of water (not milk or carbonated beverages) in order to dilute the toxic substance and provide a sufficient volume of gastric contents to be vomited. When retching and vomiting begin, the patient should be placed face down with head lower than hips. This position will prevent the vomitus from being aspirated into the lungs and causing further damage. Unfortunately, this mechanically induced vomiting is usually unsuccessful and incomplete (Ref. *3*).

When using ipecac syrup (not ipecac fluidextract) as an emetic, it should be given in doses of 1 to 2 teaspoonsful (5 to 10 milliliters (mL)) for children under 1 year of age (followed by ½ to 1 glass of water); children over 1 year old and adults should receive 1 tablespoonful (15mL) (followed by 1 to 2 glasses of water). Milk or carbonated beverages should not be used in place of water. If vomiting does not occur after 20 minutes, the dose should be repeated. The subject should be kept upright and ambulatory to speed emesis. A young child may be jiggled to speed emesis. If vomiting does not occur within 20 minutes of the second dose, the advice of a Poison Control Center, emergency medical facility, or physician should again be sought.

Vomiting should not be induced following the ingestion of most petroleum distillates because of the possibility of their being aspirated into the lung (Ref. *4*). However, there may be some cases of petroleum distillate ingestion in which the Poison Control Center, emergency medical facility, or physician will suggest that vomiting be induced.

Vomiting should also not be induced following the ingestion of acidic and alkaline corrosives because regurgitation would increase the damage to the esophagus. Large volumes of water of milk should be ingested to dilute the acidic or alkaline corrosive substances.

Chilling should be prevented by wrapping the patient in blankets, when necessary.

Alcohol in any form should not be given.

Activated charcoal should be given only after the patient vomits or when advised by a health professional. Activated charcoal acts by adsorbing a toxic substance and should not be given prior to the administration of ipecac syrup since it would adsorb the ipecac and negate its emetic action.

Although activated charcoal has a tremendous adsorptive capacity, it should be considered an adjunct for the treatment of an acute toxic ingestion rather than a specific antidote for any one poison. Following the administration of activated charcoal, a physician may still need to use specific antidotes to treat the particular poison.

The major drawback to the use of activated charcoal is its black color which often causes children not to want to ingest it. If spewed, it spots clothes and walls. The Panel, therefore, encourages the development of a palatable formulation which can be more easily administered to children.

Although activated charcoal is an effective, nonspecific adsorbent of a large number of materials, the Panel concurs with the general medical recognition that there is no true "universal antidote" (Ref. *5*). The so-called "universal antidote" recommended in the past consisted of activated charcoal, tannic acid, and magnesium oxide. However, it has been well established that the tannic acid and magnesium oxide have no significant effectiveness and may actually impede the effective ingredient, activated charcoal. The use of burnt toast as a homemade antidote has no merit. This material is not activated charcoal, and it has no significant adsorptive properties (Ref. *5*).

In many cases of accidental poisoning it is not possible to identify the substance ingested; but if the substance is known, the Poison Control Center, emergency medical facility, or physician will want this information along with the container in which the substance was stored to assist in determining the kind and amount of poison ingested and the appropriate treatment.

Although ipecac syrup is the primary mode of treatment of accidental poisoning in children, the Panel considers it rational to market ipecac syrup and activated charcoal in a combination package. The Panel has made specific recommendations in this document for the proper labeling of such a kit to encourage immediate home treatment under the direction of a physician or emergency medical facility.

Every physician treating children should have a supply of ipecac syrup and activated charcoal in his office.

References

(*1*) Arena, J. M., "The Treatment of Poisoning," *Clinical Symposia*, 30:1–47, 1978.

(*2*) National Clearinghouse for Poison Control Centers—Bulletin, U.S. Department of Health, Education, and Welfare, PHS, FDA, Bethesda, MD, February 1978.

(*3*) Arena, J. M., "Poisoning—Toxicology, Symptoms, Treatment," 2d Ed., Charles C. Thomas, Springfield, IL, p. 31, 1970.

(*4*) Arena, J. M., "Poisoning—Toxicology, Symptoms, Treatment," 2d Ed., Charles C. Thomas, Springfield, IL, p. 171, 1970.

(*5*) Done, A. K., "Poison Control," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by A. Osol, and J. E. Hoover, Mack Publishing Co., Easton, PA, pp. 1830–1831, 1975.

C. Labeling

The Panel has reviewed the labeling claims made for ingredients offered for emergency treatment of acute toxic ingestion and has categorized them as either Category I, Category II, or Category III.

For any labeling to be acceptable, it must include the established name of the drug, an accurate statement of the pharmacological category of the drug, the net quantity of contents, the indications for use, pertinent warnings and contraindications, and the recommended dosage range. Only those indications and warnings listed under the specific ingredient discussions are generally recognized as acceptable at this time.

The Panel believes that all labeling should be clear, concise, and easily readable and understandable by most consumers, including those whose

comprehension is limited. The Panel follows this concept in the development of Category I labeling. The Panel is also concerned about the size and color of the print used in labeling of these and all drug products, and recommends that the industry design labeling which can be read easily by consumers.

The Panel believes that the label should contain the active ingredient by its established name, and the label should state the quantity of the active ingredient in the recommended dosage.

The Panel recommends that drug product labeling contain directions for use which are intended to facilitate the delivery and availability of the active ingredient, and that these directions be prominently displayed on all package labeling.

The Panel agrees with the current OTC labeling regulation on warning statements at 21 CFR 330.1(g) and recommends that labeling for drug products used to treat acute toxic ingestion contain a "Warnings" section which contains the following statement in addition to any drug-specific warnings: "Keep this and all drugs out of the reach of children." The Panel believes that the other warning required by this regulation should not be required for these products, i.e., "In cases of accidental ingestion, seek professional assistance or contact a poison control center immediately."

In order to facilitate administration in emergency situations, activated charcoal should be packaged in containers designed to deliver a minimum of 30 grams (g). The amount of contents should be conspicuously displayed on the front panel of the package label. The person administering the activated charcoal would then have a better idea of the actual amount to give to the patient.

To remove as much of the toxic substance as possible from the stomach, it is essential that vomiting, when indicated, be induced prior to the administration of activated charcoal. If activated charcoal is administered before ipecac syrup, the ipecac will be adsorbed by the activated charcoal and inactivated.

If vomiting does not occur within 20 minutes after the first dose of ipecac syrup, the dose should be repeated. If vomiting does not occur within 20 minutes after the second dose, it is imperative that medical advice be obtained to determine what further procedures should be followed to remove or detoxify the ingested poison.

Labeling for ipecac syrup must contain a warning not to give this drug product if strychnine, corrosive poisons, or petroleum distillates have been ingested unless advised otherwise by a physician or emergency medical facility. The reasons for this warning are contained in the "General Discussion." (See part II. paragraph B. above—General Discussion.)

Milk must not be administered along with ipecac syrup because its coating action on the gastrointestinal tract and its ability to inactivate the ipecac alkaloids through its protein binding action would prevent the ipecac syrup from acting. Carbonated beverages should not be administered with ipecac syrup because they may cause over-distention of the stomach.

III. Categorization of Data

A. Category I Conditions

The following are Category I conditions under which drug products for the treatment of acute toxic ingestion are generally recognized as safe and effective and not misbranded.

1. *Category I active ingredients.*

Charcoal, activated
Ipecac syrup

a. *Charcoal, activated.* The Panel concludes that activated charcoal is safe and effective for OTC use in the treatment of acute toxic ingestion as discussed below.

Wood charcoal is made by burning wood out of contact with the air—the residue obtained consists of nearly pure carbon (Ref. *1*). This process is called destructive distillation. The carbon resulting from destructive distillation can also be obtained from nut shells, animal bones, or other carbonaceous material (Ref. *2*). Charcoal made by this process results in a product with varied adsorptive properties. It is "activated" by treating it with various substances such as steam, air, carbon dioxide, oxygen, zinc chloride, sulfuric acid, phosphoric acid, or a combination of some of these substances at temperatures ranging from 500° to 900° C (Ref. *1*). This treatment produces a very porous, honeycomblike internal structure formed by removing substances previously adsorbed on the charcoal. The internal surface area of activated charcoal averages about 10,000 square feet per g (Ref. *2*).

(1) *Safety.* The Panel concludes that activated charcoal is generally recognized as a safe gastrointestinal adsorbent for ingested poisons when used in the doses noted below.

Activated charcoal has been used since 1960 in uremic patients to reduce the gastrointestinal disturbances of the patient. A dose of 20 to 50 g of activated charcoal was given daily, and no side effects were observed during continuous treatment for 4 to 20 months (Ref. *3*).

Considering the above information and the fact that activated charcoal has been in use for over 150 years (Ref. *4*), the Panel concludes that activated charcoal is generally recognized as a safe gastrointestinal adsorbent for oral administration in the treatment of acute toxic ingestion.

(2) *Effectiveness.* The Panel concludes that activated charcoal is an effective gastrointestinal adsorbent that is widely used for the emergency treatment of acute toxic ingestion of a variety of drugs and toxic agents.

In treating an acute toxic ingestion, activated charcoal should only be used after first contacting a Poison Control Center, emergency medical facility, or a physician. It should generally be restricted to administration following emesis, which is usually induced by the ingestion of ipecac syrup.

Decker, Combs, and Corby (Ref. *5*) have demonstrated in vitro that the adsorption capacity of activated charcoal varies considerably according to the chemical acted on. They found that activated charcoal very efficiently adsorbed high doses of dextroamphetamine sulfate, primaquine phosphate, chlorpheniramine maleate, colchicine, diphenylhydantoin, aspirin, and propoxyphene hyrdochloride. Iodine, phenol, and, to a lesser degree, methyl salicylate were quite well adsorbed. Quinacrine, meprobamate, chlorpromazine, quinine, chloroquine, quinidine, and glutethimide were less efficiently adsorbed by activated charcoal; and inorganic acids, certain alkalies (sodium and potassium hydroxides), and sodium metasilicate (active ingredient in many cleaning preparations) were not adsorbed to any measurable extent. It was observed that the adsorptive capacity did not seem to correlate with chemical structure, although highly ionic substances of low molecular weight, such as cupric copper, ferrous iron, and boric acid, were very poorly adsorbed by activated charcoal. Drugs which are solids and insoluble in acidic aqueous solutions were likewise not adsorbed, e.g., tolbutamide. The insecticides malathion, DDT, and *N*-methylcarbamate were quite poorly adsorbed.

Picchioni, Chin, and Laird (Ref. *6*) list about 30 toxic substances which have been demonstrated to be effectively adsorbed in vivo (in man and animals) by activated charcoal. Some of the more significant ones are aspirin and other salicylates, propoxyphene, amphetamine, acetaminophen, barbiturates (barbital, phenobarbital, pentobarbital, and secobarbital), glutethimide, ethchlorvynol,

chlorpromazine, chlordane, hexachlorophene, kerosene, malathion, mercuric chloride, methyl salicylate, phenylopropanolamine, and strychnine. In addition, Decker (Ref. *7*) mentions the usefulness of activated charcoal in adsorbing tricyclic antidepressants (nortriptyline and imipramine) by interrupting enterohepatic recycling.

Originally it was felt that the activated charcoal and toxic substance complex which was formed in the stomach may possibly dissociate as it passes through the gastrointestinal tract. Recent studies indicate that the competitive effects of other constituents of the gastrointestinal fluids and associated higher pH may cause minimal dissociation to occur during the passage through the gastrointestinal tract (Ref. *7*). However, from a practical standpoint, this effect is inconsequential since it is markedly diminished with increasing doses of activated charcoal (Ref. *7*). It has also been demonstrated that, although the absorption of salicylate, barbiturate, and glutethimide was significantly reduced in rats and dogs, the activated charcoal-drug complexes were not dissociated to any significant extent in the gastrointestinal tract (Ref. *4*).

When possible, activated charcoal should be administered within 30 minutes following ingestion of the toxic substance to achieve significant inhibition of the drug absorption, although it has been shown that charcoal can "catch up" and bind certain poisons which have already passed through the pylorus (the opening through which the stomach contents are emptied into the upper intestine). Considering this, activated charcoal should be administered after ipecac syrup when large amounts of toxic substances have been ingested (Ref. *7*).

Corby, Fiser, and Decker (Ref. *4*) observed that activated charcoal can be a very valuable adjunct in the initial phases of treating acute toxic ingestion of many drugs not only in the emergency room and during the course of treatment in a hospital, but also as a first aid measure in the home.

The Panel recommends that for ease of administration, the activated charcoal be packaged in premeasured units with a minimum quantity of 30 g. If the quantity of the ingested toxic substance is known, it is generally considered that an amount of activated charcoal that is 8 to 10 times the amount of toxic substance should be administered. Otherwise, the recommended dosage of 30 g (6 level tablespoonsful) should be given.

It is obviously important to get as much activated charcoal into the patient as possible and as soon as possible after administration of ipecac syrup has produced vomiting. The Panel is aware of the difficulties in administration of this powdery substance and, therefore, encourages the development of a palatable form, such as a combination of activated charcoal and an inactive vehicle, e.g., carboxymethylcellulose, a highly activated charcoal requiring a lower dose, or coated charcoal particles. If such forms are developed, the adsorption capacity of the labeled dose must be expressed in terms of activated charcoal and determined in vivo.

The Panel recognizes that activited charcoal varies in its adsorptive capacity, but concludes that it is generally recognized as effective in the treatment of acute toxic ingestion.

(3) *Dosage.* The minimum effective dose of activated charcoal varies with the toxic dose of each substance and with several other variables, e.g., retained food, gastric emptying, and solubility. For most compounds, 5 to 10 g of activated charcoal are needed to adsorb 1 g. A theoretical dose of 20 g is required to adsorb the fatal adult dose of 2 g of phenobarbital; 30 g would be required to adsorb the toxic dose of 3 g of salicylates in a preschool child; and 500 g would be required for the fatal adult dose of 50 g of acetaminophen. In view of the wide dose range of activated charcoal and the lack of literature references as to the optimum dose, the Panel recommends that activated charcoal be used in doses, of no less than 30 g (6 level tablespoonsful) mixed with ½ glassful of water. The only upper limit on the amount which can be ingested would be governed by the feasibility of administration.

(4) *Labeling.* The Panel recommends the following labeling for activated charcoal:

(i) *Indication.* "For the treatment of acute poisoning."

(ii) *Warnings.* (*a*) "Before using, call a Poison Control Center, emergency medical facility, or physician for advice." This warning should be conspicuously boxed and in red letters.

(*b*) "Do not use in semiconscious or unconscious persons."

(*c*) "If the patient has received ipecac syrup, do not administer activated charcoal until after the patient has vomited, except under the advice and supervision of a physician.

(iii) *Directions.* "Mix 6 level tablespoonsful (30 g) in ½ glassful (4 ounces) of water. Drink entire contents of glass after mixing."

References

(*1*) Swinyard, E. A., "Gastrointestinal Drugs," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by A. Osol and J. E. Hoover, Mack Publishing Co., Easton, PA. p. 751, 1975.

(*2*) Hawley, G. G., "The Condensed Chemical Dictionary," 8th Revised Ed., Van Nostrand Reinhold Co., New York, p. 168, 1971.

(*3*) Yatzidis, H., "Activated Charcoal Rediscovered," (letter to Editor), *British Medical Journal*, 4:51, 1972.

(*4*) Corby, D. G., R. H. Fiser, and W. J. Decker, "Re-Evaluation of the Use of Activated Charcoal in the Treatment of Acute Poisoning," *Pediatric Clinics of North America*, 17:545–556, 1970.

(*5*) Decker, W. J., H. F. Combs, and D. G. Corby, "Adsorption of Drugs and Poisons by Activated Charcoal," *Toxicology and Applied Pharmacology*, 13:454–460, 1968.

(*6*) Picchioni, A. L., L. Chin, and H. E. Laird, "Activated Charcoal Preparations—Relative Antidotal Efficacy," *Clinical Toxicology*, 7:97–108, 1974.

(*7*) Corby, D. G., and W. J. Decker, "Management of Acute Poisoning with Activated Charcoal," *Pediatrics*, 54:324–328, 1974.

b. *Ipecac syrup.* The Panel is aware that ipecac syrup has previously been reviewed by the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products and that the FDA is developing the tentative final monograph (TFM) on emetic drug products. This Panel feels that the final monograph for ipecac syrup should contain the following information:

The active ingredients of ipecac syrup are the alkaloids emetine and cephaeline contained in powered ipecac. The product is packaged and marketed as ipecac syrup, United States Pharmacopeia (USP) XIX, in a 1 fluid ounce (30 mL) container or in ½ fluid ounce (15 mL) containers for use in acute toxic ingestion kits.

(1) *Indications.* The labeling of the product contains a statement of the indication under the heading "Indications" that is limited to the phrase "to cause vomiting (emesis) in case of poisoning." This phrase should be conspicuously boxed and in red letters.

(2) *Warnings.* The labeling of the product contains the following warnings, under the heading "Warnings":

(i) "Call a Poison Control Center, emergency medical facility, or physician for advice before using and if vomiting does not occur within 20 minutes after a second dose has been given." This warning should be conspicuously boxed and in red letters.

(ii) "Do not use in semiconscious, unconscious, or convulsing persons."

(iii) "This product should not be used if strychnine, corrosives such as alkalies (lye) and strong acids, or petroleum distillates such as kerosene, gasoline, paint thinner, or

cleaning fluid have been ingested, unless advised otherwise by a physician."

(iv) "Do not administer milk or carbonated beverages with this product."

(3) The warning required by the current regulation § 330.1(g) (21 CFR 330.1(g)) concerning overdoses should not be required on ipecac syrup products.

(4) *Drug interaction precautions.* The labeling of the product should contain the following statement under the heading "Drug Interaction Precautions": "Activated charcoal will adsorb the active ingredients of ipecac syrup. If both activated charcoal and ipecac syrup are used, give the activated charcoal only after vomiting has been produced by the ipecac syrup."

(5) *Directions.* The labeling of the product should contain the following statements under the heading "Directions":

(i) *Infants under 1 year of age:* Oral dosage of ipecac syrup is 1 teaspoonful (5 milliliters) to a maximum of 2 teaspoonsful (10 milliliters) followed by ½ to 1 glass of water (4 to 8 ounces) or as directed by a physician. If vomiting does not occur within 20 minutes, the dose should be repeated one.

(ii) *Infants over 1 year of age, children, and adults:* Oral dosage of ipecac syrup is 1 tablespoonful (15 milliliters) followed by 1or 2 glasses of water (8 to 16 ounces) or as directed by a physician. If vomiting does not occur within 20 minutes, the dose should be repeated once.

2. *Acute toxic ingestion kit.* The Panel recognizes that it would be in the consumer's interest to establish guidelines for the minimum components of a kit used for the treatment of acute toxic ingestion. It is suggested that the kit contain four containers of 15 mL each of ipecac syrup and two containers of 30 g each of activated charcoal. The activated charcoal containers should be of sufficient size to permit the mixing of 4 ounces of water with the activated charcoal and be equipped with a screw cap so that the mixture can be shaken without spilling.

a. *Labeling.* The following labeling is specific for the outside container of the kit alone:

(1) *Indications.* "For the treatment of acute poisoning."

(2) *Warnings.* (i) "Before using, call a Poison Control Center, emergency medical facility or physician for advice." This warning should be conspicuously boxed and in red letters.

(ii) "Do not use in semiconscious or unconscious persons."

b. *Directions.* (1) "When professional advice is not available, first give ipecac syrup to induce vomiting, after vomiting has occurred give activated charcoal to help adsorb any remaining toxic substance."

(2) In bold-faced print "READ INSTRUCTIONS AT TIME OF PURCHASE AND INSERT PHONE NUMBERS ON LABEL."

(3) "Save the container of the poison."

(4) An area of prominence should be provided to enter the telephone numbers of the Poison Control Center ———, emengency medical facility ———, personal physician ———, and ambulance ———.

B. Category II and Category III Conditions

The ingredients classified as Category II are listed in part I. paragraph C.3. above. The Panel found no Category III conditions. Therefore, Category II and III conditions will not be discussed in this document.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under 21 CFR 5.11 (see 46 FR 26052; May 11, 1981), the agency advises in this advance notice of proposed rulemaking that subchapter D of Chapter I of Title 21 of the Code of Federal Regulations would be amended by adding to Part 357, a new Subpart A, to read as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—Drug Products for Over-the-Counter Human Use for the Treatment of Acute Toxic Ingestion

Sec.

357.1 Scope.
357.3 Definitions.
357.10 Active ingredients for the treatment of acute toxic ingestion.
357.14 Acute toxic ingestion kit.
357.50 Labeling of drug products containing activated charcoal identified in § 357.10(a) for the treatment of acute toxic ingestion.
357.52 Labeling of drug products containing ipecac syrup identified in § 357.10(b) for the treatment of acute toxic ingestion.
357.54 Labeling of acute toxic ingestion kit identified in § 357.14 for the treatment of acute toxic ingestion.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704).

Subpart A—Drug Products for Over-the-Counter Human Use for the Treatment of Acute Toxic Ingestion

§ 357.1 Scope.

(a) An over-the-counter drug product for the treatment of acute toxic ingestion in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 357.3 Definitions.

As used in this subpart:

(a) *Acute toxic ingestion.* An ingestion, within a brief time, of a substance in amounts that could threaten the survival or well-being of an individual.

(b) *Emesis.* Vomiting.

(c) *Emetic.* An agent that causes vomiting (emesis).

§ 357.10 Active ingredients for the treatment of acute toxic ingestion.

The active ingredients of the product consist of any of the following when used within the dosage limits established for each ingredient:

(a) Charcoal, activated.

(b) Ipecac syrup.

§ 357.14 Acute toxic ingestion kit.

The kit is a single outer package labeled according to § 357.54 that consists of two 30-gram containers of activated charcoal identified in § 357.10(a) and labeled according to § 357.50 and four 15-milliliter containers of ipecac syrup identified in § 357.10(b) and labeled according to § 357.52. The containers of activated charcoal enclosed within the kit are of sufficient size to permit the addition of 4 ounces (120 milliliters) of water and are equipped with screw top caps to facilitate mixing of the contents.

§ 357.50 Labeling of drug products containing activated charcoal identified in § 357.10(a) for the treatment of acute toxic ingestion.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "adsorbant."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to the

phrase: "For the treatment of acute poisoning."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "Before using, call a poison control center, emergency medical facility, or physician for advice." This warning should be conspicuously boxed and in red letters.

(2) "Do not use in semiconscious or unconscious persons."

(3) "If the patient has received ipecac syrup, do not administer activated charcoal until after the patient has vomited, except under the advice and supervison of a physician.

(4) The warning required by § 330.1(g) concerning overdoses is not required on products containing activated charcoal.

(d) *Directions.* The labeling of the product contains the following statement under the heading "Directions": "Mix 6 level tablespoonsful (30 grams) in ½ glassful (4 ounces) of water. Drink entire contents of glass after mixing."

§ 357.52 Labeling of drug products containing ipecac syrup identified in § 357.10(b) for the treatment of acute toxic ingestion.

The product contains the labeling identified in proposed § 337.50 for emetic drug products. (See the **Federal Register** of September 5, 1978 (43 FR 39546).)

§ 357.54 Labeling of acute toxic ingestion kit identified in § 357.14 for the treatment of acute toxic ingestion.

In addition to the labeling identified in § 357.50 required on containers of activated charcoal and the labeling identified in § 357.52 required on containers of ipecac syrup, the outer label of the acute toxic ingestion kit bears the following:

(a) *Statement of identity.* The labeling on the outside of the kit contains the established names of the drugs, if any, and identifies the product as an "acute toxic ingestion treatment kit."

(b) *Indications.* The labeling on the outside of the kit contains a statement of the indications under the heading "Indications" that is limited to the following phrase: "For the treatment of acute poisoning."

(c) *Warnings.* The labeling on the outside of the kit contains the following warnings under the heading "Warnings":

(1) "Before using, call a Poison Control Center, emergency medical facility, or physician for advice." This warning should be conspicuously boxed and in red letters.

(2) "Do not use in semiconscious or unconscious persons."

(3) The warning required by § 330.1(g) concerning overdoses is not required on products containing activated charcoal and ipecac syrup.

(d) *Directions.* The labeling on the outside of the kit contains the following information under the heading "Directions":

(1) "When professional advice is not available, first give ipecac to indice vomiting, after vomiting has occurred give activated charcoal to help absorb any remaining toxic substance."

(2) (In bold-faced print) "READ INSTRUCTIONS AT TIME OF PURCHASE AND INSERT PHONE NUMBERS ON LABEL."

(3) "Save the container of the poison."

(e) *Other required statements.* An area of prominence should be provided to enter the telephone numbers of the following: "Poison Control Center ," "emergency medical facility ," "personal physician ," "ambulance ."

Interested persons may, on or before April 5, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this advance notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments replying to comments may also be submitted on or before May 5, 1982. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 23, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: December 17, 1981.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82–3 Filed 1–4–82; 8:45 am]

BILLING CODE 4160–01–M

federal register

Tuesday
January 5, 1982

Part VIII

Department of Health and Human Services

Food and Drug Administration

Digestive Aid Drug Products for Over-the-Counter Human Use; Establishment of a Monograph

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 357

[Docket No. 81N-0106]

Digestive Aid Drug Products for Over-the-Counter Human Use; Establishment of a Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of proposed rulemaking that would establish conditions under which over-the-counter (OTC) digestive aid drug products (drugs for the treatment of the symptoms of immediate postprandial upper abdominal distress (IPPUAD), or drugs for the treatment of the symptoms of intestinal distress) are generally recognized as safe and effective and not misbranded. This notice is based on the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by April 5, 1982, and reply comments by May 5, 1982.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's Office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on January 19, 1979 a report on OTC digestive aid drug products from the Advisory Review Panel on OTC Miscellaneous Internal Drug Products. FDA regulations (21 CFR 330.10(a)(6)) provide that the agency issue in the **Federal Register** a proposed order containing: (1) The monograph recommended by the Panel, which established conditions under which OTC digestive aid drug products are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs' not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

The unaltered conclusions and recommendations of the Panel are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The report has been prepared independently of FDA, and the agency has not yet fully evaluated the report. The Panel's findings appear in this document to obtain public comment before the agency reaches any decision on the Panel's recommendations. This document represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it.

After reviewing all comments submitted in response to this document, FDA will issue in the **Federal Register** a tentative final monograph for OTC digestive aid drug products as a notice of proposed rulemaking. Under the OTC drug review procedures, the agency's position and proposal are first stated in the tentative final monograph, which has the status of a proposed rule. Final agency action occurs in the final monograph, which has the status of a final rule.

The agency's position on OTC digestive aid drug products will be stated initially when the tentative final monograph is published in the **Federal Register** as a notice of proposed rulemaking. In that notice of proposed rulemaking, the agency also will announce its initial determination whether the proposed rule is a major rule under Executive Order 12291 and will consider the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). The present notice is referred to as an advance notice of proposed rulemaking to reflect its actual status and to clarify that the requirements of the Executive Order and the Regulatory Flexibility Act will be considered when the notice of proposed rulemaking is published. At that time FDA also will consider whether the proposed rule has a significant impact on the human environment under 21 CFR Part 25 (proposed in the **Federal Register** of December 11, 1979, 44 FR 71742).

The agency invites public comment regarding any impact that this rulemaking would have on OTC digestive aid drug products. Types of impact may include, but are not limited to, the following: increased costs due to relabeling, repackaging, or reformulating; removal of unsafe or ineffective products from the OTC market; and testing, if any. Comments regarding the impact of this rulemaking on OTC digestive aid drug products should be accompanied by appropriate documentation.

A monograph for OTC antiflatulent drug products (21 CFR Part 332) was established in response to data and information submitted with regard to the report of the Advisory Review Panel on OTC Antacid Drug Products. (See 38 FR 31266.) Because the agency recognized that information concerning other antiflatulent ingredients may have been available, but not submitted to the Antacid Panel, the agency advised interested persons to submit such information to the Advisory Review Panel on OTC Miscellaneous Internal Drug Products. (See 38 FR 31266 and 39 FR 19871). The **Federal Register** notices published on November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179) requested data and information on various miscellaneous internal drug ingredients, including "antiflatulents." These antiflatulent ingredients are used in drug products with such labeling indications as flatulence, gas, bloating, fullness, and symptoms of food indiscretions.

After reviewing the data on antiflatulent ingredients submitted to it, the Miscellaneous Internal Panel recommended in this document that antiflatulent ingredients and claims be classified in Category III, requiring further testing before inclusion in a final monograph on digestive aid drug products. The Panel also classified simethicone, the only ingredient currently included in the antiflatulent monograph (21 CFR Part 332), in Category III as a digestive aid for treating the symptoms of immediate postprandial upper abdominal distress (IPPUAD) and intestinal distress. The agency at this time requests comments on the appropriate classification of antiflatulent ingredients and claims. FDA will publish its tentative conclusions concerning antiflatulents in the tentative final monograph (notice of proposed rulemaking) on digestive aid drug products. In that publication, the agency will also address the question of whether to revoke or modify the current antiflatulent monograph (21 CFR Part 332).

In accordance with § 330.10(a)(2), the Panel and FDA have held as confidential all information concerning OTC digestive aid drug products submitted for consideration by the Panel. All the submitted information will be put on public display in the Dockets Management Branch, Food and Drug

Administration, after February 4, 1982, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs (HFD–510) (address above).

FDA published in the **Federal Register** of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The Court in *Cutler* held that the OTC drug review regulations (21 CFR 330.10) were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision is now deleted from the regulations. The regulations now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process, before the establishment of a final monograph.

Although it was not required to do so under *Cutler*, FDA will no longer use the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III because that was the framework in which the Panel conducted its evaluation of the data.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 6 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions which would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered or introduction into interstate commerce. Further, any OTC drug products subject to this monograph which are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to voluntarily comply with the monograph at the earliest possible date.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC miscellaneous internal drug products was issued in the **Federal Register** of November 16, 1973 (38 FR 31696). (In making their categorizations with respect to "active" and "inactive" ingredients, the advisory review panels relied on their expertise and understanding of these terms. FDA has defined "active ingredient" in its current good manufacturing practice regulations (§ 210.3(b)(7), (21 CFR 210.3(b)(7))), as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." An "inactive ingredient" is defined in § 210.3(b)(8) as "any component other than an 'active ingredient.' " In the **Federal Register** of August 27, 1975 (40 FR 38179), a notice supplemented the initial notice with a detailed, but not necessarily all-inclusive, list of active ingredients in miscellaneous internal drug products to be considered in the OTC drug review. The list, which included digestive aid ingredients, was provided to give guidance on the kinds of active ingredients for which data should be submitted. The notices of November 16, 1973, and August 27, 1975, informed OTC drug product manufacturers of their opportunity to submit data to the review at that time and of the applicability of the monographs from the OTC drug review to all OTC drug products.

Under § 330.10(a)(1) and (5), the Commissioner of Food and Drugs appointed the following Panel to review the information submitted and to prepare a report on the safety, effectiveness, and labeling of the active ingredients in these OTC miscellaneous internal drug products:

John W. Norcross, M.D., Chairman
Ruth Eleanor Brown, R.Ph. (resigned May 1976)
Elizabeth C. Giblin, M.N., Ed. D.
Richard D. Harshfield, M.D.
Theodore L. Hyde, M.D.
Claus A. Rohweder, D.O.
Samuel O. Thier, M.D. (resigned November 1975)
William R. Arrowsmith, M.D. (appointed March 1976)
Diana F. Rodriguez-Calvert, Pharm. D. (appointed July 1976)

Representatives of consumer and industry interests served as nonvoting members of the Panel. Eileen Hoates, nominated by the Consumer Federation of America, served as the consumer liaison until September 1975, followed by Michael Schulman, J.D. Francis J. Hailey, M.D., served as the industry liaison, and in his absence John Parker, Pharm. D., served, Dr. Hailey served until June 1975, followed by James M. Holbert, Sr., Ph. D. All industry liaison members were nominated by the Proprietary Association.

The following FDA employees assisted the Panel: Armond M. Welch, R.Ph., served as the Panel Administrator; Enrique Fefer, Ph. D., served as the Executive Secretary until July 1976, followed by George W. James, Ph. D., until October 1976, followed by Natalie Morgenstern until May 1977, followed by Arthur Auer until October 1978. Roger Gregorio served as the liaison for the Office of New Drug Evaluation beginning November 1978. Joseph Hussion, R.Ph., served as the Drug Information Analyst until July 1976, followed by Anne Eggers, R.Ph., M.S., until October 1977, followed by John R. Short, R.Ph.

To expand its scientific base, the Panel called upon the following consultants for advice in areas which required particular expertise:

Ralph B. D'Agostino, Ph. D. (statistics)
Lynn R. Brady, Ph. D. (pharmacognosy)
Arthur E. Schwarting, Ph. D. (pharmacognosy)

The Advisory Review Panel on OTC Miscellaneous Internal Drug Products was charged with the review of many categories of drugs. Due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents its conclusions and recommendations for digestive aid drug products in this document. The review of all other categories of miscellaneous internal drug products is being

continued by the Panel, and its findings are being published periodically in the **Federal Register.**

Ingredients reviewed by the Panel for treatment of the symptoms of IPPUAD were referred to as "antiflatulents" in the **Federal Register** notices published on November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179). These ingredients are used in drug products with such labeling indications as flatulence, gas, bloating, fullness, stomachic (digestive tonic), and food indiscretions. The Panel reviewed all of thiese ingredients for treatment of symptoms of IPPUAD because the claims made for them apply to conditions occurring in the upper abdomen soon after eating (within 30 minutes). (See part III. below—Drug Products for the Treatment of the Symptoms of Immediate Postprandial Upper Abdominal Distress.)

Ingredients reviewed by the Panel for treatment of the symptoms of intestinal distress were referred to as "digestive aids" in the **Federal Register** notices published on November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179). Included in this review are ingredients used in drug products which claim to correct conditions of intestinal discomfort that do not involve enzyme deficiency. Those products which claim effectiveness for the treatment of exocrine pancreatic insufficiency were reviewed in a separate document entitled "Exocrine Pancreatic Insufficiency Drug Products for Over-the-Counter Human Use," published in the **Federal Register** of December 12, 1979 (44 FR 75666).

Conditions such as irritation and inflammation of the intestinal tract were grouped by the Panel under the heading of "intestinal distress" because these are conditions that occur in the intestines from 30 minutes to several hours following a meal. Ingredients used in drug products claiming to treat symptoms of these conditions were accordingly reviewed by the Panel for treatment of the symptoms of intestinal distress. (See part IV. below—Drug Products for the Treatment of the Symptoms of Intestinal Distress.)

The Panel was first convened on January 13, 1975 in an organizational meeting. Working meetings at which digestive aid drug products were discussed were held on February 23 and 24, March 23 and 24, April 27 and 28, June 22 and 23, September 21 and 22, November 16 and 17, 1975; February 8 and 9, March 7 and 8, April 11 and 12, May 9 and 10, July 11 and 12, October 10 and 11, 1976; February 20 and 21, April 3 and 4, May 15 and 16, July 9, 10, and 11, October 15, 16, and 17, December 2, 3, and 4, 1977; January 28, 29, and 30, March 10, 11, and 12, May 5, 6, and 7, June 23, 24, and 25, August 4, 5, and 6, September 29 and 30, October 1, and November 17, 18, and 19, 1978; and January 19, 1979.

The minutes of the Panel meetings are on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above).

The following individuals were given an opportunity to appear before the Panel to express their views on OTC digestive aid drug products either at their own or at the Panel's request:

William Bachrach, M.D.
Paul Bass, Ph. D.
Allen R. Cooke
Warren Dennis, Ph. D.
Robert G. Flynn, R.Ph., M.S.
Morton I. Grossman, Ph. D., M.D.
Frank Hurley, Ph. D.
Robert John, M.D.
John Johnson
Louis Lasagna, M.D.
M. D. Levitt, M.D.
Armand Littman, M.D., Ph. D.
Myron Lover, Ph. D.
Fred J. McIlreath, M.D.
C. Harold Mielke, Jr.
Daniel Minelli
Robert G. Pinco, Esq.
Stephen Schwartz, M.S.
E. Clinton Texter, Jr., M.D.
Julian Villarreal
Ralph O. Wallerstein
Joseph M. White, M.D.
Daniel Winship, M.D.

No person who so requested was denied an opportunity to appear before the Panel to discuss digestive aid drug products.

The Panel has thoroughly reviewed the literature and data submissions, has listened to additional testimony from interested persons, and has considered all pertinent information submitted through January 19, 1979 in arriving at its conclusions and recommendations.

In accordance with the OTC drug review regulations in § 330.10, the Panel's findings with respect to OTC digestive aid drug products are set out in three categories:

Category I. Conditions under which OTC digestive aid drug products are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which OTC digestive aid drug 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 reviewed 109 active ingredients for use in treating the symptoms of IPPUAD or intestinal distress. No ingredients were placed in Category I. The Panel placed 60 ingredients in Category II and 10 ingredients in Category III for the symptoms of IPPUAD and 48 ingredients in Category II and 9 ingredients in Category III for the symptoms of intestinal distress. (The number of ingredient classifications does not equal the number of ingredients reviewed because some ingredients were reviewed for more than one labeled use.)

I. Submission of Data and Information

Pursuant to the notices published in the **Federal Register** of November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on OTC miscellaneous internal drug products, the following firms made submissions related to products used as digestive aids. The Panel defined digestive aids to encompass those ingredients used to treat the symptoms of IPPUAD and intestinal distress. (See part II. paragraph A. below—Definitions of Terms.)

A. Submission by Firms

Based on its review, the Panel classified the submission as being relevant to either IPPUAD or intestinal distress as follows:

1. *For treatment of the symptoms of IPPUAD.*

Firms and Marketed Products

Bowman Pharmaceuticals, Canton, OH 44702—Controflex Phosphorated syrup.

Carter Products, Cranbury, NJ 08512—Gastroenterase tablets.

Dorsey Laboratories, Lincoln, NB 68501—Kanulase tablets.

Father Francis' Herbs, Chicago, IL 60629M—Medicinal Herb Tea No. 3.

Lewis-Howe Co., St. Louis, MO 63102—Discarbosil tablets, Tums tablets.

Purdue Frederick Co., Norwalk, CT 06856—Probilagol liquid.

Reed and Carnrick, Kenilworth, NJ 07033—Laxsil liquid, Phasil tablets, Phazyme tablets.

Rilox Co., New Orleans, LA 70122—Brodie's Cordial liquid.

Van Patten Pharmaceutical Co., Chicago, IL 60640—Allimin tablets.

Warner-Chilcott, Morris Plains, NJ 07950—Gelusil liquid, Gelusil tablets.

Warner-Lambert Co., Morris Plains, NJ 07950—Bromo-Seltzer, Rolaids tablets, hydrate magnesium aluminate activated sulfate liquid and tablets.

2. *For treatment of the symptoms of intestinal distress.*

Firms and Marketed Products

Carter Products, Cranbury, NJ 08512—Gastroenterase tablets.

Chattanooga Medicine Co., Chattanooga, TN 37409—Cardui liquid.

Dorsey Laboratories, Lincoln, NB 68501—Kanulase tablets.

Father Francis' Herbs, Chicago, IL 60629M—Medicinal Herb Tea No. 1.
Hoechst-Roussel, Pharmaceuticals, Inc., Somerville, ND 08876—Festal tablets.
Palafox Laboratories, Inc., Anthony, TX 88021—Palagastra liquid.
Parke-Davis & Co., Detroit, MI 48232—Panteric capsules, tablets, and granules.
Purdue Frederick Co., Norwalk, CT 06856M—Probilagol liquid.
Reed and Carnrick, Kenilworth, NJ 04033—Laxsil liquid, Phasil tablets, Phazyme tablets.
Requa Mfg. Co., Inc., Bronx, NY 10470—Requa's charcoal tablets, Requa's activated charcoal tablets and capsules.
Rilox Co., New Orleans, LA 70122—Brodie's Cordial liquid.
Signet Laboratories, Inc., Burbank, CA 91502—Dihepatone tablets.
Van Patten Pharmaceuticals Co., Chicago, IL 60640—Allimin tablets.
Warner-Lambert Co., Morris Plains, NJ 07950—Bromo-Seltzer.
Winthrop Laboratories, New York, NY 10016—Stamyl tablets.

B. Ingredients Reviewed by the Panel

1. *For treatment of the symptoms of IPPUAD*—a. *Labeled ingredients contained in products submitted to the Panel.*

Acetaminophen
Aluminum hydroxide
Bean
Calcium carbonate, U.S.P.
Catechu, tincture
Cellulase
Cinnamon oil
Citric acid
Dehydrocholic acid
Dihydroxyaluminum sodium carbonate
Dog grass
Elecampane
Galega
Garlic, dehydrated
Glutamic acid hydrochloride
Homatropine methylbromide
Horsetail
Huckleberry
Hydrate magnesium aluminate activated sulfate
Johnswort
Linden
Magnesium hydroxide, N.F.
Magnesium trisilicate
Nettle
Orthophosphoric acid
Ox bile extract
Pancreatic enzyme concentrate
Pancreatin, N.F.
Peppermint oil
Peppermint spirit
Pepsin
Simethicone
Sodium bicarbonate
D-sorbitol
Strawberry
Sucrose
Tannic acid

b. *Other ingredients.* In addition to those ingredients included in the products submitted to the Panel, the following ingredients were listed in the **Federal Register** notice of August 27, 1975 (40 FR 38179).

Alcohol
Anise seed
Aromatic powder
Asafetida
Belladonna alkaloids
Belladonna leaves, powdered extract
Bismuth subcarbonate
Bismuth subgallate
Capsicum
Capsicum, fuild extract of
Carbon
Cascara sagrada extract
Catnip
Chamomile flowers
Charcoal, activated
Chloroform
Cinnamon tincture
Diastase
Ether
Ginger
Gylcine
Hydrastis fluid extract
Hydrochloric acid
Iodine
Kaolin, colloidal
Lactic acid
Lavender compound, tincture of
Mannitol
Myrrh, fluid extract of
Nux vomica extract
Pancrelipase
Pectin
Potassium bicarbonate
Potassium carbonate
Rhubarb fluid extract
Sodium salicylate
Strychnine

2. *For treatment of the symptoms of intestinal distress*—a. *Labeled ingredients contained in products submitted to the Panel.*

Acetaminophen
Amylase
Blessed thistle (*Cnicus benedictus*)
Buckthorn
Catechu, tincture
Cellulase
Charcoal, activated
Charcoal, wood
Cinnamon oil
Citric acid
Dehydrocholic acid
Duodenal substance
Garlic, dehydrated
Glutamic acid hydrochloride
Golden Seal (*Hydrastis canadensis*)
Hemicellulase
Homatropine methylbromide
Johnswort
Juniper
Knotgrass
Lipase
Magnesium hydroxide, N.F.
Ox bile extract
Pancreatic enzyme concentrate
Pancreatin, N.F.
Pancreatin (triple strength)
Papain
Peppermint
Peppermint oil
Pepsin
Protease
Senna
Simethincone
Sodium bicarbonate
Sodium bismuthyltartrate
D-sorbitol
Tannic acid
Woodrull

b. *Other ingredients.* In addition to those ingredients included in the products submitted to the Panel, the following ingredients were listed in the **Federal Register** notice of August 27, 1975 (40 FR 38179).

Aluminum hydroxide
Aspergillus oryza enzymes
Bacillus acidophilus
Betaine hydrochloride
Black radish powder
Calcium gluconate
Citrus pectin
Diastase malt
Fennel acid
Glycine
Hectorite
Iron ox bile
Lactose
Lysine hydrochloride
Mycozyme
Niacinamide
Nickel-pectin
Orthophosphoric acid
Pancrelipase
Papaya, natural
Phenacetin
Prolase
Sodium chloride
Stem bromelain
Trillium
Vitamin B–1
Vitamin B
Vitamin B–3

C. Classification of Ingredients

1. *For treatment of the symptoms of IPPUAD*—a. *Active ingredients.*

Almadrate sulfate (hydrate magnesium aluminate activated sulfate)
Aluminum hydroxide
Calcium carbonate (calcium carbonate, U.S.P.)
Cellulase
Dehydrocholic acid
Dihydroxyaluminum sodium carbonate
Garlic, dehydrated
Glutamic acid hydrochloride
Homatropine methylbromide
Magnesium hydroxide (magnesium hydroxide, N.F.)
Magnesium trisilicate
Ox bile extract
Pancreatin and pancrelipase (pancreatin, N.F.; pancreatic enzyme concentrate)
Peppermint oil
Pepsin
Simethicone
Sodium bicarbonate
Sodium citrate (citric acid)
Sorbitol (*D*-sorbitol)

b. *Inactive ingredients.*

Sucrose

c. *Other ingredients.* The Panel was neither able to locate nor it is aware of any significant body of data demonstrating the safety and

effectiveness of the following OTC ingredients in treating the symptoms of IPPUAD. The Panel, therefore, classifies these ingredients as Category II for this use, and they will not be reviewed further in this document.

Alcohol
Anise seed
Aromatic powder
Asafetida
Bean
Belladonna alkaloids
Belladonna leaves, powdered extract
Bismuth subcarbonate
Bismuth subgallate
Capsicum
Capsicum, fluid extract of
Carbon
Cascara sagrada extract
Catechu, tincture
Catnip
Chamomile flowers
Charcol, activated
Chloroform
Cinnamon oil
Cinnamon tincture
Diastase
Dog grass
Elecampane
Ether
Galega
Ginger
Glycine
Horsetail
Huckleberry
Hydrastis fluid extract
Hydrochloric acid
Iodine
Johnswort
Kaolin, colloidal
Lactic acid
Lavender compound, tincture of
Linden
Mannitol
Myrrh, fluid extract of
Nettle
Nux vomica extract
Orthophosphoric acid
Pectin
Peppermint spirit
Potassium bicarbonate
Potassium carbonate
Rhubarb fluid extract
Sodium salicylate
Strawberry
Strychnine
Tannic acid

d. *Ingredient deferred to and reviewed by the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Drug Products as published in the* **Federal Register** of July 8, 1977 (42 FR 35345).

Acetaminophen

2. *For treatment of the symptoms of intestinal distress*—a. *Active ingredients.*

Bismuth sodium tartrate (sodium bismuthyltartrate)
Blessed thistle (*Cnicus benedictus*)
Cellulase and hemicellulase
Charcoal, activated and charcoal, wood
Dehydrocholic acid
Duodenal substance
Garlic, dehydrated
Glutamic acid hydrochloride
Golden seal (*Hydrastis canadensis*)
Homatropine methylbromide
Magnesium hydroxide (magnesium hydroxide, N.F.)
Ox bile extract
Pancreatin and pancrelipase (pancreatin, N.F.; pancreation (triple strength); pancreatic enzyme concentrate)
Papain
Pepsin
Simethicone
Sodium bicarbonate
Sodium citrate (citric acid)
Sorbitol (*D*-sorbitol)

b. *Inactive ingredients.* None.

c. *Other ingredients.* The Panel was neither able to locate nor is it aware of any significant body of data demonstrating the safety and effectiveness of the following OTC ingredients in treating the symptoms of intestinal distress. The Panel, therefore, classifies these ingredients as Category II for this use, and they will not be reviewed further in this document.

Aluminum hydroxide
Amylase
Aspergillus oryza enzymes
Bacillus acidophilus
Betaine hydrochloride
Black radish powder
Buckthorn
Calcium gluconate
Catechu, tincture
Cinnamon oil
Citrus pectin
Diastase malt
Fennel acid
Glycine
Hectorite
Iron ox bile
Johnswort
Juniper
Knotgrass
Lactose
Lipase
Lysine hydrochloride
Mycozyme
Nickel-pectin
Orthophosphoric acid
Papaya, natural
Peppermint
Peppermint oil
Phenacetin
Protease
Prolase
Senna
Sodium chloride
Stem bromelains
Tannic acid
Trillium
Woodruff

d. *Ingredients deferred to and reviewed by other panels*—(1) *Ingredients deferred to and reviewed by the Advisory Review Panel on OTC Vitamin, Mineral, and Hematinic Drug Products as published in the* **Federal Register** *of March 16, 1979 (44 FR 16126)*

Niacin (niacinamide)
Thiamine (vitamin B–1)
Riboflavin (vitamin B–2)
Vitamin B–3

(2) *Ingredient deferred to and reviewed by the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Drug Products as published in the* **Federal Register** *of July 8, 1977 (42 FR 35345).*

Acetaminophen

CATEGORIZATION OF SINGLE INGREDIENTS CONSIDERED BY THE PANEL FOR SAFETY AND EFFECTIVENESS AS DIGESTIVE AIDS

Ingredients	IPPUAD [1]		ID [2]	
	Category	Basis [3]	Category	Basis
Almadrate sulfate	III	E		
Aluminum hydroxide	III	E		
Bismuth sodium tartrate			II	S, E
Calcium carbonate	III	E		
Cellulase	II	E	III	E
Charcoal, activated and Charcoal, wood			III	E
Dehydrocholic acid	II	E	II	E
Dihydroxyaluminum sodium carbonate	III	E		
Duodenal substance			II	S, E
Garlic, dehydrated	II	E	II	E
Glutamic acid hydrochloride	II	E	II	E
Hemicellulase			III	E
Homatropine methylbromide	II	E	III	E
Magnesium hydroxide	III	E	III	E
Magnesium trisilicate	III	E		
Ox bile extract	II	E	II	E
Pancreatin and pancrelipase	II	E	III	E
Papain			II	E
Peppermint oil	III	E		
Pepsin	II	E	II	E
Simethicone	III	E	III	E
Sodium bicarbonate	III	E	III	E
Sodium citrate	III	E	III	E
Sorbitol	II	E	II	E

[1] IPPUAD—Immediate postprandial upper abdominal distress.
[2] ID—Intestinal distress.
[3] Basis for Categorization: S (Safety), E (Effectiveness).

D. Referenced OTC Volumes

The "OTC Volumes" cited throughout this document include submissions made by interested persons in response to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179). All of the information included in these volumes, except for those deletions which are made in accordance with the confidentiality provisions set forth in § 330.10(a)(2), will be put on display after February 4, 1982, in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

II. General Statements and Recommendations

A. Definitions of Terms

For the purpose of this document, the Panel agreed on the following definitions:

1. *Aerophagia.* The swallowing of air.
2. *Antiflatulent.* An agent that relieves or prevents flatulence.
3. *Eructation.* The act of belching.
4. *Flatulence.* The presence of excessive amounts of air or other gas in the stomach and/or intestines.
5. *Flatus.* Gas passed by rectum.
6. *Immediate postprandial upper abdominal distress (IPPUAD).* A symptom complex consisting of the sensations of bloating, distention, fullness, or pressure with upper abdominal discomfort occurring immediately (within 30 minutes) after a meal, excluding symptoms of aerophagia or hyperacidity.
7. *Intestinal distress.* A syndrome consisting of abdominal discomfort occurring 30 minutes to several hours after a meal. It is self-limiting and not attributable to any known organic disease, nor accompanied by diarrhea or constipation. This syndrome is characterized by one or more of the following symptoms: Bloating, distention, fullness, pressure, pain, or cramps.
8. *Postprandial.* Occurring shortly after eating.
9. *Symptom.* Any subjective evidence of a patient's condition, as perceived by the patient.
10. *Syndrome.* A set of symptoms which occur together; a symptom complex.

B. General Discussion

The Panel reviewed drug products which were claimed to alleviate symptoms in the stomach as well as the intestines following the ingestion of food. The Panel has designated this group of drugs as digestive aids and has divided the group into two classifications: (1) Those drugs for treating the symptoms of IPPUAD—symptoms occurring within 30 minutes after ingestion of food, and (2) those drugs for treating the symptoms of intestinal distress—symptoms occurring from 30 minutes to several hours after ingestion of food.

1. *For treatment of the symptoms of IPPUAD.* A final monograph for "antiflatulent active ingredients" was published in the **Federal Register** of June 4, 1974 (39 FR 19877). The agency, in establishing this monograph, allowed the continued marketing of simethicone (maximum daily dose of 500 milligrams (mg)) as an OTC antiflatulent in combination with "* * * any generally recognized as safe and effective antacid ingredient(s) if it is indicated for use solely for the concurrent symptoms of gas associated with heartburn, sour stomach, or acid indigestion" (21 CFR 332.15). The term antiflatulent was specifically defined as a drug able "to alleviate or relieve the symptoms of gas" (21 CFR 332.30(a)). In the **Federal Register** of November 12, 1973 (38 FR 31266), the agency noted that other ingredients may also be useful as antiflatulents and requested that any available data be submitted to the OTC Miscellaneous Internal Drug Products Panel for review. The antiflatulent monograph would then be amended to include any additional safe and effective antiflatulent active ingredients.

The agency has concluded that at least one antiflatulent ingredient is effective and one would infer that the symptoms referred to in the statement, " 'to alleviate or relieve the symptoms of gas,' " are indeed caused by excess gas. The Panel has reviewed all available data and has found no conclusive evidence that excess gas is the causative agent in producing undesirable symptoms, specifically the symptoms of bloating, distention, fullness, or pressure associated with IPPUAD.

The Panel looked at "antiflatulent" drugs which were claimed to alleviate symptoms of discomfort (bloating, distention, fullness, or pressure) that occur in the abdomen in the immediate postprandial period. The term "flatulent" is commonly associated with some amount of gas, but because this Panel does not accept gas as a causative agent of distress in the upper gastrointestinal tract, the Panel considered it contradictory and inappropriate to review, as antiflatulents, those drugs which were claimed to relieve immediate postprandial symptoms. Therefore, the concept of IPPUAD was developed by the Panel in order to describe more accurately the therapeutic intent of these drug products.

The Panel acknowledges the fact that a large segment of the population occasionally has immediate postprandial upper abdominal complaints which are commonly and, in the opinion of the Panel, erroneously attributed to "excess gas." The terms "excess gas," "gaseousness," "flatulence," "bloating," "distention," and "fullness" have different meanings to different people; consequently, it is important to determine accurately the meaning of the terms as they are used to describe various consumer complaints.

One medical dictionary defines "flatulence" as "the presence of an excessive amount of gas in the stomach and intestines" (Ref. *1*). Another medical dictionary describes "flatulence" as "the presence of excessive amounts of air or gases in the stomach or intestine, leading to distention of the organs" (Ref. *2*). It is a well-known fact, however, that a certain amount of gas is constantly present in the gastrointestinal tract, and that not all people complain of flatulence.

The Random House Dictionary of English Usage defines "flatulent" as (1) "generating gas in the intestinal canal, as food," and (2) "attended with, caused by, or suffering from, such an accumulation of gas" (Ref. *3*). The first definition stems from the knowledge that certain foods (beans and onions) are prone to undergo bacterial fermentation in the large bowel, producing gases which are passed rectally without pain, as flatus. Preparations used for the relief of intestinal distress are also the subject of this document. (See part IV. below—Drug Products for the Treatment of the Symptoms of Intestinal Distress.)

The second definition above (Ref. *3*) apparently refers to accumulations of gas in the gastrointestinal tract which causes distress. This definition appears to be the one almost universally accepted by the lay public, and the Panel acknowledges that, on occasion, a large segment of the population may experience symptoms in the immediate postprandial period which it interprets as due to the presence of excessive gas. This ill-defined syndrome (upper abdominal bloating, distention, fullness, or pressure) which occurs in the immediate postprandial period is a common reason for taking "antiflatulent" drugs. The Panel, however, does not accept "excessive gas" as the causative agent, and, in fact, is not aware of any objective study which definitely establishes gas as the

causative agent for the IPPUAD symptom complex.

The Panel firmly believes that more studies are essential to definitely establish the etiology or etiologies of the IPPUAD syndrome. If such studies prove that gas is the etiologic agent, they must also show that the ingredient under evaluation relieves the symptoms, and that it decreases the amount of gas present.

The Panel acknowledges that everyone swallows some air, especially with food or liquid, and particularly if food is eaten rapidly and/or large quantities are ingested. It has been estimated that this "swallowed air" accounts for the major portion of gas in the gastrointestinal tract (Ref. *4*). Swallowed air (aerophagia) commonly results in eructation (belching). Gas that is released by belching consists entirely of swallowed air or carbon dioxide, and that which is not released by belching passes rapidly through the intestinal tract where it mixes with gas from food fermentation and is either absorbed or passed rectally as flatus. Such gas amounts to a normal physiologic mechanism and does not usually cause distress or require medication.

Another authority has stated that:

> Air in significant volumes may be admitted to the gastrointestinal tract without bothersome symptoms, other than flatulence, providing the gas-handling mechanisms are operational. Otherwise normal persons may become symptomatic when large quantities of food are ingested, possibly representing an overload phenomenon (Ref. *5*).

In reviewing the pertinent literature the Panel became aware of one study of 22 patients which found that the volume of gastrointestinal gas did not differ significantly in 12 patients with chronic complaints of excess gas compared to 10 controls who were free of abdominal complaints (Ref. *6*). When gas was infused into the intestines of the patients and the control group, more gas tended to reflux into the stomach of, and intestinal transit times were longer for, those patients who complained of abdominal pain (excess gas). This led the authors to conclude that an abnormal motility exists which results in disordered passage of gas through the bowel, with a painful response to an overall intestinal gas volume well tolerated by normal subjects.

Because the Panel believes that excessive gas is not the cause of IPPUAD, and has been unable to find any studies to support this excessive gas theory, it is the opinion of the Panel that the term "antiflatulent" or similar terms should not be used in the labeling or promotional material of drugs which claim to relieve the symptoms of IPPUAD, unless it is proven by scientific studies that excess gas is actually present and causing symptoms.

The Panel, of course, is aware that some persons complaining of the symptoms of IPPUAD have an organic basis for their complaints and may be suffering from abnormalities or disease of the gastrointestinal tract or other organ systems. Persons with persistent or chronic symptoms should have a thorough medical evaluation.

At the present time the Panel is not aware of any ingredients which have been adequately demonstrated to be effective in treating the symptoms of IPPUAD. However, the Panel has classified several ingredients as Category III in order to allow further testing and evaluation to establish effectiveness. (See part III, paragraph C. below—Category III Conditions.)

The Panel is aware of the following proposed mechanisms of action for ingredients which were claimed to relieve the symptoms of IPPUAD: (1) Reduction of the surface tension of the contents of the stomach, (2) altering stomach emptying by changing the acidity or osmolarity of the stomach, and (3) hastening stomach emptying by increasing smooth muscle contraction. However, the Panel is not convinced that any of these are the mechanism by which these IPPUAD ingredients work.

Studies attempting to demonstrate the effect of acids on gastric emptying have shown that the greater the acidity, the slower will be the emptying rate. Hunt and Knox (Ref. *7*) have shown that as the stomach became less acidic, the rate of gastric emptying was enhanced. Steinberg and Almy (Ref. *8*) suggest that alkalinization of the gastric contents is one of the mechanisms responsible for the relief of distention and pressure.

Steinberg and Almy (Ref. *8*) also proposed that distention of the stomach caused by evolution of carbon dioxide by certain medicinal agents and subsequent decrease in distention by eructation of gas could relieve the distress. Temporary distention such as that which is produced by the reaction of active ingredients with the gastric acid may hasten stomach emptying by the motor mechanism described by Weisbrodt et al. (Ref. *9*), i.e., high antral contractile activity and low duodenal contractile activity.

References

(*1*) "Stedman's Medical Dictionary," 22d Ed., Williams and Wilkins, Baltimore, 1972, s.v. "flatulence."

(*2*) "Dorland's Illustrated Medical Dictionary," 25th Ed., W. B. Saunders Co., Philadelphia, 1965, s.v. "flatulence."

(*3*) "The Random House Dictionary of the English Language, the Unabridged Edition," Random House, New York, 1966, s.v. "flatulence."

(*4*) Roth, J. A., "The Sympton Patterns of Gaseousness," *Annals of the New York Academy of Sciences*, 150:109–127, 1968.

(*5*) Danhof, T. E., "Gaseousness," *in* "Current Therapy, 1976," W. B. Saunders Co., Philadelphia, pp. 376–379, 1976.

(*6*) Lasser, R. B., J. H. Bond, and M. D. Levitt, "The Role of Intestinal Gas in Functional Abdominal Pain," *New English Journal of Medicine*, 293:524–526, 1975.

(*7*) Hunt, J. N., and M. T. Knox, "Regulation of Gastric Emptying," *in* "Handbook of Physiology," Volume IV, Section 6, American Physiology Society, Washington, pp. 1917–1935, 1968.

(*8*) Steinberg, H., and T. P. Almy, "Drugs for Gastrointestinal Disturbances," *in* "Drugs of Choice 1966–1967," edited by W. Modell, The C. V. Mosby Co., St. Louis, pp. 318–352, 1966.

(*9*) Weisbrodt, H. S., et al., "A Relation Between Gastroduodenal Muscle Contractions and Gastric Emptying," *Gut*, 10:543–548, 1969.

2. *For treatment of the symptoms of intestinal distress.* The Panel has recognized a syndrome of IPPUAD as described in the General Discussion above. In a significant segment of the population, the intestinal distress syndrome starts 30 minutes to several hours after eating. This syndrome is characterized by one or more of the following abdominal distress symptoms: Bloating, distention, fullness, pressure, excess flatus, pain, or cramps. The syndrome is self-limiting, not attributable to any known organic disease, and not accompanied by constipation or diarrhea. It should be emphasized that these symptoms may occur as the result of a multitude of disease states and if they persist, medical consultation should be obtained.

These symptoms have been attributed by the lay population to, and further popularized in advertising by some drug firms as caused, by, excess gas. It is probable that many physiologic factors are involved, which are poorly understood at the present time, such as the transit time of food materials through the small and large intestine, the nature of the food materials, the character of the bacterial population in the large intestine, etc. Gas is normally present in the small and large intestine in varying amounts. However, the Panel has been unable to find any conclusive proof that gas is a causative agent of any of the symptons of this syndrome.

C. Physiology Review

1. *For treatment of the symptoms of IPPUAD.* In order to better evaluate the mechanisms of action of the ingredients under its review, the Panel looks at the role of "gas" in the gastrointestinal tract

and its possible relationship to the symptoms of IPPUAD—unpleasant sensations perceived within the first 30 minutes following a meal and commonly described as bloating, distention, fullness, or pressure. These sensations are commonly attributed by the sufferer to "gas". However, some authors consider the cause to be gastric distention or altered physiology of gastric emptying.

The rate of gastric emptying is determined by the chemical and physical properties of the stomach contents as well as the gastric motility. Contents with a pH below 3.5 delay the emptying time, as does the presence of fats. Contents with an osmotic pressure of 200 milliosmoles are optimal for rapid emptying. The autonomic nervous system and various hormones also affect the rate of gastric emptying.

Stomach gas accumulates as a result of air swallowed during the meal, and air trapped in food and frothy saliva. Some people may swallow a half a liter (approximately one pint) or air with a meal. Air may also be swallowed between meals, as a result of gum chewing, smoking, or anxiety (Ref. *1*). Most swallowed air is belched or passed into the small intestine, where it either rapidly diffuses into the blood or passes into the colon. The stomach of an adult human normally contains about 50 milliliters (mL) of gas (Ref. *2*).

The Panel is unable to document through the scientific literature that gas resulting from swallowed air or any other gases present in the stomach are responsible for the symptom of bloating, distention, fullness, or pressure that occur in the immediate postprandial period. The scientific literature does, however, discuss the relationship between gas that is present in the lower gastrointestinal tract and the discomforts of intestinal distress. (See part IV. below—Drug Products for the Treatment of the Symptoms of Intestinal Distress.)

References

(*1*) Roth, J. A., "The Symptom Patterns of Caseousness, " *Annals of the New York Academy of Sciences,* 150:109–127, 1968.

(*2*) Davenport, H. W., "Physiology of the Digestive Tract," 3d ED., Year Book Medical Publishers, Inc., Chicago, p. 214, 1971.

2. *For treatment of the symptoms of intestinal distress.* Abdominal discomfort with sensations of bloating and fullness cannot be correlated with the volume of gas in the bowel. The discomfort is related to the rate of motility of the intestinal contents and may be due to abnormal sensitivity to distention of the bowel. Intestinal motility is regulated by intrinsic and extrinsic innervation. The motility is increased by mild distention but inhibited by marked distention or by irritation of the walls of the intestine. Emotional states may influence motility (Ref. *1*).

The normal transit time through the intestinal tract for intragastric oxygen ranges from 25 to 45 minutes. The transit time for food ranges from 15 to 36 hours, depending on the amount of bulk in the diet (Ref. *2*).

About 70 percent of intestinal gas is swallowed air. The remainder is the product of chemical reactions during digestion, diffusion exchange, and fermentation of partially digested food substances in the colon. The composition of the diet, the degree of the digestion, and the rate of food transit influence the amount and composition of the gases produced by bacterial fermentation. Hydrogen, carbon dioxide, and methane are the principal gaseous products of fermentation (Ref. *3*). The amount of flatus passed by individuals varies from 380 to 1,600 mL per day. Some hydrogen, methane, and carbon dioxide is excreted through the lungs.

Digestion of carbohydrates, proteins, and fats is dependent upon the activity of enzymes. Salivary amylase normally digests a portion of the polysaccharide intake and the remainder is digested by pancreatic amylase in the duodenum (Refs. *4*). The optimal pH for amylase activity is 6.9.

Only 10 to 15 percent of protein foods are split into amino acids by the action of pepsin in the stomach, and normal nitrogen balance can be maintained in the absence of this enzyme. Pancreatic proteolytic enzymes are responsible for the major part of protein digestion. About 10 percent of the protein remains undigested and enters the colon, where it is digested by bacteria (Refs. *4* and *5*).

Fats are hydrolysed by pancreatic and intestinal lipase. The optimal pH for lipase activity is from 6 to 8 (Ref. *5*).

Bile salts facilitate the activity of pancreatic lipase and absorption of fats. Bile salts are largely reabsorbed from the terminal ileum and then resecreted by the liver during digestion of a meal. Additional bile acids are synthesized by the liver to replace those that are not reabsorbed (Ref. *4*). The rate of synthesis is governed by the rate of reabsorption of the bile salts. High concentrations of bile acids are toxic to the epithelial cells of the intestine and, therefore, inhibit the absorption of sugars, amino acids, electrolytes, and water.

References

(*1*) Vander, A. J., J. H. Sherman, and D. S. Luciano, "Human Physiology, The Mechanisms of Body Function," McGraw-Hill, New York, pp. 378–391, 1970.

(*2*) Presentation by Ivan E. Danhof, M.D., to the Advisory Review Panel on OTC Miscellaneous Internal Drug Products, October 16, 1977 (Attached to letter from Hoechst-Roussel Pharmaceuticals, Inc., dated November 8, 1977, in Panel Administrator's File (OTC Volume 17GPAII).

(*3*) Gall, L.S., "The Role of Intestinal Flora in Gas Formation," *Annals of the New York Academy of Sciences,* 150:27–30, 1968.

(*4*) Davenport, H. W., "Physiology of the Digestive Tract," 3d Ed., Year Book Medical Publishers, Inc., Chicago, p. 113, 1971.

(*5*) Magee, D. F., "Secretions of the Digestive Tract," *in* "Howell-Fulton Physiology and Biophysics, Vol. III: Digestion, Metabolism, Endocrine Function and Reproduction," 20th Ed., edited by C. Ruch and H. D. Patton, W. B. Saunders, Philadelphia pp. 45–54, 1973.

D. Rationale For Use

1. *For treatment of the symptoms of IPPUAD.* The Panel believes that the rationale for use of agents intended for the treatment of the symptoms of IPPUAD is to provide significant symptomatic relief, within a short period of time, from the complaints of upper abdominal bloating, distention, fullness, or pressure occurring in the immediate postprandial period (within 30 minutes following a meal). These agents are designed to be taken when symptoms occur and are expected to benefit a clinically significant number of the target population. It is to be expected that not all persons will benefit from any one agent, nor will all agents be equally effective. It is also recognized that other agents not submitted for review or known to the Panel may be effective.

The doses recommended by the Panel are generally recognized to be safe when taken as directed by the majority of adults in good general health. Persistence of symptoms may indicate organic disease that needs professional medical attention. Those who respond only to higher than recommended doses should also seek professional care.

Prophylactic use is considered by the Panel to be inappropriate because the symptoms for which these drugs are taken occur intermittently and are self-limiting. There have been no data presented to the Panel which indicate that any agent intended for the treatment of the symptoms of IPPUAD is safe and effective for prophylactic use.

2. *For treatment of the symptoms of intestinal distress.* The Panel believes that the rationale for the use of agents intended for the treatment of the symptoms of intestinal distress is to provide significant symptomatic relief, within a short period of time, of

complaints of intestinal bloating, distention, fullness, pressure, pain, cramps, or excess flatus occurring 30 minutes to several hours after eating. These agents are designed to be taken when symptoms occur and are expected to benefit a clinically significant number of the target population. It is to be expected that not all persons will benefit from any one agent, nor will all agents be equally effective. It is also recognized that other agents not submitted for review or known to the Panel may be effective.

The doses accepted by the Panel are those generally recognized to be safe when taken as directed by the majority of adults in good general health. Persistence of symptoms may indicate organic disease that needs professional medical attention. Those who respond only to higher than recommended doses should also seek professional care.

Prophylactic use is considered by the Panel to be inappropriate because the symptoms for which these drugs are taken occur intermittently and are self-limiting. There have been no data presented to the Panel which indicate that any agent intended for the treatment of the symptoms of intestinal distress is safe and effective for prophylactic use.

E. Combination Policy

The Panel has reviewed FDA's general combination policy on OTC drug products (21 CFR 330.10(a)(4)(iv)) and believes that the policy as follows is rational.

An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

The Panel believes that all combination products used as digestive aids must conform to all three requirements of this general combination policy.

The Panel also believes that if a combination of ingredients is intended to treat separate but concurrent conditions, the labeling of the combination should convey to the consumer that it is to be used only when the symptoms of both conditions are present.

A number of combination drug products submitted to the Panel were subsequently categorized by the Panel as digestive aids and further subdivided for their usefulness in treating the symptoms of IPPUAD and intestinal distress. Each combination submitted has been classified into either Category II or Category III for its respective uses as designated in the chart below, and with the exception of the combination of blessed thistle and golden seal, they will not be reviewed further in this document.

DIGESTIVE AIDS AS COMBINATION INGREDIENTS

Combinations submitted	IPPUAD [1]		ID [2]	
	Category	Basis [3]	Category	Basis
Cellulase, pancreatin, glutamic acid HCl, ox bile extract, and pepsin	II	E	II	E
Cellulase, dehydrocholic acid, pancreatic enzyme concentrate, and pepsin	II	E	II	E
Alcohol, peppermint oil, cinnamon oil, tannic acid, and tincture of catechu	II	E	II	E
Sorbitol and homatropine methylbromide	II	E	II	E
Pancreatin and simethicone	II	E	III	E
Bean, dog grass, elecampane, galega, horsetail, huckelberry, johnswort, nettle, linden, and strawberry.	II	E		
Peppermint spirit and orthophosphoric acid	II	E		
Aluminum hydroxide and magnesium trisilicate	III	E		
Magnesium hydroxide and simethicone	III	E	III	E
Blessed thistle and golden seal			II	E
Ox bile extract, papain, pepsin, pancreatin, duodenal substance, dehydrocholic acid, and charcoal (activated).			II	E
Pancreatin, hemicellulase, and ox bile extract			II	E
Senna, buckthorn, johnswort, woodruff, juniper, peppermint, and knotgrass			II	E
Lipase, amyulase, protease, and hemicellulase			III	E
Combination of acetaminophen with a Category III digestive aid ingredient	III	E	III	E

[1] IPPUAD—Immediate postprandial upper abdominal distress.
[2] ID—Intestinal distress.
[3] Basis for Categorization: S (Safety), E (Effectiveness).

The individual ingredients in the Category II combinations for IPPUAD and intestinal distress were found to be generally recognized as safe but each combination contains at least one ingredient which was found to be ineffective for the respective indication, i.e., the symptoms of IPPUAD or intestinal distress. The Panel concludes that any combination used for the treatment of the symptoms of IPPUAD or intestinal distress and containing one or more Category II ingredients is hereby placed in Category II for the respective indication. In addition, in accordance with the adopted combination policy stated above, none of the combinations was demonstrated to be effective.

The individual ingredients in the Category III combinations for IPPUAD and intestinal distress were found to be generally recognized as safe but there are insufficient data available to demonstrate whether or not the combinations are effective in treating the symptoms of IPPUAD or intestinal distress. The Panel recommends that testing of the Category III combinations be performed according to the testing guidelines. (See part III. paragraph D.1. below—Guidelines for developing a protocol for evaluating OTC drugs for the treatment of the symptoms of IPPUAD or part IV. paragraph D. below—Guidelines for Developing Protocols for Evaluating OTC Drugs for the Treatment of the Symptoms of Intestinal Distress.) The requirements of the combination policy stated above must also be taken into consideration when devising specific studies.

One of the combination products submitted contains an internal analgesic in addition to a digestive aid ingredient. The internal analgesic ingredient is present only to relieve a concurrent condition (headache). The Panel has evaluated such a combination and considers it rational because it meets the needs of a defined target population. The Panel, therefore, recommends that acetaminophen, a safe and efffective internal analgesic ingredient (as published in the **Federal Register** of July 8, 1977 (42 FR 35412)), may be combined with any Category III (which may eventually become Category I) digestive aid ingredient when such a combination is used for the treatment of headache or minor aches and pains occurring concurently with the symptoms of IPPUAD or intestinal distress.

F. Labeling

The Panel has carefully reviewed the submitted labeling claims made for products promoted for the relief of the symptoms of IPPUAD and intestinal distress and has categorized them according to their acceptability into Category I, Category II, or Category III. The Panel is aware that there may be other terms that would be acceptable in expressing the same Category I indications.

In order for any labeling to be acceptable, it must include (a) the indication(s) for use, (b) pertinent warnings and contraindications, and (c)

the recommended dosage range. Only those indications and warnings listed under Category I are generally recognized to be acceptable at this time. (See part III. pargraph A.2. below—Category I labeling and part IV. paragraph A.2. below—Category I labeling.)

The Panel believes that all labeling should be clear, concise, and easily read and understood by most consumers. It has followed this concept in the development of all Category I labeling. The Panel is also concerned about the size and color of the print used in labeling of these and all drug products, and recommends that the industry make the necessary effort to design labeling which can be read easily by consumers.

One of the primary functions of this Panel is to attempt to eliminate confusing labeling claims. Much of the labeling on currently marketed digestive aid drug products tends to be overly complicated, vague, unsupported by scientific data, and in some cases false and misleading.

The indications for use should be simply and clearly stated, the directions for use should provide the user with enough information for safe and effective use of the product, and the label should include a statement that the product is intended only for the temporary relief of the symptoms of IPPUAD and/or intestinal distress.

The Panel is also concerned that if two ingredients are indistinguishable with regard to effectiveness, it is misleading to claim superiority for one of the ingredients. The Panel wishes to make it clear that its function is not to compare various ingredients to determine the OTC drug of choice, but to determine the safety and effectiveness for active OTC miscellaneous internal drug ingredients, as well as proper dosage ranges, warnings, and contraindications.

Undocumented, vague, or misleading claims such as "gasid indigestion," "biliousness," "indigestion," and colloquial or provincial expressions that do not have meaning to a majority of people must not be used. Statements which recommend prophylactic use to prevent the onset of symptoms shall not appear on the label. The Panel believes that this practice might lead to overuse of the medication. In the labeling, effectiveness shall not be related to the taste, odor, consistency, or other physical characteristics of the product except as they may affect the action of the active ingredients. Phrases such as "superior to ordinary," "specially improved or selected ingredients," "extra strength," and "contains more active ingredient per dose" may be vague and misleading and should be avoided unless supported by sound scientific data. Phrases such as "works internally" or "travels through the bloodstream" give the implication that the product has a unique physiological action which is unjustified.

The Panel has noted that the use of certain labeling claims related to the safety and/or effectiveness of products and their ingredients is not supported by sound scientific evidence. Until there is acceptable proof that "excess gas" is the causative agent of the syndrome of IPPUAD, the Panel concludes that labeling should not include any word or words directly or indirectly implying or indicating that the medication relieves symptoms due to "gas" or "excess gas." The labeling should not make any such claims until there has been a demonstration by acceptable scientific methods that increased gas volume does exist in this syndrome, that it is decreased by the drug for which "anti-gas" activity is claimed, and that symptomatic relief is associated with a decrease in the gas volume.

The Panel is aware of the prevalent perception among consumers who buy medicine for abdominal distress that their self-diagnosis of "gas" describes their condition and that the word "gas" is a descriptive term for those symptoms. Consequently, the Panel has authorized the phrase "sometimes described as gas" to be used in conjunction with Category I labeling claims. Any claims regarding a drug's specific "anti-gas" activity should not be allowed in the labeling until the drug's effectiveness for this purpose has been demonstrated according to the Category III proposed guidelines, and the final monograph has been appropriately amended.

Phrases like "relief of belching" are not considered by the Panel to be applicable to this group of drugs, because the common causative mechanism for "belching" is aerophagia. To the knowledge of the Panel, no proof exists that any one of these drugs reduces the incidence or extent of aerophagia.

This Panel concurs with the recommendations of the Advisory Review Panel on OTC Antacid Drug Products (as published in the Federal Register of April 5, 1973 (38 FR 8719)), and the conclusions of FDA (21 CFR 331.30(b)(4) and (5)) that warnings should be included in the labeling of drugs containing sodium and magnesium but recommends that the wording be as follows: (1) For products containing more than 5 milliequivalents (meq) of sodium in the maximum recommended daily dosage: "If you are on a sodium-restricted diet, do not take this product except under the supervision of a physician"; and (2) For products containing more than 50 meq of magnesium in the maximum recommended daily dosage: "If you have kidney disease, do not take this product except under the supervision of a physician."

The Panel is aware of the current OTC labeling regulation dealing with warning statements (21 CFR 330.1(g)). The Panel concurs with the warning, "Keep this and all drugs out of the reach of children," and believes that it should be incorporated in the labeling for digestive aid products. However, the Panel recommends that the other warning statement required by § 330.1(g) "In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately" be revised to read as follows: "In case of accidental overdose, contact a Poison Control Center, emergency medical facility, or physician immediately for advice." The Panel believes that this revision will be more informative to the consumer.

Because OTC products can be purchased by anyone, it is the view of the Panel that the public generally does not regard these products as medicines which, if used improperly, can result in injurious or potentially serious consequences. The public needs to be continually alerted to the idea that these products, like all medicine, carry some risk and should be treated with respect. The consumer should also be informed of any possible signs of known toxicity or any symptom requiring discontinuation of the use of the drug so that appropriate steps may be taken before more severe consequences become apparent.

In addition, the Panel recommends that drug product labeling contain instructions for the most effective preparation and use of the product ("shake well before using," "mix thoroughly," etc.) and that instructions for product use, which are intended to facilitate and improve the delivery and availability of the active ingredient, be prominently displayed on all package labeling.

As previously stated, the Panel believes that the labeling of combination products intended to treat separate but concurrent conditions should convey to the consumer that the product is to be used only when the concurrent symptoms, which require treatment by each type of active ingredient, are present.

The Panel believes that the label should contain a listing of all ingredients

and that it should clearly indicate which are active and which are inactive. Active ingredients should be listed by their established names, and the label should state the quantity of the active ingredients per dosage unit.

G. Dosing Considerations

Each dosage recommended in this document is within the range suggested by either the product manufacturer, official compendia, or authorities in the appropriate medical specialty. The dose ranges are usually based on average adult weight and size (70 kilograms (kg)). Some of the factors that can alter availability and the therapeutic effects for each dose are: (a) Age, (b) size (surface area), (c) body weight, (d) general physical condition, (e) allergies, (f) smoking and drinking patterns, (g) other medication taken concurrently, (h) the type of container used for measuring and administering liquid medication, and (i) when taken in relation to eating.

The Panel recognizes that many factors may alter the activity, rate of metabolism, and excretion of any drug administered. These factors are most critical in very young and elderly persons.

III. Drug Products for the Treatment of the Symptoms of Immediate Postprandial Upper Abdominal Distress

A. Category I Conditions

The following are Category I conditions under which drug products used for the treatment of the symptoms of IPPUAD are generally recognized as safe and effective and are not misbranded.

1. *Category I active ingredients.* None.

2. *Category I labeling.* Although the Panel has not classified any ingredients in Category I, it recommends the following Category I labeling for drug products used to treat the symptoms of IPPUAD as being generally recognized as safe and effective and not misbranded, as well as the specific labeling discussed in the individual ingredient statements.

a. *Indications.* The labeling of the product contains one of the following statements under the heading "Indications":

(1) "Relieves the over-full feeling in the upper abdomen which occurs soon after eating."

(2) "For relief of upper abdominal" [optional, (any or all of the following symptoms): "distress," "bloating," "distention," "fullness," and "pressure"] "which occur(s) soon after eating."

(3) "For relief of upper abdominal" (one or more of the following symptoms: "distress," "bloating," "distention," "fullness," and "pressure") "which occurs soon after eating," (optional, "and which may be described as 'gas'.")

As previously discussed, the Panel is fully aware that although "gas" has not been proven to be the cause of IPPUAD, the consumer may perceive his or her upper abdominal symptoms (distress, bloating, distention, fullness, or pressure) as being due to "gas." Therefore, the Panel, after much deliberation, concludes that claim (3) may be allowed in the labeling of these products.

The word "stomach" may be substituted for the words "upper abdomen" or "upper abdominal" in the respective claims above.

b. *Warnings.* All labeling for products used to treat the symptoms of IPPUAD should contain the following under the heading "Warnings":

(1) "If symptoms of upper abdominal distress persist, stop this medication and consult your physician."

(2) "Do not use this product in children under 12 years of age except under the supervision of a physician."

B. Category II Conditions

The following are Category II conditions under which drug products used for the treatment of the symptoms of IPPUAD are not generally recognized as safe and effective or are misbranded.

1. *Category II active ingredients.*

Cellulase
Dehydrocholic acid
Garlic, dehydrated
Glutamic acid hydrochloride
Homatropine methylbromide
Ox bile extract
Pancreatin and pancrelipase
Pepsin
Sorbitol

In addition, the Panel has classified other ingredients as Category II elsewhere in this document. (See part I. paragraph C.1.c. above—Other ingredients.)

a. *Cellulase.* The Panel concludes that cellulase is safe for OTC use in the dose noted below, but is not generally recognized as effective in treating the symptoms of IPPUAD.

(1) *Safety.* Cellulase is obtained from molds such as *Aspergillus oryzae* and *Penicillium notatum* as well as from various other sources (Refs. *1* and *2*). Cellulase has been utilized as a digestive aid in doses of 9 to 50 mg three times daily (Refs. *3* and *4*). The Panel concludes that it is safe when used as a digestive aid in these doses.

(2) *Effectiveness.* Some data were submitted demonstrating cellulase digestive activity on vegetable foods (Ref. *3*) but the Panel is not aware of any adequate and well-controlled clinical studies demonstrating the effectiveness of cellulase in treating the symptoms of IPPUAD. Therefore, the Panel concludes that cellulase is not generally recognized as an effective treatment for the symptoms of IPPUAD.

(3) *Evaluation.* The Panel concludes that cellulase is generally recognized as safe for OTC use in the dose specified but its effectiveness has not been demonstrated in treating the symptoms of IPPUAD.

Cellulase has been further reviewed by this Panel for its use in treating the symptoms of intestinal distress and the conclusions are included later in this document. (See part IV. paragraph C.1.a. below—Cellulase and hemicellulase.)

References

(*1*) Pigman, W., "Enzymes Acting on Hemicelluloses, Gum and Wood," *in* "The Enzymes," Volume I, edited by J. B. Sumner and K. Myrback, Academic Press, New York, pp. 739–744, 1951.

(*2*) Courtois, J. E., "Some Biochemical Aspects of Cellulases and Hemicellulases," *Glasnik Hemijskog Drugstvaw*, 32:365–388, 1967.

(*3*) OTC Volume 170049.

(*4*) OTC Volume 170100.

b. *Dehydrocholic acid.* The Panel concludes that dehydrocholic acid is safe for OTC use in the dose noted below, but is not generally recognized as effective in treating the symptoms of IPPUAD.

(1) *Safety.* The Panel is aware of one animal study which determined the LD_{50} (median lethal dose) of dehydrocholic acid to be 14.7 grams/kilogram (g/kg) in rats. The study further reported that no hepatic damage was found to result from the chronic administration of 3 and 5 g daily to dogs for 3 to 7 months, nor from the administration of 333 milligrams/kilogram (mg/kg) daily to rats for 32 days (Ref. *1*).

The Panel concurs with the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products, in a report published in the **Federal Register** of March 21, 1975 (40 FR 12902), which found dehydrocholic acid to be safe in an adult dose of 750 to 900 mg per day when used as a laxative (40 FR 12910). That Panel did not approve its use in children under 12 years of age.

Based on the available data, the Panel concludes that dehydrocholic acid is safe for OTC use in the above dosage.

(2) *Effectiveness.* Dehydrocholic acid, which is a partially synthetic derivative of cholic acid, stimulates the liver to increase the volume of bile by increasing its water content without increasing other constitutents (hydrocholeretic) (Refs. *2* and *3*).

Dehydrocholic acid has been used as an OTC laxative, but the Panel is not aware of any adequate and well-controlled clinical studies demonstrating its effectiveness in treating the symptoms of IPPUAD; nor is dehydrochloic acid generally recognized as an effective treatment for the symptoms of IPPUAD. Therefore, the Panel concludes that dehydrocholic acid is not an effective treatment for the symptoms of IPPUAD.

(3) *Evaluation.* The Panel concludes that dehydrocholic acid is generally recognized as safe for OTC use in the dose specified above but its effectiveness in treating the symptoms of IPPUAD has not been demonstrated. This conclusion is in agreement with the following decision of the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products (as published in the Federal Register of March 21, 1975 (40 FR 12910)):

> There is no evidence in support of the claim that dehydrocholic acid relieves "indigestion", "excessive belching", "after meal discomfort", or "the sensation of abdominal fullness". These claims constitute mislabeling and dehydrocholic acid is placed in Category II with respect to these claims.

Dehydrocholic acid has been further reviewed by this Panel for treating the symptoms of intestinal distress and the conclusions are included elsewhere in this document. (See part IV. paragraph B.1.c. below—Dehydrocholic acid.)

References

(*1*) Berman, A. L., E. Snapp, A. C. Ivy, and A. J. Atkinson, "The Effect of Long-Continued Ingestion of Oxidized Bile Acids on the Dog and Rat," *American Journal of Digestive Diseases*, 7:280–284, 1940.

(*2*) Harvey, S.C., "Gastric Antacids and Digestants," *in* "The Pharmacological Basis of Therapeutics," 5th Ed., edited by L. S. Goodman and A. Gilman, The MacMillan Co., New York, p. 973, 1975.

(*3*) DiPalma, J. R., "Drill's Pharmacology in Medicine," 4th Ed., McGraw-Hill, New York, pp. 972–973, 1971.

c. *Garlic, dehydrated.* The Panel concludes that dehydrated garlic is safe for OTC use in the dose noted below, but is not generally recognized as effective in treating the symptoms of IPPUAD.

(1) *Safety.* Garlic has been widely used as a food for many years with no known harmful effects. It is considered by the Panel to be safe in the recommended OTC dose of 0.6 gram (g) after meals (Ref. *1*).

(2) *Effectiveness.* The principal active ingredients of dehydrated garlic are allyl propyl disulfide and diallyl disulfide (Ref. *2*).

Some data were submitted regarding dehydrated garlic's effectiveness as a carminative (expelling gas from the alimentary canal), but the Panel is not aware of any adequate and well-controlled clinical studies demonstrating the effectiveness of dehydrated garlic or its principal active ingredients in treating the symptoms of IPPUAD; nor is it generally recognized as an effective treatment for the symptoms of IPPUAD.

(3) *Evaluation.* The Panel concludes that dehydrated garlic is generally recognized as safe for OTC use in the dose specified, but its effectiveness has not been demonstrated in treating the symptoms of IPPUAD.

Dehydrated garlic has been further reviewed by this Panel for treating the symptoms of intestinal distress and the conclusions are included elsewhere in this document. (See part IV. paragraph B.1.e. below—Garlic, dehydrated.)

References

(*1*) OTC Volume 170003.

(*2*) Bordia, A., H. C. Bonsal, S. K. Arora, and S. V. Singh, "Effect of the Essential Oils of Garlic and Onion on Alimentary Hyperlipemia," *Atherosclerosis*, 21:15–19, 1975.

d. *Glutamic acide hydrocholoride.* The Panel concludes that glutamic acid hydrochloride is safe for OTC use in the dose noted below, but is not generally recognized as effective in treating the symptoms of IPPUAD.

(1) *Safety.* Available clinical data and marketing experience have shwon glutamic acid hydrochloride to be safe for OTC use in the dose of 1.02 g three times daily as a stomach acidifier. (Ref. *1*).

(2) *Effectiveness.* Glutamic acid hydrochloride has been marketed as an agent intended to increase the amount of acid present in the stomach and thus favorably alter the pH of the gastric environment (Refs. *2* and *3*). However, the Panel knows of no proven relationship between hypoacidity or anacidity of the stomach and the symptoms of IPPUAD, nor is the Panel aware of any adequate and well-controlled clinical studies demonstrating the effectiveness of glutamic acid hydrochloride in treating the symptoms of IPPUAD. Furthermore, glutamic acid hydrochloride is not generally recognized as an effective treatment for this condition.

(3) *Evaluation.* The Panel concludes that glutamic acid hydrochloride is generally recognized as safe for OTC use in the dose specified, but its effectiveness has not been demonstrated in treating the symptoms of IPPUAD.

The Panel is aware that glutamic acid hydrochloride has been employed as a stomach acidifier in the treatment of achlorhydria and hypochlorhydria but does not find it has any usefulness in treating these conditions. The Panel has published a separate document on OTC stomach acidifier drug products in the Federal Register of October 19, 1979 (44 FR 60316).

Glutamic acid hydrochloride has been further reviewed by this Panel for treating the symptoms of intestinal distress, and the conclusions are included elsewhere in this document. (See part IV. paragraph B.1.f. below—Glutamic acid hydrochloride.)

References

(*1*) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, pp. 1082–1083, 1977.

(*2*) OTC Volume 170023.

(*3*) OTC Volume 170049.

e. *Homatropine methylbromide.* The Panel concludes that homatropine methylbromide is safe for OTC use in the dose noted below, but is not generally recognized as effective in treating the symptoms of IPPUAD.

(1) *Safety.* In a study to determine the minimal toxic dose of homatropine methylbromide, Berger and Ballinger reported toxicity in individuals ingesting doses ranging from 68 to 273 mg per day (Ref. *1*). This is far in excess of the usually recommended dosage of 2.5 to 5.0 mg four times daily (Ref. *2*). There was no evidence of toxic or cumulative effects at the smaller dosage of 1 mg three times daily before meals (Ref. *1*).

"Slight cerebral symptoms" have resulted from the use of maximum doses of 20 mg per day, but no cumulative effects have been reported (Ref. *3*). Homatropine methylbromide is about one-half as potent as atropine in its effect on the gastrointestinal tract and is claimed to be one-thirtieth as toxic on the central nervous system (Ref. *4*). Its use is generally accompanied by fewer central nervous system side effects than atropine (Ref. *4*). Therefore, the Panel concludes that homatropine methylbromide is generally recognized as safe in the above doses.

(2) *Effectiveness.* Homatropine methylbromide is a quaternary ammonium cholinergic blocking agent and is much less active than atropine on the central nervous system. Like homatropine, it is a weaker autonomic blocking agent than atropine. It is used to reduce the motility of the intestinal tract (Ref. *2*).

Although the effectiveness of atropine-like substances on the motility of the gastrointestinal tract is well recognized, the Panel is not aware of any adequate and well-controlled

clinical studies demonstrating the effectiveness of homatropine methylbromide in treating the symptoms of IPPUAD nor is it generally recognized as an effective treatment for the symptoms of IPPUAD.

(3) *Evaluation.* The Panel concludes that homatropine methylbromide is generally recognized as safe for OTC use in a maximum dose of 5 mg four times daily, but its effectiveness in treating the symptoms of IPPUAD has not been demonstrated.

Homatropine methylbromide has been further reviewed by this Panel for treating the symptoms of intestinal distress and the conclusions are included elsewhere in this document. (See part IV. paragraph C.1.c. below—Homatropine methylbromide.)

References

(*1*) Berger, A. R., and J. Ballinger, "The Relative Toxicity of Atropine and Novatrine in Man," *American Journal of Medical Sciences*, 214:156–158, 1947.

(*2*) Harvey, S. C., "Antimuscarinic Drugs," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by A. Osol and J. E. Hoover, Mack Publishing Co., Easton, PA, p. 841, 1975.

(*3*) Grollman, A., and E. F. Grollman, "Pharmacology and Therapeutics," 7th Ed., Lea and Febiger, Philadelphia, p. 351, 1970.

(*4*) Krantz, J. C., and C. J. Carr, "The Pharmacologic Principles of Medical Practice," 7th Ed., Williams and Wilkins, Baltimore, p. 404, 1969.

f. *Ox bile extract.* The Panel concludes that ox bile extract is safe for OTC use in the dose noted below, but is not generally recognized as effective in treating the symptoms of IPPUAD.

(1) *Safety.* The Panel believes the usual dose of 300 to 500 mg given two to three times daily after meals to be safe for healthy individuals (Ref. *1*). However, for individuals who have biliary obstruction or some other forms of liver disease, exogenous bile salts further contribute to an already undesirable increase in plasma and blood concentrations of bile salts (Ref. *2*). Commercial ox bile preparations may produce diarrhea (Ref. *3*).

(2) *Effectiveness.* Ox bile extract is a powdered or granular extract of ox bile with a characteristic odor and taste containing an amount of the sodium salts of ox bile acids equivalent to approximately 45 percent cholic acid (Ref. *1*).

Bile contains bile salts, bile pigments, lecithin, cholesterol, mucin, and other proteins, fatty acids, and inorganic salts. Of these constituents, the most important are the bile salts, which occur as sodium salts of conjugated bile acids (Ref. *1*). The bile salts constitute approximately three percent of the total bile secreted daily (Ref. *2*).

Bile acids are synthesized by the liver and secreted into the duodenum as conjugated bile salts. A high percentge of the bile salts is reabsorbed in the lower small intestine and is recirculated through the liver by way of the enterohepatic circulation.

Bile salts enhance the absorption of lipids and are necessary for the absorption of fat-soluble vitamins and cholesterol. They play an important role in maintaining the normal solubility of cholesterol in the bile (Ref. *3*). Bile salts also promote digestion of fats by stimulating pancreatic secretion and by activating pancreatic lipase (Ref. *2*).

The large volume of bile secreted into the duodenum helps to neutralize the acidic contents but is less important than pancreatic secretions in this respect (Ref. *2*).

Bile salts "* * * can be given to promote the flow of bile or to increase intrabiliary pressure; however, much expert medical opinion now holds that the administration of bile salts is often unnecessary or inappropriate and can sometimes cause undue pain or danger to the patient" (Ref. *2*). "Bile salts are no better than placebos in nonobstructive, noncholestatic biliary tract disorders or in various malfunctions of the intestine" (Ref. *2*).

Ox bile extract "* * * is promoted for the replacement therapy in patients who have an insufficient concentration of bile salts in the intestine, but it is ineffective. Use of ox bile extract is inadvisable, for it does not provide an adequate amount of bile salts" (Ref. *3*).

Ox bile extract has been used for many years in OTC products, but the Panel is not aware of any adequate and well-controlled clinical studies demonstrating its effectiveness in treating the symptoms of IPPUAD, nor is ox bile extract generally recognized as an effective treatment for the symptoms of IPPUAD.

(3) *Evaluation.* The Panel concludes that ox bile extract is generally recognized as safe for OTC use in the dose specified but its effectiveness has not been demonstrated in treating the symptoms of IPPUAD.

Ox bile extract has been further reviewed by this Panel for treating the symptoms of intestinal distress, and the conclusions are included elsewhere in this document. (See part IV. paragraph B.1.g. below—Ox bile extract.)

References

(*1*) "The United States Dispensatory," 27th Ed., edited by A. Osol and R. Pratt, J. B. Lippincott Co., Philadelphia, p. 820, 1972.

(*2*) Harvey, S. C., "Gastric Antacids and Digestants," *in* "The Pharmacological Basis of Therapeutics," 5th Ed., edited by L. S. Goodman and A. Gilman, The MacMillan Co., New York, pp. 971–973, 1975.

(*3*) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, p. 1084, 1977.

g. *Pancreatin and pancrelipase.* The Panel concludes that pancreatin preparations (pancreatin or pancrelipase) are safe for OTC use in the dose noted below, but are not generally recognized as effective in treating the symptoms of IPPUAD.

(1) *Safety.* The Panel has determined that pancreatin preparations (pancreatin or pancrelipase) are safe in the usual recommended daily dosage of up to 14 g of triple strength pancreatin when given in divided doses (Ref. *1*). Side effects of nausea, vomiting, and diarrhea may occur at high doses (Ref. *1*). Because pancreatin preparations are obtained mainly from hogs, they should not be used by individuals who are allergic to pork.

(2) *Effectiveness.* Pancreatin preparations (pancreatin or pancrelipase) are a combination of natural enzymes usually obtained from the pancreas of hogs. Their principal components are amylase, lipase, and protease (Refs. *1, 2,* and *3*).

Pancreatin preparations (pancreatin or pancrelipase) are effective as aids to digestion when normal exocrine pancreatic secretion is deficient and have considerable usage for treatment of this condition (Refs. *1, 2,* and *3*).

Pancreatin preparations (pancreatin or pancrelipase) are components of several combination digestive aid preparations, but the Panel is not aware of any adequate and well-controlled clinical studies demonstrating their effectiveness in treating the symptons of IPPUAD. In addition, pancreatin preparations (pancreatin or pancrelipase) are not generally recognized as providing effective treatment for the symptons of IPPUAD.

(3) *Evaluation.* The Panel concludes that pancreatin preparations (pancreatin or pancrelipase) are generally recognized as safe for OTC use in the dose specified but their effectiveness has not been demonstrated in treating the symptons of IPPUAD.

Pancreatin preparations (pancreatin or pancrelipase) have been further reviewed by this Panel for treating the symptons of intestinal distress, and the conclusions are included elsewhere in this document. (See part IV. paragraph C. 1.e. below—Pancreatin and pancrelipase).

References

(1) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, pp. 1085–1086, 1977.

(2) Harvey, S. C., "Gastric Antacids and Digestants," *in* "The Pharmacological Basis of Therapeutics," 5th Ed., edited by L. S. Goodman and A. Gilman, The MacMillan Co., New York, p. 971, 1975.

(3) Gibb, J. W., "Enzymes," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by A. Osol and J. E. Hoover, Mack Publishing Co., Easton, PA, p. 973, 1975.

h. *Pepsin.* The Panel concludes that pepsin is safe for OTC use in the dose noted below, but is not generally recognized as effective in treating the symptons of IPPUAD.

(1) *Safety.* No safety data were submitted. However, based upon the continued marketing of pepsin over many years with no reports of adverse effects the Panel concludes that it is safe in a daily dose of up to 1,000 mg (Ref. *1*).

(2) *Effectiveness.* Pepsin is a proteolytic enzyme obtained from the glandular layer of fresh hog stomach (Ref. *2*) and is similar to human pepsin (Ref. *1*). Although its presence is not required for protein digestion, since intestinal enzymes can function without it, pepsin has been used when endogenous human pepsin is deficient or absent. The Panel is not aware of any convincing evidence that added pepsin is of therapeutic usefulness (Refs. *2, 3,* and *4*).

No data were submitted for the effectiveness of pepsin and the Panel is not aware of any adequate and well-controlled clinical studies demonstrating its effectiveness in treating the symptoms of IPPUAD nor is it generally recognized as an effective treatment for the symptons of IPPUAD.

(c) *Evaluation.* The Panel concludes that pepsin is generally recognized as safe for OTC use in the dose specified but its effectiveness has not been demonstrated in treating the symptoms of IPPUAD.

Pepsin has been further reviewed by this Panel for treating the symptoms of intestinal distress and the conclusions are included elsewhere in this document. (See part IV. paragraph B.1.i. below—Pepsin.)

References

(1) "The United States Dispensatory and Physician's Pharmacology," 26th Ed., edited by A. Osol, R. Pratt, and M. D. Altschule, J. B. Lippincott Co., Philadelphia, p. 874, 1967.

(2) Wilson, C. O., O. Grisvold, and R. F. Doerge, "Text Book of Organic Medical and Pharmacological Chemistry," 6th Ed., J. B. Lippincott Co., Philadelphia, pp. 904–905, 1971.

(3) Harvey, S. C., "Gastric Antacids and Digestants," *in* "The Pharmacological Basis of Therapeutics," 5th Ed., edited by L. S. Goodman and A. Gilman, The MacMillan Co., New York, p. 971, 1975.

(4) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, p. 1083, 1977.

i. *Sorbitol.* The Panel concludes that sorbitol, also known as *D*-sorbitol, is safe for OTC use in the dose noted below, but is not generally recognized as effective in treating the symptoms of IPPUAD.

(1) *Safety.* The Panel considers sorbitol safe in the suggested oral dose of 4.5 g three times daily (Ref. *1*).

Steinke et al. (Ref. *2*) reported finding no evidence of gastrointestinal side effects and no increase in insulin requirements in 143 juvenile diabetics, aged 5 to 15 years, following the administration of 41 g of sorbitol per day in 3 equal doses for periods of 8 to 48 days. In another study some patients were reported to develop borborygmus (intestinal rumblings) and hyperperistalsis or diarrhea following either large single doses of sorbitol (40 g) for gall bladder studies or the administration of 7 g before meals for up to 20 to 60 days (Ref. *3*).

(2) *Effectiveness.* Sorbitol is a six-carbon polyhydric alcohol. It is more slowly absored from the gastrointestinal tract than dextrose. Its main use is as an osmotic diuretic. Fifty percent is metabolized or converted to glycogen and stored in the liver (Ref. *4*). Oxidation to fructose occurs in both the liver and kidney (Ref. *2*).

Maximal contraction of the gall bladder has been found to occur 30 minutes after the administration of 9, 18, and 27 g of sorbitol (Ref. *5*). Eighty percent of 64 patients with hepatobiliary disorders who were treated with 7 g of sorbitol before meals for periods of from 20 to 60 days were reported to have obtained relief from dyspepsia and abdominal swelling, as well as some other symptoms (Ref. *3*).

The Panel is aware that sorbitol is used as an osmotic diuretic and more generally as a laxative, sweetener, humectant, and vehilce (70 percent weight/weight solution) (Ref. *6*); but the Panel is not aware of any adequate and well/controlled clinical studies demonstrating the effectiveness of this ingredient in treating the symptoms of IPPUAD in the absence of hepatobiliary disease. In addition, sorbitol is not generally recognized as an effective treatment for the symptoms of IPPUAD.

(3) *Evaluation.* The Panel concludes that sorbitol is generally recognized as safe for OTC use in the dose specified but its effectiveness has not been demonstrated in treating the symptoms of IPPUAD.

Sorbitol has been further reviewed by the Panel for treating the symptoms of intestinal distress, and the conclusions are included elsewhere in this document. (See part IV. paragraph B.1.j. below—Sorbitol.)

References

(1) OTC Volume 170042 (Section V.A.I.).

(2) Steinke, J., et al., "Evaluation of Sorbitol in the Diet of Diabetic Children at Camp, "*Diabetes,* 10:218–227, 1961.

(3) Piccinelli, O., and G. Timossi, "D–Glucitol in the Therapy of Hepatobiliary Diseases," *Minerva Medica,* 49:77–82, 1958.

(4) DiPalma, J. R., "Drill's Pharmacology in Medicine," 4th Ed., McGraw-Hill, New York, p. 229, 1971.

(5) OTC Volume 170042 (Section V.A.I.).

(6) Swinyard, E. A., "Pharmaceutical Necessities," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by A. Osol and J. E. Hoover, Mack Publishing Co., Easton, PA, p. 1235, 1975.

2. *Category II labeling.* The Panel concludes that some labeling claims are either vague, misleading, unsupported by scientific data, unrelated to the symptoms of IPPUAD, or in some instances unsupported by sound theoretical reasoning. The claims listed below and other related terms are, therefore, classified as Category II labeling for drug products used to relieve the symptoms of IPPUAD.

a. "Stomach acid medication."
b. "Carminative."
c. "For mild stomach disturbances."
d. "Astringent."
e. "For prompt relief of nausea."
f. "Relieves belching."
g. "Stomachic."
h. "Fast," "fast acting," "long lasting," and any other claims which vaguely and nonspecifically relate to the speed of action.
i. "For the prevention of IPPUAD symptoms."
j. "For relief of gasid indigestion."
k. "For relief of biliousness."
l. "Indigestion."
m. "Superior to ordinary."
n. "Specially improved."
o. "Selected ingredients."
p. "Extra strength."
q. "Contains more active ingredients per dose."
r. "Works internally."
s. "Travels through the bloodstream."
t. "Guaranteed."

C. Category III conditions

The following are Category III conditions for which the available data are insufficient to permit final classification at this time.

1. *Category III active ingredients.* The Panel concludes that the safety of the following ingredients in the recommended doses is unquestioned, except as noted in the individual ingredient writeups:

Almadrate sulfate
Aluminum hydroxide
Calcium carbonate
Dihydroxyaluminum sodium carbonate
Magnesium hydroxide
Magnesium trisilicate
Peppermint oil
Simethicone
Sodium bicarbonate
Sodium citrate

a. *Almadrate sulfate.* The Panel concludes that almadrate sulfate is safe for OTC use in the dose noted below, but data are insufficient to demonstrate its effectiveness in treating the symptoms of IPPUAD.

Almadrate sulfate is also known as aluminum magnesium hydroxide oxide sulfate and hydrate magnesium aluminate activated sulfate.

(1) *Safety.* The Panel believes that almadrate sulfate is safe at the dose stated below.

Since the publication of the final monograph for OTC antacid drug products on June 4, 1974 (39 FR 19862), information has been reported strongly suggesting that ingested aluminum is absorbed, resulting in increased blood and brain levels of aluminum (Ref. *1*). Experimental evidence suggests that hyperparathyroidism, such as found in patients with severe kidney disease, may further increase the ability of the body to absorb aluminum and cause increased deposition in the brain which may lead to encephalopathy. An appropriate warning is included under the heading "Labeling" section below.

(2) *Effectiveness.* Almadrate sulfate is a chemical combination of aluminum hydroxide and magnesium sulfate which, in the presence of gastric hydrochloric acid, forms aluminum hydroxide (the principal active antacid) and magnesium chloride (Ref. *2*). The Panel could find no reports in the medical or pharmaceutical literature regarding the use of this ingredient for treatment of the symptoms of IPPUAD. Almadrate sulfate has been evaluated by the Advisory Review Panel on OTC Antacid Drug Products, in a report published in the **Federal Register** of April 5, 1973 (38 FR 8714). The agency concurred with the evaluation of that Panel and placed almadrate sulfate in Category I as an antacid (21 CFR 331). One series of studies submitted to this Panel failed to distinguish between the accepted antacid activity of almadrate sulfate and its effectiveness in relieving the symptoms of IPPUAD (Ref. *2*). The Panel therefore recommends that almadrate sulfate be tested according to the proposed testing guidelines to determine whether or not it is effective for the treatment of the symptoms of IPPUAD.

(3) *Proposed dosage.* The Panel believes that it is not possible to impose strict dosage limitations at this time, because there are so little data upon which to base a recommended effective dose. However, the Panel believes that the usually administered dosage of up to 1.7 g four times daily is safe for OTC use but should not be taken for longer than 2 weeks except upon the advice of a physician.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used for the treatment of symptoms of IPPUAD. (See part III. paragraph A.2. above—Category I labeling.) In addition, the Panel recommends that the following warnings statements be required to appear in the labeling of drug products containing almadrate sulfate:

(i) "If you have kidney disease, do not use this product except under the supervision of a physician."

(ii) "If you are taking other drugs, consult your physician as this drug may interfere with their effectiveness."

(iii) "Do not take for longer than 2 weeks or in greater than recommended amounts, except upon the advice of a physician."

(5) *Evaluation.* The Panel recommends that adequate testing of almadrate sulfate be performed according to the proposed testing guidelines to determine whether or not it is effective for treatment of the symptoms of IPPUAD. (See part III. paragraph D.1. below—Guidelines for developing a protocol for evaluating OTC drugs used for the treatment of the symptoms of IPPUAD.)

References

(*1*) Mayor, G. H., J. A. Keiser, D. Makdani, and P. K. Ku, "Aluminum Absorption and Distribution: Effect of Parathyroid Hormone," *Science*, 197:1187–1189, 1977.

(*2*) OTC Volume 170128.

b. *Aluminum hydroxide.* The Panel concludes that aluminum hydroxide is safe for OTC use in the dose noted below, except for individuals with severe kidney diseases, but data are insufficient to demonstrate its effectiveness in treating the symptoms of IPPUAD.

(1) *Safety.* Aluminum hydroxide has been widely used as an antacid and has been evaluated as safe for this use by the Advisory Review Panel on OTC Antacid Products, in a report published in the **Federal Register** of April 5, 1973 (38 FR 8714). FDA concurred with the evaluation of that Panel regarding the safety of aluminum hydroxide (21 CFR 331).

Since the publication of the final monograph for OTC antacid drug products on June 4, 1974 (39 FR 19862), information has been reported that strongly suggests that ingested aluminum is absorbed, resulting in increased blood and brain levels of aluminum (Ref. *1*). Experimental evidence suggests that hyperparathyroidism, such as found in patients with severe kidney disease, may further increase the ability of the body to absorb aluminum and cause increased deposition in the brain which may lead to encephalopathy. An appropriate warning is included below under the heading "Labeling."

Aluminum hydroxide has the potential for affecting the actions of various drugs, including tetracyclines, phenothiazines, isoniazid, oral anticoagulants, anticholinergics, barbiturates, quinine, quinidine, and digoxin (Refs. *2* and *3*). The Panel believes that the lableing of antacids containing aluminum should alert the consumer to potential drug interactions as specified below under the heading "Labeling."

(2) *Effectiveness.* Aluminum hydroxide reacts with hydrocholoric acid in the stomach to form aluminum chloride. However, preparations of aluminum hydroxide vary widely in their capacity to neutralize acid. On the average, each ml of aluminum hydroxide gel neutralizes 1.2 to 2.5 meq of acid, and 1 g of the dried compound neutralizes 25 meq of acid (Ref. *4*).

Aluminum hydroxide is considered to be a potentially useful drug for the treatment of the symptoms of IPPUAD. Further testing according to the proposed testing guidelines should be conducted to determine whether or not it is effective.

(3) *Proposed dosage.* The Panel concludes that aluminum hydroxide is safe in the usually recommended doses up to 500 mg taken between meals and at bedtime with a maximum daily dose of 2 g, but should not be taken for longer than 2 weeks except upon the advice of a physician.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of IPPUAD. (See part III. paragraph A.2. above—Category I labeling.) In addition, the Panel recommends that the following warning statements be required to appear in the labeling of drug products containing aluminum hydroxide.

(i) "If you are taking other drugs, consult your physician as this drug may interfere with their effectiveness."

(ii) "If you have kidney disease, do not take this product except under the supervision of a physician."

(iii) "Do not take for longer than 2 weeks or in greater than recommended amounts, except upon the advice of a physician."

(5) *Evaluation.* The Panel recommends that adequate testing of aluminum hydroxide (specifying the degree of reactivity) be performed according to the proposed testing guidelines to determine whether or not it is effective for treatment of the symptoms of IPPUAD. (See part III. paragraph D.1. below—Guidelines for developing a protocol for evaluating OTC drugs for the treatment of the symptoms of IPPUAD.)

References

(*1*) Mayor, G. H., J. A. Keiser, D. Makdani, and P. K. Ku, "Aluminum Absorption and Distribution: Effect of Parathyroid Hormone," *Science*, 197:1187–1189, 1977.

(*2*) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, p. 1036, 1977.

(*3*) "Evaluations of Drug Interactions," American Pharmaceutical Association, 2d Ed., Washington, pp. 25 and 227, 1976.

(*4*) Harvey, S. C., "Gastric Antacids and Digestants," *in* "The Pharmacological Basis of Therapeutics," 5th Ed., edited by L. S. Goodman and A. Gilman, The MacMillan Co., New York, pp. 961–962, 1975.

c. *Calcium carbonate.* The Panel concludes that calcium carbonate is safe for OTC use in the dose noted below, but data are insufficient to demonstrate its effectiveness in treating the symptoms of IPPUAD.

(1) *Safety.* Calcium carbonate was reviewed by the Advisory Review Panel on OTC Antacid Products, in a report published in the **Federal Register** of April 5, 1973 (38 FR 8714). FDA concurred with the evaluation of that Panel regarding the safety of the drug (21 CFR 331) when taken in a dosage of not more than 8 g per day. The Panel concurs that such a dosage is safe when used for relief of symptoms of IPPUAD.

Some antacids are known to decrease the effectiveness of many drugs and an appropriate warning must be included on the label. In addition, the Panel is concerned with other potentially unsafe characteristics of excessive amounts of calcium carbonate. Documented adverse reactions which are well known include alkalosis, hypercalcemia, acid rebound, milk-alkali syndrome, and constipation. These reactions usually occur with igestion of larger than recommended doses and/or with chronic engestion (Ref. *1*). Appropriate warnings are included below under the heading "Labeling."

(2) *Effectiveness.* Calcium carbonate acts to neutralize acid in the stomach, releasing carbon dioxide in the process. It has been suggested that increasing the pH of the stomach contents results in more rapid emptying and that rapid emptying relieves the symptoms of IPPUAD (Ref. *2*). It has also been suggested that carbon dioxide released by calcium carbonate in the stomach increases gastric distention which is also conducive to more rapid gastric emptying. To the Knowledge of the Panel no one has conclusively established a correlation between gastric emptying time and symptoms of IPPUAD, and the actual pathogenesis of this syndrome remains in doubt.

Although studies were presented comparing calcium carbonate to placebo (Refs. *3* and *4*) and to simethicone (Ref. *2*) in an attempt to demonstrate relief of the symptoms of IPPUAD, the Panel considered these studies to be unsatisfactory with respect to test design, setting, and method of sample population selection. The Panel therefore recommends that calcium carbonate be tested according to the proposed testing guidelines to determine whether or not it is effective in relieving the symptoms of IPPUAD.

(3) *Proposed dosage.* The Panel concurs with § 331 (21 CFR 331) that calcium carbonate is safe in a dose of not more than 8 g/day taken in four divided doses, but should not be taken for longer than 2 weeks except upon the advice of a physician.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of IPPUAD. (See part III. paragraph A.2. above—Category I labeling.) In addition, the Panel recommends that the following warning statements be required to appear in the labeling of drug products containing calcium carbonate:

(i) "If you are taking other drugs, consult your physician as this drug may interfere with their effectiveness."

(ii) "Do not take for longer than 2 weeks or in greater than recommended amounts, except on the advice of a physician."

(5) *Evaluation.* The Panel recommends that adequate testing of calcium carbonate be performed according to the proposed testing guidelines to determine whether or not it is effective for treatment of the symptoms of IPPUAD. (See part III. paragraph D.1. below—Guidelines for developing a protocol for evaluating OTC drugs for the treatment of the symptoms of IPPUAD.)

References

(*1*) Levant, J. A., J. H. Walsh, and J. I. Isenberg, "Stimulation of Gastric Secretion and Gastrin Release by Single Oral Doses of Calcium Carbonate in Man," *New England Journal of Medicine*, 289:555–558, 1973.

(*2*) OTC Volume 170053.

(*3*) OTC Volume 170098.

(*4*) OTC Volume 170058.

d. *Dihydroxyaluminum sodium carbonate.* The Panel concludes that dihydroxyaluminum sodium carbonate (DASC) is safe for OTC use in the dose noted below, except for individuals with severe kidney diseases, but data are insufficient to demonstrate its effectiveness in treating the symptoms of IPPUAD.

(1) *Safety.* DASC was reviewed by the Advisory Review Panel on OTC Antacid Products, in a report published in the **Federal Register** of April 5, 1973 (38 FR 8714), and found "* * * safe in amounts usually taken orally in antacid products * * *" (38 FR 8717). That Panel established that the maximum safe daily dosage of antacids containing sodium is 200 meq of sodium for persons under 60 years of age and 100 meq for persons aged 60 or older (38 FR 8719). This Panel agrees with this dosage restriction and the warning statement for those persons who are on a sodium-restricted diet (38 FR 8719). FDA also concurs with these recommendations (21 CFR Part 331).

Since the publication of the final monograph for OTC antacid drug products on June 4, 1974 (39 FR 19862), information has been reported strongly suggesting that ingested aluminum is absorbed, resulting in increased blood and brain levels of aluminum (Ref. *1*). Experimental evidence suggests that hyperparathyroidism, such as found in patients with severe kidney disease, may further increase the ability of the body to absorb aluminum and cause increased deposition in the brain which may lead to encephalopathy. An appropriate warning is included below under the heading "Labeling."

The Panel agrees that DASC is safe for individuals who are not on a sodium-restricted diet when taken for symptomatic treatment of IPPUAD in a dosage of up to 8 g in a 24-hour period by those persons not on a sodium-restricted diet (Ref. *2*).

Some antacids are known to interact adversely with such drugs as digoxin, isoniazid, sodium polystyrene sulfonate, and oral tetracyclines (Ref. *3*). A warning concerning the possibility of interactions with other drugs must be included on the label.

(2) *Effectiveness.* DASC acts as a buffering antacid in the stomach. Reaction products are sodium ion, carbon dioxide, and aluminum chloride (Ref. *2*). Such reactions would be expected to shorten the emptying time of the stomach and alter mechanical pressures as well as having a neutralizing effect on gastric contents.

Submissions received by the Panel included four research reports for evaluating the effectiveness of DASC in relieving the symptoms of IPPUAD. Of these, one study used either one or two tablets each of two presumably active

preparations which were taken before, during, or after meals (Ref. *4*). The medications were undisguised; the study was not placebo controlled and was based on a diary method of reporting symptoms, some of which were clearly in the spectrum of hyperacidity. The Panel considered the data unreliable due to defects in the protocol.

Another study was well designed and supervised and demonstrated effectiveness only at a p value of 0.083 (Ref. *5*). A third study evaluated results in 99 subjects using the diary method (Ref. *6*). The subjects took the tablets before, during, or after meals, and the study showed no statistical difference between the active substances and placebo in providing relief from the symptoms of IPPUAD. This evaluation postulated that menthol, used as a flavoring agent, might actually be an active ingredient. The same question was raised in a fourth study which also revealed no statistical difference between DASC and placebo in relief of IPPUAD symptoms (Ref. *7*). In view of these inconclusive results the Panel recommends that further testing be performed according to the proposed testing guidelines to determine whether or not DASC is effective for relief of the symptoms of IPPUAD.

(3) *Proposed dosage.* Dihydroxylauminum sodium carbonate is safe when taken in doses not to exceed a total of 8 g (55 meq of sodium) in a 24 hour period, but should not be taken for longer than 2 weeks except under the advice of a physician (Ref. *2*).

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of IPPUAD. (See part III. paragraph A.2. above—Category I labeling.) In addition, the Panel recommends that the following warning statements be required to appear in the labeling of drug products containing DASC:

(i) "If you are taking other drugs, consult your physician as this drug may interfere with their effectiveness."

(ii) "If you have kidney disease, do not take this product except under the supervision of a physician."

(iii) "Do not take for longer than 2 weeks or in greater than recommended amounts, except on the advice of a physician."

(iv) *For products containing more than 5 meq of sodium in the maximum recommended daily dose.* "If you are on a sodium-restricted diet, do not use this product except under the supervision of a physician."

(5) *Evaluation.* The Panel recommends that adequate testing of dihydroxyaluminum sodium carbonate (DASC) be performed according to the proposed testing guidelines to determine whether or not it is effective for treatment of the symptoms of IPPUAD. (See part III. paragraph D.1. below—Guidelines for developing a protocol for evaluating OTC drugs for the treatment of the symptoms of IPPUAD.)

References

(*1*) Mayor, G. H., J. A. Keiser, D. Makdani, and P. K. Ku, "Aluminum Absorption and Distribution: Effect of Parathyroid Hormones," *Science*, 197:1187–1189, 1977.

(*2*) OTC Volume 170061.

(*3*) "Adverse Interactions of Drugs," *The Medical Letter on Drugs and Therapeutics*, The Medical Letter, Inc., New Rochelle, NY, 19:8–9, 1977.

(*4*) OTC Volume 170061 (Research report 966–0004—Section V.C.1.c.).

(*5*) OTC Volume 170061 (Research report 955–0787—Section V.C.1.d.).

(*6*) OTC Volume 170137 (Research report 955–0880).

(*7*) OTC Volume 170137 (Research report 955–0892).

e. *Magnesium hydroxide.* The Panel concludes that magnesium hydroxide is safe for OTC use in the dose noted below, but data are insufficient to demonstrate its effectiveness in treating the symptoms of IPPUAD.

(1) *Safety.* If kidney function is normal, magnesium hydroxide is considered safe for use when taken in the dosage noted below.

Magnesium hydroxide is generally considered to be a poorly absorbed antacid. However, absorption of as little as 5 to 10 percent (Ref. *1*) to as much as 15 to 30 percent (Ref. *2*) has been reported. It is well known that excessive magnesium blood levels may result from ingestion of magnesium by persons with kidney damage, and, therefore, a warning label should be present on any magnesium hydroxide preparation in which the maximal daily dose exceeds 50 meq of magnesium.

Magnesium hydroxide has the potential for drug interactions with bishydroxycoumarin and related anticoagulants (Ref. *3*), and tetracycline antibiotics (Ref. *4*). The Panel believes that the consumer should be alerted to the potential for drug interactions and recommends that a warning appear on the label.

(2) *Effectiveness.* Convincing data supporting the effectiveness of magnesium hydroxide in the treatment of the symptoms of IPPUAD have not been presented. The Panel considers magnesium hydroxide to be a potentially useful drug for the treatment of the symptoms of IPPUAD and recommends that it be tested according to the proposed testing guidelines to determine whether or not it is effective.

(3) *Proposed dosage.* The Panel concludes that the OTC use of magnesium hydroxide is safe in the usual recommended dose of up to 15 mL of a suspension of up to 8.5 percent magnesium hydroxide taken three to four times daily (Ref. *1*). This is equivalent to a total daily dose of up to 5.1 g of magnesium hydroxide, but should not be taken for more than 2 weeks except upon the advice of a physician.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of IPPUAD. (See part III. paragraph A.2. above—Category I labeling.) In addition, the Panel recommends that the following warning statements be required to appear in the labeling of drug products containing magnesium hydroxide:

(i) "If you are taking other drugs, consult your physician as this drug may interfere with their effectiveness."

(ii) "Do not take for longer than 2 weeks or in greater than recommended amounts, except upon the advice of a physician."

(iii) *For products containing more than 50 meq of magnesium in the recommended daily dosage.* "If you have kidney disease, do not use this product except under the supervision of a physician."

(5) *Evaluation.* The Panel recommends that adequate testing of magnesium hydroxide be performed according to the proposed testing guidelines to determine whether or not it is effective for treatment of the symptoms of IPPUAD. (See part III. paragraph D.1. below—Guidelines for developing a protocol for evaluating OTC drugs for the treatment of the symptoms of IPPUAD.)

Magnesium hydroxide has also been reviewed by this Panel for treatment of the symptoms of intestinal distress and the conclusions are included elsewhere in this document. (See part IV. paragraph C.1.d. below—Magnesium hydroxide.)

References

(*1*) Harvey, S. C., "Gastric Antacids and Digestants," *In* "The Pharmacological Basis of Therapeutics," 5th Ed., edited by L. S. Goodman and A. Gilman, The MacMillan Co., New York, pp. 964–965, 1975.

(*2*) Dretchen, K., D. Hollander, and J. B. Kirsner, "Roundup on Antacids and Anticholinergics, *"Patient Care*, 9:94–114, 1975.

(*3*) Ambre, J. J., and L. J. Fischer, "Effect of Co-Administration of Aluminum and Magnesium Hydroxides on Absorption of Anticoagulants in Man," *Clinical Pharmacology and Therapeutics*, 14:231–237, 1973.

(*4*) Hussar, D. A., "Drug Interactions," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by A. Osol and J. E. Hoover, Mack Publishing Co., Easton, PA, p. 1741, 1975.

f. *Magnesium trisilicate.* The Panel concludes that magnesium trisilicate is safe for OTC use in the dose noted below, but data are insufficient to demonstrate its effectiveness in treating the symptoms of IPPUAD.

(1) *Safety.* If kidney function is normal, magnesium trisilicate is generally considered safe for use when taken in the dosage cited below.

One study reviewed by the Panel showed that significant elevation of serum magnesium resulted from the oral ingestion of magnesium trisilicate in some subjects (Ref. *1*). The dosage used in this study was in excess of that being recommended by the Panel.

It is well known that excessive magnesium levels may result from magnesium ingestion by persons with kidney damage. The Panel concurs with the Advisory Review Panel on OTC Antacid Drug Products (38 FR 8714) and with FDA (21 CFR Part 331) that a warning label should be present on any magnesium trisilicate preparation for which the maximal daily dose exceeds 50 meq of magnesium (38 FR 8719).

There is also an increase in silica absorption from ingestion of magnesium trisilicate, but formation of silica renal calculi has rarely been associated with magnesium trisilicate ingestion (Ref. *2*).

Mangesium trisilicate has been found to absorb various alkaloids and antibiotics in vitro under certain conditions (Refs. *3* and *4*). The possibility of drug interactions involving magnesium trisilicate should be more adequate explored.

(2) *Effectiveness.* Magnesium trisilicate reacts with gastric acid to form hydrated silica gel and magnesium ion for acid neutralization. Hydrated silica gel is known to have absorptive and antifoam properties in addition to antacid properties (Ref. *5*). There is partial gastrointestinal absorption of magnesium ion and silicate with subsequent excretion via the kidney in the normal person.

Magnesium trisilicate has been demonstrated to have antifoam action in vitro (Ref. *5*) but data are insufficient to demonstrate its effectiveness in treating the symptoms of IPPUAD.

The Panel reviewed two submitted studies that suggest the effectiveness of magnesium trisilicate in treating the symptoms of IPPUAD (Ref. *6*). However, the Panel was concerned with some of the details of the studies, particularly the selection of the subjects. Other studies discussed the effect of magnesium trisilicate on gas (Ref. *7*); the Panel, however, does not accept gas as the cause of the IPPUAD symptoms. The Panel recommends further testing according to the proposed protocol to determine whether or not magnesium trisilicate is effective in treating the symptoms of IPPUAD.

(3) *Proposed dosage.* The Panel concludes that magnesium trisilicate is safe at a maximum dose of 1 g three times daily, but should not be taken for longer than 2 weeks except upon the advice of a physician.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of IPPUAD. (See part III. paragraph A.2. above—Category I labeling.) In addition, the Panel recommends that the following warning statements be required to appear on the labeling of drug products containing magnesium trisilicate:

(i) "If you are taking other drugs, consult your physician as this drug may interfere with their effectiveness."

(ii) "Do not take for longer than 2 weeks or in greater than recommended amounts, except on the advice of a physician."

(iii) *For products containing more than 50 meq of magnesium in the recommended daily dosage.* "If you have kidney disease, do not use this product except under the supervision of a physician."

(5) *Evaluation.* The Panel recommends that adequate testing of magnesium trisilicate be performed according to the proposed testing guidelines to determine whether or not it is effective for treatment of the symptoms of IPPUAD. (See part III. paragrapn D.1. below—Guidelines for developing a protocol for evaluating OTC drugs for the treatment of the symptoms of IPPUAD.)

References

(*1*) West, E. S., and C. Pennoyer, "Some Effects of Magnesium Trisilicate Ingestion Upon Blood, Urine, and Feces of Human Subjects," *American Journal of Digestive Diseases,* 12:199–202, 1945.

(*2*) Joekes, A. M., G. A. Rose, and J. Sutor, "Multiple Renal Silica Calculi," *British Medical Journal,* 1:146–147, 1973.

(*3*) El-Nakeeb, M. A., and R. T. Yousef, "Influence of Various Materials on Antibiotics in Liquid Pharmaceutical Preparations," *Acta Pharmaceutica Suecica,* 5:1–8, 1968.

(*4*) Khalil, S. A., and M. A. Moustafa, "The In-Vitro-Adsorption of Some drugs on Antacids," *Pharmazie,* 28:116–118, 1973.

(*5*) OTC Volume 170054.

(*6*) OTC Volume 170054 (Studies I and II).

(*7*) OTC Volume 170054 (Research Reports 932–0332 and 950–0001).

g. *Peppermint oil.* The Panel concludes that peppermint oil is safe for OTC use in the dose noted below, but data are insufficient to demonstrate its effectiveness in treating the symptoms of IPPUAD.

Oil of peppermint is the rectified volatile oil obtained by distillation from the fresh leaves and stems of *Mentha piperita.* It contains not less than 50 percent menthol both as the alcohol and as the menthyl acetate ester (Ref. *1*). The other constituents are a complex of numerous terpenes and aliphatic alcohols, aldehydes, and acids.

(1) *Safety.* Peppermint oil has been in substantial use for many years with no reports of clinical toxicity, although volatile oils as a group are generally regarded as potent substances. It is important to distinguish between oil of peppermint and "spirit" of peppermint since the potency of the oil is ten times as potent as the spirit. Oil of peppermint has been used extensively in pharmaceutical preparations with no known adverse effects, and the Panel concludes that it is safe in a maximum dose of 0.3 mL daily.

About 70 percent of the annual domestic production of peppermint oil, representing millions of pounds, is used in confections and foods.

(2) *Effectiveness.* Clinical and pharmacological studies have described the action of oil of peppermint (Refs. *1* through *11*). The physiologic action of the oil is to decrease gastric emptying time, relax the lower esophageal sphincter, increase gastric secretion and stomach motility, and either stimulate or inhibit muscular activity of isolated intestinal tissue, depending on the concentration.

The Panel knows of no study which demonstrates that oil of peppermint is effective in relieving the symptoms of IPPUAD. However, due to its known physiologic effects on the stomach, the Panel recommends that it be tested in order to determine whether or not it is effective for this indication.

The Panel recognizes that oil of peppermint is used as a flavoring agent in many pharmaceutical formulations, but in the quantities used it would have no benefit in relieving the symptoms of IPPUAD.

(3) *Proposed dosage.* The dosage of oil of peppermint considered to be safe is no more than 0.1 mL (approximately 1 drop) per dose three times a day, a total daily maximum of 0.3 mL. This dosage is based on the dose of peppermint spirit, as an official preparation in National Forumlary XIV, of 1 mL three times daily. Peppermint oil is the primary constituent of the spirit in a concentration of 10 percent.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of IPPUAD. (See part III: paragraph A.2. above—Category I labeling.)

(5) *Evaluation.* The Panel recommends that data be required to determine whether or not peppermint oil is effective in relieving the symptoms of

IPPUAD; however, the proposed testing guidelines may not be appropriate since double-blind studies are probably precluded for this ingredient. (See part III. paragraph D.1. below—Guidelines for developing a protocol for evaluating OTC drugs for the treatment of the symptoms of IPPUAD.)

References

(*1*) Swinyard, E. A., and W. Lowenthal, "Pharmaceutical Necessities," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by A. Osol and J. E. Hoover, Mack Publishing Co., Easton, PA, p. 1233, 1975.

(*2*) Sapoznik, H. I., R. A. Arens, J. Meyer, and H. Necheles, "The Effect of Oil of Peppermint on the Emptying Time of the Stomach," *Journal of the American Medical Association*, 104:1792–1794, 1935.

(*3*) Sigmund, C. J., and E. F. McNally, "The Action of a Carminative on the Lower Esophageal Sphincter," *Gastroenterology*, 56:13–18, 1969.

(*4*) Meyer, J., L. Scheman, and H. Necheles, "Action of Oil of Peppermint on the Secretion and Motility of the Stomach in Man," *Archives of Internal Medicine*, 56:88–97, 1935.

(*5*) van Liere, E. J., and D. W. Northrup, "The Effect of Carminatives on the Emptying Time of the Normal Human Stomach," *Journal of Pharmacology and Experimental Therapeutics*, 76:39–43, 1942.

(*6*) Necheles, H., and J. Meyer, "On the Inhibition of Gastric Secretion by Oil of Peppermint," *American Journal of Physiology*, 110:686–691, 1935.

(*7*) Plant, O. H., "The Effect of Carminative Volatile Oils on the Muscular Movements of the Intestine," *Journal of Pharmacology and Experimental Therapeutics*, 16:311–325, 1921.

(*8*) Plant, O. H., and G. H. Miller, "Effects of Carminative Volatile Oils on the Muscular Activity of the Stomach and Colon," *Jounal of Pharmacology and Experimental Therapeutics*, 26:149–164, 1926.

(*9*) Muirhead, A. L., and H. F. Gerald, "The Action of Certain Volatile Oils on Isolated Intestinal Segments," *The Journal of Pharmacology and Experimental Therapeutics*, 8:253–260, 1916.

(*10*) Berk, J. E., "Gastrointestinal Gas," *Annals of the New York Academy of Sciences*, 150:178–190, 1968.

(*11*) Thompson, W. G., "Burbulence (Indigestion Due to Gas)," *Canadian Medical Association Journal*, 106:1220, 1972.

h. *Simethicone.* The Panel concludes that simethicone is safe for OTC use in the dose noted below, but available evidence is insufficient to demonstrate its effectiveness in treating the symptoms of IPPUAD.

(1) *Safety.* The Panel concurs with the determination of FDA, as stated in the antiflatulent final monograph (21 CFR 332.10), that simethicone is safe in a maximum daily dosage of 500 mg as an OTC product.

Simethicone is a mixture of dimethylpolysiloxane and approximately 5 percent silica gel. Toxicological studies and the wide use of dimethylpolysiloxane in chemical combination with silica gel for many years without evidence of adverse effects have established its safety for human use (Ref. *1*). This Panel has determined that silica gel is nontoxic in normally ingested amounts (Ref. *2*).

(2) *Effectiveness.* The Panel, in reviewing all submissions of data and information on drug products containing simethicone that claim to receive the symptoms of IPPUAD, and in reviewing the current literature, concludes that there are insufficient data demonstrating that simethicone is effective in the OTC treatment of the symptoms of IPPUAD.

Dimethylpolysiloxane has been used in many food preparations as an antifoam agent since 1947. Silica gel is added as a dispersing agent and adsorbs the dimethylpolysiloxane, probably by hydrogen bonding. In a study by Birtley et al. (Ref. *3*), this combination was found to be more effective than either agent alone in reducing foam produced in rat stomachs.

The antifoaming properties of simethicone have been established in vitro (Ref. *4*), and simethicone has been demonstrated to decrease the presence of foam or bubbles found occasionally in the human stomach during gastroscopy. Its use as an antifoaming agent has been recommended as a treatment for bloating in ruminants, in which its use would permit "* * * gases to pass freely through the food mass" (Ref. *5*). Other researchers have been disappointed in the results of using silicones to prevent foaming of ingested material in ruminants (Ref. *6*).

One research group has proposed several hypotheses for small gas bubbles causing gastrointestinal symptoms in humans: the small bubbles may be tenacious and resist movement, the specific gravity of multiple small bubbles having a mucus covering is greater than that of the same gas in the free form, and there is resistance to deformation of a bubble wall due to the effects of surface tension (Ref. *7*). The group further postulated that surface tension is not a factor when air is not entrapped in bubbles, resistance of the mucus-entrapped gas may result in decreased movement through narrowed portions of the gut, the resistance is not as great for free gas, and the total liquid volume (liquid and entrapped gas) of the gastrointestinal tract will be decreased by the elimination of the gas trapped in the mucus.

Although the above hypotheses may be valid, the Panel is not aware of any evidence which actually establishes that small bubbles entrapped in mucus are the cause of the symptoms of IPPUAD. The Panel, therefore, concludes that data are insufficient to demonstrate that simethicone is effective in treating the symptoms of IPPUAD, notwithstanding its action on gas bubbles in the stomach. Further testing according to the proposed testing guidelines should be performed to determine whether or not simethicone is effective in relieving the symptoms of IPPUAD.

(3) *Proposed dosage.* The Panel concludes that a maximum recommended daily dosage of 500 mg of simethicone is safe (21 CFR 332.10) for treatment of IPPUAD.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of IPPUAD. (See part III. paragraph A.2. above—Category I labeling.)

(5) *Evaluation.* The Panel has extensively reviewed the pertinent literature and listened to medical gastrointestinal experts, and to the best of the Panel's knowledge, no data have been presented which demonstrate to the satisfaction of the Panel that gas is the etiologic agent of IPPUAD. Therefore, the Panel concludes that data are insufficient to demonstrate the effectiveness of simethicone for OTC use in relieving the specific symptoms of IPPUAD: Bloating, distention, fullness, and pressure.

In arriving at its decision, the Panel is aware of FDA's conclusion regarding antiflatulent products (21 CFR Part 332). The agency concluded that simethicone is an effective antiflatulent drug. This Panel emphasizes that no convincing evidence was submitted that demonstrates that "gas" is the cause of IPPUAD. The Panel recommends that adequate testing be performed according to the proposed testing guidelines to determine whether or not simethicone is effective for treatment of the symptoms of IPPUAD. (See part III. paragraph D.1. below—Guidelines for developing a protocol for evaluating OTC drugs for the treatment of the symptoms of IPPUAD.) Special attention must be paid to the addendum to the proposed protocol for products wishing to claim "anti-gas" activity.

Simethicone has been further reviewed by this Panel for treating the symptoms of intestinal distress and the conclusions are included elsewhere in this document. (See part IV. paragraph C.1.f below—Simethicone.)

References

(*1*) Rowe, V. K., H. C. Spencer, and S. L. Bass, "Toxicological Studies on Certain Commercial Silicones: II. Two Year Dietary Feeding of DC 'Antifoam A' to Rats," *Archives of Industrial Hygiene and Occupational Medicine*, 1:539–544, 1950.

(*2*) OTC Volume 170054.

(3) Birtley, R. D. N., et al., "The Effect of Free Silica on the Mucosal Protective and Antiflatulent Properties of Polydimethylsiloxane," *Journal of Pharmacy and Pharmacology*, 25:859–863, 1973.

(4) Rider, J. A., "Experience with the Use of a Defoaming Agent in the Treatment of Gastrointestinal Gas," *Annals of the New York Academy of Sciences*, 150:170–178, 1968.

(5) Barondes, R. de R., W. D. Judge, C. G. Towne, and M. L. Baxter, "The Silicones of Medicine," *The Military Surgeon*, 106:379–387, 1950.

(6) Berk, J. E., Moderator, "Panel Discussion: Part III," *Annals of the New York Academy of Sciences*, 150: 178–190, 1968.

(7) Comments to Antacid Proposed Monograph, Docket No. 75N–0357, C00010, Volume II, Exhibit C, Plough, Inc. (6/1/73), pp. 67–80, in Panel Administrator's File (OTC Volume 17GPAII).

i. *Sodium bicarbonate.* The Panel concludes that sodium bicarbonate is safe for OTC use in the doses noted below, but data are insufficient to demonstrate its effectiveness in treating the symptoms of IPPUAD.

(1) *Safety.* Sodium bicaronate (baking soda) is an alkalinizing agent which releases carbon dioxide when neutralized by acid. Sodium bicarbonate has a long history of use as an antacid and for the symptomatic relief of upper addominal distress. It may be used as an ingredient in effervescent preparations in which the alkali is buffered or partially neutralized by an acidic compound. The Panel considers sodium bicarbonate to be safe when used as specified in the dosage section below, and under the labeling restrictions noted.

(2) *Effectiveness.* The Panel is not aware of any scientific evidence which establishes the effectiveness of sodium bicarbonate as a treatment for the symptoms of IPPUAD.

One gram of sodium bicarbonate will neutralize approximately 115 mL of O.1 N hydrochloric acid, releasing carbon dioxide (Ref.*1*). Reduction of gastric acidity, decreasing gastric emptying time, and the belching of carbon dioxide alter intragastric pressures. The Panel considers sodium bicarbonate to be a potentially useful drug for the treatment of the IPPUAD syndrome, and recommends further testing according to the proposed testing guidelines to determine whether or not it is effective.

(3) *Proposed dosage.* This Panel concurs with the recommendation of the Advisory Review Panel on OTC Antacid Drug Products published in the **Federal Register** of April 5, 1973 (38 FR 8714), that a maximum safe daily dosage of preparations containing sodium is 200 meq of sodium for persons under 60 years of age and 100 meq for persons aged 60 years or older (38 FR 8719). Because of the sodium content the dose of sodium bicarbonate should not exceed 16.8 g (200 meq of sodium) per day.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of IPPUAD. (See part III. paragraph A.2. above—Category I labeling.)

The Panel concurs with the recommendation of the Advisory Review Panel on OTC Antacid Drug Products, published in the **Federal Register** of April 5, 1973 (38 FR 8714), that a warning statement should be required on preparations containing sodium (38 FR 8719). This Panel recommends that the following warning statements be required in the labeling of preparations containing sodium:

(i) "If you are 60 years of age or older, the maximum *daily* dose should not exceed 8.4 g 1 heaping teaspoon) of this drug."

(ii) "Do not take for longer than 2 weeks or in greater than recommended amounts, except upon the advice of a physician."

(iii) *For products containing more than 5 meq of sodium in the recommended daily dose.* "If you are on a sodium-restricted diet, do not use this product except under the supervision of a physician."

(5) *Evaluation.* The Panel recommends that adequate testing of sodium bicarbonate be performed according to the proposed testing guidelines to determine whether or not it is effective for treatment of the symptoms of IPPUAD. (See part III. paragraph D.l. below—Guidelines for developing a protocol for evaluating OTC drugs for the treatment of the symptoms of IPPUAD.)

Sodium bicarbonate has been further reviewed by this Panel for treatment of the symptoms of intestinal distress and the conclusions are included elsewhere in this document. (See part IV. paragraph C.l.g. below—Sodium bicarbonate.)

Refference

(*1*) *Swinyard, E. A., "Gastrointestinal Drugs," in* "Remington's Pharmaceutical Sciences," 15th ED., edited by A. Osol and J. E. Hoover, Mack Publishing Co., Easton, PA, pp. 736–737, 1975.

j. *Sodium citrate.* The Panel concludes that sodium citrate (sodium salt of citric acid) is safe for OTC use in the dose noted below, but data are insufficient to demonstrate its effectiveness in treating the symptoms of IPPUAD.

(1) *Safety.* Sodium citrate was reviewed by the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Drug Products, in a report published in the **Federal Register** of September 9, 1976 (41 FR 38367), and found to be safe when used within the dosage limitation of 24 g daily. This Panel concurs with the antacid monograph (21 CFR 331) which limits the daily sodium intake to 200 meq for persons under 60 years of age and 100 meq for persons 60 years or older.

(2) *Effectiveness.* Commonly, citric acid is formulated in combination with sodium bicarbonate in a solid dosage form. When this combination is dissolved in water, effervescence occurs (carbon dioxide evolves) and the active antacid ingredient, buffered sodium citrate, is produced. The Panel is aware of the antacid property of sodium citrate but data are insufficient to demonstrate its effectiveness in relieving the symptoms of IPPUAD. The Panel recommends that sodium citrate be tested according to the proposed testing guidelines in order to determine whether or not it is effective for this indication.

(3) *Proposed dosage.* The Panel concludes that a maximum safe daily dose of preparations containing sodium is 200 meq of sodium for persons under 60 years of age and 100 meq for persons aged 60 years or older; therefore, the oral dose of sodium citrate should not exceed 17.2 g daily (200 meq of sodium).

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of IPPUAD. (See part III. paragraph A.2. above—Category I labeling.)

The Panel concurs with the recommendation of the Advisory Review Panel on OTC Antacid Drug Products, published in the **Federal Register** of April 5, 1973 (38 FR 8714), that a warning statement should be required on preparations containing sodium (38 FR 8719). This Panel recommends that the following warning statements be required in the labeling of preparations containing sodium:

(i) "If you are 60 years of age or older, the maximum *daily* dose should not exceed 8.6 g (1 heaping teaspoon) of this drug."

(ii) "Do not take for longer than 2 weeks or in greater than recommended amounts, except upon the advice of a physician."

(iii) *For products containing more than 5 meq of sodium in the recommended daily dose.* "If you are on a sodium-resticted diet, do not use this product except under the supervision of a physician."

(5) *Evaluation.* The Panel recommends that the adequate testing of sodium citrate be performed according to the proposed testing guidelines to determine whether or not it is effective for treatment of the symptoms of IPPUAD. (See part III. paragraph D.1 below—Guidelines for developing a protocol for evaluating OTC drugs for the treatment of the symptoms of IPPUAD.)

Sodium citrate has been further reviewed by this Panel for treatment of the symptoms of intestinal distress and the conclusions are included elsewhere in this document. (See part IV. paragraph C.1.h below—Sodium citrate.)

2. *Category III labeling.* The Panel has repeatedly stated that, at present, it does not accept "gas" or "excess gas" as the cause of IPPUAD. The Panel recommends that firms not use the following "anti-gas" claims for these products while they are attempting to demonstrate by objective measures that increased gas is a cause of IPPUAD symptoms and that the reduction of the volume of gas by their product is associated with a decrease in the symptoms of IPPUAD:

a. "Anti-gas."
b. "For relief of distress and/or discomfort due to gas."
c. "Reduces distress and/or discomfort caused by excess gas in the stomach."
d. "For expelling gas from the stomach."
e. "For flatulence (or gas)."
f. "Antiflatulent."
g. "Releases entrapped gas."
h. "Relieves discomfort and pain of entrapped gas."
i. "Reduces gaseousness."

The Panel requires data to substantiate any claim which reflects the specific time range of action of these drugs, and therefore places the following claim in Category III:

j. "Effective within—minutes." (anytime within 30 minutes).

This claim is compatible with the time range allowed by the Panel's proposed testing guidelines. (See part III paragraph D.1 below—Guidelines for developing a protocol for evaluating OTC drugs for the treatment of the symptoms of IPPUAD.)

Any nonspecific claim for speed of action ("Fast-acting") has been previously categorized and will not be allowed in the labeling. (See part III. paragraph B.2. above—Category II labeling.)

D. Data Required for Evaluation

Guidelines for developing a protocol for evaluating OTC drugs for the treatment of the symptoms of IPPUAD.

The Panel recognizes that currently there is a lack of guidelines for testing products used for the treatment of the symptoms of IPPUAD. It has developed a proposed protocol to aid investigators in designing tests of effectiveness for these drugs. This Panel does not imply that the protocol presented below is the only means by which these ingredients may be evaluated. However, it suggests that if an investigator's protocol deviates from this protocol, it should be discussed with appropriate FDA personnel prior to initiation of testing.

a. *Objective of the study.* The objective is to determine whether the substance under study provides significantly better relief of the symptoms of IPPUAD than placebo. This will be accomplished by use of a randomized, placebo-controlled, double-blind, crossover study design which uses a test meal to produce symptoms.

b. *Test population.* The sample population for the study will be subjects who have presented themselves to physicians complaining of symptoms occurring with some regularity and with varying frequency in the absence of organic gastrointestinal disease. The results from the study of this sample population will be assumed to be applicable to the target population, which includes those with only occasional symptoms.

c. *Test setting.* The test should be conducted by qualified gastroenterologists in a large clinic or academic setting where there may be a greater probability of obtaining the proper sample population in sufficient numbers. The extensive screening required prior to entrance into the study would probably restrict the study to subjects who have already required the services of a specialist located in a clinic or academic setting because of the persistence and frequency of their symptoms.

d. *Criteria for admisssibility into sample.* In order to exclude all but the functional gastrointestinal problems which give rise to the symptoms being evaluated, patients will have been screened to exclude significant organic disease, with special reference to gastrointestinal disorders, to the satisfaction of the gastroenterologist conducting the study.

Within 6 months preceding entrance into the study, appropriate data will have been generated on the subjects, including at least: History and physical exam, complete blood count, blood chemistries (SMA-12 or equivalent), urinalysis, gall bladder X-ray, chest X-ray, upper GI X-ray, and a guaiac test for fecal occult blood.

e. *Symtoms.* Acceptable symptoms of IPPAUD are those which occur during the test meal or within 15 minutes after the test meal and which the patient may attribute to "gas" and describe as bloating, distention, fullness, or pressure. The investigator should be certain that the meaning of the symptom(s) as described by the patient are understood.

f. *Test meal.* The symptom-producing meal must be tested by being consumed on two occasions prior to the test and the patient must repond consistently. The meal must be (1) standardized as to composition and, individually, as to amount, (2) capable of consistently producing symptoms which last more than 30 minutes in the susceptible individual (the total timed duration of the provoked symptoms should be noted), and (3) completely consumed within a standardized time period. The enviornment should be held constant during the test. The subjects should be adequately separated to prevent communication betaween them during the test meal and for a period immediately after eating. The test meals should be separated by at least 4-day intervals.

g. *Concomitant medication.* Concomitant medication, including vitamins and aspirin, is not allowed for 24 hours prior to and during the testing period. Alcohol must be avoided the day of the test meal.

h. *Test design.* The test design shall be randomized, placebo-controlled, double-blind, and crossover in which approximately half the subjects receive the placebo before the drug and approximately half receive the drug before the placebo. The drug or placebo will be taken at the time the first symptom appears, the time required to obtain clear and complete relief of symptoms will be determined, and the test will end 30 minutes after the onset of symptoms. If complete relief is not obtained, this treatment will be recorded as a failure.

If a positive control is used in addition to a placebo, a Latin square design is recommended.

If more than one person is to be tested on any day, then some of the subjects on that day should receive the placebo and the others the drug product.

i. *Analysis of data.* The statistical analysis should include at least the correlated proportions test.

j. *Number of patients.* The assumption is made that 30 percent of patients would respond to placebo. If 60 pe. cent respond beneficially to treatment, the results would be clinically significant. On this basis, at least 33 who complete the study would be sufficient to detect differences between drug and placebo that are clinically and statistically significant. (Type I error=0.05, type II error=0.20).

k. *Number of studies.* Two separate studies, each consisting of at least 33 patients who complete the study, will be required. Each study must be conducted at a different geographical site and performed by different investigators. The sample population from each site should be representative, with respect to

age and sex, of the patients at that clinic who meet the test population criteria explained above.

1. *Addendum.* For those manufacturers wishing to claim "anti-gas" on their label they must first demonstrate by acceptable objective methods that increased gas volume actually does exist in patients with immediate postprandial distress symptoms, that this gas is decreased by the drug for which they claim anti-gas activity, and that symptomatic relief is associated with this decrease.

2. *Background on the guidelines for developing a protocol for evaluating OTC drugs for the treatment of the symptoms of IPPUAD*—a. *Objective of the study.* The stated objective of the proposed protocol is "to determine whether the substance under study provides significantly better relief of symptoms of IPPUAD than placebo." Originally, the protocol was to be written to supply a proper procedure for evaluating "antiflatulent" drugs (drugs having an "anti-gas" effect) or those drugs which are claimed to relieve symptoms attributable to "gas." After extensive discussions by the Panel, in which the input of a number of experts was considered in addition to the Panel's extensive reviews of the submissions made by pharmaceutical firms for "antiflatulent" drugs, the Panel reached two important conclusions:

(1) The relationship of the presence of gas in the upper gastrointestinal tract to the symptoms of IPPUAD has not been established, and it has not been established that the removal of gas is correlated with the relief of the symptoms of IPPUAD.

(2) While the studies submitted by drug firms and reviewed by the Panel discussed "excess gas," "gaseousness," "flatulence," etc., the real concern of these studies was to establish that the drugs were effective in the relief of IPPUAD. In some cases, drugs which actually cause gas to elaborate (calcium carbonate) have been evaluated as "antiflatulent" drugs.

After reaching these conclusions, the Panel deleted the term "antiflatulent" from the proposed protocol and replaced it with "treatment of the symptoms of IPPUAD." To be judged effective by this protocol a drug does not have to demonstrate an "anti-gas" effect. However, for those desiring to make an "anti-gas" claim, an addendum to the protocol requires that they "demonstrate by acceptable objective methods that increased gas actually does exist in patients with IPPUAD symptoms, that this gas is decreased by using the drug for which they claim "anti-gas" activity, and that symptomatic relief is associated with this decrease."

b. *Test population.* The target population includes individuals who have recurrent symptoms with varying frequency but who do not have organic disease causing the symptoms. At first glance it might be thought that the ideal procedure to follow would be to obtain a random sample of this target population and use it in the study; however, from a statistical point of view this is not optimal. In order to judge the effectiveness of the drug, the individuals in the study must have the symptoms during the study so that the drug can be given to them. They must be bothered by IPPUAD to such a degree and frequency that it is possible to evoke the symptoms consistently and specifically for the study. Persons who only occasionally have the symptoms, therefore, would not be good subjects for the study. In light of this, the Panel decided that an appropriate test or sample population would be subjects "who have presented themselves to physicians complaining of symptoms occurring with some regularity and with varying frequency in the absence of organic gastrointestinal disease." The Panel believes the results of the study done on these subjects will be applicable to the target population.

c. *Test setting and criteria for admissibility into sample.* The protocol states that the study "should be conducted by qualified gastroenterologists in a large clinic or academic setting." In this way, the study would usually be restricted to subjects who have required the services of a medical specialist because of the regularity and frequency of their symptoms.

Many "antiflatulent" studies submitted to the Panel were not carried out in a clinical or academic setting and none involved the stringent admissibility criteria demanded by this protocol. After the Panel's discussion and consultation with outside experts, the protocol's settings were deemed appropriate. There exist many such settings where a large pool of admissible subjects would be available. Furthermore, while the clinical screening studies involved in the admissibility criteria are extensive, it is realistic to require them. First, the study should not include those persons with organic diseases. Second, it is assumed that the patients under consideration probably will have required the services of a specialist and already would have had many of the required studies.

The Panel recognizes that there may be other appropriate test populations, test settings, and admissibility criteria. A good valid study does not necessarily have to be restricted to those who have required the services of a medical specialist nor does it necessarily need all the extensive testing of the proposed protocol. In particular, the Panel realizes that an experienced investigator is the key element in such a study and deviations from the proposed protocol could be made and still perform a good study. The Panel suggests that if an investigator desires to perform a study whose protocol deviates from the proposed protocol on these or other matters, then these deviations should be discussed with appropriate FDA personnel prior to initiation of the study.

d. *Symptoms.* The symptoms of IPPUAD, which the patient may attribute to "gas" and describe as bloating, distention, fullness, or pressure, are all subjective. After extensive investigation, the Panel determined that a satisfactory objective measure related to IPPUAD and its relief has not yet been found.

For the protocol the term "immediate" is defined as occurring during the test meal or within 15 minutes after completion of the test meal. While the definition of IPPUAD does include symptoms occurring up to 30 minutes after the meal, the Panel decided to use 15 minutes in the protocol in order to ensure that the subjects in the study are experiencing IPPUAD and not some other condition such as intestinal distress which also may occur after a meal. Symptoms of intestinal distress have been defined as those beginning 30 minutes or later after a meal. However, in particular subjects, they may begin earlier. The Panel wanted to exclude such subjects from the study.

In the studies submitted to the Panel at least eight symptoms were investigated (bloating, distention, fullness, and pressure, plus heartburn, acid eructation, belching, and indigestion). After a review of these studies, it was determined that, except for the first four symptoms, the others might indicate conditions other than those with which the Panel is concerned. For example, heartburn and acid eructation are generally due to hyperacidity, and belching is most commonly caused by swallowed air.

It is understood that there is no agreement among individual patients with regard to the exact meaning of the four symptoms (bloating, distention, fullness, and pressure) and that it is possible that two people with exactly the same IPPUAD symptoms will use different terms to describe the condition (one person may say "distention" and others may describe the symptom as "fullness" or "bloating" or "pressure").

In order to have a meaningful statistical analysis, there must be agreement between the subjects and the investigator. To ensure this, the protocol states that "the investigator should be certain that the meaning of the symptom(s) as described by the patient is understood." The discussion between the patient and the investigator will make it clear to the investigator whether the patient is suffering from symptoms germane to this study.

e. *Test meal.* In order to test the drug under investigation, the symptoms must be produced during the study. This is the function of the test meal. It is not necessary to state explicitly in the protocol the content and amount of this meal. This will be the responsibility of the investigator. Different studies do not need to use the same test meal. The important requirements are that this symptom-producing meal must be taken twice prior to the test; and the patient must respond consistently both times. To guarantee standardization the protocol requires that:

(1) The meal must be "standardized as to composition and individually as to amount." Each patient in a study should eat the same test meal throughout the study and all patients will qualitatively receive the same meal.

(2) The meal must be "capable of consistently producing symptoms which last more than 30 minutes in the susceptible individual (the total timed duration of the provoked symptoms should be noted)." The symptoms under investigation are often of short duration. If, during the placebo and drug-administering stage of the study, complete relief is attained within 30 minutes after onset of the first symptom, this will be judged to be the result of a drug or a placebo effect. It is essential that this relief not be the natural consequence of a short duration distress.

(3) The meal should be "completely consumed within a standardized time period." The protocol does not impose the actual fixed time period in which the meal should be consumed. It is, however, essential that each study should have such a time period.

(4) Each patient will eat four meals during the complete run of the study (twice prior to the test, i.e., the placebo and drug-administering stage of the study, once before receiving the placebo and once before receiving the drug). To remove any carryover effect, both psychological and physiological, the "meals should be separated by at least 4-day intervals."

As stated in the Panel's proposed protocol, the test meal must be taken twice prior to the test and the patient must have the symptoms on both of these occasions. It was pointed out to the Panel that the inclusion of this screening process, as part of the study, might be responsible for a large dropout rate. The Panel was well aware of this and realized that a valid study might be possible without including these two screening meals. A study could consist of only two test meals: One given before the drug and one given before the placebo. A subject then would be considered included in the study only if the symptoms occurred on both occasions. This latter study has some major problems and the Panel does not recommend it. First, without the screening meals it would be uncertain if the symptoms would last 30 minutes. Second, in such a test there could possibly be a substantial number of individuals who would have symptoms on only one occasion. The temptation would then be present to attempt to include the data on these cases in the analysis. The interpretation of such an analysis is extremely difficult.

The environment should be held constant during the test and the subjects should be adequately separated to prevent communication between them. The Panel was concerned about the validity of the study's results if subjects were allowed to eat together and witness each others' distress. While there are statistical procedures which can be used with varying degrees of success to make adjustments for the possible confounding effects of environmental influence, it is best not to allow these effects to enter into the study.

Some information not mentioned in the protocol may prove useful and may be collected during and after the test meal. First, the length of time the subject takes to finish the test meal could be noted. Distress and the intensity of distress may be related to speed of eating. Second, some subjects may not consume all their meal before the onset of the symptoms. A record of the amount of food consumed up to this point might be useful if the amount of food in the stomach at the time of occurrence of symptoms is related to time of relief. Similarly, the length of time from completion of the meal to onset of distress may also produce useful information.

Although the protocol does not concern itself with relief of symptoms other than the four described above (bloating, distention, fullness, and pressure), the subjects may experience other forms of distress. A stratification or statistical control by these other symptoms may be useful in the statistical analysis but is not of prime interest to the Panel. Adjustments would be made then for possible nonhomogeneous subjects with predisposing factors to differential treatment response. Further, it might be the case that the subjects experience distress in varying degrees of intensity. A stratification or control according to this or a rating scale to quantify the intensity of distress may also be useful. If desired, a stratification or control by both "non-gas" symptoms and intensity of the protocol's symptoms may also produce useful information. A greater number of patients would be required for these additional studies.

f. *Concomitant medication.* In order not to confound, interfere with, or cloud the drug's effect, the protocol states that "concomitant medication, including vitamins and aspirin, is not allowed for 24 hours prior to and during the test period. Alcohol must be avoided during the day of the test meal."

g. *Test design.* In a study of the type of drugs under consideration, it is possible for subjects to act as their own control (receive both the drug and placebo, each at different times). Thus, a crossover is possible and most desirable. Further, to guard against any unsuspecting biases the drug should be administered in a random fashion "in which approximately half the subjects receive the placebo before the drug and approximately half receive the drug before the placebo." The double-blind feature will control biases favoring the drug coming from either subjects or the investigator.

. The subject must respond to the test meal twice as a prerequisite to entering the study and must not obtain complete relief without medication within 30 minutes. Then, if complete relief is attained after the test meal and within 30 minutes of the appearance of the first symptom and taking the medication, it is appropriate to view this as a success (drug or placebo success). The time of complete relief should be recorded. Further, rather than waiting indefinitely for complete relief, the Panel decided that if distress from any symptom continued beyond 30 minutes, then the complete relief is said not to be attained and this result should be considered a failure. The analysis of the data should involve both the time to complete relief (from appearance of first symptom to total relief) and the dichotomous variable "complete relief or incomplete relief."

In order to control for the variation related to the test meal being prepared on different days, the protocol stipulates that "if more than one person is to be tested on any day, then some of the

subjects on that day should receive the placebo and the others the drug products."

The Panel also considered the possibility that, in addition to a placebo, the study might also consist of a direct evaluation of the drug and a positive control. In such a case a Latin-square is recommended.

h. *Analysis of data.* The statistical analysis should include at least the correlated proportions test where the dependent variable is the dichotomous variable, "complete relief or incomplete relief" within 30 minutes of the onset of the first symptom. Relief that is "clear and complete relief of all symptoms" is considered to be of prime concern. In addition to this, the correlated "test" appears to be appropriate. This is especially true if relief is obtained by most subjects regardless of receiving the placebo or the drug. Analyses can also be done on the ordering effect (drug then placebo as compared to placebo then drug).

In addition to the above, analyses which take into account the stratification or knowledge of intensity of the protocol's symptoms and/or other "nongas" symptoms might be appropriate. Age and sex could also be considered here. Multiple logistic or multiple regression analyses could be employed.

Further, a comparison of the results obtained from the two different testing sites would be essential. Differences in these results should be explained.

i. *Number of patients.* At least 33 patients are required at each of at least two test sites. The quantity 33 arises from assuming that a random sample of subjects is possible and that all subjects are homogeneous in all important respects. A random sample is impossible and there are a number of factors (some stated above) on which the available subjects may be nonhomogeneous. The investigators should view the 33 patients as the minimum sample size required and be prepared to include more subjects in their studies.

j. *Number of studies.* While the test setting and admissibility criteria are considered to be appropriate and realistic, they do not guarantee that the resulting sample will be a random sample or a representative sample of the sample population. Even under the most favorable conditions it is possible that the subjects finally selected for the study will not be representative of the patients of the setting from which the subjects are being selected. In order to ensure that generally applicable results are obtained, two separate studies are required. These are to be performed by different investigators at different geographical sites. Further, the sample for each study should be representative, with respect to age and sex, of patients at that site.

The Panel has determined that researchers conducting the study should take care not to use sites with peculiar patient populations (e.g., all males over 65 years of age). It is expected that the two selected sites will offer a patient profile similar to what is believed to be the profile of the sample population. Further, researchers are expected to perform statistical analyses comparing the two sites with respect to the patients' response(s) to the drug.

IV. Drug Products for the Treatment of the Symptoms of Intestinal Distress

A. Category I Conditions

The following are Category I conditions under which drug products used for the treatment of the symptoms of intestinal distress are generally recognized as safe and effective and are not misbranded.

1. *Category I active ingredients.* None.

2. *Category I labeling.* The Panel recommends the following Category I labeling for drug products used to relieve the symptoms of intestinal distress as being generally recognized as safe and effective and not misbranded. Any specific labeling discussed in the individual ingredient statements should also be considered.

Indications. The product labeling should contain one of the following statements:

a. "For relief of intestinal distress occurring 30 minutes to several hours after eating and often accompanied by complaints of bloating, distention, fullness, pressure, pain, or cramps."

b. "For relief of" (one or more of the following symptoms: "Bloating," "distention," "fullness," "pressure," "pain," or "cramps,") "sometimes described as 'gas', which occurs 30 minutes to several hours after eating."

The Panel is fully aware that although "gas" has not been proven to be the cause of intestinal distress, the consumer may perceive his or her symptoms as being due to "gas." Therefore, the Panel, after much deliberation, concludes that indication b. above may be allowed on these products.

B. Category II Conditions

The following are Category II conditions under which drug products used for the treatment of the symptoms of intestinal distress are not generally recognized as safe and effective or are misbranded.

1. *Category II active ingredients.*

Bismuth sodium tartrate
Blessed thistle and golden seal
Dehydrocholic acid
Duodenal substance
Garlic, dehydrated
Glutamic acid hydrochloride
Ox bile extract
Papain
Pepsin
Sorbitol

In addition, the Panel has classified other ingredients as Category II elsewhere in this document. (See part I. paragraph C.2.c. above—Other ingredients.)

a. *Bismuth sodium tartrate.* The Panel concludes that bismuth sodium tartrate, also referred to as sodium bismuthyltartrate, is not generally recognized as safe or effective for OTC use in treating the symptoms of intestinal distress.

(1) *Safety.* The Panel has not been presented with evidence demonstrating the oral safety of this compound nor is it aware of any such evidence.

This Panel is aware that the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products, in a report published in the **Federal Register** of March 21, 1975 (40 FR 12930), found bismuth subsalicylate to be safe orally in doses of 0.6 to 2 g taken three to four times daily but the safety of bismuth subnitrate in maximum doses of 5.6 g for adults and 0.475 g for children ages 3 to 6 in 4 hours is in question.

However, since publication of the Panel's report, bismuth encephalopathy has been reported from the oral use of 5 to 20 g daily (for several months to several years) of bismuth salts in Australia and France (Refs. 1 through 5) and from topical use of bismuth skin creams in England (Ref. 6). The bismuth salts causing this syndrome include the subgallate, subnitrate, silicate, aluminate, carbonate, subcarbonate, phosphate, oxyquinolate, pectate, and citrate. The implication is that the bismuth portion of the compound is toxic to the nervous system in these cases, although the mechanism involved is not clear.

The Panel concludes that evidence is not available to establish the safety of bismuth sodium tartrate for OTC use in treating the symptoms of intestinal distress.

(2) *Effectiveness.* Although some studies have suggested that bismuth preparations may be helpful in healing peptic ulcerations (Ref. 7), no studies have been presented nor is the Panel aware of any studies that demonstrate bismuth sodium tartrate to be effective in treating the symptoms of intestinal distress. In the absence of such data the Panel concludes that bismuth sodium

tartrate is not generally recognized as effective in treating this condition.

(3) *Evaluation.* The Panel concludes that bismuth sodium tartrate is not generally recognized as safe and effective for OTC use in treating the symptoms of intestinal distress. The safety of bismuth salts in oral preparations is seriously questioned by the recent demonstration that they may cause encephalopathy, and there is no information available to the Panel demonstrating the effectiveness of bismuth sodium tartrate in the treatment of the symptoms of intestinal distress.

References

(*1*) Meyboom, R. H. B., "Metals," *in* "Meyler's Side Effects of Drugs," Volume 8, edited by M. N. G. Dukes, Excerpta Medica, Amsterdam, pp. 502–504, 1975.

(*2*) Robertson, J. F., "Mental Illness or Metal Illness? Bismuth Subgallate," *The Medical Journal of Australia*, 1:887–888, 1974.

(*3*) Morgan, F. P., and J. J. Billings, "Is This Subgallate Poisoning?," *The Medical Journal of Australia*, 2:662–663, 1974.

(*4*) Buge, A., et al., "Twenty Cases of Acute Encephalopathy with Myoclonia During Treatment with Oral Bismuth Salts," *Annales de Medicine Interne*, 125:877–888, 1974.

(*5*) Martin-Bouyer, G., "Intoxications par les sels de bismuth administres par voie orale. Enquete epidemiologique," *Therapie*, 31:683–702, 1976.

(*6*) Kruger, G., et al., "Disturbed Oxidative Metabolism in Organic Brain Syndrome Caused by Bismuth in Skin Creams," *The Lancet*, 2:485–487, 1976.

(*7*) OTC Volume 170135.

b. *Blessed thistle and golden seal.* The Panel reviewed one preparation containing the extract of the whole plant blessed thistle (*Cnicus benedictus*), and the roots and rhizomes of golden seal *(Hydrastis canadensis)* and concludes that the preparation is safe for OTC use in the dose recommended by the manufacturer, but is not generally recognized as effective in treating the symptoms of intestinal distress. The effectiveness data submitted do not convince the Panel that it is effective for this indication and the Panel, therefore, places it in Category II. Both ingredients have a history of use in folk medicine as a bitter tonic.

c. *Dehydrocholic acid.* The Panel concludes that dehydrocholic acid is safe for OTC use in the dose noted below, but is not generally recognized as effective in treating the symptoms of intestinal distress.

(1) *Safety.* The Panel is aware of one animal study which determined the LD^{50} of dehydrocholic acid to be 14.7 g/kg in rats (Ref. *1*). The study further reported that no hepatic damage was found to result from the chronic administration of 3 and 5 g daily to dogs for 3 to 7 months, nor from the administration of 333 mg/kg daily to rats for 32 days (Ref. *1*).

The Panel concurs with the recommendations of the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products, published in the **Federal Register** of March 21, 1975 (40 FR 12902), that dehydrocholic acid is safe in an adult dose of 750 to 900 mg per day when used as a laxative (40 FR 12910). That Panel did not approve its use in children under 12 years of age.

Based on the available data, the Panel concludes that dehydrocholic acid is safe for OTC use in the above dosage.

(2) *Effectiveness.* Dehydrocholic acid, which is a partially synthetic derivative of cholic acid, stimulates the liver to increase the volume of bile by increasing its water content without increasing its constituents (hydrocholeretic) (Ref. *2* and *3*).

Dehydrocholic acid has been used as an OTC laxative, but the Panel is not aware of any adequate and well-controlled clinical studies demonstrating its effectiveness in treating the symptons of intestinal distress nor is dehydrocholic acid generally recognized as an effective treatment for the symptoms of intestinal distress.

(3) *Evaluation.* Although dehydrocholic acid is considered to be generally recognized as safe for OTC use in the dose specified above, the Panel concludes that it has not been demonstrated to be effective for relief of the symptoms of intestinal distress. This conclusion is in agreement with the following decision of the Advisory Review Panel on OTC Laxative Antidiarrheal, Emetic, and Antiemetic Drug Products (published in the **Federal Register** of March 21, 1975 (40 FR 12910):

> There is no evidence in support of the claim that dehydrocholic acid relieves "indigestion", "excessive belching", "after meal discomfort", or "the sensation of abdominal fullness." These claims constitute mislabeling and dehydrocholic acid is placed in Category II with respect to these claims.

References

(*1*) Berman, A. L., E. Snapp, A. C. Ivy, and A. J. Atkinson, "The Effect of Long-Continued Ingestion of Oxidized Bile Acids on the Dog and Rat," *American Journal of Digestive Diseases*, 7:280–284, 1940.

(*2*) Harvey, S.C., "Gastric Antacids and Digestants," *in* "The Pharmacological Basis of Therapeutics," 5th Ed., edited by L. S. Goodman and A. Gilman, The MacMillan Co., New York, p. 973, 1975.

(*3*) DiPalma, J. R., "Drill's Pharmacology in Medicine," 4th Ed., McGraw-Hill, New York, pp. 972–973, 1971.

d. *Duodenal substance.* The term duodenal substance appears to lack a precise meaning in the current medical literature. Presumably the term refers to one or more mixtures of peptide substances such as cholecystokinin, gastrin, pancreozymin, and secretin which are secreted by the intestinal mucosa. The latter peptide substances act physiologically to facilitate digestion by stimulating the release by the gastrointestinal tract or the pancreas of various enzymes and other exocrine substances. The Panel is unware of any accepted therapeutic indication for these peptides.

In the absence of such data, the Panel concludes that duodenal substance is not generally recognized as safe and effective in treating the symptoms of intestinal distress.

e. *Garlic, dehydrated.* The Panel concludes that dehydrated garlic is safe for OTC use at the dose noted below, but is not generally recognized as effective in treating the symptoms of intestinal distress.

(1) *Safety.* Garlic has been widely used as a food for many years with no known harmful effects. It is considered by the Panel to be safe as a carminative (expelling gas from the alimentary canal) in the recommended OTC dose of 0.6 g after meals (Ref. *1*).

(2) *Effectiveness.* The principal active ingredients of dehydrated garlic are allyl propyl disulfide and diallyl disulfide (Ref. *2*).

Some data were submitted regarding dehydrated garlic's effectiveness as a carminative, but the Panel is not aware of any adequate and well-controlled clinical studies demonstrating the effectiveness of dehydrated garlic or its principal active ingredients in treating the symptoms of intestinal distress; nor is it generally recognized as an effective treatment for the symptoms of intestinal distress.

(3) *Evaluation.* The Panel concludes that dehydrated garlic is generally recognized as safe for OTC use in the dose specified but its effectiveness has not been demonstrated in treating the symptoms of intestinal distress.

References

(*1*) OTC Volume 170003.

(*2*) Bordia, A., H. C. Bonsal, S. K. Arora, and S. V. Singh, "Effect of the Essential Oils of Garlic and Onion on Alimentary Hyperlipemia," *Atherosclerosis*, 21:15–20, 1975.

f. *Glutamic acid hydrochloride.* The Panel concludes that glutamic acid hydrochloride is safe for OTC use in the dose noted below, but is not generally recognized as effective in testing the symptoms of intestinal distress.

(1) *Safety.* Available clinical data and marketing experience have shown

glutamic acid hydrochloride to be safe for OTC use in the dose of 1.02 g three times daily as a stomach acidifier (Ref. *1*).

(2) *Effectiveness.* Glutamic acid hydrochloride has been marketed as an agent intended to increase the amount of acid present in the stomach, and thus favorably altering the pH of the gastric environment (Refs. *2* and *3*). However, the Panel knows of no proven relationship between hypoacidity or anacidity of the stomach and the symptoms of intestinal distress, nor is the Panal aware of any adequate and well-controlled clinical studies demonstrating the effectiveness of glutamic acid hydrochloride in treating the symptoms of intestinal distress. Furthermore, glutamic acid hydrochloride is not generally recognized as an effective treatment of this condition.

(3) *Evaluation.* The Panel concludes that glutamic acid hydrochloride is generally recognized as safe for OTC use in the dose specified but its effectiveness has not been demonstrated in treating the symptoms of intestinal distress.

The Panel is aware that glutamic acid hydrochloride has been employed as a stomach acidifier in the treatment of achlorhydria and hypochlorhydria but does not find it has any usefulness in treating these conditions. The Panel has prepared a separate document on OTC stomach acidifier drug products discussing the merits of stomach acidifiers published in the **Federal Register** of October 19, 1979 (44 FR 60316).

References

(*1*) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, pp. 1082–1083, 1977.

(*2*) OTC Volume 170023.

(*3*) OTC Volume 170049.

g. *Ox bile extract.* The Panel concludes that ox bile extract is safe for OTC use in the dose noted below, but is not generally recognized as effective in treating the symptoms of intestinal distress.

(1) *Safety.* The Panel believes the usual dose of 300 to 500 mg given two to three times daily after meals to be safe for healthy individuals (Ref. *1*). However, for individuals who have biliary obstruction or some other forms of liver disease, exogenous bile salts further contribute to an already undesirable increase in plasma and blood concentrations of bile salts (Ref. *2*). Commercial ox bile preparations may produce diarrhea (Ref. *3*).

(2) *Effectiveness.* Ox bile extract is a powdered or granular extract of ox bile with a characteristic odor and taste containing an amount of sodium salts of ox bile acids equivalent to approximately 45 percent cholic acid (Ref. *1*).

Bile contains bile salts, bile pigments, lecithin, cholesterol, mucin, and other proteins, fatty acids, and inorganic salts. Of these constituents, the most important are the bile salts, which occur as sodium salts of conjugated bile acids (Ref. *1*). The bile salts constitute approximately 3 percent of the total bile secreted daily (Ref. *2*).

Bile acids are synthesized by the liver and secreted into the duodenum as conjugated bile salts. A high percentage of the bile salts is reabsorbed in the lower small intestine and recirculated through the liver by way of the enterohepatic circulation.

Bile salts enhance the absorption of lipids and are necessary for the absorption of fat-soluble vitamins and cholesterol. They play an important role in maintaining the normal solubility of cholesterol in the bile (Ref. *3*). Bile salts also promote digestion of fats by stimulating pancreatic secretion and by activating pancreatic lipase (Ref. *2*).

The large volume of bile secreted into the duodenum helps to neutralize the acidic contents but is less important than pancreatic secretions in this respect (Ref. *2*).

Bile salts "* * * can be given to promote the flow of bile or to increase intrabiliary pressure; however, much expert medical opinion now holds that the administration of bile salts is often unnecessary or inappropriate and can sometimes cause undue pain or danger to the patient" (Ref. *2*). "Bile salts are no better than placebos in nonobstructive, noncholestatic biliary tract disorders or in various malfunctions of the intestine" (Ref. *2*).

Ox bile extract "* * * is promoted for the replacement therapy in patients who have an insufficient concentration of bile salts in the intestine, but it is ineffective. Use of ox bile extract is inadvisable, for it does not provide an adequate amount of bile salts" (Ref. *3*).

Even though ox bile extract has been used for many years in OTC products, the Panel is not aware of any adequate and well-controlled clinical studies demonstrating its effectiveness in treating the symptoms of intestinal distress, nor is ox bile extract generally recognized as an effective treatment for the symptoms of intestinal distress.

(3) *Evaluation.* The Panel concludes that ox bile extract is generally recognized as safe for OTC use in the dose specified but its effectiveness has not been demonstrated in treating the symptoms of intestinal distress.

References

(*1*) "The United States Dispensatory," 27th Ed., edited by A. Osol and R. Pratt, J. B. Lippincott Co., Philadelphia, p. 820, 1973.

(*2*) Harvey, S. C., "Gastric Antacids and Digestants," *in* "The Pharmacological Basis of Therapeutics," 5th Ed., edited by L. S. Goodman and A. Gilman, The MacMillan Co., New York, pp. 971–973, 1975.

(*3*) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, p. 1084, 1977.

h. *Papain.* The Panel concludes that papain is safe for OTC use at the dose noted below, but is not generally recognized as effective in the treatment of the symptoms of intestinal distress.

(1) *Safety.* Papain is used as a meat tenderizer and about one-half million pounds are imported annually for this purpose (Ref. *1*). The Panel is unaware of any toxic or adverse symptoms that have arisen from its use, except the occasional allergic reaction in patients sensitive to papain. The Panel concludes that it is otherwise safe in the recommended daily dose of 100 to 600 mg (Ref. *2*). However, papain is contraindicated in patients taking anticoagulant medication (Ref. *2*).

(2) *Effectiveness.* Papain is a proteolytic enzyme from the fruit of the tropical melon tree (*Carica papaya*) (Ref. *3*). Over the years it has been used in products intended to prevent or treat a variety of inflammatory states (Ref. *3* and *4*). No data were submitted, nor is the Panel aware of data demonstrating the effectiveness of papain in treating the symptoms of intestinal distress.

(3) *Evaluation.* The Panel concludes that papain is generally recognized as safe for OTC use in the dose specified but its effectiveness has not been demonstrated in treating the symptoms of intestinal distress.

References

(*1*) Breeling, L., "The Nature and Nutritive Value of Papaya Juice," *Journal of the American Medical Association*, 210:2100, 1969.

(*2*) "The United States Dispensatory," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 829–830, 1973.

(*3*) Gibb, J. W., "Enzymes," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by A. Osol and J. E. Hoover, Mack Publishing Co., Easton, PA, p. 975, 1975.

(*4*) Swinyard, E. A., "Locally Acting Drugs," *in* "The Pharmacological Basis of Therapeutics," 5th Ed., edited by L. S. Goodman and A. Gilman, MacMillan Publishing Co., Inc., New York, pp. 958–959, 1975.

i. *Pepsin.* The Panel concludes that pepsin is safe for OTC use at the dose noted below, but is not generally recognized as effective in treating the symptoms of intestinal distress.

(1) *Safety.* No safety data were submitted. However, based upon the continued marketing of pepsin over many years with no reports of adverse effects the Panel concludes that it is safe in a daily dose of up to 1,000 mg (Ref. *1*).

(2) *Effectiveness.* Pepsin, a proteolytic enzyme obtained from the glandular layer of fresh hog stomach, (Ref. *2*) is similar to human pepsin. Although its presence is not required for protein digestion, because intestinal enzymes can function without it, pepsin has been used when endogenous human pepsin is deficient or absent. The Panel is not aware of any convincing evidence that added pepsin is of therapeutic usefulness (Ref. *2, 3,* and *4*). It also is eventually inactivated by the higher pH of the intestines (Ref. *5*).

No data were submitted to demonstrate the effectiveness of pepsin and the Panel is not aware of any adequate and well-controlled clinical studies demonstrating its effectiveness in treating the symptoms of intestinal distress, nor is pepsin generally recognized as an effective treatment for the symptoms of intestinal distress.

(3) *Evaluation.* The Panel concludes that pepsin is generally recognized as safe for OTC use in the dose specified but its effectiveness has not been demonstrated in treating the symptoms of intestinal distress.

References

(*1*) "The United States Dispensatory and Physician's Pharmacology," 26th Ed., edited by A. Osol, R. Pratt, and M. D. Altschule, J. B. Lippincott Co., Philadelphia, p. 874, 1967.

(*2*) Wilson, C. O., O. Grisvold, and R. F. Doerge, "Text Book of Organic Medical and Pharmacological Chemistry," 6th Ed., J. B. Lippincott Co., Philadelphia, pp. 904–905, 1971.

(*3*) Harvey, S. C., "Gastric Antacids and Digestants," *in* "The Pharmacological Basis of Therapeutics," 5th Ed., edited by L. S. Goodman and A. Gilman, The Macmillan Co., New York, p. 971, 1975.

(*4*) "AMA Drug Evaluations," 2d Ed., Publishing Sciences Group, Inc., Acton, MA, p. 812, 1973.

(*5*) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, p. 1083, 1977.

j. *Sorbitol.* The Panel concludes that sorbitol, also known as *D*-sorbitol, is safe for OTC use in the dose noted below, but is not generally recognized as effective in treating the symptoms of intestinal distress.

(1) *Safety.* The Panel considers sorbitol safe for use in the suggested oral dose of 4.5 g three times daily (Ref. *1*).

Steinke reported finding no evidence of gastrointestinal side effects and no increase in insulin requirements in 143 juvenile diabetics, aged 5 to 13 years, following the administration of 41 g of sorbotol per day in 3 equal doses, for periods of 8 to 48 days (Ref. *2*). In another study some patients were reported to develop borborygmus and hyperperistalsis or diarrhea following either single large doses of sorbitol (40 g) for gall bladder studies or the chronic administration of 7 g before meals for 20 to 60 days (Ref. *3*).

(2) *Effectiveness.* Sorbitol is a six-carbon polyhydric alcohol. It is more slowly absorbed from the gastrointestinal tract than dextrose. Its main use is as an osmotic diuretic. Fifty percent is metabolized or converted to glycogen and stored in the liver (Ref. *4*). Oxidation to fructose occurs in both the liver and kidney (Ref. *2*).

Maximal contraction of the gall bladder has been found to occur 30 minutes after the administration of 9, 18, and 27 g of sorbitol (Ref. *5*). Eighty percent of 64 patients with hepatobiliary disorders who were treated with 7 g of sorbitol before meals for periods of from 20 to 60 days were reported to have obtained relief from dyspepsia and abdominal swelling, as well as some other symptoms (Ref. *3*).

The Panel is aware of the use of sorbitol as an osmotic diuretic and its more general usage as a laxative, sweetener, humectant, and as a vehicle (70 percent weight/weight solution) (Ref. *6*), but the Panel is not aware of any adequate and well-controlled clinical studies demonstrating the effectiveness of sorbitol in treating the symptoms of intestinal distress in the absence of hepatobiliary disease. In addition, sorbitol is not generally recognized as an effective treatment for the symptoms of intestinal distress.

(3) *Evaluation.* The Panel concludes that sorbitol is generally recognized as safe for OTC use in the dose specified but its effectiveness has not been demonstrated in treating the symptoms of intestinal distress.

References

(*1*) OTC VoLume 170042 (Section V.A.I.).

(*2*) Steinke, J., et al., "Evaluation of Sorbitol in the Diet of Diabetic Children at Camp," *Diabetes,* 10:218–227, 1961.

(*3*) Piccinelli, O., and G. Timossi, "D-Glucitol in the Therapy of Hepatobiliary Diseases," *Minerva Medica,* 49:77–82, 1958.

(*4*) DiPalma, J. R., "Drill's Pharmacology in Medicine," 4th Ed., McGraw-Hill, New York, p. 299, 1971.

(*5*) OTC Volume 170042 (Section V.A.I.).

(*6*) Swinyard, E. A., "Pharmaceutical Necessities," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by A. Osol and J. E. Hoover, Mack Publishing Co., Easton, PA, p. 1235, 1975.

2. *Category II labeling.* The Panel concludes that some portions of the following labeling claims are either unsupported by scientific date, vague, misleading, unrelated to the symptoms of intestinal distress, or in some instances unsupported by sound reasoning. The claims listed below and other related terms are, therefore, classified as Category II labeling for drug products used to treat the symptoms of intestinal distress.

a. "Stimulates the cells of the stomach to help increase the amount of gastric juice and thus improve digestion and nutrition."

b. "Helps create a healthy intestinal environment for more normal digestion."

c. "Stomachic."

d. "For relief of biliary indigestion."

e. "Choleretic."

f. "Digestive."

g. "Carminative."

h. "Helps to improve poor appetite."

i. "Gastrointestinal distress due to irritation and inflammation of the intestinal tract."

j. "Helps prevent loose bowels due to excess fat content."

k. "For enteritis."

l. "Digestive supplement."

m. "Aids digestion of hard to digest foods."

n. "Digestant." (Except as noted under Category III Labeling.)

o. "For relief of gastrointestinal digestive disturbances."

p. "Permits a regular, comfortable digestion of foods previously not tolerated."

q. "For temporary relief of indigestion due to overeating."

r. "For expelling gas from the stomach and intestine."

s. "Helps to relieve heartburn due to indigestion."

t. "Relieves discomfort and pain of entrapped gas caused by air swallowing and overindulgence in food."

u. "Relieves belching, bloating, and flatulence."

v. "Helps reduce discomfort due to gas in the stomach and intestines."

w. "An anti-gas digestive aid to help relieve belching, bloating, or an over-full feeling."

x. "For relief of constipation and headache, heartburn and gas that may be caused by constipation."

y. "For relief of constipation, especially when accompanied by flatulence or gas distress."

z. "For relief of constipation."

aa. Phrases such as "long-lasting" which vaguely and nonspecifically relate to the speed of action.

bb. "For the prevention of intestinal distress."

cc. "Superior to ordinary."

dd. "Specially improved."

ee. "Selected ingredients."

ff. "Extra strength."

gg. "Contains more active ingredients per dose."

hh. "Works internally."

ii. "Travels through the bloodstream."

jj. "Can be used to improve digestion of geriatric patients."

kk. "To alleviate simple postprandial discomfort (bloating, belching, flatulence, and a sense of fullness) due to over eating or insufficient mastication of food."

ll. "Postgastrectomy syndrome."

mm. "Chronic pancreatitis."

nn. "Pancreatic necrosis."

oo. "Chronic hepatitis."

pp. "Gallbladder disease."

qq. "Surgical patients following cholecystectomy, subtotal pancreatectomy, and other surgery of the upper gastrointestinal tract."

rr. "Overindulgence in excessively fatty meals."

ss. "Abdominal rumblings."

C. Category III conditions

The following are Category III conditions for which the available data are insufficient to permit final classification at this time.

1. *Category III active ingredients.* The Panel concludes that the safety of the following ingredients in the recommended doses is unquestioned, except as noted in the individual ingredient writeups:

Cellulase and hemicellulose
Charcoal, activated and charcoal, wood
Homatropine methylbromide
Magnesium hydroxide
Pancreatin and pancrelipase
Simethicone
Sodium bicarbonate
Sodium citrate

a. *Cellulase and hemicellulase.* The concludes panel that cellulase and hemicellulase are safe for OTC use in the dose noted below, but data are insufficient to demonstrate their effectiveness in treating symptoms of intestinal distress.

(1) *Safety.* Cellulase and hemicellulase are obtained from molds such as *Aspergillus oryzae* and *Penicillium notatum* as well as from various other sources (Refs. *1* and *2*). Those derived for medicinal use are normally obtained from *Aspergillus oryzae.* Cellulases have been utilized as digestive aids for many years. Based on the available data, the Panel Concludes that they are safe when used as OTC digestive aids and in the doses recommended below.

(2) *Effectiveness.* Cellulase and hemicellulase are not normal constituents of the human bowel. These enzymes are capable of hydrolyzing cellulose and hemicellulose contained in ingested plant foods. They have been reported to be effective in dissolving bezoars and phytobezoars (Ref. *3*) and in reducing the amount of roughage in the stool (Refs. *4* and *5*).

The Panel is not aware of any adequate and well-controlled clinical studies demonstrating the effectiveness of cellulase or hemicellulase in treating the symptoms of intestinal distress. Based upon the pharmacological action, the Panel concludes that cellulase and hemicellulase have the potential for this OTC use and therefore, recommends that they be further tested according to the testing guidelines to determine whether or not they are effective.

(3) *Proposed dosage.* The Panel concludes that cellulase and hemicellulase are safe as single ingredient products in the usual and recommended daily doses of 9 to 50 mg for cellulase (Refs. *6* and *5*) and 50 to 100 mg for hemicellulase (Refs. *6* and *7*) taken three times daily.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of intestinal distress (See part IV. paragraph A.2. above—Category I labeling.)

(5) *Evaluation.* The Panel recommends that adequate testing of cellulase and hemicellulase be performed according to the testing guidelines to determine whether or not they are effective for treatment of the symptoms of intestinal distress. (See part IV. paragraph D. below—Data Required for Evaluation: Guidelines for Developing Protocols for Evaluating OTC Drugs for the Treatment of the Symptoms of Intestinal Distress.)

References

(*1*) Pigman, W., "Enzymes Acting on Hemicelluloses, Gums, and Wood," *in* "The Enzymes," Volume I, edited by J. B. Sumner and K. Myrback, Academic Press, Inc., New York, pp. 739–744, 1951.

(*2*) Courtois, J. E., "Some Biochemical Aspects of Cellulases and Hemicellulases," *Glasnik Hemijskog Drustvaw,* 32:365–388, 1967.

(*3*) OTC Volume 170100.

(*4*) Friend, D. G., "Effect of Oral Enzyme Therapy on Roughage Content of Stools," *The Journal of New Drugs,* 5:236–239, 1965.

(*5*) OTC Volume 170049.

(*6*) OTC Volume 170034.

(*7*) OTC Volume 170144.

b. *Charcoal, activated and charcoal, wood.* The Panel concludes that activated charcoal and wood charcoal are safe for OTC use in the dose noted below, but data are insufficient to demonstrate their effectiveness in treating the symptoms of intestinal distress.

(1) *Safety.* Activated charcoal is ingested in usual doses of 30 g or more as an adjunct in the treatment of acute toxic ingestion. Yatzidis has given up to 50 g of activated charcoal daily to uremic patients for up to 20 months with no apparent ill effects (Ref. *1*); however, the Panel is concerned that because activated charcoal is a nonspecific adsorbent, chronic usage might cause depletion of certain essential nutrients. The Panel is aware of no studies which conclusively establish the safety of the chronic ingestion of activated charcoal in humans and at the present time the Panel recommends that the dosage be restricted to no more than 10 g daily in divided doses for a period of no more than 7 days for the treatment of symptoms of intestinal distress. In addition, activated charcoal will adsorb many other drugs which a person might be taking concurrently, and a suitable warning is included below under the heading "Labeling."

Based on the available data, the Panel concludes that activated charcoal is safe when used as a digestive aid and in accordance with the restrictions noted below.

(2) *Effectiveness.* Activated charcoal is known to adsorb many gases, organic and inorganic compounds, toxins, etc. The causes of intestinal distress have not been conclusively established and the effectiveness of activated charcoal in relieving these symptoms has not been demonstrated at the present time.

Nonactivated charcoal has one-third or less the adsorbent capacity of activated charcoal and because of this lack of uniform activity, its use for this condition is not recommended.

Activated charcoal has been used for many years in the management of ostomy patients by some physicians to reduce odor and gas (Ref. *2*). It has also been recommended in the past for treatment of dysentery. The Panel is not aware of any adequate and well-controlled clinical studies demonstrating the effectiveness of activated charcoal for its use in treating the symptoms of intestinal distress. Based on the pharmacological action, the Panel concludes that activated charcoal has the potential for this OTC use and, therefore, recommends that further testing be done according to the testing guidelines to determine whether or not it is effective for treatment of the symptoms of intestinal distress.

(3) *Proposed dosage.* The Panel concludes that activated charcoal is safe for OTC use when its ingestion is limited to 10 g daily in divided doses for a period of no more than 7 days for treating the symptoms of intestinal distress.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of intestinal distress. (See part IV. paragraph A.2. above—Category I labeling.) In addition, the Panel recommends that the following warning statements be required to appear in the labeling of drug products containing activated charcoal:

(i) "If you are taking other drugs, consult your physician as this drug may interfere with their effectiveness."

(ii) "Do not take for longer than 1 week or in greater than recommended amounts, except upon the advice of a physician."

(5) *Evaluation.* The Panel recommends that adequate testing of activated charcoal be performed according to the testing guidelines to determine whether or not it is effective for treatment of the symptoms of intestinal distress. (See part IV, paragraph D. below—Data Required for Evaluation: Guidelines for Developing Protocols for Evaluating OTC Drugs for the Treatment of the Symptoms of Intestinal Distress.)

References

(*1*) Yatzidis, H., "Activated Charcoal Rediscovered," *British Medical Journal*, 4:51, 1972.

(*2*) Marino, A. W. M. Jr., H. W. N. Mancini, and A. W. M. Marino Sr., "Colostomy Simplified", *Modern Treatment*, 8:892–908, 1971.

c. *Homatropine methylbromide.* The Panel concludes that homatropine methylbromide is safe for OTC use in the dose noted below, but data are insufficient to demonstrate effectiveness in treating the symptoms of intestinal distress.

(1) *Safety.* In a study to determine the minimal toxic dose of homatropine methylbromide, Berger and Ballinger reported toxicity in individuals ingesting doses ranging from 68 to 273 mg per day (Ref. *1*). This is far in excess of the usually recommended prescribed dosage of 2.5 to 5.0 mg four times daily (Ref. *2*). There was no evidence of toxic or cumulative effects at the smaller dosage of 1 mg three times daily before meals (Ref. *1*).

"Slight cerebral symptoms" have resulted from the use of maximum doses of 20 mg per day, but no cumulative effects have been reported (Ref. *3*). Homatropine methylbromide is about one-half as potent as atropine in its effect on the gastrointestinal tract, and it is claimed to be only one-thirtieth as toxic on the central nervous system (Ref. *4*). Its use is generally accompanied by fewer central nervous system side effects than atropine (Ref. *4*).

The Panel concludes that homatropine methylbromide is safe for OTC use in treating the symptoms of intestinal distress at a maximum dose of 5 mg four times daily.

(2) *Effectiveness.* Homatropine methylbromide is a quaternary ammonium cholinergic blocking agent and is much less active than atropine on the central nervous system. Like homatropine, it is a weaker autonomic blocking agent than atropine. It is used to reduce the motility of the intestinal tract (Ref. *2*).

The Panel is not aware of any adequate and well-controlled clinical studies demonstrating the effectiveness of homatropine methylbromide in treating the symptoms of intestinal distress. The effectiveness of atropine-like substances on the motility of the intestinal tract is well recognized and based on this pharmacological action, the Panel concludes that homatropine methylbromide has the potential for this OTC use and, therefore, recommends that it be further tested according to the testing guidelines to determine whether or not it is effective.

(3) *Proposed dosage.* The Panel concludes that homatropine methylbromide is safe for OTC use at a maximum dose of 5 mg four times daily.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of intestinal distress (See part IV. paragraph A.2. above—Category I labeling.)

(5) *Evaluation.* The Panel recommends that adequate testing of homatropine methylbromide be performed according to the testing guidelines to determine whether or not it is effective for treatment of the symptoms of intestinal distress. (See part IV. paragraph D. below—Data Required for Evaluation: Guidelines for Developing Protocols for Evaluating OTC Drugs for the Treatment of the Symptoms of Intestinal Distress.)

References

(*1*) Berger, A. R., and J. Ballinger, "The Relative Toxicity of Atropine and Novatrine in Man," *American Journal of Medical Sciences*, 214:156–158, 1947.

(*2*) Harvey, S. C., "Antimuscarinic Drugs," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by A. Osol and J. E. Hoover, Mack Publishing Co., Easton, PA, p. 841, 1975.

(*3*) Grollman, A., and E. F. Grollman, "Pharmacology and Therapeutics," 7th Ed., Lea and Febiger, Philadelphia, p. 351, 1970.

(*4*) Krantz, J. C., and C. J. Carr, "The Pharmacologic Principles of Medical Practice," 7th Ed., Williams and Wilkins, Baltimore, p. 404, 1969.

d. *Magnesium hydroxide.* The Panel concludes that magnesium hydroxide is safe for OTC use in the dose noted below, but data are insufficient to demontrate its effectiveness in treating the symptoms of intestinal distress.

(1) *Safety.* If kidney function is normal, magnesium hydroxide is considered safe for use when taken in the dosage noted below.

Magnesium hydroxide is generally considered to be a poorly absorbed antacid. However, absorption of as little at 5 to 10 percent (Ref. *1*) to as much as 15 to 30 percent has been reported (Ref. *2*). It is well known that excessive magnesium blood levels may result from ingestion of magnesium by persons with kidney damage, and, therefore, a warning label should be present on any magnesium hydroxide preparation in which the maximal daily dose exceeds 50 meq of magnesium.

Magnesium hydroxide has the potential for drug interactions with bishydroxycoumarin and related anticoagulants (Ref. *3*) and with tetracycline antibiotics (Ref. *4*). The Panel believes that the consumer should be alerted to the potential for drug interactions and recommends that a warning appear on the label.

(2) *Effectiveness.* The Panel is aware of the antacid and laxative properties of magnesium hydroxide but other action in the intestines is not well established. The Panel recommends further testing according to the testing guidelines to determine whether or not magnesium hydroxide is effective in treating the symptoms of intestinal distress.

(3) *Proposed dosage.* The Panel concludes that the OTC use of magnesium hydroxide is safe in the usual recommended dose of up to 15 mL of a suspension of up to 8.5 percent magnesium hydroxide taken three to four times daily (Ref. *1*). This is equivalent to a total daily dose of up to 5.1 g of magnesium hydroxide, but should not be taken for more than 2 weeks except upon the advice of a physician.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of intestinal distress. (See part IV. paragraph A.2. above—Category I labeling.) In addition, the Panel recommends that the following warning statements be required to appear in the labeling of drug products containing magnesium hydroxide:

(i) "If you are taking other drugs, consult your physician as this drug may interfere with their effectiveness."

(ii) "Do not take for longer than 2 weeks or in greater than recommended amounts, except on the advice of a physician."

(iii) *For products containing more than 50 meq of magnesium in the recommended daily dosage.* "If you have kidney disease, do not use this product except under the supervision of a physician."

(5) *Evaluation.* The Panel recommends that adequate testing of magnesium hydroxide be performed according to the testing guidelines to determine whether or not it is effective for treatment of the symptoms of intestinal distress. (See part IV. paragraph D. below—Data Required for Evaluation: Guidelines for Developing Protocols for Evaluating

OTC Drugs for the Treatment of the Symptoms of Intestinal Distress.)

References

(*1*) Harvey, S. C., "Gastric Antacids and Digestants," *in* "The Pharmacological Basis of Therapeutics," 5th Ed., edited by L. S. Goodman and A. Gilman, The Macmillan Co., New York, pp. 964–965, 1975.

(*2*) Dretchen, K., D. Hollander, and J. B. Kirsner, "Roundup on Antacids and Anticholinergics," *Patient Care*, 9:94–114, 1975.

(*3*) Ambre, J. J., and L. J. Fischer, "Effect of Co-Administration of Aluminum and Magnesium Hydroxides on Absorption of Anticoagulants in Man," *Clinical Pharmacology and Therapeutics*, 14:231–237, 1973.

(*4*) Hussar, D. A., "Drug Interactions," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by A. Osol and J. E. Hoover, Mack Publishing Co., Easton, PA, p. 1741, 1975.

e. *Pancreatin and pancrelipase.* The Panel concludes that pancreatin preparations (pancreatin or pancrelipase) are safe for OTC use in the dose noted below, but data are insufficient to demonstrate their effectiveness in treating the symptoms of intestinal distress in the absence of a deficiency of pancreatic enzymes.

(1) *Safety.* The Panel has determined that pancreatic preparations (pancreatin or pancrelipase) are safe in the usual daily dosage of up to 14 g of triple strength pancreatin when given in divided doses (Ref. *1*). Side effects of nausea, vomiting, and diarrhea may occur at high doses (Ref. *1*). Because pancreatin preparations (pancreatin or pancrelipase) are obtained mainly from hogs, they should not be used by individuals who are allergic to pork.

(2) *Effectiveness.* The enzymes of the pancreas are obtainable as a preparation known as pancreatin. Pancreatin is an amorphous substance obtained from fresh hog pancreas. It contains principally amylase, protease, and lipase (Ref. *1*). Pancreatin is principally employed in the treatment of conditions in which the secretion of pancreatic juice is deficient. The evidence for effectiveness of pancreatic enzymes as an aid to digestion in the absence of decreased secretion of pancreatic juice is less impressive than when compared with a pancreatic deficiency. Pancreatin was shown to be ineffective in steatorrhea in patients when the condition was due to disease of the small bowel or other conditions in which pancreatic secretion was normal (Ref. *2*). There are numerous reports of improvement in symptoms of intestinal distress following administration of pancreatic preparations (Ref. *3*), but in general these are uncontrolled or poorly controlled studies. Preliminary reports of controlled studies suggest that there may be some benefit, but the evidence is inconclusive (Ref. *3*).

The Panel recommends that pancreatic preparations (pancreatin or pancrelipase) be tested according to the testing guidelines to determine whether or not they are effective in treating the symptoms of intestinal distress, in the absence of a deficiency of pancreatic enzymes.

(3) *Proposed dosage.* The Panel concludes that pancreatic preparations (pancreatin or pancrelipase) for OTC use are safe in the usual and recommended daily dose of up to 14 g of triple strength pancreatin (or its equivalent) when given in divided doses with meals. These preparations may contain variations of the standard pancreatin proportions of amylase, lipase, and protease as defined in the National Formulary.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used to treat the symptoms of intestinal distress where no pancreatic deficiency exists. (See part IV. paragraph A.2. above—Category I labeling.) In addition, the Panel recommends that the following warning statement be required on pancreatin preparations (pancreatin or pancrelipase):

"If you are allergic to pork products, do not take this product."

(5) *Evaluation.* The Panel recommends that adequate testing of pancreatin preparations (pancreatin or pancrelipase) be performed according to the testing guidelines to determine whether or not they are effective for treatment of the symptoms of intestinal distress. (See part IV. paragraph D. below—Data Required for Evaluation: Guidelines for Developing Protocols for Evaluating OTC Drugs for the Treatment of the Symptoms of Intestinal Distress.) The Panel considers that individuals with any exocrine pancreatic insufficiency (as shown by usual laboratory tests) should be excluded from intestinal distress testing.

The Panel is aware that pancreatin preparations (pancreatin or pancrelipase) are used extensively in treating patients with a prediagnosed exocrine pancreatic insuffiency. The Panel has prepared a separate document on OTC Exocrine Pancreatic Insufficiency Drug Products published in the Federal Register of December 21, 1979 (44 FR 75666).

References

(*1*) "AMA Drug Evaluations," 3d Edition, Publishing Sciences Group, Inc., Littleton, MA, pp. 1085–1086, 1977.

(*2*) Marks, I. N., S. Bank, and E. M. Airth, "Pancreatic Replacement Therapy in the Treatment of Pancreatic Steatorrhoea" *Gut*, 4:217–222, 1963.

(*3*) OTC Volumes 170144, 170145, and 170146.

f. *Simethicone.* The Panel concludes that simethicone is safe for OTC use in the dose noted below, but data are insufficient to demonstrate its effectiveness in treating the symptoms of intestinal distress.

(1) *Safety.* The Panel concurs with the determination of FDA, as stated in the antiflatulent final monograph (21 CFR 332.10), that simethicone is safe in a maximum daily dosage of 500 mg as an OTC product.

Simethicone is a mixture of dimethylpolysiloxane and approximately 5 percent silica gel. Toxicological studies and the wide use of dimethylpolysiloxane in chemical combination with silica gel for many years without evidence of adverse effects have established its safety for human use (Ref. *1*). This Panel has determined that silica gel is nontoxic in usually ingested amounts (Ref. *2*).

(2) *Effectiveness.* The antifoaming properties of simethicone have been established in vitro (Ref. *3*), and simethicone has been shown to decrease the presence or foam or bubbles found occasionally in the human stomach during gastroscopy (Ref. *4*).

Simethicone has been found to accelerate the transit time of various gases through the intestine but it did not decrease the amount of gas or frequency of passage of gas (Ref. *5*).

Although many papers have been published with the conclusions that simethicone is effective in reducing symptoms attributed to gas in the small and large intestine, of those reviewed only one study was conducted in a well-controlled double-blind manner (Ref. *6*). This double-blind study found simethicone to produce a statistically significant reduction of the symptoms of intestinal bloating, distention, fullness, and pressure.

There is some suggestion that simethicone is effective in relieving the symptoms of post-operative intestinal distress (Ref. *5*). However, since the Panel believes that additional studies are needed to determine the effectiveness of simethicone in treating the symptoms of intestinal distress occurring 30 minutes to several hours after eating, the Panel recommends further testing according to the testing guidelines to determine whether or not simethicone is effective in treating the symptoms of intestinal distress.

(3) *Proposed dosage.* The Panel concludes that a maximum recommended daily dosage of 500 mg is

safe (21 CFR 332.10). The administration of doses should be at appropriate intervals.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of intestinal distress. (See part IV. paragraph A.2. above—Category I labeling.)

(5) *Evaluation.* The Panel recommends that adequate testing of simethicone be performed according to the testing guidelines to determine whether or not it is effective for treatment of the symptoms of intestinal distress. (See part IV. paragraph D. below—Data Required for Evaluation: Guidelines for Developing Protocols for Evaluating OTC Drugs for the Treatment of the Symptoms of Intestinal distress.)

References

(1) Rowe, V. K., H. C. Spencer, and S. L. Bass, "Toxicologic Studies on Certain Commercial Silicones: II. Two Year Dietary Feeding of 'DC Antifoam A' to Rats." *Archives of Industrial Hygiene and Occupational Medicine,* 1:539–544, 1950.

(2) OTC Volume 170054.

(3) Rider, J. A., "Experience with the Use of a Defoaming Agent in the Treatment of Gastrointestinal Gas" *Annals of the New York Academy of Science,* 150:170–178, 1968.

(4) Gasster, M., J. O. Westwater, and W. E. Molle, "Use of Defoaming Agent in Gastroscopy," *Gastroenterology,* 27:652–655, 1954.

(5) Danhof, I. E., and J. J. Stavola, "Accelerated Transit of Intestinal Gas with Simethicone," *Obstetrics and Gynecology,* 44:148–154, 1974.

(6) Bernstein, J. E., and A. M. Kasich, "A Double-Blind Trial of Simethicone in Functional Disease of the Upper Gastrointestinal Tract," *The Journal of Clinical Pharmacology,* 14:617–623, 1974.

g. *Sodium bicarbonate.* The Panel concludes that sodium bicarbonate is safe for OTC use in the doses noted below, but data are insufficient to demonstrate its effectiveness in treating the symtoms of intestinal distress.

(1). *Safety.* Sodium bicarbonate (baking soda) is an alkalinizing agent which releases carbon dioxide when neutralized by acid. Sodium bicarbonate has a long history of use as an antacid and for the symptomatic relief of upper abdominal distress. It may be used as an ingredient in effervescent preparations in which the alkali is buffered or partially neutralized by an acidic compound. The Panel considers sodium bicarbonate to be safe when used as specified in the dosage section below, and under the labeling restrictions noted.

(2). *Effectiveness.* The Panel is aware of the antacid properties of sodium bicarbonate but its action in the intestines is not well established. The Panel recommends further testing according to the testing guidelines to determine whether or not sodium bicarbonate is effective in treating the symptoms of intestinal distress.

(3). *Proposed dosage.* This Panel concurs with the recommendations of the Advisory Review Panel on OTC Antacid Products, published in the **Federal Register** of April 5, 1973 (38 FR 8714), that a maximum safe daily dosage of preparations containing sodium is 200 meq of sodium for persons under 60 years of age and 100 meq for persons aged 60 years or older (38 FR 8719). Because of the sodium content the dose of sodium bicarbonate should not exceed 16.8 g (200 meq of sodium) per day.

(4). *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of intestinal distress. (See part IV. paragraph A.2. above—Category I labeling.)

The Panel concurs with the recommendation of the Advisory Review Panel on OTC Antacid Products, published in the **Federal Register** of April 5, 1973 (38 FR 8714), that warning statements should be required in the labeling of preparations containing sodium. This Panel recommends that the following warning statements be required in the labeling of products containing sodium:

(i) "If you are 60 years of age or older, the maximum *daily* dose should not exceed 8.4 g (1 heaping teaspoon) of this drug."

(ii) "Do not take for longer than 2 weeks or in greater than recommended amounts, except upon the advice of a physician."

(iii). *For products containing more than 5 meq of sodium in the recommended daily dose.* "If you are on a sodium-restricted diet, do not use this product except under the supervision of a physician."

(5). *Evaluation.* The Panel recomends that the adequate testing of sodium bicarbonate be performed according to the testing guidelines to determine whether or not it is effective for treatment of the symptoms of intestinal distress. (See part IV. paragraph D. below—Data Required for Evaluation: Guidelines for Developing Protocols for Evaluating OTC Drugs for the Treatment of the Symptoms of Intestinal Distress.)

h. *Sodium citrate.* The Panel concludes that sodium citrate (sodium salt of citric acid) is safe for OTC use in the doses noted below, but data are insufficient to demonstrate its effectiveness in relieving the symptoms of intestinal distress.

(1) *Safety.* Sodium citrate was reviewed by the Advisory Review Panel on OTC Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products, in a report published in the **Federal Register** of September 9, 1976 (41 FR 38367), and found to be safe when used within the dosage limitation of 24 g daily. This Panel concurs with the antacid monograph (21 CFR Part 331), which limits the daily sodium intake to 200 meq for persons under 60 years of age and 100 meq for persons 60 years or older.

(2) *Effectiveness.* Commonly, citric acid is formulated in combination with sodium bicarbonate in a solid dosage form. When this combination is dissolved in water, effervescence occurs (carbon dioxide evolves) and the active ingredient, buffered sodium citrate, is produced.

The Panel recommends that sodium citrate be tested according to the testing guidelines in order to determine whether or not it is effective in the treatment of the symptoms of intestinal distress.

(3) *Proposed dosage.* The Panel concludes that a maximum safe daily dose of preparations containing sodium is 200 meq of sodium for persons under 60 years of age and 100 meq for persons aged 60 years and older; therefore, the oral dose of sodium citrate should not exceed 17.2 g daily (200 meq of sodium).

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used in the treatment of the symptoms of intestinal distress. (See part IV. paragraph A.2. above—Category I labeling.)

The Panel concurs with the recommendation of the Advisory Review Panel on OTC Antacid Products published in the **Federal Register** of April 5, 1973 (38 FR 8714), that a warning statement should be required on preparations containing sodium. This Panel recommends that the following warning statements be required in the labeling of preparations containing sodium:

(i) "If you are 60 years of age or older, the maximum *daily* dose should not exceed 8.6 g (1 heaping teaspoon) of this drug."

(ii) "Do not take for longer than 2 weeks or in greater than recommended amounts, except upon the advice of a physician."

(iii) *For products containing more than 5 meq of sodium in the recommended daily dose.* "If you are on a sodium-restricted diet, do not use this product except under the supervision of a physician."

(5) *Evaluation.* The Panel recommends that adequate testing of sodium citrate be performed according to the testing guidelines to determine whether or not it is effective for treatment of the symptoms of intestinal distress. (See

part IV. paragraph D. below—Data Required for Evaluation: Guidelines for Developing Protocols for Evaluating OTC Drugs for the Treatment of the Symptoms of Intestinal Distress.)

2. *Category III labeling.* The Panel concludes that available data are insufficient to permit final classification of the following claims:

a. "For intestinal gas."
b. "For the distress of intestinal gas."
c. "Digestive aid." (When used as a claimed indication.)
d. "As an aid to digestion."
e. "Assists digestion."
f. "Digestant." (Enzyme-containing products only.)
g. "For relief of indigestion arising 30 minutes to several hours following a meal."
h. "Supplementation of natural digestive enzymes." (Enzyme-containing products only.)
i. "Improved digestion and relief of the discomfort due to excess intestinal gas (including rectal gas)."
j. "A temporary aid in the adsorption of intestinal gas causing flatulence."
k. "To relieve the discomforts of intestinal gas."
l. "As a digestive aid for the temporary relief of the symptoms of gastrointestinal gas (including rectal gas)."
m. "An adsorbent to arrest toxins and/or gas in the intestine which may cause discomfort, cramping, and flatulence."

D. Data Required for Evaluation: Guidelines for Developing Protocols for Evaluating OTC Drugs for the Treatment of the Symptoms of Intestinal Distress

The Panel recognizes that currently there is not available a generally accepted protocol for the testing of drug products used for the treatment of the symptoms of intestinal distress. Further, because of the several categories of drugs marketed for the relief of these symptoms and the different mechanisms of these drugs, the Panel realizes that it is unlikely that a single protocol, that would be appropriate for all of these drugs, can be developed and it did not attempt to produce one. However, the Panel does believe that there are important issues that must be considered to ensure proper evaluation of these drugs and has developed the following guidelines to aid investigators in designing tests of effectiveness. The Panel suggests that deviations from these guidelines be discussed with the appropriate FDA personnel prior to initiation of a study.

1. *Objective(s) of the study.* The primary objective is to determine whether the drug under investigation provides significantly better relief of the symptoms of intestinal distress than a placebo indistinguishable from the drug. If the drug is believed to have a specific mechanism (relief of gas) for which the drug company desires to make a label claim, then the study objectives should include specific reference to that claim. The objectives should be stated in a complete and unambiguous manner.

2. *Study population.* The preferred sample population for the study is one of outpatient subjects who have presented themselves to physicians complaining of symptoms occurring with some regularity and with varying frequency (at least twice weekly) in the absence of organic gastrointestinal disease. The selected sample population should be fully specified and pertinent characteristics should be thoroughly described.

3. *Study setting and investigator.* The Panel prefers the study to be conducted by qualified gastroenterologists in large clinics or academic settings. Other investigators and settings may be acceptable to FDA. The drug company should be prepared to justify deviations from the Panel's suggestion.

4. *Admissibility and exclusion criteria.* In order to exclude all but the functional gastrointestinal problems which give rise to the symptoms being evaluated and also to exclude other potential sources of bias and confounding, subjects should be screened to determine their suitability. A reasonable set of exclusion criteria are:

a. Organic gastrointestinal tract disease or anatomic abnormality.
b. Enzyme deficiency (lactase or pancreatic).
c. Recent intestinal surgery.
d. Sensitivity to the test drug(s).
e. Patients requiring other drug therapy which might confuse the interpretation of the results.
f. Significant recent involuntary weight loss.

If the drug under investigation is believed to have a specific mechanism for which the drug company desires to make a label claim, subjects admitted into the study must be shown to have the appropriate condition. For example, for drugs claiming to relieve gas, it must be shown by appropriate techniques that the subjects in the study have "excess gas" and that this is related to their distress. Later, in order to establish the efficacy claim, it must be shown that the amount of gas is reduced and that relief of the symptoms is related to the reduction.

5. *Study designs.* The study must be a randomized, double-blinded, placebo controlled, crossover design. The Panel also prefers that the study involve a test meal. (See part III. paragraph D.1. above—Guidelines for developing a protocol for evaluating OTC drugs for the treatment of the symptoms of IPPUAD.) The test meal should be given twice as screening meals before the medication stage (drug or placebo) in order to establish that the symptoms can be consistently produced in the study setting and that they last for sufficient time (starting 30 minutes or more after eating and lasting for several hours). The test meal should be given once before the placebo administration and once before the drug administration in order to produce the symptoms for relief by the medication. The test meals should be separated by an adequate number of days to eliminate any carry over effects. Similarly in the crossover, there should be a sufficient "wash-out period" between the placebo and drug administrations.

The Panel realizes that there may be some drugs for which a study involving a test meal may not be appropriate and where a diary study design may be needed. The Panel feels that diary studies contain many problematic elements (patient recall, appropriate length of study, and patient adherence to protocol) and does not recommend them. An investigator who feels that a diary study is needed should be prepared to justify why a study with a test meal would be impossible or inappropriate.

6. *Study variables of effectiveness.* The primary effectiveness variable should be relief of symptoms of intestinal distress. The Panel feels that for test meal studies the most appropriate version of this variable is the dichotomous variable: complete relief of all symptoms within a fixed time period (4 hours after the meal) versus incomplete or no relief within that time period. The Panel, however, also recognizes the validity of degrees of relief (none, some, complete) and the use of composite scores in which each symptom group is rated separately and the ratings are then combined. For these composite scores the Panel recognizes three symptom groups (Group 1—bloating, distention, fullness, pressure; Group 2—excess flatus; Group 3—pain or cramps). For diary studies the composite score adjusted for the pretreatment score is appropriate. Also of use, but on a secondary level, are variables such as investigators' and/or patients' overall evaluations (evaluations made at the end of a study in which the investigator and/or patient is asked to say which medication was more effective).

Wherever possible, objective measurements should be made in preference to subjective judgments. However, such measurements should be

relevant to the symptoms of intestinal distress. Also, as stated previously, in those studies involving drugs for which a label claim concerning a specific mechanism of action is desired, appropriate objective techniques must be used to show that the action does take place and relief of the symptoms is related to it.

7. *Statistical tests and sample size.* Appropriate statistical tests should be used to establish efficacy. Sample sizes should be determined to give a P value of .05 for testing equality in effectiveness of the drug and the placebo, and a sufficiently small probability of error of not detecting a significant clinical superiority of the drug over the placebo. The drug company should be prepared to discuss what it means by a significant clinical superiority.

8. *Number of clinical trials.* Two separate trials, at different geographical sites and performed by different investigators, should be conducted.

The drug company should select study sites which have a patient profile similar to what is believed to be the profile of the sample population. Further, the sample from each site should be representative of the site with respect to important variables (age and sex).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under 21 CFR 5.11 (see 46 FR 26052; May 11, 1981), the agency advises in this advance notice of proposed rulemaking that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations would be amended by adding in Part 357, a new Subpart D, to read as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart D—Digestive Aid Drug Products

Sec.

357.301 Scope.
357.303 Definitions.
357.310 Digestive aid active ingredients for the treatment of immediate postprandial upper abdominal distress. [Reserved]
357.312 Digestive aid active ingredients for the treatment of intestinal distress. [Reserved]
357.350 Labeling of digestive aid drug products.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704).

Subpart D—Digestive Aid Drug Products

§ 357.301 Scope.

(a) An over-the-counter digestive aid drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 357.303 Definitions.

As used in this subpart:

(a) *Aerophagia.* The swallowing of air.

(b) *Immediate postprandial upper abdominal distress.* A symptom complex consisting of the sensations of bloating, distention, fullness, or pressure with upper abdominal discomfort occurring immediately (within 30 minutes) after a meal, excluding symptoms of aerophagia or hyperacidity.

(c) *Intestinal distress.* A syndrome consisting of abdominal discomfort occurring 30 minutes to several hours after a meal. It is self-limiting and not attributable to any known organic disease, nor accompanied by diarrhea or constipation. This syndrome is characterized by one or more of the following symptoms: bloating, distention, fullness, pressure, pain, or cramps.

(d) *Symptom.* Any subjective evidence of a patient's condition, as perceived by the patient.

(e) *Syndrome.* A set of symptoms which occur together; a symptom complex.

§ 357.310 Digestive aid active ingredients for the treatment of immediate posprandial upper abdominal distress. [Reserved]

§ 357.312 Digestive aid active ingredients for the treatment of intestinal distress. [Reserved]

§ 357.350 Labeling of digestive aid drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "digestive aid."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to the following phrases:

(1) *For products containing any ingredient identified in § 357.310 for the treatment of immediate postprandial upper abdor. inal distress.* (i) "For relief of upper abdominal" (one or more of the following symptoms: "distress," "bloating," "distention," "fullness," and "pressure") "which occurs soon after eating" (optional, "and which may be described as 'gas'.").

(ii) "Relieves the over-full feeling in the upper abdomen which occurs soon after eating."

(iii) *Other allowable statement.* The word "stomach" may be substituted for the words "upper abdomen" or "upper abdominal" in the indications in paragraphs (a)(1) (i) and (ii) of this section.

(2) *For products containing any ingredient identified in § 357.312 for the treatment of intestinal distress.* (i) "For relief of intestinal distress occurring 30 minutes to several hours after eating and often accompanied by complaints of bloating, distention, fullness, pressure, pain, or cramps."

(ii) "For relief of" (one or more of the following symptoms: "Bloating," "distention," "fullness," "pressure," "pain," or "cramps") "sometimes described as 'gas', which occurs 30 minutes to several hours after eating."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing any ingredient identified in § 357.310 for the treatment of immediate postprandial upper abdominal distress.* (i) "If symptoms of upper abdominal distress persist, stop this medication and consult your physician."

(ii) "Do not use this product in children under 12 years of age except under the supervision of a physician."

(2) *For products containing any ingredient identified in § 357.312 for the treatment of intestinal distress.* [Reserved]

(d) *Direction.* [Reserved]

Interested persons may, on or before April 5, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this advance notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals may

submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments replying to comments may also be submitted on or before May 5, 1982. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 23, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: December 17, 1981.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-10 Filed 1-4-82; 8:45 am]

BILLING CODE 4160-01-M

federal register

Tuesday
January 5, 1982

Part IX

Department of Health and Human Services

Food and Drug Administration

Smoking Deterrent Drug Products for Over-the-Counter Human Use; Establishment of a Monograph

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 357

[Docket No. 81N-0027]

Smoking Deterrent Drug Products for Over-the-Counter Human Use; Establishment of a Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of a proposed rulemaking that would establish conditions under which over-the-counter (OTC) smoking deterrent drug products are generally recognized as safe and effective and not misbranded. This notice is based on the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by April 5, 1982, and reply comments by May 5, 1982.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's Office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on February 23, 1980 a report of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products on smoking deterrent drug products. FDA regulations (21 CFR 330.10(a)(6)) provide that the agency issue in the **Federal Register** a proposed order containing: (1) The monograph recommended by the Panel, which establishes conditions under which OTC smoking deterrent drug products are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel. Although the Panel's report on smoking deterrent drug products for OTC use contains no recommendations for Category I ingredients, the Panel is proposing Category I labeling in this document in the event that data are submitted which result in the classification of any smoking deterrent active ingredient into Category I prior to the publication of a final rule.

The unaltered conclusions and recommendations of the Panel are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The report has been prepared independently of FDA, and the agency has not yet fully evaluated the report. The Panel's findings appear in this document to obtain public comment before the agency reaches any decision on the Panel's recommendations. This document represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it.

After reviewing all comments submitted in response to this document, FDA will issue in the **Federal Register** a tentative final monograph for OTC smoking deterrent drug products as a notice of proposed rulemaking. Under the OTC drug review procedures, the agency's position and proposal are first stated in the tentative final monograph, which has the status of a proposed rule, final agency action occurs in the final monograph, which has the status of a final rule.

The agency's position on OTC smoking deterrent drug products will be stated initially when the tentative final monograph is published in the **Federal Register** as a notice of proposed rulemaking. In that notice of proposed rulemaking, the agency also will announce its initial determination whether the proposed rule is a major rule under Executive Order 12291 and will consider the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). The present notice is referred to as an advance notice of proposed rulemaking to reflect its actual status and to clarify that the requirements of the Executive Order and the Regulatory Flexibility Act will be considered when the notice of proposed rulemaking is published. At that time FDA also will consider whether the proposed rule has a significant impact on the human environment under 21 CFR Part 25 (proposed in the **Federal Register** of December 11, 1979, 44 FR 71742).

The agency invites public comment regarding any impact that this rulemaking would have on OTC smoking deterrent drug products. Types of impact may include, but are not limited to, the following: Increased costs due to relabeling, repackaging, or reformulating; removal of unsafe or ineffective products from the OTC market; and testing, if any. Comments regarding the impact of this rulemaking on OTC smoking deterrent drug products should be accompanied by appropriate documentation.

In accordance with § 330.10(a)(2), the Panel and FDA have held as confidential all information concerning OTC smoking deterrent drug products submitted for consideration by the Panel. All the submitted information will be put on public display in the Dockets Management Branch, Food and Drug Administration, after February 4, 1982, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs (HFD-510) (address above).

FDA published in the **Federal Register** of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The Court in *Cutler* held that the OTC drug review regulations (21 CFR 330.10) were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision is now deleted from the regulations. The regulations now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process, before the establishment of a final monograph.

Although it was not required to do so under *Cutler*, FDA will no longer use the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III because that was the framework in which the Panel conducted its evaluation of the data.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will

be effective 6 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions which would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce. Further, any OTC drug products subject to this monograph which are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to voluntarily comply with the monograph at the earliest possible date.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the Federal Register of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the Federal Register of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC miscellaneous internal drug products was issued in the Federal Register of November 16, 1973 (38 FR 31696). (In making their categorizations with respect to "active" and "inactive" ingredients, the advisory review panels relied on their expertise and understanding of these terms. FDA has defined "active ingredient" in its current good manufacturing practice regulations (§ 210.3(b)(7), (21 CFR 210.3(b)(7))), as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." An "inactive ingredient" is defined in § 210.3(b)(8) as "any component other than an 'active ingredient.' ") In the Federal Register of August 27, 1975 (40 FR 38179) a notice supplemented the initial notice with a detailed, but not necessarily all-inclusive, list of active ingredients in miscellaneous internal drug products to be considered in the OTC drug review. This list, which included smoking deterrent ingredients, was provided to give guidance on the kinds of active ingredients for which data should be submitted. The notices of November 16, 1973, and August 27, 1975, informed OTC drug product manufacturers of their opportunity to submit data to the review at that time and of the applicability of the monographs from the OTC review to all OTC drug products.

Under § 330.10(a) (1) and (5), the Commissioner of Food and Drugs appointed the following Panel to review the information submitted and to prepare a report on the safety, effectiveness, and labeling of the active ingredients in these OTC miscellaneous internal drug products:

Diana F. Rodriguez-Calvert, Pharm. D. (appointed July 1976), Acting Chairman.
John W. Norcross, M.D., Chairman (resigned March 1979).
Ruth Eleanor Brown, R.Ph. (resigned May 1976).
Elizabeth C. Giblin, M.N., Ed. D.
Richard D. Harshfield, M.D.
Theodore L. Hyde, M.D.
Claus A. Rohweder, D.O. (deceased April 13, 1979).
Samuel O. Thier, M.D. (resigned November 1975).
William R. Arrowsmith, M.D. (appointed March 1976).

Representatives of consumer and industry interests served as nonvoting members of the Panel. Eileen Hoates, nominated by the Consumer Federation of America, served as the consumer liaison until September 1975, followed by Michael Schulman, J.D. Francis J. Hailey, M.D., served as the industry liaison, and in his absence John Parker, Pharm. D., served. Dr. Hailey served until June 1975, followed by James M. Holbert, Sr., Ph. D. All industry liaison members were nominated by the Proprietary Association.

The following FDA employees assisted the Panel: Armond M. Welch, R.Ph., served as the Panel Administrator until July 1979, followed by John R. Short, R.Ph. Enrique Fefer, Ph. D., served as the Executive Secretary until July 1976, followed by George W. James, Ph. D., until October 1976, followed by Natalia Morgenstern until May 1977, followed by Arthur Auer until October 1978. Roger Gregorio served as the liaison for the Office of New Drug Evaluation beginning November 1978. Joseph Hussion, R.Ph., served as the Drug Information Analyst until July 1976, followed by Anne Eggers, R.Ph., M.S., until October 1977, followed by John R. Short, R.Ph., until July 1979.

In order to expand its scientific base, the Panel called upon the following consultants for advice in areas which required particular expertise:

Lynn R. Brady, Ph. D. (pharmacognosy).
Arthur E. Schwarting, Ph.D. (pharmacognosy).
Ralph B. D'Agostino, Ph. D. (statistics).

The Advisory Review Panel on OTC Miscellaneous Internal Drug Products was charged with the review of many categories of drugs, but due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents its conclusions and recommendations for smoking deterrent drug products in this document. The review of all other categories of miscellaneous internal drug products is being continued by the Panel, and its findings are being published periodically in the Federal Register.

The Panel was first convened on January 13, 1975 in an organizational meeting. Meetings at which smoking deterrent drug products were discussed were held on the following dates: March 2 and 3, April 17 and 18, June 2 and 3, September 29 and 30, December 8 and 9, 1979, and February 23 and 24, 1980.

The minutes of the Panel meetings are on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration (address above).

Donald J. Flaster, M.D., was given an opportunity to appear before the Panel to express his views on smoking deterrent drug products at his own request.

No person who so requested was denied an opportunity to appear before the Panel to discuss smoking deterrent drug products.

The Panel has thoroughly reviewed the literature and data submissions, has listened to additional testimony from an interested person, and has considered all pertinent data and information submitted through February 23, 1980 in arriving at its conclusions and recommendations for OTC smoking deterrent drug products.

In accordance with the OTC drug review regulations in § 330.10, the Panel reviewed smoking deterrent drug products with respect to the following three categories:

Category I. Conditions under which OTC smoking deterrent drug products are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which OTC smoking deterrent drug products are not generally recognized as safe and effective or are misbranded.

Category III. Conditions for which the available data are insuficient to permit final classification at this time.

The Panel reviewed 45 smoking deterrent active ingredients and classified no ingredients in Category I, 43 ingredientas in Category II, and 2 ingredients in Category III.

I. Submission of Data and Information

Pursuant to the notices published in the Federal Register of November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on OTC miscellaneous internal drug products, the following firms made submissions related to products used as smoking deterrents:

A. Submissions by Firms.

Firms and Products

Anti-Tobacco Information Center, Inc., Rouses Point, NY 12979—Nicocortyl tablets.

Campana Corp., Batavia, IL 60510—Bantron tablets.

S.A. Cravotta Co., Arlington, VA 22201—I Quit spray.

Edgefield Corp., Convent, NJ 07961—Tabmint chewing gum.

Health Sciences Associates, Inc., Bethesda, MD 20014—Nicoprive tablets.

B. Ingredients Reviewed by the Panel

1. *Labeled ingredients contained in products submitted to the Panel.*

Alcohol
Ammonium chloride
Calcium phosphate, tribasic
Cloves, ground
Co-carboxylase
Coriander, ground
Cornstarch
Eucalyptus oil
Ginger, ground Jamaica
Gum arabic, powdered
Hawthorne, dry alcoholic extract of
Lactose
Lemon oil, terpeneless
Licorice root extract
Lobelia alkaloids, natural
Magnesium carbonate
Magnesium stearate
Menthol
Methyl salicylate
Nicotinic acid
Pyridoxine hydrochlorate
Quinine ascorbate
Silver acetate
Sodium ascorbate
Sugar
Talc
Thiamine mononitrate
Thymol

2. *Other ingredients.* In addition to those ingredients included in the products submitted to the Panel, the Panel reveiwed the following ingredients which were listed in the Federal Register notice of August 27, 1975 (40 FR 38179).

Aloin
Aluminium hydroxide
Belladonna leaves, extract of
Benzocaine
Capsicum
Cascara sagrada, extract of
Chlorophyllins
Cimicifuga
Gentain, solid extract of
Lobelia
Lobeline sulfate
Methapyrilene hydrochloride
Nux vomica, extract of
Potassium gentian root
Potassium nux vomica
Propylene glycol
Silver nitrate
Sodium chloride

C. Classification of Ingredients

1. *Active ingredients.*

Cloves, ground
Coriander, ground
Eucalyptus oil
Ginger, ground Jamaica
Lemon oil, terpeneless
Licorice root extract
Lobeline (in the form of the lobeline sulfate or its pharmacological equivalent as natural lobelia alkaloids or *obelia inflata* herb)
Menthol
Methyl salicylate
Quinine ascorbate
Silver acetate
Thymol

2. *Other ingredients.* The Panel was neither able to locate nor is it aware of any significant body of data demonstrating the safety and effectiveness of the following OTC ingredients when used as smoking deterrents. The Panel, therefore, classifies these ingredients as Category II for this use, and they will not be reviewed further in this document.

Alcohol
Aloin
Aluminium hydroxide
Ammonium chloride
Belladonna leaves, extract of
Benzocaine
Capsicum
Cascara sagrada, extract of
Chlorophyllins
Cimicifuga
Co-carboxylase
Cornstarch
Gentian, solid extract of
Gum arabic, powdered
Hawthorne, dry alcoholic extract of
Lactose
Magnesium strearate
Methapyrilene hydrochloride
Nicotinic acid
Nux vomica, extract of
Potassium gentian root
Potassium nux vomica
Propylene glycol
Pyridoxine hydrochlorate
Silver nitrate
Sodium ascorbate
Sodium chloride
Sugar
Talc
Thiamine mononitrate

3. *Adjuvants.* These are ingredients incorporated in drug products which may aid in the action of the active ingredient. The possible role of these ingredients is discussed below. (See part III. paragraph C.1.a. below—Lobeline.)

Calcium phosphate, tribasic
Magnesium carbonate

D. Referenced OTC Volumes

The "OTC Volumes" cited throughout this document include submissions made by interested persons in response to the call-for-data notices published in the Federal Register of November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179). All of the information included in these volumes, except for those deletions which are made in accordance with the confidentiality provisions set forth in § 330.10(a)(2), will be put on public display after February 4, 1982, in the Dockets Management Branch (HFA–305), Food and Drug Administration, Room 4–62, 5600 Fishers Lane, Rockville, MD 20857.

II. General Statements and Recommendations

A. Definitions of Terms

For the purposes of this document the Panel has agreed on the following definitions:

1. *Heavy smokers.* Those persons who smoke at least 20 cigarettes per day.

2. *Long-term, chronic smokers.* Those persons who have smoked cigarettes regularly for at least 5 years.

3. *Recidivism.* Return to previous cigarette smoking pattern.

4. *Smoking deterrent.* A substance which helps one to stop smoking cigarettes.

B. General Discussion

Products have been submitted to the Advisory review Panel on OTC Miscellaneous Internal Drug Products bearing labeling claims "to stop smoking" or "to reduce smoking." However, this document deals solely with OTC smoking deterrent drug products which help one to stop smoking cigarettes. Smoking deterrent drug products, in general, either alter the tobacco taste so that smoking becomes less pleasant to the smoker or substitute a nicotine-like drug in an oral dosage form in an amount sufficient to produce a pharmacological effect that alters the smoker's habit or addiction. The Panel believes that drugs which are purported merely to reduce smoking without the objective of stopping smoking entirely are a waste of the consumer's time and money because of rapid and virtually universal recidivism. The Panel believes

that the willpower and motivation of the consumer are essential for the action of products designed to help the individual reduce or stop smoking.

After tobacco was introduced in Europe by the 16th century explorers returning from North America, its use and cultivation rapidly spread throughout the world (Ref. *1*). In 1623, Sir Francis Bacon observed that "the use of tobacco is growing greatly; it conquers men with a certain secret pleasure so that those who have once become accustomed thereto can hardly be restrained therefrom" (Ref. *1*). Three hundred and fifty-seven years later, the Panel finds no reason to dispute this statement.

Over the years substances such as corn silk, coffee grounds, and dried lettuce leaves have been substituted as smoking material with little acceptance. This leads to the conclusion that there is indeed something in tobacco which imparts a "certain secret pleasure." Of the various substances in tobacco (nicotine, pyridine and other nitrogenous bases, a family of isoprenoid compounds, volatile acids, tarry and phenolic substances, furfural, and acrolein), nicotine, which is believed to have addictive or habit forming properties, is known to exert a strong stimulating effect on the central nervous system and a peripheral stimulating effect on the autonomic nervous system (Ref. *2*).

Attempts by confirmed smokers to stop smoking are as numerous as are the different methods used. There is little evidence supporting a long-term success rate of significant proportion in modifying smoking behavior, whether or not oral medications (tranquilizers, stimulants, or nicotine substitutes) are used, with or without various psychological techniques. Short-term success rates are often found with all techniques. The high rate of resumption of smoking after a period of abstinence is influenced by many factors (personality, psychosocial stress, etc.). These factors are clearly unrelated to the effectiveness of the drug whose purpose is to help the individual break the smoking habit. The responsibility of this Panel is to evaluate only the effectiveness of the drug in helping the person to break the habit.

Since 1969, 29 million smokers have quit smoking, and it is estimated that 95 percent have done so without counseling or a structured program as indicated in the Surgeon General's report on "Smoking and Health" (Ref. *3*). Also it is known that among smokers experiencing a first myocardial infarction, 30 to 50 percent will stop permanently upon minimal advice of a physician. The characteristics of these groups have been little explored.

Some techniques used to help a smoker reduce or stop smoking have been reviewed by the Surgeon General (Ref. *3*) and are briefly summarized by this Panel:

(1) Counseling programs consisting of individual or group therapy have produced 1-year abstinence rates of 13 to 30 percent.

(2) Educational campaigns have reduced cigarette consumption by 20 to 30 percent below its predicted 1975 level.

(3) Proprietary or public service clinics have produced good immediate abstinence rates with approximately 30 percent reporting abstinence at 1 year.

(4) Fifteen to twenty percent of subjects highly susceptible to hypnosis can be expected to have a long-term abstinence from smoking through this technique.

(5) Sensory deprivation techniques have produced a long-term success rate of up to 27 percent in small numbers of subjects.

(6) Behavior modification has had a long-term success rate of approximately 25 percent.

(7) Aversion techniques such as satiation and rapid smoking have been reported to have up to 60 percent of subjects abstinent at 6 months in a few studies. However, these techniques present a considerable cardiovascular risk because of increased nicotine and carbon monoxide in the body. Aversion to smoking through electric shocks has been reported to have a success rate of 80 percent in small numbers of subjects in combination with other treatment methods.

Interpretation of results in many studies involving a change in smoking behavior is difficult because of differences or defects in study design. Many studies have been uncontrolled or poorly controlled, and few have used long-term followups with objective measurements. It also has been impossible to differentiate between "long-term" and "1-year" abstinence. Most reports have been based on unverified self-reporting of the number of cigarettes smoked during a period. Objective methods to measure smoking behavior such as measuring blood levels of nicotine, cotinine (a major metabolite of nicotine), carbon monoxide, and thiocyanate must be included in studies recommended by this Panel because false reporting by persons trying to stop smoking has been confirmed by such methods in several programs involving smoking modification.

Within 5 minutes after smoking, blood levels of nicotine peak and about half of this amount of nicotine is excreted in 30 minutes. Plateau levels are reached in 2 to 3 hours by chronic smokers and the blood is cleared in approximately the same time when smoking is stopped (Ref. *4*). Excretion of nicotine in the urine varies greatly with changes in the urine pH (an acidic urine increases excretion). Urine will be free of nicotine within 12 hours after the individual has stopped smoking. Therefore, blood or urine measurements of nicotine would only confirm that the subject has smoked within the last several hours.

Cotinine, the major metabolite of nicotine, has about one-fiftieth the pharmacologic activity of nicotine. Fifty percent excretion of cotinine occurs in about 30 hours so the presence of cotinine in the blood would indicate that the subject has smoked within the last 5 to 7 days (Ref. *5*).

Carbon monoxide in expired air of smokers is easily and relatively inexpensively measured, and its presence indicates smoking activity within a period of about 12 hours; however, its presence is modified by environmental factors, e.g., living in an area where normal levels of carbon monoxide in the air are higher than average. Therefore, this measurement is not a reliable indication of cigarette smoking activity.

Blood thiocyanate levels indicate exposure to hydrocyanic acid which is present in cigarette smoke in small amounts. Elevated levels are present for approximately 1 month after smoking is stopped. Since certain foods, such as cabbage and brussel sprouts, also cause increased blood levels of thiocyanate, thiocyanate levels by themselves are unreliable as indicators of smoking behavior. A combination of elevated carbon monoxide in expired air and elevated thiocyanate levels is considered proof of smoking activity (Ref. *6*).

The Panel recognizes that a high percentage of recidivism is likely to occur within the first 4 months after stopping smoking (Ref. *7*). The Panel also recognizes that recidivism may occur after stopping smoking for a short time, but the Panel believes that the most difficult time period for an individual to stop smoking is the first few weeks. Although this time is variable, the Panel has selected a period of 3 weeks in order to evaluate the effectiveness of smoking deterrents.

References

(*1*) Brecher, E. M., "Licit and Illicit Drugs," Little, Brown and Co., Boston, p. 209, 1972.

(*2*) Bolle, R. L., and G. D. Koelle, "Ganglionic Stimulating and Blocking Agents," *in* "The Pharmacological Basis of

Therapeutics," 5th Ed., edited by L. S. Goodman and A. Gilman, The MacMillan Co., New York, pp. 567–568, 1975.

(3) "Smoking and Health. A Report of the Suregeon General," U.S. Department of Health, Education, and Welfare, DHEW Publication No. (PHS) 79–50066, 1979.

(4) Isaac, P. F., and M. J. Rand, "Cigarette Smoking and Plasma Levels of Nicotine," *Nature*, 236:308–310, 1972.

(5) Zeidenberg, P., et al., "Nicotine: Cotinine Levels in Blood During Cessation of Smoking," *Comprehensive Psychiatry*, 18:93–101, 1977.

(6) Vogt, T. M., et al., "Expired Air Carbon Monoxide and Serum Thiocyanate as Objective Measures of Cigarette Exposure," *American Journal of Public Health*, 67:545–549, 1977.

(7) "Guidelines for Research on the Effectiveness of Smoking Cessation Programs. A Committee Report," National Interagency Council on Smoking and Health, New York, 1974.

C. Labeling

The Panel has carefully reviewed the submitted labeling claims for products promoted as smoking deterrents and has classified them as Category I or Category II. The Panel did not identify any Category III labeling. The Panel realizes that other terms may be developed to express the same Category I indications. However, only those indications and warnings listed under Category I are generally recognized to be acceptable at this time.

In order for any labeling to be acceptable, it must include (1) the indication(s) for use, (2) pertinent warnings and contraindications, and (3) clear directions for use that include the recommended dosage.

The Panel believes that all labeling should be clear, concise, easily read, and understood by most consumers. It has followed this concept in the development of all Category I labeling. The Panel is also concerned about the size and color of the print used in labeling of these and all OTC drug products, and recommends that manufacturers make an effort to design legible labeling.

One of the primary functions of this Panel is to attempt to eliminate confusing labeling claims. Some of the labeling on currently marketed smoking deterrent drug products is unsupported by scientific data and in some cases misleading. The Panel believes that if two ingredients are indistinguishable with regard to effectiveness, it is misleading to claim superiority for one. Accordingly, such labeling has been placed in Category II.

The indications for use should be simply and clearly stated; the directions for use should provide the user with enough information for safe and effective use of the product.

Undocumented or misleading claims such as "does not require any willpower" and colloquial or provincial expressions that have no meaning to most people must not be used. In the labeling, effectiveness shall not be related to the physical characteristics of the product, except as those characteristics may relate to the action of the active ingredients.

The Panel believes that the pharmacological effect of the drug being studied is only temporary and by itself is not sufficient to cause long-term stopping of smoking which instead must result from the smoker's willingness and motivation to refrain from smoking after the use of the drug product is stopped. The Panel believes that claims for long-term effectiveness of the drug are misleading unless documented by studies of adequate duration.

The Panel is aware of the current OTC labeling regulation dealing with warning statements (21 CFR 330.1(g). The Panel concurs with the warning, "Keep this and all drugs out of the reach of children," and believes that it should be incorporated in the smoking deterrent labeling. However, the Panel recommends that the other warning statement required by § 330.1(g) ("In case of accidential overdose, seek professional assistance or contact a Poison Control Center immediately") be revised to read as follows: "In case of accidential overdose, contact a Poison Control Center, Emergency Medical Facility, or Physician immediately for advice." The Panel believes that this revision will be more informative to the consumer.

Because OTC products can be purchased by anyone, it is the view of the Panel that the public generally does not regard them as products which can result in injurious or potentially serious consequences if improperly used. The public needs to be continually alerted to the idea that these products, like all medicine, carry some risk and should be used with caution. The consumer should also be informed of signs or symptoms of known toxicity requiring use of the drug to be discontinued.

In addition, the Panel recommends that the drug product labeling contain instructions for the most effective use of the product. These instructions should be displayed prominently on all package labeling.

The Panel recommends that the label should contain a listing of all ingredients, clearly indicating which are active and which are inactive. Active ingredients should be listed by their established names, and the label should state the quantity of the active ingredient included in a single dose.

D. Combination Policy

The Panel agrees with FDA's general combination policy as stated in § 330.10(a)(4)(iv) (21 CFR 330.10(a)(4)(iv)) and with the agency's "General Guidelines for OTC Drug Combination Products" for which the notice of availability was published in the **Federal Register** of November 28, 1978 (43 FR 55466). As they apply to the combination smoking deterrent drug products reviewed in this document, the following two sections are particularly appropriate in the Panel's view:

1. The portion of regulation § 330.10(a)(iv) which states,

An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each ingredient makes a contribution to the claimed effect(s); * * *, and

2. The portion of FDA's "General Guidelines for OTC Drug Combination Products" which states,

Category I active ingredients from the same therapeutic category that have the same mechanism of action should not ordinarily be combined unless there is some advantage over the single ingredients in terms of enhanced effectiveness, safety, patient acceptance, or quality of formulation. They may be combined in selected circumstances to treat the same symptoms or conditions if the combination meets the OTC combination policy in all respects, the combination offers some advantage over the active ingredients used alone, and the combination is, on a benefit-risk basis, equal to or better than each of the active ingriendients used alone at its therapeutic dose.

III. Smoking Deterrent Drug Products

A. Category I Conditions

The following are Category I conditions under which smoking deterrent drug products are generally recognized as safe and effective and are not misbranded.

1. *Category I active ingredients.* None.

2. *Category I labeling.* Although the Panel has not classified any ingredients in Category I, it recommends the following Category I labeling for smoking deterrent drug products which contain ingredients found to be generally recognized as safe and effective and not misbranded, as well as any specific labeling discussed in the individual ingredient statements.

a. *Indications.* The product labeling should contain one or more of the following statements:

(1) "A temporary aid to those who want to stop smoking cigarettes."

(2) "Helps you stop the cigarette urge temporarily."

(3) "Helps you stop smoking cigarettes temporarily."

(4) " A temporary aid to breaking the cigarette habit."

b. *Other required statement.* All product labeling must contain the following statement: "This product's effectiveness is directly related to the user's motivation to stop smoking cigarettes."

Other allowable statement. In addition to the above required labeling, the Panel will allow product labeling to contain a descrition (in lay language) of the specifc proven mechanism of action of the active ingredients under the heading "Mechanism of Action."

B. Category II Conditions

The following are Category II conditions under which smoking deterrent drug products are not generally recognized as safe and effective or are misbranded.

1. *Category II active ingredient—Quinine ascorbate.* Quinine ascorbate was submitted to the Panel as part of a product which also contains vitamins and a dry alcoholic extract of hawthorne. The submission to the Panel did not identify the active ingredient(s). However, the Panel assumes that the quinine ascorbate is the intended active ingredient and concludes that it is safe in the dose noted below, but is not generally recognized as an effective smoking deterrent.

(1) *Safety.* The Panel found quinine ascorbate to be discussed only in the Merck Index (Ref. *1*), and only as a chemical. No discussion of any pharmacological action could be found other than as quinine. The usual daily dose of quinine (calculated as the sulfate salt) is 650 milligrams (mg) every 8 hours which greatly exceeds the manufacturer's suggested daily dose for quinine ascorbate of 8 mg taken 8 times a day as a smoking deterrent (Ref. *2*).

Ascorbic acid (vitamin C), and ascorbate salts (ascorbyl palmitate, calcium ascorbate, niacinamide ascorbate, and sodium ascorbate), were reviewed by the Advisory Review Panel on OTC Vitamin, Mineral, and Hematinic Drug Products and its conclusions were published in the Federal Register of March 16, 1979 (44 FR 16126). That Panel found that doses of vitamin C in excess of 1 gram (g) may produce increased excretion of oxalate, uric acid, and calcium, which in turn may enhance the risk of crystal formation in the kidney and bladder (44 FR 16140). But that Panel concluded that a maximum safe daily dose is 500 mg (44 FR 16141), which greatly exceeds the possible dose from quinine ascorbate used as a smoking deterrent.

Ascorbic acid and ascorbate salts are common articles of the diet and are sometimes consumed in large doses by the American public. The Panel, therefore, considers that quinine ascorbate is safe when used at a dose of 8 mg taken eight times daily as a smoking deterrent.

Since quinine is generally recognized as safe and since ascorbic acid and ascorbate salts are generally recognized as safe, the Panel concludes that quinine ascorbate is generally recognized as safe for OTC use as a smoking deterrent.

(2) *Effectiveness.* The effectiveness of quinine ascorbate as a smoking deterrent is not substantiated in the submission (Ref. *2*). Reference to its use as a smoking deterrent could not be found in any scientific literature, and no references to such literature were included in the submission. There is no indication from the clinical results reported that the "studies" are any more than testimonials and are not compatible with recognized standards of adequate and well-controlled clinical investigations. Quinine ascorbate was incorporated in a clinical study submitted by another firm (Ref. *3*); however, due to limited conclusions that could be drawn from the statistical analysis, its efficacy in that study could not be determined. (See part III. paragraph B.2.a. below—Licorice root extract, ground coriander, ground ginger (Jamaica), ground cloves, lemon oil (terpeneless), and orange oil.) Furthermore, the Panel is not aware of quinine ascorbate ever being marketed in this country as a smoking deterrent. Therefore, the Panel concludes that quinine ascorbate is not generally recognized as an effective smoking deterrent.

(3) *Evaluation.* The Panel concludes that quinine ascorbate is generally recognized as safe, but it is not generally recognized as an effective smoking deterrent.

The combination product containing this ingredient has never been marketed in the United States. The Panel considers the entire combination irrational since no effectiveness has been demonstrated for the quinine ascorbate, the vitamins most likely would have no effect as a smoking deterrent, and the Panel has not been able to find any reference to the use of hawthorne extract as a smoking deterrent.

References

(*1*) "Merck Index," 9th Ed., Merck and Co., Inc., Rahway, NJ, p. 1048, 1976.

(*2*) OTC Volume 170001.

(*3*) OTC Volume 170169.

2. *Category II combinations.*

Licorice root extract, ground coriander, ground ginger (Jamaica), ground cloves, lemon oil (terpeneless), and orange oil

Methyl salicylate, eucalyptus oil, menthol, and thymol.

a. *Licorice root extract, ground coriander, ground ginger (Jamaica), ground cloves, lemon oil (terpeneless), and orange oil.* The Panel concludes that a combination of these spices and flavors is safe for OTC use in the doses noted below, but it is not generally recognized as an effective smoking deterrent.

(1) *Safety.* These common spices and essential oils are generally recognized as safe for human use as food additives in §§ 182.10 and 182.20 (21 CFR 182.10 and 182.20). The Panel realizes that the concentration of the ingredients in this type of formulation will be greater than that used as a food additive. This would be necessary in order for the product to achieve its intended purpose of overwhelming the gustatory and olfactory senses. The Panel believes that the margin of safety of these ingredients is wide enough so that quantities in excess of those used as food flavors may be safely used in smoking deterrent drug products.

In review of the formulation submitted to the Panel as a smoking deterrent, the Panel does not consider the concentration of any of the ingredients to pose a safety problem when used as a smoking deterrent and, therefore, concludes that the entire formulation is generally recognized as safe for OTC use as a smoking deterrent.

(2) *Effectiveness.* The recommended use for this combination of spices and essential oils involves sucking on a tablet whenever there is a desire to smoke. These ingredients are claimed to act as physiological satisfiers of the gustatory and olfactory senses by overwhelming them while simultaneously satisfying the physical sensation of oral gratification.

Only one clinical study (Ref. *1*) was submitted to the Panel, and the Panel is not aware of any others. This study involves the comparative testing of the spice and essential oil formulation (Formula I) and a quinine ascorbate formulation (Formula II) as smoking deterrents. All subjects received "support therapy" which included medical supervision and medications for other conditions as necessary. Seventy-four individuals were assigned to one of three drug therapy groups as follows:

(1) Formula I plus support therapy (41 individuals),

(2) Formula II plus support therapy (19 individuals), and

(3) Formula I and Formula II plus support therapy (14 individuals).

Results of the study show that 30 (73.2 percent) of the individuals in group (1) reduced their cigarette consumption by more than 50 percent, along with 13 (68.4 percent) in group (2), and 9 (64.3 percent) in group (3). The numbers and percentages for those who stopped smoking in each group are 10 (24.4 percent), 3 (21.1 percent), and 3 (21.4 percent), respectively.

The Panel found several problems with this study. The study was neither placebo-controlled nor double-blind. Subjects were not randomly assigned to groups. Support therapy was provided for each group. Because of these problems, conclusions drawn from any statistical analysis of the study are extremely limited. It is appropriate to conclude that with regard to reduction (by more than 50 percent) and stopping of smoking there are no statistically significant differences among the 3 groups. However, the Panel was unable to provide any conclusions or statements on the effectiveness of the spice and essential oil formulation (or any of the other drug groups) because there was no information which allowed the Panel to differentiate between the effects of the drug(s) and the effects of the support therapy.

(3) *Evaluation.* The Panel concludes that the combination of spices and essential oils mentioned above is generally recognized as safe for OTC use when used in doses intended as a smoking deterrent, but it is not generally recognized as an effective smoking deterrent.

Reference

(1) OTC Volume 170169.

b. *Methyl salicylate, eucalyptus oil, menthol, and thymol.* The Panel concludes that a combination of methyl salicylate, eucalyptus oil, menthol, and thymol is safe for OTC use in doses used as a smoking deterrent, but is not generally recognized as an effective smoking deterrent.

(1) *Safety.* Eucalyptus oil, menthol, methyl salicylate, and thyme oil (contains 20 to 30 percent thymol) have been classified by the National Academy of Sciences (Ref. *1*) as flavoring agents for foods. In addition, eucalyptol (eucalyptus oil contains not less than 70 percent of eucalyptol), menthol, and thymol are permitted by FDA as food additives (synthetic flavoring substances) when used in the minimum quantities required to produce their intended effect (21 CFR 172.515).

Since methyl salicylate is the only one of these four ingredients not specifically permitted as a food additive by FDA regulations, the Panel felt obligated to review its toxicity. Methyl salicylate toxicity is similar to that of other salicylate preparations, such as aspirin and sodium salicylate. The minimum lethal dose for children is 4 milliliters (mL) (Ref. *2*). The fact that it is a liquid with a pleasant aroma makes it very attractive and increases its potential for consumption by children.

Davison et al. (Ref. *3*) were able to demonstrate that methyl salicylate is quickly hydrolyzed to free salicylate in animals and man and therefore concluded that toxicity is due to free salicylate and not to the unhydrolyzed methyl ester (methyl salicylate). Results of their study show negligible plasma levels of methyl salicylate in dogs and rats 60 minutes after administration, whereas 21 percent of the total salicylate in human plasma was still present as methyl salicylate after 90 minutes. This more rapid hydrolysis of methyl salicylate in animals (dogs and rats) probably explains the greater toxicity of methyl salicylate in these animals as compared to humans and substantiates the conclusion that methyl salicylate toxicity is due to free salicylate.

In review of the formulation submitted (Ref. *4*) to the Panel as a smoking deterrent, the toxicity of the methyl salicylate component is not considered to be a risk because of the small amount included. Therefore, the product itself is generally recognized as safe for its intended OTC use as a smoking deterrent.

(2) *Effectiveness.* No clinical studies were submitted for this combination of ingredients, and the Panel was unable to find any reference to clinical studies in the literature since this combination of ingredients has not been marketed in the United States as a smoking deterrent. There were merely a few testimonials in the material submitted to the Panel (Ref. *4*). The Panel concludes that a combination of methyl salicylate, eucalyptus oil, menthol, and thymol is not generally recognized as an effective smoking deterent.

(3) *Evaluation* The Panel concludes that a combination of methyl salicylate, eucalyptus oil, menthol, and thymol is generally recognized as safe for OTC use when used in doses intended as a smoking deterrent, but it is not generally recognized as an effective smoking deterrent.

References

(*1*) "Food Chemicals Codex." 2d Ed., Committee on Specifications of the Committee on Food Protection, National Research Council, National Academy of Sciences, Washington, 1972.

(*2*) Woodbury, D. M., and E. Fingl, "Analgesic-Antipyretics Anti-inflammatory Agents, and Drugs Employed in the Therapoy of Gout," *in* "The Pharmacological Basis of Therapeutics," 5th Ed., edited by L. S. Goodman and A. Gilman, The MacMillan Co., New York, p. 336, 1975.

(*3*) Davison, C., et al., "On the Metabolism and Toxicity of Methyl Salicylate," *Journal of Pharmacology and Experimental Therapeutics*, 132:207–211, 1961.

(*4*) OTC Volume 170168.

3. *Category II labeling.* The Panel concludes that the following labeling claims are either unsupported by scientific data or are misleading. Claims of reduction in smoking rather than stopping are included in this list because the Panel does not consider reduction a satisfactory achievement due to rapid and virtually universal recidivism. The claims listed below and other related terms are classified as Category II labeling for smoking deterrent drug products:

a. "A tempoorary aid to cut down on smoking."

b. "An aid to those who want to reduce the smoking habit."

c. "Curbs the tobacco urge."

d. "Helps to stop smoking without requiring will power."

C. Category III Conditions.

The following are Category III conditions for which the available data are insufficient to permit final classification at this time.

1. *Category III active ingredients.*

Lobeline (in the form of lobeline sulfate or its pharmacological equivalent as natural lobelia alkaloids or *Lobelia inflata* herb).

Silver acetate.

a. *Lobeline (in the form of lobeline sulfate or its pharmacological equivalent as natural lobelia alkaloids or* Lobelia inflata *erb).* The Panel concludes that lobeline sulfate is safe for OTC use in the dose noted below, but data are insufficient to demonstrate its effectiveness as a smoking deterrent.

(1) *Safety.* Lobeline is an alkaloid obtained from *Lobelia inflata.* Lobeline is normally employed as the sulfate salt, but the less purified forms of the ingredient, i.e., natural lobelia alkaloids or *Lobelia inflata* herb, may be used in amounts that contain pharmacologically equivalent amounts of lobeline. The neuropharmacologic actions of lobeline are similar to those of nicotine but much weaker, and its principal effects are considered to be due to its action on the

autonomic ganglia, vomiting center, and respiratory center (Ref. *1*). From a single dose of 8 mg lobeline sulfate the most frequent symptoms reported (Ref. *1*) include gaseous eructations (belching), epigastric pain (stomach ache), severe heartburn, nausea, vomiting, and faintness. Few symptoms have been reported following doses of 2 mg three times a day. Rapp (Ref. *2*) found no significant changes in blood pressure, pulse, or respiration during a 10-day treatment using 6 mg lobeline sulfate (2 mg three times daily), when given in combination with antacids, in 23 healthy subjects between the ages of 17 and 43.

Rapp, Dusza, and Blanchet (Ref. *3*) claimed that tribaasic calcium phosphate and magnesium carbonate in doses of 130 mg each served as antacid adjuvants to increase the absorption of 2 mg lobeline sulfate and enhance the blood levels. To date this has not been independently confirmed. A single dose (2 mg) of the buffered product was found to have no more effect on blood pressure, pulse, respiratory rate, digital skin temperature, or gastric symptoms than a starch placebo (Ref. *4*). Studies designed to demonstrate effectiveness have not reported any evidence of clinical toxicity resulting from up to 6 weeks of use (Refs. *3* through *14*). No chronic toxicity studies have been made available to the Panel.

The Panel, therefore, concludes that lobeline sulfate is safe for OTC use at a dose of 2 mg up to three times a day for no longer than 6 weeks. Any claim for longer use would require chronic toxicity studies.

(2) *Effectiveness.* Although Rapp, Dusza, and Blanchet (Ref. *3*) found that the blood level of lobeline sulfate, when given in combination with antacids, was directly related to success in curbing smoking in 28 smokers who wanted to quit smoking, this has not been substantiated by other double-blind, placebo-controlled studies. There was a 74-percent reduction in the number of cigarettes smoked and a 57-percent reduction in the amount of tobacco consumed. The effective level was reported to be around 100 to 140 micrograms (μg) per 100 mL of blood. They also reported that the 25 subjects who did not want to stop smoking reduced the amount of tobacco consumed by 62 percent while there was actually an increase (by 7 percent) in the number of cigarettes smoked.

In a placebo-controlled study of 200 chronic smokers, Rapp and Olen (Ref. *4*) reported that more than 80 percent of the individuals on the drug had stopped smoking at the end of 5 to 6 days. A dose of 2 mg of the buffered lobeline sulfate was given three times a day. Less than 10 percent had stopped smoking when taking the placebo.

In addition to the Rapp studies mentioned above, the Panel was able to locate 10 other placebo-controlled studies (Refs. *5* through *14*). In only two of these (Refs. *10* and *11*) was lobeline significantly more effective than the placebo in aiding subjects to stop smoking. The other eight studies were all noncorroborative, possibly due to design defects in some of them. However, one of these (Ref. 5) employed the same study design as used in the Rapp and Olen study (Ref. *4*), but was unable to demonstrate the effectiveness of lobeline.

Since studies on lobeline sulfate as a smoking deterrent have shown conflicting results, the Panel concludes that further testing should be performed according to the testing guidelines to determine whether or not it is effective. (See part III. paragraph D. below—Data Required for Evaluation.)

(3) *Proposed dosage.* The Panel concludes that lobeline (in the form of lobeline sulfate or its pharmacological equivalent in terms of natural lobelia alkaloids or *Lobelia inflata* herb) is safe for OTC use in a dose of 2 mg up to three times a day.

(4) *Labeling.* The Panel recommends the Category I labeling for smoking deterrents. (See part III. paragraph A.2. above—Category I labeling.) In addition, because of a lack of chronic toxicity studies, the Panel recommends the following warning: "Do not use this drug for longer than 6 weeks." Any claim for longer use would require chronic toxicity studies.

(5) *Evaluation.* The Panel finds lobeline (in the form of lobeline sulfate or its pharmacological equivalent in terms of natural lobelia alkaloids or *Lobelia inflata* herb) safe for OTC use in the dosage described above, but recommends that testing of this ingredient be done according to the testing guidelines to determine whether it is effective. (See part III. paragraph D. below—Data Required for Evaluation.) These studies may be done with or without an appropriate buffer (antacids), but, if buffers are used, the protocol should be designed to show the effect of the buffer.

References

(*1*) Wright, I. S., and D. Littauer, "Lobeline Sulfate. Its Pharmacology and Use in Treatment of the Tobacco Habit," *Journal of the American Medical Association*, 109:649–654, 1937.

(*2*) OTC Volume 170038 (Section IV. c (3)).

(*3*) Rapp, G. W., B. T. Dusza, and L. Blanchet, "Absorption and Utilization of Lobeline as a Smoking Deterrent," *American Journal of Medical Sciences*, 237:287–292, 1959.

(*4*) Rapp, G. W., and A. A. Olen, "A Critical Evaluation of a Lobeline Based Smoking Deterrent," *The American Journal of Medical Sciences*, 230:9–14, 1955.

(*5*) Barlett, W. A., and R. W. Whitehead, "The Effectiveness of Meprobamate and Lobeline as Smoking Deterrents," *Journal of Laboratory and Clinical Medicine*, 50:278–281, 1957.

(*6*) Rosenberg, A., "An Attempt to Break the Smoking Habit," *Applied Therapeutics*, 4:1029–1033 and 1064, 1962.

(*7*) Scott, G. W., et al., "Buffered Lobeline as a Smoking Deterrent," *Lancet*, 1:54–55, 1962.

(*8*) Merry, J., and G. Preston, "The Effect of Buffered Lobeline Sulphate on Cigarette Smoking," *Practitoner*, 190:628–631, 1963.

(*9*) "Smoking Deterrent Study—A Report from the Research Committee of the British Tuberculosis Association," *British Medical Journal*, 2:486–487, 1963.

(*10*) Perlstein, I. B., "Smoking Deterrent Therapy in Private Practice," *in* "The First Annual M. R. Thompson Symposium on Recent Advances in the Medical Aspects of Smoking," Matthew Publishing Co., New York, pp. 40–45, 1964.

(*11*) London, S. J., "Clinical Evaluation of a New Lobeline Smoking Deterrent," *Current Therapeutic Research*, 5:167–175, 1963.

(*12*) Edwards, G., "Double-Blind Trial of Lobeline in an Anti-Smoking Clinic," *Medical Officer*, 112:158–160, 1964.

(*13*) Leone, L. A., et al., "A Study of the Effectiveness of the Smoking Deterrence Clinic," *Rhode Island Medical Journal*, 51:247–257, 260, 1968.

(*14*) Ross, C. A., "Smoking Withdrawal Research Clinics," *American Journal of Public Health*, 57:677–681, 1967.

b. *Silver acetate.* The Panel concludes that silver acetate is safe for OTC use in the dose noted below, but data are insufficient to demonstrate its effectiveness as a smoking deterrent.

(1) *Safety.* Silver acetate is one of the soluble silver salts which, with the exception of silver nitrate, have no known undesirable effects other than discoloration of the tissues, particularly the skin. Extensive animal studies in doses several times the human dose showed no evidence of any systemic effect other than staining of the tissue by the deposited silver (Ref. *1*). The Panel is unaware or any reports of toxicity in humans other than the discoloration. One reference (Ref. *2*). states:

> Silver appears to have a very low systemic toxicity. Chronic exposure to silver salts may cause argyrism (a permanent bluish discoloration of the skin or mouth) which appears to be solely of cosmetic concern. The famous "blue man" of the Barnum & Bailey Circus was said to have a total silver body burden of 90 to 100 gm. without obvious deleterious symptoms.

(2) *Effectiveness.* Silver salts are said to affect the mucous membrane of the mouth in such a way that when tobacco smoke comes in contact with these salts a nasty metallic sweet taste is produced, the effect lasting for up to 4 hours. Because of this, smoking becomes less desirable, and the individual is said to be able to reduce the number of cigarettes smoked per day.

The results of three placebo-controlled studies were submitted to support the effectiveness claim for silver acetate (Refs. *3* through *6*). The Rosenberg study was a 2-week double-blind parallel sample study involving 60 volunteers (30 in the silver acetate group and 30 in the placebo group) (Ref. *3*). This study was supplemented by Ref. *4*. In this and the other two studies cited, a chewing gum dosage form was used in order to keep the silver acetate present in the oral cavity for a relatively long period. Subjects were asked to keep a daily record of the number of cigarettes smoked each year. Weekly results were mailed or telephoned in to investigators. By the end of the 2 weeks, 11 of the 30 in the silver acetate group reported that they had stopped smoking. The difference between the stopping rates of the silver acetate and placebo group in statistically significant (p less than 0.05). The Panel believes that smoking behavior data that are reported by subjects either by telephone or by mail are not scientifically sound unless confirmed by objective measures or personal interviews. The Panel concludes that the Rosenberg study does suggest effectiveness, but does establish it.

Arvidsson (Ref. *5*) also conducted a 2-week double-blind parallel sample study. It involved 50 subjects (25 in the silver acetate group and 25 in the placebo group). Results were evaluated by comparing the mean number of cigarettes smoked on the 13th and 14th days for each group. These means were 10.6 and 18.4, for the silver acetate group and the placebo group, respectively, and the difference of 7.8 cigarettes per day is claimed to be statistically significant (p is less than 0.001). No details are given regarding the number of subjects who stopped smoking nor how the data on the number of cigarettes smoked were obtained. Again, the Panel considers this study only suggestive of effectiveness.

The third placebo-controlled study submitted was conducted by Schmidt (Ref. *6*) and consisted of 1,000 subjects who volunteered to enter a stop smoking study announced in the press and on the radio. Of the 1,000 subjects, 500 were assigned, in a double-blind fashion, to silver acetate and the other 500 to a placebo. Preparations were mailed to the subjects. Four or five weeks after this mailing, each test participant received a "validation" questionnaire. Of the 1,000 test participants, 796 returned the questionnaire. Of these, 617 questionnaires were usable (316 in the silver acetate group and 301 in the placebo group). Ninety-eight of the 316 (31.0 percent) in the silver acetate group and 75 of the 301 (24.9 percent) in the placebo group reported complete stopping of smoking. This difference is marginally significant ($p = 0.09$). No attempts to obtain information concerning stopping of smoking in the nonrespondents were attempted. While information obtained in the manner of the Schmidt study can be helpful, the Panel does not believe it can serve as a substitute for results from a well-controlled clinical study. Such a study would result from following the proposed guidelines for determining the effectiveness of OTC smoking deterrents as indicated below under "Evaluation."

(3) *Proposed dosage.* The Panel recommends a dosage of up to 6 mg silver acetate in a chewing gum every 4 hours, with not more than 6 such doses in a 24-hour period.

(4) *Labeling.* The Panel recommends the Category I labeling for OTC smoking deterrents. (See part III, paragraph A.2. above—Category I labeling.) In addition, the Panel recommends that the following *"Warning"* be included in the labeling: "*Warning.* Do not use this product for longer than 3 weeks. Frequent or prolonged use of this medication may result in permanent discoloration of the skin or mouth."

(5) *Evaluation.* The Panel finds silver acetate safe for OTC use in the dosage described above, but recommends that testing of this ingredient be performed according to the testing guidelines to determine whether it is effective. (See part III. paragraph D. below—Data Required for Evaluation.)

References

(*1*) OTC Volume 170129 (Section III).

(*2*) "Clinical Toxicology of Commercial Products," 4th Ed., edited by Gosselin, R.E., et al., The Williams and Wilkins Co., Baltimore, Section II, p. 101, 1976.

(*3*) Rosenberg, L. A. "An Investigation of the Effectiveness of Tabmint, an Anti-Smoking Chewing-Gum", in section V.2., OTC Volume 170129.

(*4*) OTC Volume 170178.

(*5*) Arvidsson, T., "A Double Blind Investigation of the Effectiveness of Tabmint, an Anti-Smoking Chewing Gum," in section V.3., OTC Volume 170129.

(*6*) Schmidt, F., "Tabacco Cure by Means of Anti-Smoking Chewing Gum in a Double Blind Test," in OTC Volume 170178.

2. Category III labeling. None.

D. Data Required for Evaluation.

Guidelines for developing protocols for evaluating OTC smoking deterrents. The Panel recognizes that a generally accepted protocol for the evaluation of drugs used as smoking deterrents is not available. Further, because of the different mechanisms of action of smoking deterrents and because of the numerous other techniques (counseling and behavior modification) often used jointly with these drugs, it is impossible to develop a single protocol that would be universally appropriate. However, given the numerous methodological problems associated with attempting to evaluate these products (Refs. *1* and *2)* and considering the contradictory published results (Ref. *3*) regarding the effectiveness of these drugs and smoking withdrawal programs in general, it is imperative that well-controlled clinical trials be performed to evaluate these drugs. In designing these trials important issues must be considered carefully in order to ensure proper evaluation. To this end the Panel has developed the following guidelines to aid investigators in designing tests of effectiveness. The Panel suggests that deviations from these guidelines should be discussed with appropriate FDA personnel prior to initiating a study.

Other useful guidelines exist (Ref. *2*), but they are broader in scope than the Panel's guidelines. They deal with the evaluation of stop-smoking programs in general and not with just the evaluation of smoking deterrent drugs. Further, they deal with attempts to evaluate the effects of the various techniques in studies involving samples from the full target population (all cigarette smokers rather than long-term chronic cigarette smokers). Such studies often involve large numbers of subjects, but the Panel believes small scale, double-blind, placebo-controlled studies employing a sample population of chronic cigarette smokers who are motivated to stop smoking are sufficient to demonstrate drug effectiveness. The Panel's guidelines concern such studies.

1. *Objective of the study.* The primary objective is to determine the effectiveness of the drug under study in aiding individuals to stop smoking. The claim for some smoking deterrents is that they will aid in reducing smoking but not necessarily in stopping it. The Panel does not accept the premise that a temporary reduction in smoking has any lasting benefit and believes that it should be possible in a well-controlled study to demonstrate that a drug is

effective in aiding a significant number of individuals to stop smoking.

2. *Sample population.* The preferred sample population for the study is the population of long-term, chronic cigarette smokers who are presently heavy smokers, are motivated to stop, and have good expectations concerning the ability of drugs to be effective in aiding a person to stop smoking. "Long-term, chronic" should be taken to mean smoking regularly for at least 5 years, and "heavy smokers" should be taken to mean smoking at least 20 cigarettes per day.

If the drug is effective, it can be expected that the effectiveness should be demonstrable in the sample population described above. This population eliminates many of the problems, such as variable smoking experience, lack of motivation, and skepticism on the part of the subjects that often confound stop-smoking studies.

For any particular study the selected sample population should be fully specified and smoking habits should be thoroughly described.

3. *Study setting and investigators.* The study should be conducted by qualified investigators in clinical centers, academic settings, or private practices. The important component is the qualification of the investigator.

4. *Admissibility and exclusion criteria.* The study subjects must satisfy all the criteria of the sample population. That is, subjects must be long-term, chronic cigarette smokers who are presently heavy smokers, are well motivated, and have good expectations concerning drug effectiveness. In addition, the subjects should:

a. Be in apparent good health,

b. Have no known sensitivity to the test drug,

c. Have significantly elevated levels of carbon monoxide and thiocyanate (or nicotine and cotinine) as determined by objective measures at the beginning of the study,

d. Not have participated in similar studies within the past year,

e. Not be taking other medications, including OTC medications, which might influence the response of the subject in the study, and

f. Be able to comprehend instructions and adhere to the study protocol (take drug as required by the protocol and keep track of daily consumption of cigarettes and other tobacco products).

5. *Variables to measure in the pretest period.* Prior to giving the test medication, basic information on the subject should be obtained. This is required not only to decide upon admissibility into the study but also to use a reference point for evaluating effectiveness. The pretest variables should include:

a. Age (exact, not categorized),

b. Sex,

c. Age when started to smoke with some degree of regularity, not counting any earlier, sporadic experimentation with cigarettes,

d. Current daily rate of cigarette smoking when entering treatment and use of other tobacco products, if any (exact number of cigarettes should be requested),

e. Appropriate objective measurements (carbon monoxide and blood thiocyanate levels) should be taken at two different pretest times,

f. Education,

g. Previous attempts to stop smoking (number of attempts, time since last attempt, degree of success at last attempt, number of times systematic help sought (a smoking clinic)),

h. Motivation (desire and commitment to stop),

i. Level of expectation concerning the ability of drugs to be effective in aiding a person to stop smoking,

j. Attitudes towards smoking, and

k. Knowledge of detrimental effects of smoking.

6. *Study design.* The study design must be randomized, double-blinded, and placebo-controlled. A parallel sample design appears to be preferred over a crossover design. Since a successful treatment with an effective drug results in stopping smoking, the subject does not necessarily return to smoking after the treatment period. Crossover designs are employed usually in situations where there is a return of the subject to smoking.

7. *Length of the study.* The length of the study should be at least 4 weeks: 1 week of pretest and at least a 3-week study period. It is not necessary that the drug be taken for 3 weeks. However, an evaluation of effectiveness should take place at least 3 weeks after the drug was started. Any difference between the drug and placebo for periods shorter than this may be statistically significant, but cannot be considered clinically significant.

8. *Variables to measure during the study.* A daily diary should be kept in which is recorded:

a. The amount and times of taking the test drug,

b. The number of cigarettes smoked each day,

c. Any significant change in lifestyle or environment which results in an increased or decreased exposure to carbon monoxide, and

d. The use of any other tobacco product.

9. *Effective measures.* The only effectiveness variable is to stop smoking. In computing the proportion of those who stop smoking the denominator should be all those who were originally in the study group (placebo or drug) and not just those completing the study. Absolute levels of and changes in baseline objective measurements are essential. Data should be obtained from the subjects in a face-to-face interview and should not be obtained via mailings or telephone conversations.

10. *Statistical tests and sample sizes.* Appropriate statistical tests should be used to establish effectiveness. The analysis comparing the drug and placebo groups should include at least the "two independent sample difference in proportions test" where the dependent variable is the dichotomous variable, "cessation of smoking or not" (Ref. *4*). In addition, analyses of the objective data (carbon monoxide and thiocyanate levels) are imperative. Also, analyses investigating the relation of stopping smoking to age, sex, education, etc. should be performed. Statistical analyses techniques such as logistic regression are appropriate here.

Sample sizes for the drug and placebo groups should be determined to give a p value of 0.05 for testing equality of effectiveness of the drug and placebo and a sufficiently small probability of error of not detecting a significant clinical superiority of the drug over the placebo (a Type II error of 0.2). The drug company should be prepared to discuss what it means by a significant clinical superiority, of the drug over the placebo (a Type II error of 0.2). The drug company should be prepared to discuss what it means by a significant clinical superiority.

11. *Followup.* Effectiveness should be established at the end of 3 weeks. If a claim for long-term effectiveness is made, the smoking status of the subjects should be evaluated at the end of 4 months. Recidivism is greatest within 4 months (Ref. *2*), and this followup will indicate long-term effectiveness of the treatment. The Panel recommends but does not require that there be a 4-month followup of all subjects.

12. *Drop-outs.* The entire study population must be accounted for at all points of data collecting, including the followup. Persons who cannot be reached for evaluation should be counted as failures (smokers), rather than assuming that those who respond are representative of the total study group.

13. *Number of clinical trials.* Two separate trials should be conducted by

different investigators at different geographical sites. The samples from each of these sites should be representative of the sample population.

References

(1) "Smoking and Health. A Report of the Surgeon General," U.S. Department of Health, Education, and Welfare, DHEW Publication No. (PHS) 79–50066, 1979.

(2) "Guidelines for Research on the Effectiveness of Smoking Cessation Programs. A Committee Report," National Interagency Council on Smoking and Health, New York, 1974.

(3) Schwartz, J. L., "A Critical Review and Evaluation of Smoking Control Methods," *Public Health Reports*, 84:483–506, 1969.

(4) Dixon, W. J., and F. J. Massey, Introduction to Statistical Analysis, 3d Ed., McGraw-Hill, New York, p. 249, 1969.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554,702, 703, 704)), and under 21 CFR 5.11 (see 46 FR 26052; May 11, 1981)), the agency advises in this advance notice of proposed rulemaking that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations would be amended by adding in Part 357, a new Subpart G, to read as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart G—Smoking Deterrent Drug Products

Sec.

357.601 Scope.
357.603 Definitions.
357.610 Smoking deterrent active ingredients. [Reserved]
357.650 Labeling of smoking deterrent drug products.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321 (p), 352, 355, 371); secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704).

SUBPART G—SMOKING DETERRENT DRUG PRODUCTS

§ 357.601 Scope.

(a) An over-the-counter smoking deterrent drug 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 conditions in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 357.603 Definition.

As used in this subpart:

Smoking deterrent. A substance which helps one to stop smoking cigarettes.

§ 357.610 Smoking deterrent active ingredients. [Reserved]

§ 357.650 Labeling of smoking deterrent drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "smoking deterrent."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or more of the following statements:

(1) "A temporary aid to those who want to stop smoking cigarettes."

(2) "Helps you stop the cigarette urge temporarily."

(3) "Helps you stop smoking cigarettes temporarily."

(4) "A temporary aid to breaking the cigarette habit."

(5) *Other required statement.* The labeling of the product contains the following statement: "This product's effectiveness is directly related to the user's motivation to stop smoking cigarettes."

(6) *Other allowable statement.* The labeling of the product may contain a description (in lay language) of the specific proven mechanism of action of the active ingredients under the heading "Mechanism of Action."

(c) *Warnings.* [Reserved]

(d) *Directions.* [Reserved]

Interested persons may, on or before April 5, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this advance notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments replying to comments may also be submitted on or before May 5, 1982. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 23, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: December 17, 1981.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82–2 Filed 1–4–82; 8:45 am]

BILLING CODE 4160–01–M

federal register

Tuesday
January 5, 1982

Part X

Department of Health and Human Services

Food and Drug Administration

Orally Administered Drug Products for the Treatment of Fever Blisters for Over-the-Counter Human Use; Establishment of a Monograph

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 357

[Docket No. 81N-0060]

Orally Administered Drug Products for the Treatment of Fever Blisters for Over-the-Counter Human Use; Establishment of a Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of a proposed rulemaking that would establish conditions under which over-the-counter (OTC) orally administered drug products for the treatment of fever blisters are generally recognized as safe and effective and not misbranded. This notice is based on the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by April 5, 1982, and reply comments by May 5, 1982.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's Office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on September 28, 1980 a report on OTC orally administered drug products for the treatment of fever blisters from the Advisory Review Panel on OTC Miscellaneous Internal Drug Products. FDA regulations (21 CFR 330.10(a)(6)) provide that the agency issue in the **Federal Register** a proposed order containing: (1) The monograph recommended by the Panel, which establishes conditions under which OTC orally administered drug products for the treatment of fever blisters are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs' not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

The unaltered conclusions and recommendations of the Panel are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The report has been prepared independently of FDA, and the agency has not yet fully evaluated the report. The Panel's findings appear in this document to obtain public comment before the agency reaches any decision on the Panel's recommendations. This document represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it.

After reviewing all comments submitted in response to this document, FDA will issue in the **Federal Register** a tentative final monograph for OTC orally administered drug products for the treatment of fever blisters as a notice of proposed rulemaking. Under the OTC drug review procedures, the agency's position and proposal are first stated in the tentative final monograph, which has the status of a proposed rule. Final agency action occurs in the final monograph, which has the status of a final rule.

The agency's position on OTC orally administered drug products for the treatment of fever blisters will be stated initially when the tentative final monograph is published in the **Federal Register** as a notice of proposed rulemaking. In that notice of proposed rulemaking, the agency also will announce its initial determination whether the proposed rule is a major rule under Executive Order 12291 and will consider the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). The present notice is referred to as an advance notice of proposed rulemaking to reflect its actual status and to clarify that the requirements of the Executive Order and the Regulatory Flexibility Act will be considered when the notice of proposed rulemaking is published. At that time FDA also will consider whether the proposed rule has a significant impact on the human environment under 21 CFR Part 25 (proposed in the **Federal Register** of December 11, 1979, 44 FR 71742).

The agency invites public comment regarding any impact that this rulemaking would have on OTC orally administered drug products for the treatment of fever blisters. Types of impact may include, but are not limited to, the following: Increased costs due to relabeling, repackaging, or reformulating; removal of unsafe or ineffective products from the OTC market; and testing necessary, if any. Comments regarding the impact of this rulemaking on OTC orally administered drug products for the treatment of fever blisters should be accompanied by appropriate documentation.

In accordance with § 330.10(a)(2), the Panel and FDA have held as confidential all information concerning OTC orally administered drug products for the treatment of fever blisters submitted for consideration by the Panel. All the submitted information will be put on public display in the Dockets Management Branch, Food and Drug Administration, after February 4, 1982, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs (HFD-510) (address above).

FDA published in the **Federal Register** of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The Court in *Cutler* held that the OTC drug review regulations (21 CFR 330.10) were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision is now deleted from the regulations. The regulations now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process, before the establishment of a final monograph.

Although it was not required to do so under *Cutler*, FDA will no longer use the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III because that was the framework in which the Panel conducted its evaluation of the data.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally

recognized as safe and effective and not misbranded (monograph conditions) will be effective 6 months after the date of publication of the final monograph in the **Federal Register.** On or after that date, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions which would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce. Further, any OTC drug products subject to this monograph which are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to voluntarily comply with the monograph at the earliest possible date.

A proposed review of the safety, effectiveness, and labeling of oral OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC miscellaneous internal drug products was issued in the **Federal Register** of November 16, 1973 (38 FR 31696). (In making their categorizations with respect to "active" and "inactive" ingredients, the advisory review panels relied on their expertise and understanding of these terms. FDA has defined "active ingredient" in its current good manufacturing practice regulations (§ 210.3(b)(7), (21 CFR 210.3(b)(7))), as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." An "inactive ingredient" is defined in § 210.3(b)(8) as "any component other than an 'active ingredient.' " in the **Federal Register** of August 27, 1975 (40 FR 38179) a notice supplemented the initial notice with a detailed, but not necessarily all-inclusive, list of active ingredients in miscellaneous internal drug products to be considered in the OTC drug review. This list, which did not include ingredients in orally administered drug products for the treatment of fever blisters, was provided to give guidance on the kinds of ingredients for which data should be submitted. The notices of November 16, 1973, and August 27, 1975, informed OTC drug product manufacturers of their opportunity to submit data to the review at that time and of the applicability of the monographs from the OTC drug review to all OTC drug products.

Under § 330.10(a) (1) and (5), the Commissioner of Food and Drugs appointed the following Panel to review the information submitted and to prepare a report on the safety, effectiveness, and labeling of the active ingredients in these OTC miscellaneous internal products:

James L. Tullis, M.D., Chairman (appointed December 1979)
John W. Norcross, M.D., Chairman (resigned March 1979) Diana F. Rodriquez-Calvert, Pharm. D. (appointed July 1976)
Ruth Eleanor Brown, R.Ph. (resigned May 1976)
Elizabeth C. Giblin, M.N., Ed. D.
Richard D. Harshfield, M.D.
Theodore L. Hyde, M.D.
Claus A. Rohweder, D.O. (deceased April 13, 1979)
Samuel O. Thier, M.D. (resigned November 1975)
William R. Arrowsmith, M.D. (appointed March 1976)

Representatives of consumer and industry interests served as nonvoting members of the Panel. Eileen Hoates, nominated by the Consumer Federation of America, served as the consumer liaison until September 1975, followed by Michael Schulman, J.D. Francis J. Hailey, M.D., served as the industry liaison, and in his absence John Parker, Pharm. D., served. Dr. Hailey served until June 1975, followed by James M. Holbert, Sr., Ph. D. All industry liaison members were nominated by the Proprietary Association.

The following FDA employees assisted the Panel: Armond M. Welch , R.Ph., served as the Panel Administrator until July 1979, followed by John R. Short, R.Ph. Enrique Fefer, Ph. D., served as the Executive Secretary until July 1976, followed by George W. James, Ph. D., until October 1976, followed by Natalia Morgenstern until May 1977, followed by Arthur Auer until October 1978. Roger Gregorio served as the liaison for the Office of New Drug Evaluation beginning November 1978. Joseph Hussion, R.Ph., served as the Drug Information Analyst until July 1976, followed by Anne Eggers, R.Ph., M.S., until October 1977, followed by John R. Short, R.Ph., until July 1979.

In order to expand its scientific base the Panel called upon the following consultants:

Ralph B. D'Agostino, Ph. D. (statistics)
Lynn R. Brady, Ph. D. (pharmacognosy)
John A. Ulrich, Ph. D. (microbiology)

The Advisory Review Panel on OTC Miscellaneous Internal Drug Products was charged with the review of many categories of drugs, but due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents its conclusions and recommendations for OTC orally administered drug products for the treatment of fever blisters in this document. The review of all other categories of miscellaneous internal drug products is being continued by the Panel, and its findings are being published periodically in the **Federal Register.**

The Panel was first convened on January 13, 1975 in an organizational meeting. Meetings at which orally administered fever blister drug products were discussed were held on the following dates: February 23 and 24, April 18 and 19, June 6 and 7, August 8 and 9, and September 28, 1980.

The minutes of the Panel meetings are on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above).

The following persons were given an opportunity to appear before the Panel at their own request to express their views on OTC orally administered drug products for the treatment of fever blisters:

Theodore R. Carski, M.D.
Terrence J. Thines, D.D.S.

No person who so requested was denied an opportunity to appear before the Panel to discuss orally administered drug products for the treatment of fever blisters.

The Panel has thoroughly reviewed the literature and data submissions, has listened to additional testimony from interested persons, and has considered all pertinent data and information submitted through September 28, 1980 in arriving at its conclusions and recommendations for OTC orally administered drug products for the treatment of fever blisters.

In accordance with the OTC drug review regulations in § 330.10, the Panel reviewed OTC orally administered drug products for the treatment of fever

blisters with respect to the following three categories:

Category I. Conditions under which OTC orally administered drug products for the treatment of fever blisters are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which OTC orally administered drug products for the treatment of fever blisters 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 reviewed eight active ingredients in orally administered drug products for the treatment of fever blisters and classified no ingredients in Category I, five ingredients in Category II, and three ingredients in Category III.

I. Submission of Data and Information

A. Submissions by Firm

Pursuant to notices published in the **Federal Register** of November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179), Hynson, Westcott, and Dunning, Baltimore, MD 21201, was the only firm to make submissions (Lactinex tablets and granules) for OTC orally administered drug products for the treatment of fever blisters.

B. Ingredients Reviewed by the Panel

1. *Labeled ingredients contained in marketed products submitted to the Panel.*

Lactobacillus acidophilus
Lactobacillus bulgaricus

2. *Other ingredients.* In addition to those ingredients included in the products submitted to the Panel, the Panel reviewed the ingredient lysine and the product Herp-eze Tablets (Anjonic, Inc., Hawthorne, CA 90250), both of which were brought to the Panel's attention by FDA's Office of Compliance, Bureau of Drugs. The labeled ingredients contained in these products are as follows:

Acetaminophen
Caffeine
Chlorpheniramine maleate
Lysine
Phenylephrine hydrochloride
3,3-Bis (*p*-hydroxyphenyl) Phthalide

C. Classification of Ingredients

1. *Active ingredients.*
Lactobacillus acidophilus
Lactobacillus bulgaricus

Lysine (lysine hydrochloride)

2. *Other ingredients.* The Panel was neither able to locate nor is it aware of any data demonstrating the safety and effectiveness of the following OTC ingredients when used as orally administered drug products for the treatment of fever blisters. The Panel, therefore, classifies these ingredients as Category II for this use, and they will not be reviewed further in this document.

Acetaminophen
Caffeine
Chlorpheniramine maleate
Phenolphthalein (3,3-Bis (*p*-hydroxyphenyl) Phthalide)
Phenylephrine hydrochloride

D. Referenced OTC Volumes

The "OTC Volumes" cited throughout this document include submissions made by interested persons in response to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179). All of the submitted information included in these volumes, except for those deletions which are made in accordance with the confidentiality provisions set forth in § 330.10(a)(2), will be put on public display after February 4, 1982, in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishes Lane, Rockville, MD 20857.

II. General Statements and Recommendations

A. Definitions of Terms

For the purpose of this document, the Panel agreed upon the following definitions:

1. *Aphthous stomatitis.* Canker sore.
2. *Aphthous ulcer.* Canker sore.
3. *Canker sores.* Sores which occur on the mucous membranes of the oral cavity (often the movable areas) and may be associated with a variety of viruses, bacteria, or fungi. They are characterized by small whitish ulcerative lesions surrounded by a red border.
4. *Cold sores.* Fever blisters.
5. *Fever blisters.* Recurrent sores on the lips and other areas around the mouth, usually caused by herpes simplex virus. They are characterized by local tissue swelling followed by inflammation which evolve into vesicular eruptions, and then crust and fade.
6. *Vesicular eruption.* A small blister containing fluid.

B. General Discussion

Although this document deals with orally administered drug products for the treatment of fever blisters (cold sores), the Panel believes that there is sufficient confusion among consumers in differentiating between feaver blisters and canker sores (aphthous stomatitis or aphthous ulcer) to warrant a discussion of both in this "General Discussion." The discussions regarding effectiveness will center on relieving the discomfort of fever blisters, not on shortening the duration of the episode, because it is difficult from the literature description of the disease to determine the time of the onset of symptoms.

Fever blisters or "cold sores," generally caused by herpes simplex virus, are recurrent sores on the lips and other areas around the mouth that may cause discomfort and annoyance to millions of Americans (Ref. *1*). Usually, the initial manifestation of the virus occurs in children under 5 years of age as a primary infection. This infection is frequently so mild it goes unnoticed by the individual. Later in a person's life, the virus, having been dormant in the body, may be reactivated when provoked by nonspecific stimuli, such as colds, exposure to sunlight, menstruation, a variety of common bacterial and viral infections, fever, and neurosurgical operations (Ref. *1, 2,* and *3*). Psychological stress is also accepted as capable of provoking the virus. The viral reactivation manifests itself in the form of localized vesicular eruptions, characteristically involving the mouth, nose, or external genitalia and sometimes other areas. During the first few days, the virus can be cultivated from the vesicular fluid (Refs. *1* and *4*), or transmitted by close person-to-person contact (Refs. *5* and *6*). The primary vesicles usually evolve, crust, and fade in 1 week, with secondary healing sometimes taking 2 weeks. Recurrence, ofter at the same site, is common, although some persons who harbor the virus throughout their lifetime may never have the skin lesions.

The OTC drug products for treating fever blisters consist of internal and external medications. Only those which are internally administered will be considered in this document. Externally applied preparations will be considered by the Advisory Review Panel on OTC Miscellaneous External Drug Products.

The Panel recognizes that canker sores in the mouth commonly have been confused with fever blisters as being of similar herpetic origin. Although some canker sores are of such origin, they generaly are entirely different diseases. Canker sores are of diverse etiology (cause), including certain viruses, bacteria, and fungi. Like fever blisters, they are generally painful and recurrent. Canker sores are characterized by small whitish ulcerative lesions surrounded by a red border (Ref. *7*) and are often found on the movable areas of the lining of the mouth (e.g., the inner lining of the cheeks and lips, the tongue, and the soft

palate) (Ref. *1*). They usually appear initially in persons between 10 and 20 years of age, but may appear as early as 2 years of age (Ref. *1*). Canker sores can occur later in life and may be of spontaneous origin or may be secondary to other disease states, including immune suppression. If left untreated, canker sores usually heal in 10 to 14 days (Ref. *1*). The ulcers tend to recur when the patient has experienced local injury (e.g., scratch of a toothbrush bristle), has an allergic reaction (e.g., following ingestion of certain foods), has an endocrine-associated condition (e.g., menstruation), or is subject to emotional stress (Refs. *1* and *7*). Poor oral care may also be cause of canker sores.

Because of the varied appearance of the lesions and the variability of the clinical symptoms, canker sores have been given many names, and many drug products have been tried for treating them. Most of these are topicaly applied and include dyes, resins such as myrrh, hydrocolloid films such as aloe, astringents and protein precipitators such as alum, and antibacterials such as hydrogen peroxide.

The treatment of canker sores with oral wound cleansers was previously reviewed by the Advisory Review panel on OTC Dentifrice and Dental Care Drug Products in its report, published in the Federal Register of November 2, 1979 (44 FR 63270) on OTC Oral Mucosal Injury Drug Products. That Panel concluded that oral wound cleansers should not be used to treat canker sores because the term "canker sore" is vague to consumers, the condition cannot be self-diagnosed and is serious, and self-treatment may delay diagnosis (44 FR 63283). The Advisory Review Panel on OTC miscellaneous Internal Drug Products has reviewed this conclusion and believes thaat, although canker sores may be self-diagnosable, their cause cannot be determined by the consumer, and therefore thay cannot be self-treated appropriately. This is because, although canker sores are not dangerous in themselves, they may be related to a serious condition, and an ingredient might be shown to be effective for one type of canker sore but not for others. One then takes the chance that a serious condition may go untreated, or, at best, treatment will be delayed. Therefore, the Panel will not review further the treatment of canker sores.

References

(*1*) "Canker Sores and Fever Blisters," United States Department of Health, Education, and Welfare, DHEW Publication No. (NIH) 79-247, 1979.

(*2*) Cruickshank, R., "Medical Microbiology," 11th Ed., The Williams and Wilkins Co., Baltimore, pp. 382-386, 1965.

(*3*) Wilson, G. S., and A. A. Miles, "Topley and Wilson's Principles of Bacteriology, Virology and Immunity, 6th Ed., Vol. II, The Williams and Wilkins Co., Baltimore, pp. 2414-2422, 1975.

(*4*) Freeman, B. A., "Burrows Textbook of Microbiology," 21st Ed., W. B. Saunders Co., Philadelphia, pp. 973-976, 1979.

(*5*) Joklik, W. K., and H. P. Willett, "Zinsser Microbiology," 16th Ed., Appleton-Century-Crofts, New York, pp. 944-947, 1976.

(*6*) Davis, B. D., et al., "Microbiology," Harper and Row, New York, pp. 1238-1244, 1967.

(*7*) "Dorland's Illustrated Medical Dictionary," 25th Ed., W. B. Saunders, Philadelphia, 1974, s. v. "stomatitis, aphthous."

C. Labeling

The Panel has carefully reviewed the submitted labeling claims for products promoted as orally administered drug products for the treatment of fever blisters and has classified them as Category I, Category II, or Category III. The Panel realizes that other terms may be developed to express the same Category I indications. However, only those indications and warnings listed under Category I are generally recognized to be acceptable at this time.

In order for any labeling to be acceptable, it must include (1) the indiction(s) for use, (2) pertinent warnings and contraindications, and (3) clear directions for use that include the recommended dosage.

The Panel belteves that all labeling should be clear, concise, easily read, and understood by most consumers. It has followed this concept in the development of all Category I labeling. The Panel also is concerned about the size and color of the print used in labeling of these and all OTC drug products and recommends that the manufacturers make the necessary effort to design labeling which is legible.

One of the functions of this Panel is to attempt to eliminate inadequate labeling claims. Some of the labeling on currently marketed orally administered drug products for the treatment of fever blisters is misleading or unsupported by scientific data. Accordingly, such labeling has been placed in Category II.

The indications for use should be simply and clearly stated; the directions for use should provide enough information for safe and effective use of the product.

The Panel believes that if two ingredients are indistinguishable with regard to effectiveness, it is misleading to claim superiority for one of the ingredients. The Panel understands that its function is not to compare various ingredients in order to determine the OTC drug of choice, but to determine only safety and effectiveness for active OTC miscellaneous internal ingredients, as well as proper dosage ranges, warnings, and contraindications.

Misleading or undocumented claims, such as "for the relief of the discomfort of sun blisters," and colloquial or provincial expressions that do not have meaning to most people must not be used. In the labeling, effectiveness shall not be relate to the physical characteristics of the product, except as those characteristics may related to the action of the active ingredients.

The Panel is aware of the current OTC labeling regulation dealing with warning statements (§ 330.1(g)). The Panel concurs with the warning, "Keep this and all drugs out of the reach of children," and believes that it should be incorporated in the labeling for orally administered drug products for the treament of fever blisters. However, the Panel recommends that the other warning statement required by § 330.1(g), "In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately," be deleted because no toxicity has been demonstrated for ingredients used in these products.

In addition, the Panel recommends that the drug product labeling contain instructions for the most effective use of the product. These instructions should be displayed prominently on all package labeling.

The Panel recommends that the label should contain a listing of all ingredients, clearly indicating which are active and which are inactive. Active ingredients should be listed by their established names, and the label should state the quantity of the active ingredient included in a single dose.

III. Orally Administered Drug Products for the Treatment of Fever Blisters

A. *Category I Conditions*

The following are Category I conditions under which OTC orally administered drug products for the treatment of fever blisters are generally recognized as safe and effective and are not misbranded.

1. *Category I active ingredients.* None.

2. *Category I labeling.* Although the Panel has not classified any ingredients in Category I, it recommends the following Category I labeling for OTC orally administered drug products for the treatment of fever blisters, as well as any specific labeling discussed in the individual ingredient statement, in the event that any ingredients that are in

Category III should be reclassified as Category I. The product labeling relating to fever blisters should contain a statement under the heading "Indications" that is limited to the phrase "For the relief of the discomfort of fever blisters (cold sores)."

B. Category II Conditions

The following are Category II conditions under which OTC orally administered drug products for the treatment of fever blisters are not generally recognized as safe and effective or are misbranded.

1. *Category II active ingredients.* The ingredients which the Panel has classified as Category II are included elsewhere in this document. (See part I. paragraph C.2. above—Other ingredients.)

2. *Category II labeling.* The Panel concludes that the following labeling claims for orally administered drug products for the treatment of fever blisters are misleading or unsupported by scientific data. Therefore, the claims listed below and other related terms are classified as Category II labeling:

a. "For the relief of discomfort of sun blisters."

b. "Useful for fever blisters of herpetic origin."

c. "Arrests the symptoms associated with cold sores and sun blisters on the lips."

C. Category III Conditions

The following are Category III conditions for which the available data are insufficient to permit final classification at this time.

1. *Category III active ingredients.*

Lactobacillus acidophilus
Lactobacillus bulgaricus
Lysine (lysine hydrochloride)

a. *Lactobacillus acidophilus and Lactobacillus bulgaricus.* The Panel has reviewed the use of orally administered live *Lactobacillus acidophilus* and *Lactobacillus bulgaricus* for the treatment of fever blisters (herpetic origin) and concludes that when these ingredients are used separately or in combination they are safe for OTC use in the dose noted below, but data are insufficient to demonstrate effectiveness for this use.

The marketed preparation is a mixture of these two organisms and is prepared from fermented milk cultures which are dried in a lactose-enriched medium and marketed in such a form. There is also a preparation on the market which contains the *Lactobacillus acidophilus* alone.

Being living organisms rather than single chemical compounds, the active ingredients, *Lactobacillus acidophilus* and *Lactobacillus bulgaricus*, are not recognized as official by such compendia as the U.S. Pharmacopeia and the National Formulary. Therefore, there are no compendial standards to which these ingredients must conform. The Panel is concerned that identification of these strains of bacteria by their name alone is not sufficiently specific to insure that all products containing these organisms will be equivalent in terms of safety and effectiveness. Therefore, the Panel has chosen to specify these ingredients further by using the identification number assigned to them by the American Type Culture Collection (ATCC): *Lactobacillus acidophilus* (ATCC 4962) and *Lactobacillus bulgaricus* (ATCC 33409).

(1) *Safety.* The use of *Lactobacillus acidophilus* and *Lactobacillus bulgaricus* has been reviewed by the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products as published in the **Federal Register** of March 21, 1975 (40 FR 12902), and that Panel concluded that these ingredients are safe in amounts taken orally in antidiarrheal preparations (40 FR 12931). The OTC Miscellaneous Internal Drug Products Panel agrees with the Advisory Review Panel on OTC Laxative, Antidiarreal, Emetic, and Antiemetic Drug Products and concludes that *Lactobacillus acidophilus* and *Lactobacillus bulgaricus* (separately or in combination) are safe for OTC use and recommends the manufacturer's suggested dose of up to 4 grams (g) per day in divided doses (Ref. *1*). This is equivalent to approximately 400,000,000 organisms.

Because many people are sensitive to milk products and because this preparation may contain residual milk products, a warning regarding possible sensitivity should be included.

(2) *Effectiveness.* A 1961 study by Abbott (Ref. *2*) reported the use of a live mixture of *Lactobacillus acidophilus* and *Lactobacillus bulgaricus* in treating 78 subjects. Forty-six children with acute generalized herpetic gingivostomatitis (virus infection of the gums) were cured within 6 days of treatment (untreated usually taking 14 to 21 days). Ten adults with histories of recurrent herpes simplex lip lesions (fever blisters) were treated at the onset of burning or itching but before any vesicular eruption, and in no cases did the eruptions occur. The study was uncontrolled and not blinded.

In 1965, Rapoport and Levine (Ref. *3*) reported the treatment of pain of herpetic (fever blisters) and aphthous stomatitis oral ulcerations with *Lactobacillus acidophilus* and *Lactobacillus bulgaricus* in 40 cases with positive results in 38 cases. Pain was relieved in 38 patients within 48 hours, and lesions disappeared within 5 days in 36 patients, which the authors considered to be "a statistically notable number of remissions." From the data given it is impossible to separate the herpetic stomatitis lesions from the aphthous stomatitis. No placebo controls or blinding were used in this study, and the findings were reported by the subjects to the investigator by telephone.

In 1963, a study was reported by Scott (Ref. *4*) in which 44 cases of oral lesions were treated using *Lactobacillus acidophilus*. The lesions consisted of aphthous stomatitis, cheilosis (lesions at the corner of the mouth), and herpes simplex infections (fever blisters), but from the data given it is impossible to separate the herpes simplex infection cases from the other conditions. Thirty-seven of the patients (84 percent) responded positively to the treatment within "a few days." The study was uncontrolled and not blinded.

A 1964 study by Unfug (Ref. *5*) at Colorado State University using *Lactobacillus acidophilus* and *Lactobacillus bulgaricus* involved 61 students, some with acute fever blisters and others with canker sores. The study was double-blinded and placebo-controlled, but not completed, and it did not show a significant difference between the two treatment groups (45 percent success in drug group vs. 31 percent success in placebo group). Details of this study were not available, but it is known that the study was prematurely terminated due to a lack of cooperation from the students, a lack of a virology facility, and a lack of interest among the physicians covering the student health service.

In 1963, Weekes (Ref. *6*) studied the effect of *Lactobacillus acidophilus* and *Lactobacillus bulgaricus* on 174 patients. Sixty-four were identified as having herpes simplex labialis (fever blisters) and 97 as having aphthous stomatitis. The remainder had dendritic ulcers or herpes progenitalis. Ninety-five percent of those with herpes simplex labialis were reported to have favorable results (healing or improvement in 1 to 4 days). However, the Panel criticizes the study because it has no placebo control nor was it a double-blind study.

An incomplete study by Weekes (Ref. *7*) from 1966 to 1968, which was double-blinded and placebo-controlled and involved 106 patients, showed no significant difference between placebo and a preparation containing *Lactobacillus acidophilus* and

Lactobacillus bulgaricus in treating fever blisters and canker sores (64 percent success rate vs. 59 percent for placebo). A subsequent expansion of this study to 178 cases (72 with no case report forms) showed the treated group to have "significantly superior" results. This unpublished study was unsatisfactory in that the treatment assignments were not completely randomized, completed case report forms were available on only 106 subjects, and the followup time to judge the effect of the treatment was inconsistent (2 days or longer). From the data given it is impossible to separate the results of the fever blister and canker sore cases.

A double-blind, placebo-controlled parallel sample study by Gertenrich and Hart (Ref. *8*) involving 80 mentally retarded subjects showed no significant differences between *Lactobacillus acidophilus* and a placebo in healing time for oral lesions. Only 10 percent of the lesions observed in this study were fever blisters; the other 90 percent were canker sores. Because of the small number of fever blister cases, a statistical analysis could not be adequately performed. Each patient was examined and the lesions photographed every 3 days from the time of onset through a 10-day period. In contrast to other studies in general the lesions were unhealed after at least 4 days, and almost half had incomplete hearing after 10 days.

A presentation was made by Carski and Thimes (Ref. *9*) to the Panel of a double-blind, placebo-controlled, crossover study undertaken by Thines and Uthman (Ref. *10*) at the State University of New York at Buffalo School of Dentistry. Twenty-five students with histories of recurrent herpes simplex infections were treated with *Lactobacillus acidophilus* and *Lactobacillus bulgaricus*. Only 16 students completed the treatment. Based on the subjective evaluation of each episode by the observer and subject, 75 percent reported improvement during the episode that was treated with the *Lactobacillus acidophilus* and *Lactobacillus bulgaricus* combination, whereas only 31 percent of the subjects reported episode improvement under the influence of the placebo. Improvement was based on comparison with prestudy episodes. The differences between this percentage of improvements is statistically significant at a level greater than 0.05 but less than 0.10. Further, the mean duration between episodes for those subjects who were first on the drug was 105 days, and the mean duration between episodes was 53 days for those subjects who were first on the placebo. The difference between the mean durations was tested for statistical significance level by using the Wilcoxon Rank test, and the difference attained a significance level between 0.05 and 0.10. While this study indicates that the lactobacillus therapy had a positive effect, it had a large dropout rate (36 percent); it employed as an effectiveness measure a comparison prestudy episodes, rather than a direct comparison with with the crossover episodes, and it did not achieve the usual acceptable level of 0.05 or less of statistical significance to establish effectiveness. Therefore, the Panel does not believe the study is sufficient to establish effectiveness.

Three other studies were reviewed, but none of them contained an evaluation of fever blisters, which is the primary subject of this document.

The Panel concludes that the studies reviewed are merely indicative of possible effectiveness of *Lactobacillus acidophilus* and *Lactobacillus bulgaricus* in treating fever blisters. Well-designed and well-controlled studies are still needed to definitely establish effectiveness of these ingredients.

Although the mechanism of action of *Lactobacillus acidophilus and Lactobacillus bulgaricus is not understood, an unpublished study presented in a submission to the Panel by McCuen, Holman, and Cook (Ref. 11)* suggests that these organisms when given to human volunteers in multiple doses, induce in human saliva the ability to inhibit *Herpesvirus hominis*, type I. The results of this study indicated that further clinical study should be encouraged. A single-dose study by McCuen (Ref. *12*) did not demonstrate any indication of salivary inhibition of herpes virus.

The Panel considers *Lactobacillus acidophilus* (ATCC 4962) and *Lactobacillus bulgaricus* (ATCC 33409) similar enough in their taxonomy and action to recommend that the combination of these ingredients be exempt from FDA's combination policy regulation (21 CFR 330.10(a)(4)(iv)). Therefore, clinical studies of the two ingredients together would be acceptable, i.e., one would not have to demonstrate an advantage of one ingredient over the other to substantiate the combination. However, a claim for either ingredient alone would require demonstration of effectiveness by separate studies.

The Panel concludes that available data suggest that *Lactobacillus acidophilus* and *Lactobacillus bulgaricus* (separately or in combination) may be effective in treating fever blisters, but data are insufficient to permit a final determination. The Panel, therefore, recommends that these ingredients (separately or in combination) be tested according to the testing guidelines to determine their effectiveness as orally administered drugs for the treatment of fever blister. (See part III. paragraph D. below—Data Required for Evaluation.)

Because it is necessary that these bacteria be alive in order to perform their intended function, they must be kept refrigerated at temperatures between 36° and 46° F. A statement to this effect should be required on the labeling.

(3) *Proposed dosage.* The Panel concludes that *Lactobacillus acidophilus* and *Lactobacillus bulgaricus* (separately or in combination) are safe for OTC use in a dose of up to 4 g per day in divided doses. This is equivalent to approximately 400,000,000 organisms.

(4) *Labeling.* The Panel recommends Category I labeling for orally administered drug products for the treatment of fever blisters. (See part III. paragraph A.2. above—Category I labeling.) In addition, the Panel recommends the following statements be added for products containing *Lactobacillus acidophilus* and *Lactobacillus bulgaricus:*

(i) *Warning.* "Do not use this product if you are sensitive to milk products."

(ii) *Other required statement.* "Refrigerate between 36° and 46° F."

(5) *Evaluation.* The Panel concludes that *Lactobacillus acidophilus* and *Lactobacillus bulgaricus* (separately or in combination) are safe for OTC use in the dose noted above, but data are insufficient at this time to make final determination regarding general recognition of effectiveness. The Panel recommends that adequate testing be performed according to the testing guidelines to determine whether these ingredients are effective in treating fever blisters. (See part III. paragraph D. below—Data Required for Evaluation.)

References

(*1*) OTC Volume 170052.

(*2*) Abbott, P. L., "Viable Mixture of Lactobacillus Acidophilus and Bulgaricus in Treatment of Herpetic and Aphthous Stomatitis," *Journal of Oral Surgery, Anesthesia, and Dental Service*, 19:310–312, 1961.

(*3*) Rapoport, B. S., and W. I. Levine, "Treatment of Oral Ulceration with Lactobacillus Tablets," *Oral Surgery, Oral Medicine, Oral Pathology*, 20:591–593, 1965.

(4) Scott, P. H., "Preliminary Report on Lactobacillus Acidophilus and Its Therapeutic Application for Oral Lesions," *New York State Dental Journal*, 29:19–24, 1963.

(5) Unfug, H., untitled clinical study contained in OTC Volume 170052 (Section V, pp. 14–16).

(6) Weekes, D. J., "Management of Herpes Simplex with a Viro-Static Bacterial Agent," reprinted from *E.E.N.T. Digest*, Volume 25, Number 12, 1963, as attachment to letter to Panel Administrator from Dr. Theodore R. Carski, April 25, 1980, in Panel Administrator's File, Volume 17IAPI.

(7) Weekes, D. J., untitled clinical study contained in OTC Volume 170052 (Section V, pp. 17–18).

(8) Gertenrich, R. L., and R. W. Hart, "Treatment of Oral Ulcerations with Bacid *(Lactobacillus acidophilus)*," *Oral Surgery, Oral Medicine, and Oral Pathology*, 30:196–200, 1970.

(9) Presentation by Carski and Thines to the Panel included in the Summary Minutes of the 35th meeting of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products held on April 18–19, 1980.

(10) Uthman, A. A., and T. Thines, "Clinical Evaluation of the Effect of Lactinex Administration for the Treatment of Recurrent Herpes," in OTC Volumes 170185.

(11) McCuen, P. J., D. A. Holman, and D. L. Cook, "Evaluation of the Effect of Lactinex Administration on the Ability of the Saliva from Human Volunteers to Inhibit Herpesvirus," contained in OTC Volume 170180 (Section IV).

(12) McCuen, P. J., "Evaluation of the Effect of Single Dose Lactinex Administration on the Ability of the Saliva from Human Volunteers to Inhibit Herpesvirus," contained in OTC Volume 170180 (Section V).

b. *Lysine (lysine hydrochloride).* The Panel concludes that lysine hydrochloride is safe in the dose noted below, but data are insufficient to demonstrate its effectiveness in treating fever blisters.

(1) *Safety.* Lysine is an essential amino acid present in protein derived from many food stuffs. The adult human requires a daily ingestion of 0.4 to 0.8 g daily; for optimum health, however, a larger "safe intake" of 1.6 g has been recommended (Ref. *1*). Infants and children require a much larger intake in proportion to their weight for adequate growth. The Panel has found no information on toxic dosages of lysine, but was informed that a dermatologist in the Southwest United States prescribes 3 g per day; no mention was made of any toxic effects (Ref. *2*).

(2) *Effectiveness.* An in vitro study by Tankersly (Ref. *3*) demonstrated that lysine exerted an inhibitory effect on herpes simplex virus multiplication in human cells grown in tissue culture. The ratio of lysine to arginine in the culture medium seemed to be important. Kagan (Ref. *4*), in 1974, administratered 390 milligrams (mg) of *L*-lysine orally to 10 patients at the first onset of symptoms of oral (8 patients) or vulvar (2 patients) herpetic lesions and observed rapid resolution of these lesions. A further study by Griffith, Norins, and Kagan (Ref. *5*) found that the continuous ingestion of 312 to 1,200 mg of *L*-lysine (administered as *L*-lysine monohydrochloride) daily in single or multiple doses (for 2 months to 3 years) by 45 patients suffering from recurrent herpetic lesions resulted in suppression of the lesions in 40 patients. Results showed that new vesicles failed to appear, healing was more rapid, frequency of recurrences was reduced, and there was a "disappearance of pain overnight." This study was not controlled.

Modern Medicine cities Pipkin as claiming that a 3-g per day dose of lysine is more effective than the lower doses tested by other investigators (Ref. *2*).

The Panel realizes that neither of the two following studies pertain to the relief of fever blister discomfort, but are referenced herein for completeness. A double-blinded, placebo-controlled, randomized study was conducted by Milman, Scheibel, and Jessen (Ref. *6*) using 500 mg of *L*-lysine monohydrochloride twice daily in 119 patients. They found lysine to have no effect on the rate of healing, the appearance of the lesion, or the interval between recurrance of oral herpetic lesions. In a 24-week double-blind, placebo-controlled study by Milman, Scheibel, and Jessen (Ref. *7*) involving 65 patients and the same dosage of lysine as in the last study, lysine had no significant prophylactic effect, either on the duration or on the frequency of recurrances of herpes simplex labialis. However, in this study significantly more patients were recurrence-free (i.e., that subset of patients who had no recurrences during the study) during the lysine treatment than during the placebo treatment (18 vs. 8 with a p of 0.05). This finding suggests an effect of lysine on some patients.

The Panel concludes that the effectiveness of lysine hydrochloride in amelioration or prevention of herpes simplex lesions is unproven.

(3) *Proposed dosage.* The Panel concludes that lysine hydrochloride is safe for OTC use in a dose of up to 3 g daily.

(4) *Labeling.* The Panel recommends Category I labeling for OTC orally administered drug products for the treatment of fever blisters. (See part III. paragraph A.2. above—Category I labeling.)

(5) *Evaluation.* The Panel concludes that lysine hydrochloride is generally recognized as safe for OTC use in a dose of up to 3 g daily, but data are insufficient to demonstrate its effectiveness in treating fever blisters. The Panel recommends that adequate testing be performed according to the testing guidelines set forth below to determine whether lysine hydrochloride is effective in treating fever blisters. (See part III. paragraph D. below—Data Required for Evaluation.)

References

(1) Best, C. H., and N. B. Taylor, "The Physiological Basis of Medical Practice," 8th Ed., Williams and Wilkins Co., Baltimore, p. 1319, 1966.

(2) Anon., "News Fronts," *Modern Medicine*, 48:17, 1980.

(3) Tankersly, R. W., "Amino Acid Requirements of Herpes Simplex Virus in Human Cells," *Journal of Bacteriology*, 87:609–613, 1964.

(4) Kagan, C., "Lysine Therapy for Herpes Simplex," *Lancet*, 1:137, 1974.

(5) Griffith, R. S., A. L. Norins, and C. Kagan, "A Multicentered Study of Lysine Therapy in Herpes Simplex Infection," *Dermatologica*, 156:257–267, 1978.

(6) Milman, N., J. Scheibel, and O. Jessen, "Failure of Lysine Treatment in Recurrent Herpes Simplex Labialis," *Lancet*, 2:942, 1978.

(7) Milman, N., J. Scheibel, and O. Jessen, "Lysine Prophylaxis in Recurrent Herpes Simplex Labialis: a Double-Blind, Controlled Crossover Study," *Acta Dermato Venereologica*, 60:85–87, 1980.

2. *Category III labeling.* The Panel concludes that available data are insufficient to demonstrate the effectiveness of orally administered drug products for the treatment of fever blisters on the duration of the episode and places the following claim in Category III: "Will shorten the duration of fever blisters (cold sores) if taken at the first signs of itching and swelling."

D. Data Required for Evaluation

Guidelines for developing protocols for evaluating OTC orally administered drug products for the treatment of fever blisters. The Panel recognizes that currently there is not available a generally accepted protocol for the evaluation of the effectiveness of OTC orally administered drug products for the treatment of fever blisters. The Panel has reviewed carefully the published scientific literature and has not been able to find any well-controlled studies for these drugs. Further, the Panel has reviewed unpublished controlled studies undertaken for one of the sponsors of these drugs and has found these studies to be defective in one or more important facets. In order to move a Category III drug to Category I, successful, well-controlled studies must be performed. To aid investigators in designing these

tests of effectiveness, the Panel has developed the following guidelines. They are not meant to be definitive. There may be at present, or in the future, other appropriate techniques or improved methodologies not contained here. However, these guidelines illustrate the important issues that must be considered in clinical trials involving drugs for the treatment of fever blisters and, for that reason, should be an aid to investigators. The Panel suggests that deviations from these guidelines should be discussed with appropriate FDA personnel prior to initiation of a study.

1. *Objective of the study.* The primary objective is to determine whether the drug under investigation is more effective than a placebo in relieving the discomfort of fever blisters. "Relieving the discomfort" means relieving subjective symptoms such as pain, irritation, and itching. If a drug company desires to make a claim that the drug is effective in shortening the duration of fever blisters or in prolonging the interval between episodes, then the study objectives should include specific reference to such claims. The objectives should be stated in a complete and unambiguous manner.

2. *Target and sample population.* The target population consists of those individuals who develop fever blisters. The preferred sample population is those individuals who have frequent episodes of fever blisters (at least three times a year). Restriction to this sample population will increase the possibility that the study subjects will develop a fever blister during the study period. This would minimize the possibility of having individuals available for the study who do not develop fever blisters during the study.

If the drug is effective, it can be expected that its effectiveness will be demonstrated in the above sample population. If the drug is effective for these individuals, the Panel believes it would also be effective for the full target population.

For any particular study, the selected sample population should be specified fully, and pertinent characteristics should be described thoroughly.

3. *Study setting and investigators.* The study should be conducted by qualified investigators in clinical centers, academic settings, or private practices. The important component is the qualification of the investigator.

4. *Admissibility and exclusion criteria.* The study subjects must satisfy the criterion of the sample population, i.e., have frequent fever blisters (cold sores). In addition, the subjects:

a. Should be in good health,

b. Should have no known sensitivity to the test drug,

c. Should not be using other medications (including OTC medications), skin creams, or food products (e.g., milk products) which might influence the response of the subject in the study, and

d. Should be able to comprehend instructions and adhere to the study protocol (e.g., take the drug as required and report daily for examination as required).

5. *Variables to measure in the pre-episode period.* Prior to an episode of fever blisters, basic information on the subjects should be obtained. This is required not only to decide on admissibility into the study, but also to use as a reference point for evaluating efficacy. These variables should include:

a. Usual frequency, on a yearly basis, of episodes of fever blisters,

b. Usual areas of fever blisters,

c. Usual size of fever blisters,

d. Subjective evaluation of the usual discomfort from a fever blister on a 0 to 4 scale, with 0 representing no discomfort and 4 maximum discomfort (this scale should summarize all the components of discomfort such as itching, burning, irritation, and pain),

e. Usual time duration of fever blisters (both vesicular eruption and crusted stages),

f. Usual time duration of subjective discomfort, and

g. Events or situations that are associated with or precipitate an episode of a fever blister.

Other variables, such as age, sex, and health status of the subjects, that are routinely of interest in clinical studies, should also be collected at this time. Further, the distance of the subject from the clinical facility and the person's ability to come to the facility on a daily basis during an episode of a fever blister should be determined at this time.

6. *Study design.* The study must be randomized, double-blinded, and placebo-controlled. A parallel sample design appears to be preferred over a crossover design. A crossover design requires each study subject to have two separate episodes of fever blisters during the course of the study. This may require a long period of time and thus increases the potential for a substantial droupout rate. The parallel sample design requires only one occurrence of a fever blister per subject.

In the parallel sample design, subjects can be randomly assigned to one of two treatments (drug or placebo) at the initial interview. When a fever blister develops, the subject should record the time of first becoming aware of its impending development and should come to the investigator as soon as possible, definitely within the first 24 hours. At that time, the fever blister can be examined, and the subject can be given the appropriate treatment (drug or placebo), along with instructions for taking the treatment.

If a drug company is interested in investigating the effect of the drug on the length of time between episodes, a crossover design would be preferable.

7. *Duration of study from onset of the fever blister.* The length of the parallel sample study from onset of the fever blister should be at least 8 days. The average duration of an untreated fever blister is 10 to 14 days. The effectiveness of a treatment should be demonstrated by the eighth day. During the 8-day period the subject should be interviewed and examined daily by the investigator or an assistant.

8. *Variable to measure during the study.* At the first visit after onset, the lesion should be examined in detail to establish that it is in fact a fever blister. The time of day when the subject was first aware of it should also be recorded. Further, the subject should be interviewed to establish what events may have brought on the episode.

At all visits the subject should state on a scale of 0 to 4 a subjective evaluation of the discomfort from the fever blister experienced during the preceding 24 hours. As before, this scale should summarize all the components of discomfort such as itching, burning, irritation, and pain. Also, at all visits the lesion should be examined for physical characteristics, such as presence of vesicles, presence of dry crust, and size.

9. *Effectiveness measure.* The major effectiveness variable of the study is the subject's own subjective evaluation of the discomfort experienced from the fever blister. To establish effectiveness, comparisons of these evaluations for subjects on the drug should be made with those on the placebo. A time-series comparison over the 7 treatment days and/or separate comparisons for specific days (e.g., after 5 days) can be made. A drug company should be prepared to explain which comparisons are used to establish effectiveness.

If a claim of a reduction in the duration of an episode is desired, then investigation of the variable "number of days to healing of the fever blisters" will be needed for establishing this claim.

If a claim of a prolongation of the interval between episodes is desired, investigation of the variable "number of days to appearance of next lesion" will be needed to establishing the claim.

10. *Statistical tests and sample size.* Appropriate statistical tests should be

used to establish effectiveness. Sample sizes should be determined to give a p value of 0.05 or less for testing equality of effectiveness of the drug and placebo and a sufficiently small probability of error (e.g., 0.20) of not detecting a significant clinical superiority of the drug over the placebo. A drug company should be prepared to discuss what is meant by a significant clinical superiority.

11. *Number of clinical trials.* Two separate trials should be conducted by different investigators at different geographical sites. The samples from each of these sites should be representative of the sample population.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under 21 CFR 5.11 (see 46 FR 26052; May 11, 1981), the agency advises in this advance notice of proposed rulemaking that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations would be amended by adding in Part 357, a new Subpart H, to read as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart H—Orally Administered Drug Products for the Treatment of Fever Blisters

Sec.

357.701 Scope.
357.703 Definitions.
357.710 Orally administered active ingredients for the treatment of fever blisters. [Reserved]
357.750 Labeling of orally administered drug products for the treatment of fever blisters.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704).

Subpart H—Orally Administered Drug Products for the Treatment of Fever Blisters

§ 357.701 Scope.

(a) An over-the-counter drug product for the treatment of fever blisters in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 357.703 Definitions.

As used in this subpart:

(a) *Fever blisters.* Recurrent sores on the lips and other areas around the mouth, usually caused by herpes simplex virus. They are characterized by local tissue swelling followed by inflammation which evolve into vesicular eruptions, and then crust and fade.

(b) *Cold sores.* Fever blisters.

§ 357.710 Orally administered active ingredients for the treatment of fever blisters. [Reserved]

§ 357.750 Labeling of orally administered drug products for the treatment of fever blisters.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "fever blister treatment."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to the phrase "for the relief of the discomfort of fever blisters (cold sores)."

(c) *Warnings.* The warning required by § 330.1(g) concerning overdoses is not required on orally administered active ingredients for the treatment of fever blisters.

(d) *Directions.* [Reserved]

Interested persons may, on or before April 5, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville MD 20857, written comments on this advance notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments replying to comments may also be submitted on or before May 5, 1982. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 23, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: December 17, 1981.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-5 Filed 1-4-82; 8:45 am]

BILLING CODE 4160-01-M

federal register

Tuesday
January 5, 1982

Part XI

Department of Health and Human Services

Food and Drug Administration

Deodorant Drug Products for Internal Use for Over-the-Counter Human Use; Establishment of a Monograph

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 357

[Docket No. 81N-0064]

Deodorant Drug Products for Internal Use for Over-the-Counter Human Use; Establishment of a Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of a proposed rulemaking that would establish conditions under which over-the-counter (OTC) deodorant drug products for internal use are generally recognized as safe and effective and not misbranded. This notice is based on the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by April 5, 1982, and reply comments by May 5, 1982.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's Office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on June 7, 1980 a report on OTC deodorant drug products for internal use from the Advisory Review Panel on OTC Miscellaneous Internal Drug Products. FDA regulations (21 CFR 330.10(a)(6)) provide that the agency issue in the **Federal Register** a proposed order containing: (1) The monograph recommended by the Panel, which establishes conditions under which OTC deodorant drugs products for internal use are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

The unaltered conclusions and recommendations of the Panel are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The report has been prepared independently of FDA, and the agency has not yet fully evaluated the report. The Panel's findings appear in this document to obtain public comment before the agency reaches any decision on the Panel's recommendations. This document represents the best scientific judgement of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it.

After reviewing all comments submitted in response to this document, FDA will issue in the **Federal Register** a tentative final monograph for OTC deodorant drug products for internal use as a notice of proposed rulemaking. Under the OTC drug review procedures, the agency's position and proposal are first stated in the tentative final monograph, which has the status of a proposed rule. Final agency action occurs in the final monograph, which has the status of a final rule.

The agency's position on OTC deodorant drug products for internal use will be stated initially when the tentative final monograph is published in the **Federal Register** as a notice of proposed rulemaking. In that notice of proposed rulemaking, the agency also will announce its initial determination whether the proposed rule is a major rule under Executive Order 12291 and will consider the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). The present notice is referred to as an advance notice of proposed rulemaking to reflect its actual status and to clarify that the requirements of the Executive Order and the Regulatory Flexibility Act will be considered when the notice of proposed rulemaking is published. At that time FDA also will consider whether the proposed rule has a significant impact on the human environment under 21 CFR Part 25 (proposed in the **Federal Register** of December 11, 1979, 44 FR 71742).

The agency invites public comment regarding any impact that this rulemaking would have on OTC deodorant drug products for internal use. Types of impact may include, but are not limited to, the following: Increased costs due to relabeling, repackaging, or reformulating; removal of unsafe or ineffective products from the OTC market; and testing necessary, if any. Comments regarding the impact of this rulemaking on OTC deodorant drug products for internal use should be accompanied by appropriate documentation.

In accordance with § 330.10(a)(2), the Panel and FDA have held as confidential all information concerning OTC deodorant drug products for internal use submitted for consideration by the Panel. All the submitted information will be put on public display in the Dockets Management Branch, Food and Drug Administration, after February 4, 1982, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs (HFD-510) (address above).

FDA published in the **Federal Register** of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The Court in *Cutler* held that the OTC drug review regulations (21 CFR 330.10) were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision is now deleted from the regulations. The regulations now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process, before the establishment of a final monograph.

Although it was not required to do so under *Cutler*, FDA will no longer use the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III because that was the framework in which the Panel conducted its evaluation of the data.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbanded (monograph conditions) will be effective 6 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug products that are subject

to the monograph and that contain nonmonograph conditions, i.e., conditions which would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce. Further, any OTC drug products subject to this monograph which are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to voluntarily comply with the monograph at the earliest possible date.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC miscellaneous internal drug products was issued in the **Federal Register** of November 16, 1973 (38 FR 31696). (In making their categorizations with respect to "active" and "inactive" ingredients, the advisory review panels relied on their expertise and understanding of these terms. FDA has defined "active ingredient" in its current good manufacturing practice regulations (§ 210.3(b)(7), (21 CFR 210.3(b)(7))), as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." An "inactive ingredient" is defined in § 210.3(b)(8) as "any component other than an 'active ingredient.' ") In the **Federal Register** of August 27, 1975 (40 FR 38179) a notice supplemented the initial notice with a detailed, but not necessarily all-inclusive, list of active ingredients in miscellaneous internal drug products to be considered in the OTC drug review. The list, which did not include ingredients in deodorants for internal use, was provided to give guidance on the kinds of active ingredients for which data should be submitted. The notices of November 16, 1973, and August 27, 1975, informed OTC drug product manufacturers of their opportunity to submit data to the review at that time and of the applicability of the monographs from the OTC drug review to all OTC drug products.

Under § 330.10(a) (1) and (5), the Commissioner of Food and Drugs appointed the following Panel to review the data and information submitted and to prepare a report on the safety, effectiveness, and labeling of the active ingredients in these OTC miscellaneous internal drug products:

Diana F. Rodriguez-Calvert, Pharm. D. (appointed July 1976), Acting Chairman
John W. Norcross, M.D., Chairman (resigned March 1979)
Ruth Eleanor Brown, R.Ph. (resigned May 1976)
Elizabeth C. Giblin, M.N., Ed. D.
Richard D. Harshfield, M.D.
Theodore L. Hyde, M.D.
Claus A. Rohweder, D.O. (deceased April 13, 1979)
Samuel O. Thier, M.D. (resigned November 1975)
William R. Arrowsmith, M.D. (appointed March 1976)

Representatives of consumer and industry interests served as nonvoting members of the Panel. Eileen Hoates, nominated by the Consumer Federation of America, served as the consumer liaison until September 1975, followed by Michael Schulman, J.D. Francis J. Hailey, M.D., served as the industry liaison, and in his absence John Parker, Pharm. D., served. Dr. Hailey served until June 1975, followed by James M. Holbert, Sr., Ph. D. All industry liaison members were nominated by the Proprietary Association.

The following FDA employees assisted the Panel: Armond M. Welch, R.Ph., served as the Panel Administrator until July 1979, followed by John R. Short, R.Ph. Enrique Fefer, Ph. D., served as the Executive Secretary until July 1976, followed by George W. James, Ph. D., until October 1976, followed by Natalia Morgenstern until May 1977, followed by Arthur Auer until October 1978. Roger Gregorio followed as the liaison for the Office of New Drug Evaluation beginning November 1978. Joseph Hussion, R.Ph., served as the Drug Information Analyst until July 1976, followed by Anne Eggers, R.Ph., M.S., until October 1977, followed by John R. Short, R.Ph, until July 1979.

In order to expand its scientific base the Panel called upon Ralph B. D'Agostino, Ph. D., for advice in statistics.

The Advisory Review Panel on OTC Miscellaneous Internal Drug Products was charged with the review of many categories of drugs, but due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents its conclusions and recommendations for deodorant drug products for internal use in this document. The review of other categories of miscellaneous internal drug products is being continued by the Panel, and its findings are being published periodically in the **Federal Register.**

The Panel was first convened on January 13, 1975 in an organizational meeting. Meetings at which deodorant drug products for internal use were discussed were held on: March 2 and 3, April 17 and 18, June 2, and 3, July 21, September 29 and 30, December 8 and 9, 1979; February 23 and 24, April 18 and 19, and June 6 and 7, 1980.

The minutes of the Panel meetings are on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration (address above).

The following persons were requested by the Panel to appear to express their views on deodorant drug products for internal use:

Donald P. Binder
Norma N. Gill, E.T.
Rupert B. Turnbull, M.D.

No person who so requested was denied an opportunity to appear before the Panel to discuss deodorant drug products for internal use.

The Panel has thoroughly reviewed the literature and data submissions, has listened to additional testimony from interested persons, and has considered all pertinent data and information submitted through June 7, 1980 in arriving at its conclusions and recommendations for OTC deodorant drug products for internal use.

In accordance with the OTC drug review regulations (21 CFR 330.10), the Panel considered OTC deodorant drug products for internal use with respect to the following three categories:

Category I. Conditions under which OTC deodorant drug products for internal use are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which OTC deodorant drug products for internal use 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 reviewed three active ingredients in OTC deodorant drug

products for internal use and classified all three in Category III.

I. Submission of Data and Information

Pursuant to the notices published in the **Federal Register** of November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179) requested the submission of data on OTC miscellaneous internal drug products, the following firms made submissions related to deodorant drug products for internal use:

A. Submissions by Firms

Firms and Marketed products

Requa Manufacturing Co., Inc., Greenwich, CT 06830—Requa's Activated Charcoal capsules and tablets.

Rystan Co., Inc., White Plains, NY 10605—Derefil tablets and Chloresium tablets.

The Parthenon Co., Inc., Salt Lake City, UT 84119—Devrom chewable tablets.

B. Labeled Ingredients Contained in Marketed Products Submitted to the Panel

Bismuth subgallate
Charcoal, activated
Chlorophyllin, water-soluble

C. Classification of Ingredients

1. *Active ingredients.*
Bismuth subgallate
Charcoal, activated
Chlorophyllin, water-soluble

2. *Inactive ingredients.*
None.

D. Referenced OTC Volumes

The "OTC Volumes" cited throughout this document include submissions made by interested persons in response to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179). All of the information included in these volumes, except for those deletions which are made in accordance with the confidentiality provisions set forth in §330.10(a)(2), will be put on public display after February 4, 1982, in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

II. General Statements and Recommendations

A. Definitions of Terms

For the purposes of this document the Panel has agreed on the following definitions:

1. *Colostomy.* An external operative opening from the colon.

2. *Deodorant for internal use.* An ingredient taken internally to render offensive odors less perceptible.

3. *Enterostomates.* Those persons who have an opening into the intestine through the abdominal wall, e.g., a colostomy or ileostomy.

4. *Ileostomy.* An external operative opening from the ileum.

5. *Incontinent patients.* Those persons who are unable to control the elimination of urine or feces.

6. *Ostomate.* General terminology referring to a person who has an operative ostomy.

7. *Ostomy.* General term referring to any operative opening for the external discharge of urine or feces.

B. General Discussion

Since antiquity, humans have been bothered by the problem of body odors, most of which can be controlled or diminished by adequate personal hygiene. But there are conditions over which individuals do not have complete control, such as when an individual has an ostomy or when individuals are incontinent. In such cases, it has been advocated by some that drugs be administered internally to control the offensive odor produced. Others believe that odors related to urinary and fecal incontinence can be controlled by attention to dietary intake and adequate fluid intake as well as adequate personal and environmental hygiene. Still others believe that ostomy odors can be controlled by the use of external appliances with or without deodorants. Odors of emissions from enterostomies are primarily due to bacterial action on food residues. Such bacterial action takes place in the colon. Hence, odors from enterostomy emission are mainly confined to colostomies.

The Panel reviewed three ingredients, bismuth subgallate, activated charcoal, and water-soluble chlorophyllin, intended as deodorants for internal use and reviewed specific claims for reducing or controlling enterostomy odor, urinary or fecal incontinence odor, body odor, and the odor of surface lesions. Very little data were available for review on the two latter claims; therefore, the Panel has concentrated its review on claims for reduction of enterostomy odor and urinary or fecal incontinence odor.

The Panel believes that a deodorant for internal use should be capable of significantly decreasing odors which are not related to faulty personal hygiene. The Panel has followed this principle in reviewing the specific ingredients for effectiveness and in establishing the testing guidelines for these ingredients.

C. Labeling

The Panel has carefully reviewed the submitted labeling claims for products promoted as deodorants for internal use and has categorized them in Category I, Category II, or Category III. The Panel realizes that other terms may be developed to express the same Category I indications. Only those indications listed under Category I are generally recognized to be acceptable at this time.

In order for any labeling to be acceptable, it must include (1) the indication(s) for use, (2) pertinent warnings and contraindications, and (3) the recommended dosage.

The Panel believes that all labeling should be clear, concise, easily read, and understood by most consumers. It has followed this concept in the development of all Category I labeling. The Panel is also concerned about the size and color of the print used in labeling of these and all drug products, and recommends that the industry make the necessary effort to design labeling which is legible.

One of the functions of this Panel is to attempt to eliminate improper labeling claims. Some of the labeling on drug products currently marketed as deodorants for internal use is unsupported by scientific data, and, in some cases, is misleading. Accordingly, such labeling has been placed in Category II.

The indications for use should be simply and clearly stated; the directions for use should provide the user with enough information for safe and effective use of the product.

The Panel believes that if two ingredients are indistinguishable with regard to effectiveness, it is misleading to claim superiority for one of the ingredients. Undocumented or misleading claims such as "Prompt reduction * * *" and colloquial or provincial expressions that do not have meaning to most people must not be used. In the labeling, effectiveness should not be related to the taste, odor, consistency, or other physical characteristics of the product, except as these physical characteristics may relate to the action of the active ingredients.

The Panel is aware of the current OTC labeling regulation dealing with warning statements in § 330.1(g). The Panel concurs with the warning, "Keep this and all drugs out of the reach of children," and believes that it should be incorporated in the labeling of drug products indicated as deodorants for internal use. However, the Panel recommends that the other warning statement required by § 330.1(g), "In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately," be revised to read as follows: "In case of accidental overdose, contact a Poison Control Center, emergency medical

facility, or doctor immediately for advice." The Panel believes that this revision will be more informative to the consumer.

Since OTC drug products can be purchased by anyone, it is the view of the Panel that the public may not regard them as products which can result in injurious or potentially serious consequences if used improperly. The public needs to be continually alerted to the idea that these products, like all medicine, carry some risk and should be used with caution. The consumer should also be informed of signs or symptoms of toxicity that warrant discontinuing use of the drug.

In addition, the Panel recommends that the drug product labeling contain instructions for the most effective use of the product. These instructions should be displayed prominently on all package labeling.

The Panel recommends that the label should contain a listing of all ingredients and that it should clearly indicate which are active and which are inactive. Active ingredients should be listed by their established names, and the label should state the quantity of the active ingredient per dose.

III. Deodorant Drug Products for Internal Use

A. Category I Conditions

The following are Category I conditions under which OTC deodorant drug products for internal use are generally recognized as safe and effective and are not misbranded.

1. *Category I active ingredients.* None.

2. *Category I labeling.* Although the Panel has not classified any ingredients as Category I, it recommends the following Category I labeling for deodorant drug products for internal use in the event that one or more ingredients are found to be generally recognized as safe and effective and not misbranded.

a. *Indications.* The product labeling should contain one or more of the following statements:

(1) "A colostomy or ileostomy deodorant."
(2) "An aid to reduce odor from colostomies or ileostomies."

b. *Other required statement.* All product labeling shall contain the following statement: "This product cannot be expected to be effective in the reduction of odor due to faulty personal hygiene."

B. Category II Conditions

The following are Category II conditions under which a deodorant drug product for internal use is not generally recognized as safe and effective or is misbranded.

1. *Category II active ingredients.* None.

2. *Category II labeling.* The Panel concludes that some labeling claims for deodorants for internal use are either vague, misleading, or unsupported by scientific data. The claims listed below and other related terms are therefore classified as Category II labeling for deodorant drug products for internal use.

a. "For the control of breath and body odors."
b. "To reduce breath and body odors."
c. "For the control of odor from surface lesions."
d. "To reduce odor from surface lesions."
e. "For management of mouth, breath, and body odors."
f. "For prompt reduction of oral malodors caused by foods, beverages, tobacco, catarrh, and other sources."
g. "For the control of perspiration odors (underarm, feet, and crotch) and bad breath."
h. "An internal deodorant."

The claim "To reduce body (perspiration) odor or surface lesion odor" has been placed in Category III labeling but only for water-soluble chlorophyllin. (See part III. paragraph C.2. below—Category III labeling.)

C. Category III Conditions

The following are Category III conditions for which the available data are insufficient to permit final classification at this time.

1. *Category III active ingredients.*

Bismuth subgallate.
Charcoal, activated.
Chlorophyllin, water-soluble.

a. *Bismuth subgallate.* The Panel has reviewed the use of bismuth subgallate as a deodorant for internal use for reducing enterostomy odors and concludes that it is safe for OTC use in the dosage proposed below, but data are insufficient to demonstrate its effectiveness.

(1) *Safety.* The bismuth salts, which have been used internally to reduce the odor of feces and gases released from the intestinal tract, are relatively insoluble. The majority of people who use such a product have an ileostomy or colostomy resulting from surgery for a pre-existing illness.

Injectable bismuth salts have been used in the past for treatment of syphilis and other conditions, and nephrotoxicity related to bismuth overdose has been well documented. In 1974, a different type of toxic reaction was reported in Australia in which the chronic ingestion of bismuth subgallate resulted in a severe, chronic, reversible encephalopathy (Ref. *1*). Bismuth subnitrate was indicated in France in six reported cases of reversible encephalopathy (Ref. *2*). By 1976, Martin-Bouyer (Ref. *3*) had recorded in France 360 cases of intoxication associated with chronic ingestion of various bismuth salts (subnitrate, silicate, aluminate, carbonate, basic nitrate, subgallate, subcarbonate, aluminol silicate, phosphate, oxyquinolate, pectate, and citrate). These cases involved 294 persons, of whom 16 died. Four cases of encephalopathy associated with bismuth subgallate were reported by Burns, Thomas, and Barron (Ref. *4*). The Panel is not aware of any reports of such incidents occurring in the United States. Although these salts of bismuth are considered relatively insoluble and poorly absorbed from the gastrointestinal tract, there is a significant absorption of some bismuth salts by some people (Refs. *2* and *5*). Factors controlling this absorption have not been explained; however, a decline of blood levels of bismuth correlates well with the degree of clinical improvement of the encephalopathy syndrome (Ref. *5*). Symptoms and signs commonly associated with the syndrome are asthenia (generalized weakness and fatigue), tremor, unsteadiness, muscular discomfort, loss of memory, confusion, and intellectual impairment. These disappear weeks to months after bismuth salt ingestion is discontinued.

Although these reactions have occurred in France and Australia following chronic ingestion of very high doses of bismuth preparations, this Panel is not aware of any such occurrences in the United States with bismuth subgallate when used at a maximum dose of 1.6 grams (g) per day (200 to 400 milligrams (mg) four times daily). This was verified by presentations to the Panel at its July 21, 1979 meeting (Ref. *6*). It should also be noted that at the time Australia was experiencing cases of bismuth-induced encephalopathy it was importing all its bismuth from France. Since 1977, when the importation of French bismuth was prohibited, Australia has not experienced a single case of bismuth-induced encephalopathy (Ref. *7*).

The Panel is aware that bismuth preparations other than bismuth subgallate have been used for neutralizing enterostomy odors; but, because they have been used to a considerably lesser degree than bismuth subgallate and because the Panel found very little information on which to base any conclusions, they will not be evaluated here.

(2) *Effectiveness.* The use of bismuth subgallate as an enterostomy deodorant

has been recommended by several well-recognized experts on ostomy care. However, there are few clinical studies to support this view. In one double-blind study bismuth subgallate was reported to be statistically significantly better than placebo (p less than 0.01) when used by ileostomates in a dosage of 400 mg before meals to control odor (Refs. *8* and *9*). The details of the study were not available.

In another study, which was uncontrolled, questionnaires were sent to 100 ostomy patients, both ileostomates and colostomates, concerning their use of bismuth subgallate (Ref. *10*). Forty-nine responses (41 from ileostomates and 8 from colostomates) were received, of which 23 (21 ileostomates and only 2 colostomates) indicated a significant use of bismuth subgallate. Of these, 13 (12 ileostomates and 1 colostomate) found the product to be very effective or completely effective in reducing enterostomy odor.

These studies, in addition to presentations made to the Panel on July 21, 1979, give some indication that bismuth subgallate may be effective as an enterostomy deodorizer (Ref. *6*). However, conclusive proof has not been established. This is based on the well-known fact that ileostomy odors are minor as compared to colostomy odors. The Panel recommends that further testing be done according to the proposed testing guidelines to determine whether or not bismuth subgallate is effective as an enterostomy deodorant.

(3) *Proposed dosage.* The Panel concludes that bismuth subgallate is safe for OTC use in a dose of 200 to 400 mg up to four times daily.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used as deodorants for internal use. (See part III. paragraph A.2. above—Category I labeling.)

(5) *Evaluation.* The Panel concludes that bismuth subgallate as generally recognized as safe for OTC use in the proposed dosage noted above, but finds insufficient data to demonstrate its effectiveness as a deodorant for internal use for reducing enterostomy odors. The Panel, therefore, recommends that it be tested according to the proposed testing guidelines. (See part III. paragraph D. below—Data Required for Evaluation.)

References

(*1*) Morgan, F. P., and J. J. Billings, "Is This Subgallate Poisoning?," *Medical Journal of Australia*, 2:662–663, 1974.

(*2*) Buge, A., et al., "Encephalopathies myocloniques par les sels de bismuth," *La Nouvelle Presse Medicale*, 3:2315–2320, 1974.

(*3*) Martin-Bouyer, G., "Intoxications par les sels de Bismuth administres par voie orale. Enquete epidemiologique," *Therapie*, 31:683–702, 1976.

(*4*) Burns, R., D. W. Thomas, and V. J. Barron, "Reversible Encephalopathy Possibly Associated with Bismuth Subgallate Ingestion," *British Medical Journal*, 1:220–223, 1974.

(*5*) Boiteau, H. L., et al., "Relations entre l'evolution des encephalopathies bismuthiques et les taux de bismuth dans le sang et dans les urines," *European Journal of Toxicology*, 9:233–239, 1976.

(*6*) Summary Minutes of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products meeting held on July 21, 1979.

(*7*) Buge, A., et. al., "Correlations Evolutives: Cliniques Electroencephalographiques, tomodensitometriques et toxicologiques, Dans Cinq Cas D'Encephalopathies bismuthiques," *La Semaine Des Hopitaux De Paris*, 55:1466–1472, 1979.

(*8*) Sparberg, M., "Bismuth Subgallate as an Effective Means for the Control of Ileostomy Odor: A double-Blind Study," *Gastroenterology*, 66:476, 1974.

(*9*) Sparberg, M., additional information regarding his study titled "Bismuth Subgallate as an Effective Means for the Control of Ileostomy Odor: A Double-Blind Study" contained under cover letter dated September 18, 1979 in Panel Administrator's File (OTC Volume 17HPAII).

(*10*) OTC Volume 170172 (uncontrolled study conducted by M. Goldsmith and N. Gill).

b. *Charcoal, activated.* The Panel has reviewed activated charcoal as a deodorant for internal use for reducing enterostomy gas and odor and concludes that it is safe for OTC use in the dosage proposed below, but data are insufficient to demonstrate its effectiveness for this use.

(1) *Safety.* There is no information available to the Panel indicating that activated charcoal is harmful for human use. Chronic ingestion by uremic patients in doses up to 50 g daily for up to 20 months produced no apparent ill effects (Ref. *1*). Vitamin deficiency has been induced in chicks on a diet containing 2 percent charcoal (Ref. *2*) and in rats (Refs. *3*, *4*, and *5*), presumably as a result of adsorption of nutrients by the charcoal. Because of the large amounts of charcoal used in these studies, plus the absence of reports of similar vitamin deficiencies in humans who have taken activated charcoal for relatively long periods of time, the Panel believes that the probability of nutrient deficiency in humans when taking activated charcoal is remote. However, the Panel is concerned that activated charcoal, due to its nonspecific adsorptive capacity, will adsorb ingested drugs, thereby decreasing their pharmacological activity. Therefore, the Panel recommends that the labeling of activated charcoal, when intended as an enterostomy deodorant, include a drug interaction precaution regarding any concurrent drug therapy.

The Panel has also reviewed activated charcoal as a digestive aid and for the treatment of acute toxic ingestion.

(2) *Effectiveness.* Activated charcoal has a long history of use as an effective adsorbent in various medical, industrial, and home situations. This Panel has previously reviewed the use of activated charcoal in the treatment of acute toxic ingestion and found it to be effective. The Panel has received one submission regarding the use of activated charcoal as a deodorant for internal use to reduce enterostomy gas and odor (Ref. *6*). As supporting evidence of this claim, the same firm referred to a study (Ref. *7*) submitted to the Panel when it previously reviewed digestive aid drug products. This was a preliminary double-blind study which indicated that activated charcoal would reduce the incidence of gas in normal healthy males after a meal containing beans, but no mention is made of the odor or the volume of the gas released.

Despite the absence of convincing double-blind studies or other scientific proof of effectiveness of activated charcoal as an enterostomy deodorant, the Panel believes it is reasonable to assume that the claims of its effectiveness for reducing gas and thereby reducing enterostomy odor are in keeping with its scientifically proven adsorptive capability (Ref. *8*). This opinion was also expressed in the presentations made to the Panel on July 21, 1979 (Ref. *9*).

On the basis of evidence presented as to the high adsorptive capability of activated charcoal also and the expert knowledge of the Panel, the Panel concludes that activated charcoal may be effective as a deodorant for internal use for reducing enterostomy gas and odor. The Panel recommends that further testing be done according to the proposed testing guidelines to determine whether or not activated charcoal is effective for such use.

(3) *Proposed dosage.* The Panel concludes that activated charcoal is safe for OTC use in a dose of up to 10 g daily in divided doses.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used as deodorants for internal use. (See part III. paragraph A.2. above—Category I labeling.) In addition, the Panel recommends that the following statement be included in a "Drug Interaction Precautions" section: "Because this medication may decrease the effectiveness of any other drug you are taking, consult your doctor before using it."

(5) *Evaluation.* The Panel concludes that activated charcoal is generally recognized as safe for OTC use in the dose noted above, but finds insufficient data to demonstrate its effectiveness as a deodorant for internal use for reducing enterostomy odor and gas. The Panel recommends that this ingredient be tested according to the proposed testing guidelines. (See part III. paragraph D. below—Data Required for Evaluation.)

References

(*1*) Yatzididis, H., "Activated Charcoal Rediscovered," *British Medical Journal*, 4:51, 1972.

(*2*) Almquist, H. J., and D. Zander, "Adsorbing Charcoal in Chick Diets," *Proceeding of the Society of Experimental Biology and Medicine*, 45:303–305, 1940.

(*3*) Cailleau, R., and J. Adrian, "L'Influence du Charbon sur L'Efficacite Vitaminique d'un Regime Equilibre," *Bulletin de la Societe Scientifique d'Hygiene Alimentaire et d'Alimentation Rationelle*, 36:114–121, 1948.

(*4*) Messerli, N., "De L'Influence des Substances Adsorbantes Ajoutees A une Alimentation Unilaterale sur le Developpement de L'Etat D'Avitaminose," *Archives Internationales de Physiologie (Liege)*, 19:103–114, 1922.

(*5*) Matet, A., and J Matet, "Regimes au Charbon Actif et Avitaminose A Precoce. Application a la Preparation de Regimes sans Vitamine A," *Bulletin de la Societe de Chemie Biologique*, 27:513–518, 1945.

(*6*) OTC Volume 170179.

(*7*) Hall, R. G., "Effectiveness of Charcoal in the Treatment of Intestinal Flatus," in Part III, OTC Volume 170151.

(*8*) OTC Volume 170125.

(*9*) Summary Minutes of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products meeting held on July 21, 1979.

c. *Chlorophyllin, water-soluble.* The Panel has reviewed water-soluble chlorophyllin, which according to New and Nonofficial Remedies (Ref. *1*) is 100 percent potassium sodium copper chlorophyllin, as a deodorant for internal use and concludes that it is safe for OTC use in the dosage proposed below, but data are insufficient to demonstrate its effectiveness in reducing enterostomy odor, urinary or fecal incontinence odor, body odor, or the odor from surface lesions.

(1) *Safety.* The median lethal dose (LD_{50}) for oral ingestion of a 15-percent aqueous solution of potassium sodium copper chlorophyllin for mice was found to be 7 grams per kilogram (g/kg) body weight. No toxic effects were found in rats from long-term feeding of a diet containing a 3–percent concentration of this chlorophyllin. There were no adverse effects on growth, survival, ability to conceive, or survival of offspring (Ref. *2*).

Few side effects have been reported in humans following the administration of water-soluble chlorophyllin in oral doses of up to 800 mg (in divided doses) daily for varying durations, each exceeding 1 week (Refs. *3* through *7*). The most frequent side effect reported was mild diarrhea, along with an expected green coloration of the stools. There was also one case of abdominal cramps and one case of excessive gas.

Acceptable daily intake of up to 15 mg/kg of a cholorophyllin copper complex, sodium and potassium salts, was established as temporarily acceptable by the Expert Committee on Food Additives of the World Health Organization (Ref. *8*).

(2) *Effectiveness.* The Panel was unable to find any well-controlled clinical studies demonstrating a reduction of enterostomy odor, urinary or fecal incontinence odor, body (perspiration) odor, or odor from surface lesions by the oral ingestion of water-soluble chlorophyllin.

The Panel is aware of 4 reports of uncontrolled clinical trials with a total of 47 enterostomy patients in which it was claimed that 46 had marked decrease or absence of odor from the ostomies with varying doses of water-soluble chlorophyllin (Refs. *6, 7, 9,* and *10*).

The Panel is also aware of 6 reports of uncontrolled clinical trials on the use of water-soluble chlorophyllin as a deodorant for internal use in a total of some 300 fecal or urinary incontinent patients in psychiatric institutions or nursing homes. The doses ranged from 100 to 200 mg daily. The odor was reported to be markedly reduced or absent within 1 to 2 weeks (Refs. *3, 4, 5, 10, 11,* and *12*).

Two of the studies mentioned above also showed good results in the reduction of body odor (Ref. *5*) and odor from malodorous surface lesions (Refs. *5* and *6*).

The studies summarized above, involving several hundred patients, reported excellent efficacy of water-soluble chorophyllin in multiple doses for the control of odors. From a statistical point of view, all of these studies were defective and the conclusions are unacceptable. Some of the defects which are common to the nine studies are as follows:

(a) None of the studies was double-blinded. (The investigators always knew whether the subjects were receiving the drug.)

(b) None of the studies properly employed placebos. Golden and Burke (Ref. *5*) apparently employed a placebo intermittently; however, this was not done in any systematic way. A crossover study employing a placebo could be performed easily to evaluate these drugs, but this was not done.

(c) It cannot be ascertained if proper controls were applied to minimize the effects of confounding variables, such as patient hygiene and patient care. It is unknown if the successes reported were due to the drug or to these variables.

(d) Only one study appears to have attempted to evaluate in quantitive terms the outcome/success variables dealing with reduction of odors (Ref. *12*).

Most of the studies reported simply state that odors were reduced or eliminated. No attempts were made to quantify baseline odors and changes over time. Thus, the results of the studies cannot be evaluated by statistical procedures. Further, their validity and reliability cannot be established in any objective manner.

Much of the odor of feces is due to the production of malodorous hydrogen sulfide. An in vitro test with water-soluble chlorophyllin has demonstrated a decrease of fecal odor (possible by adsorption of hydrogen sulfide) and the inhibition of the production of hydrogen sulfide in cultures of hydrogen sulfide-producing enteric organisms (Ref. *13*). The author attributes the mechanism of deodorization to a change in the bacterial metabolism.

A double-blind investigation on the systemic control of chronic foul foot odor in 88 psychiatric patients over a 4-week period shows no significant differences in subjective evaluation of the intensity of odor following administration of chlorophyll or placebo (Ref. *14*). There is no indication as to exactly what chlorophyll preparation was used in this study, nor is there any mention of the strength used.

The Panel concludes that there is insufficient evidence to demonstrate the effectiveness of water-soluble chlorophyllin as a deodorant for internal use for reducing enterostomy odor, urinary or fecal incontinence odor, body odor, or the odor from surface lesions, and recommends that it be tested further according to the proposed testing guidelines to determine whether or not it is effective.

(3) *Proposed dosage.* The Panel concludes that the water-soluble chlorophyllin is safe for OTC use up to 800 mg daily in divided doses.

(4) *Labeling.* The Panel recommends Category I labeling for ingredients used as deordorants for internal use. (See part III. paragraph A.2. above—Category I labeling.)

(5) *Evaluation.* The Panel concludes that water-soluble chlorophyllin copper chlorophyllin) is safe for OTC use in the proposed dosage stated above, but finds insufficient data to demonstrate its effectiveness as a deodorant for internal

use for reducing enterostomy odor, urinary or fecal incontinence odor, body odor, or the odor from suface lesions. The Panel, therefore, recommends that it be tested according to the proposed testing guidelines. (See part III. paragraph D. below—Data Required for Evaluation.)

References

(1) "New and Nonofficial Remedies," J.B. Lippincott Co., Philadelphia, p. 570, 1957.

(2) Harrison, J. W. E., S. E. Levin, and B. Trabin, "The Safety and Fate of Potassium Sodium Copper Chlorophyllin and Other Copper Compounds," *Journal of American Pharmaceutical Association*, 43:722–737, 1954.

(3) Morrison, J. E., "Oral Tablets Help Control Ward Odors, Study Shows," *Hospital*, 33:97, 1959.

(4) Laitner, W., "Odor Control in the Incontinent Mental Patient," *Phychiatric Quarterly*, (Supplement 2), 29:190–192, 1055.

(5) O'Connell, I., "A Useful Adjunct for Odor Control in Malodorous Surface Lesions and Incontinence," *Journal of the Central Islip State Hospital*, 1:23–26, 1968.

(6) Golden, T., And J. F. Burke, "Effective Management of Offensive Odors" *Gastroenterology*, 31:260–265, 1956.

(7) Siegel, L. H., "The Control of Ileostomy and Colostomy Odors," *Gastroenterology*, 38:634–636, 1960.

(8) The Eighteenth Report of the Joint FAO/WHO Expert Committee on Food Additives, *World Health Organization Technical Report Series*, No. 557, pp. 16–17, 1974.

(9) Weingarten, M., and B. Payson, "Deodorization of Colostomies with Chlorophyll," *The Review of Gastroenterology*, 18:602–604, 1951.

(10) Joseph, M., "The Control of Fecal Odors with Chlorophyll Tablets," *Western Journal of Surgery, Obstetrics and Gynecology*, 60:363–364, 1952.

(11) Dory, A. E., "The Control of Odor in Urinary Incontinence," *Nursing Homes*, 20:28, 1971.

(12) Noonan, L., "Summary of Derifil Tablets Trial," Rockland State Hospital, Orangeburg, NY, April 1972 (unpublished) contained in OTC Volume 170014 (Exhibit Y).

(13) Coren, O. J., and R. D. Barnard, "Probable Mechanism of Bowel Content Deodorization by Chloresium Ingestion. A confirmatory Bacteriologic Study," *New York State Journal of Medicine*, 54:2195–2199, 1954.

(14) Blake, R., "Determination of Extent of Deodorizing Properties of Chlorophyll," *Journal of American Podiatry Association*, 58:109–112, 1968.

2. *Category III labeling.* The Panel concludes that data are insufficient to demonstrate the effectiveness of internal deodorants in reducing the odor associated with incontinence or to reduce gas in enterostomy conditions. for water-soluble chlorophyllin, data are also insufficient to demonstrate effectiveness for reducing body (perspiration) odor or surface leasion odor. The following labeling claims are placed in Category III:

a. "For the reduction of fecal or urinary odor associated with incontinence."

b. "To reduce gas and odor associated with enterostomies."

c. *For products containing water-soluble chlorophyllin.* "To reduce body (perspiration) odor or surface lesion odor." Similar claims for other deodorants for internal use have been classified as Category II. (See part III. paragraph B.2. above—Category II labeling.)

D. Data Required for Evaluation

Guidelines for developing protocols for evaluating OTC deodorant drug products for internal use. The Panel recognizes that currently there is not available a generally accepted protocol for evaluating OTC deodorants for internal use. The Panel has reviewed carefully the scientific literature and has not been able to find any well-controlled studies for these drugs. Still, in order to bring a Category III drug into Category I, well-controlled studies must be performed. To aid investigators in designing tests of effectiveness, the Panel has developed the following guidelines. These guidelines are restricted to studies whose target population is subjects with enterostomies, and they are not meant necessarily to extend to other populations (e.g., to incontinent patients); however, many of the principles established here would be applicable. The guidelines are not meant to be definitive even for the target population of enterostomates. There may be at present or in the future other appropriate techniques, advances, or improved methodologies not contained here. However, these quidelines illustrate the important issues that must be considered in clinical trials involving the present set of drugs and, for that reason, should be a useful aid to investigators. The Panel would have preferred to use an objective measure to detect odor produced but is not aware of the availability of any practical methodology of adequate sensitivity and, therefore, is relying on the sense of smell, which is obviously subjective.

The Panel suggests that investigators discuss with appropriate FDA personnel proposed deviations from the following guidelines, as well as studies directed at other target populations, prior to initiation of such studies.

1. *Objective of the study.* The objective of the study is to determine whether the drug under investigation is more effective than a placebo as a deodorant for internal use for reducing colostomy odor.

2. *Target and sample populations.* The target population is the population of enterostomates who perceive a need for an internal deodorant to control odors that are not due to faulty personal hygiene. For the study, the sample population should consist only of individuals with colostomies. Odor is more likely to be a problem with these individuals than with other ostomates (e.g., ileostomates). Restriction of a study to this sample population will eliminate the potential of having many individuals in the study who do not have an odor problem and for whom a clinically significant drug effect will be impossible to document. If the drug is effective, it can be expected that its effectiveness will be demonstrable in a sample of colostomates. Further, if the drug is effective for these individuals, the Panel believes it should also be effective for the full target population of enterostomates.

For any particular study, the selected sample population should be fully specified, and pertinent characteristics should be thoroughly described. Also, the appropriate target population to whom study results can be extended should be stated, and the logic underlying the extension should be justified.

3. *Study setting and investigators.* The study should be conducted by qualified investigators in clinical centers, academic settings, or private practices. The important component is the qualification of the investigator.

4. *Admissibility and exclusion criteria.* The study subjects should be individuals with colostomies (other ostomates are to be excluded). In addition, the subjects

a. Should be free of active disease,

b. Should have no known sensitivity to the test drug,

c. Should not be taking other medications, including OTC medications, which might influence the response of the subject in the study,

d. Should be able to comprehend instructions and adhere to the study protocol (e.g., take drug as required by the protocol and keep a daily diary), and

e. Should not have an odor problem that might be related to faulty personal hygiene.

5. *Variables to measure in the pretest period.* Prior to giving the test medication, basic information on the subjects should be obtained. This is required not only to decide upon admissibility into the study, but also to use as a reference point for evaluating efficacy. The pretest variables should include:

a. Subjective measure of odor, on a 0 to 4 scale with 0 representing no odor and 4 representing maximum odor, by at least two individuals (subject and, for example, a staff member),

b. Enumeration of physical hygiene measures (e.g., type of colostomy appliance used),

c. Frequency of change of colostomy appliance,

d. Frequency of use of external deodorants in colostomy appliance, and

e. Quantification of dietary and other factors that may impact on odor.

Other variables, such as age, sex, and health status of the subjects, that are routinely of interest in clinical studies should also be collected at the prestudy stage.

6. *Study design.* The study should be randomized, double-blind, placebo-controlled crossover. Subjects should first go for 1 week without any treatment and then be randomly assigned to one treatment for a period of 14 days (½ to the drug and ½ to the placebo). This should be followed by a 7-day washout period and then subjects should be crossed over to the other treatment for a second period of 14 days.

7. *Instruction to study subjects.* The subjects should be given instructions for drug use according to the drug company's directions. The investigator should be certain the instructions are understood. Further, in order to insure consistency throughout the study, very strict rules to exclude variations in personal hygiene should be included in the instructions to the subjects. The use of external deodorants should be eliminated. Also, in order to produce the proper setting to judge the drug's effectiveness, the investigator may want to include the use of odor-producing foods in the diet during the course of the study. If this is desirable, the type and amount of food should be standardized by subject and should be uniform in both stages of the crossover.

8. *Variables to measure during the study.* A daily diary should be kept to record the amounts and times of day that the treatment (drug or placebo) is taken. Daily food intake and changes in hygiene should also be recorded. Also, a subjective measure of odor should be recorded daily by the individual. As in the prestudy measure, this should be on a 0 to 4 scale with 0 representing no odor and 4 representing maximum odor. Further, the subjects should be interviewed by a member of the project staff once at the beginning, once during, and once at the end of each of the 14-day periods (six interviews). During these interviews a rating on the 0 to 4 scale of the subject's odor should be made by a project staff member.

9. *Effectiveness measures.* The Panel recognizes that a subject's ability to measure his personal odor will lessen with time, but believes that the primary measure of odor in the study should be subject's own perception of it. This should be supplemented by independent evaluation whenever feasible. The major effectiveness measures to use for comparison of the drug with the placebo should be the change in odor over the treatment periods (i.e., two segments of crossover) and the subject's odor rating at the end of each treatment period. Other measures, such as changes in the project staff member's ratings and a subjective comparison of treatments by the patient at the end of the study, should also be of help in evaluating effectiveness.

10. *Statistical tests and sample size.* Appropriate statistical tests for crossover designs should be used to establish effectiveness. Sample sizes should be determined to give a p value of 0.05 for testing equality of effectiveness of the drug and placebo and a sufficiently small probability of error (e.g., 0.20) of not detecting a significant clinical superiority of the drug over the placebo. The drug company should be prepared to discuss what is meant by a significant clinical superiority.

11. *Number of clinical trials.* Two separate trials, performed by different investigators at different geographical sites, should be conducted. The samples from each of these sites should be representative of the sample population.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under 21 CFR 5.11 (see 46 FR 26052; May 11, 1981), the agency advises in this advance notice of proposed rulemaking that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations would be amended by adding in Part 357, a new Subpart I, to read as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart I—Deodorant Drug Products for Internal Use

Sec.

357.801 Scope.
357.803 Definitions.
357.810 Active ingredients for deodorant drug products for internal use. [Reserved]
357.850 Labeling of deodorant drug products for internal use.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704).

Subpart I—Deodorant Drug Products For Internal Use

§ 357.801 Scope.

(a) An over-the-counter deodorant drug product for internal use in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 357.803 Definitions.

As used in this subpart:

(a) *Colostomy.* An external operative opening from the colon.

(b) *Deodorant for internal use.* An ingredient taken internally to render offensive odors less perceptible.

(c) *Ileostomy.* An external operative opening from the ileum.

§ 357.810 Active ingredients for deodorant drug products for internal use. [Reserved]

§ 357.850 Labeling of deodorant drug products for internal use.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "deodorant for internal use."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or more of the following phrases:

(1) "A colostomy of ileostomy deodorant."

(2) "An aid to reduce odor from colostomies or ileostomies."

(c) *Other required statement.* The labeling of the product contains the following statement "this product cannot be expected to be effective in the reduction of odor due to faulty personal hygiene."

(d) *Warnings.* [Reserved]

(e) *Directions.* [Reserved]

Interested persons may, on or before April 5, 1982 submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this advance notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be

identified with the docket number found in brackets in the heading of this document. Comments replying to comments may also be submitted on or before May 5, 1982. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 23, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: December 17, 1981.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-8 Filed 1-4-82; 8:45 am]

BILLING CODE 4160-01-M

federal register

Tuesday
January 5, 1982

Part XII

Department of Health and Human Services

Food and Drug Administration

Corn and Callus Remover Drug Products for Over-the-Counter Human Use; Establishment of a Monograph

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 358

[Docket No. 81N-0122]

Corn and Callus Remover Drug Products for Over-the-Counter Human Use; Establishment of a Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of a proposed rulemaking that would establish conditions under which over-the-counter (OTC) corn and callus remover drug products are generally recognized as safe and effective and not misbranded. This notice is based on the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products and is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by April 5, 1982, and reply comments by May 5, 1982.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's Office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on June 22, 1980 a report on OTC corn and callus remover drug products from the Advisory Review Panel on OTC Miscellaneous External Drug Products. FDA regulations (21 CFR 330.10(a)(6)) provide that the agency issue in the **Federal Register** a proposed order containing: (1) The monograph recommended by the Panel, which establishes conditions under which OTC corn and callus remover drug products are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs' not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

The unaltered conclusions and recommendations of the Panel are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The report has been prepared independently of FDA, and the agency has not yet fully evaluated the report. The Panel's findings appear in this document to obtain public comment before the agency reaches any decision on the Panel's recommendations. This document represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it.

After reviewing all comments submitted in response to this document, FDA will issue in the **Federal Register** a tentative final monograph for OTC corn and callus remover drug products as a notice of proposed rulemaking. Under the OTC drug review procedures, the agency's position and proposal are first stated in the tentative final monograph, which has the status of a proposed rule. Final agency action occurs in the final monograph, which has the status of a final rule.

The agency's position on OTC corn and callus remover drug products will be stated initially when the tentative final monograph is published in the **Federal Register** as a notice of proposed rulemaking. In that notice of proposed rulemaking, the agency also will announce its initial determination whether the proposed rule is a major rule under Executive Order 12291 and will consider the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). The present notice is referred to as an advance notice of proposed rulemaking to reflect its actual status and to clarify that the requirements of the Executive Order and the Regulatory Flexibility Act will be considered when the notice of proposed rulemaking is published. At that time FDA also will consider whether the proposed rule has a significant impact on the human environment under 21 CFR Part 25 (proposed in the **Federal Register** of December 11, 1979, 44 FR 71742).

The agency invites public comment regarding any impact that this rulemaking would have on OTC corn and callus remover drug products. Types of impact may include, but are not limited to, the following: Increased costs due to relabeling, repackaging, or reformulating; removal of unsafe or ineffective products from the OTC market; and testing, if any. Comments regarding the impact of this rulemaking on OTC corn and callus remover drug products should be accompanied by appropriate documentation.

In accordance with § 330.10(a)(2), the Panel and FDA have held as confidential all information concerning OTC corn and callus remover drug products submitted for consideration by the Panel. All the submitted information will be put on public display in the Dockets Management Branch, Food and Drug Administration, after February 4, 1982, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs (HFD-510) (address above).

FDA published in the **Federal Register** of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The Court in *Cutler* held that the OTC drug review regulations (21 CFR 330.10) were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision is now deleted from the regulations. The regulations now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process, before the establishment of a final monograph.

Although it was not required to do so under *Cutler*, FDA will no longer use the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III because that was the framework in which the Panel conducted its evaluation of the data.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 6 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions which would cause the drug

to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce. Further, any OTC drug products subject to this monograph which are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to voluntarily comply with the monograph at the earliest possible date.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, requests for data and information on all active ingredients used in OTC miscellaneous external drug products were issued in the **Federal Register** of November 16, 1973 (38 FR 31697). (In making their categorizations with respect to "active" and "inactive" ingredients, the advisory review panels relied on their expertise and understanding of these terms. FDA has defined "active ingredient" in its current good manufacturing practice regulations (§ 210.3(b)(7), (21 CFR 210.3(b)(7))), as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." An "inactive ingredient" is defined in § 210.3(b)(8) as "any component other than an 'active ingredient,' ") In the **Federal Register** of August 27, 1975 (40 FR 38179), a notice supplemented the original notice with a detailed, but not necessarily all-inclusive, list of ingredients in miscellaneous external drug products. This list, which included ingredients for corn and callus removers, was provided to give guidance on the kinds of active ingredients for which data should be submitted. The notices of November 16, 1973, and August 27, 1975, informed OTC drug product manufacturers of their opportunity to submit data to the review at that time and of the applicability of the monographs from the OTC drug review to all OTC drug products.

Under § 330.10(a) (1) and (5), the Commissioner of Food and Drugs appointed the following Panel to review the information submitted and to prepare a report on the safety, effectiveness, and labeling of the active ingredients in these miscellaneous external drug products:

William E. Lotterhos, M.D., Chairman
Rose Dagirmanjian, Ph. D.
Vincent J. Derbes, M.D. (resigned July 1976)
George C. Cypress, M.D. (resigned November 1978)
Yelva L. Lynfield, M.D. (appointed October 1977)
Harry E. Morton, Sc. D.
Marianne N. O'Donoghue, M.D.
Chester L. Rossi, D.P.M.
J. Robert Hewson, M.D. (appointed September 1978)

Representatives of consumer and industry interests served as nonvoting members of the Panel. Marvin M. Lipman, M.D., of Consumers Union served as the consumer liaison. Gavin Hildick-Smith, M.D., served as industry liaison from January until August 1975, followed by Bruce Semple, M.D., until February 1978. Both were nominated by the Proprietary Association. Saul A. Bell, Pharm. D., nominated by the Cosmetic, Toiletry, and Fragrance Association, also served as an industry liason since June 1975.

Two nonvoting consultants, Albert A. Belmonte, Ph. D., and Jon J. Tanja, R.Ph., M.S., have provided assistance to the Panel since February 1977.

The following FDA employees assisted the Panel: John M. Davitt served as Executive Secretary until August 1977, followed by Arthur Auer until September 1978, followed by John T. McElroy, J.D. Thomas D. DeCillis, R.Ph., served as Panel Administrator until April 1976, followed by Michael D. Kennedy until Janaury 1978, followed by John T. McElroy, J.D. Joseph Hussion, R.Ph., seved as Drug Information Analyst until April 1976, followed by Victor H. Lindmark, Pharm. D., until March 1978, followed by Thomas J. McGinnis, R.Ph.

The Advisory Review Panel on OTC Miscellaneous External Drug Products was charged with the review of many categories of drugs. Due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents its conclusions and recommendations for corn and callus remover drug products in this document. The findings of the Panel with respect to other categories of miscellaneous external drug products are being published periodically in the **Federal Register.**

The Panel was first convened on January 13, 1975 in an organizational meeting. Working meetings which dealt with the topic in this document were held on: April 20 and 21, 1975, April 2 and 3, 1976; August 5 and 6, September 30, October 1, December 11 and 12, 1977; April 16 and 17, June 11 and 12, August 11 and 12, September 30, October 1, December 11 and 12, 1978; September 28 and 29, October 28 and 29, December 9 and 10, 1979; January 27 and 28, March 7 and 8, April 20 and 21, and June 22 and 23, 1980.

The minutes of the Panel meetings are on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration (address above).

The following individuals were given an opportunity to appear before the Panel, either at their own request or at the request of the Panel, to express their views on corn and callus remover drug products:

Robert Blank, Ph. D.
Phillip Brachman, D.P.M.
Barry Brooks, J.D.
Frank Dunlap, M.D.
Donald Hartung
Adam Kara, D.P.M.
Herbert Lapidus, Ph. D.
William Mueller
Mark Taylor

No person who so requested was denied an opportunity to appear before the Panel.

The Panel has thoroughly reviewed the literature and data submissions, has listened to additional testimony from interested persons, and has considered all pertinent information submitted through June 23, 1980 in arriving at its conclusions and recommendations.

In accordance with the OTC drug review regulations in § 330.10, the Panel reviewed OTC corn and callus remover drug products with respect to the following three categories:

Category I. Conditions under which OTC corn and callus remover drug products are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which OTC corn and callus remover drug 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 reviewed 16 active ingredients in corn and callus remover drug products and classified 1 ingredient

in Category I, 13 ingredients in Category II, and 2 ingredients in Category III.

I. Submission of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as corn and callus remover active ingredients. Twenty-nine ingredients were identified as follows: Alkaloids of belladonna, allantoin (5-ureidohydantoin), ascorbic acid, beeswax, benzocaine, camphor gum, castile soap, castor oil, chlorobutanol, chlorophyll, collodion, cotton seed oil, ether, glacial acetic acid, ichthyol, iodine, lard, menthol, methylbenzethonium chloride, methyl salicylate, oil of eucalyptus, panthenol, pyroxylin, salol (phenyl salicylate), sodium carbonate, thymol, turpentine, vitamin A, and zinc chloride. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC corn pads, plasters, and remedies, henceforth referred to as OTC corn and callous remover drug products.

A. Submissions

Pursuant to the above notices, the following submissions were received:

Firms and Marketed products

Chattem Drug & Chemical Co., Chattanooga, TN 37409—Blis-To-Sol.

Combe, Inc., White Plains, NY 10604—Blue Jay Corn Plasters.

E. G. Behren, Jackson, MI 49202—Corn/Callous Remover.

Scholl, Inc., Chicago, IL 60610—Callous Salve, Corn Salve, "2" Drop Corn/Callous Remover, Fixo Corn Plasters, Pink Medicated Disks for Corn Removal, Kurotex Corn Pads, Waterproof Corn Pads, Waterproof Small Corn Pads, Waterproof Callous Pads, Plastic Film Corn Pads, Pink Medicated Disks For Callous Removal, Medicated Disks for use with Zino Pads for Removing Soft Corns, Medicated Disks for use with Zino Pads for Removing Corns, Medicated Disks for use with Zino Pads for Removing Callouses, Presto Callous Pads, Presto Soft Corn Pads, Presto Corn Pads, Presto Small Corn Pads, Zino Small Corn Pads, Zino Corn Pads, Zino Callous Pads, Zino Soft Corn Pads.

Whitehall Laboratories, New York, NY 10017—Freezone.

B. Ingredients Reviewed by the Panel

1. *Labeled ingredients contained in marketed products submitted to the Panel.*

Alcohol
Camphor
Castor oil
Diperodon hydrochloride
Ether
Oil of eucalyptus
Phenoxyacetic acid
Pyroxylin
Salicylic acid
Starch
Zinc chloride

2. *Other ingredients reviewed by the Panel.*

Alkaloids of belladonna
Allantoin (5-ureidohydantoin)
Ascorbic acid
Beeswax
Benzocaine
Camphor gum
Castile soap
Chlorobutanol
Chlorophyll
Collodion
Cotton seed oil
Glacial acetic acid
Ichthyol (ichthammol)
Iodine
Lard
Menthol
Methylbenzethonium chloride
Methyl salicylate
Panthenol
Salol (phenyl salicylate)
Sodium carbonate
Thymol
Turpentine
Vitamin A

C. Classification of Ingredients

1. *Active ingredients.*

Phenoxyacetic acid
Salicylic acid
Zinc chloride

2. *Inactive ingredients.*

Alcohol
Beeswax
Benzocaine
Camphor
Camphor gum
Castile soap
Castor oil
Chlorophyll
Collodion
Cotton seed oil
Ether
Eucalyptus oil (oil of eucalyptus)
Lard
Menthol
Pyroxylin
Sodium carbonate
Starch
Thymol
Turpentine

3. *Other ingredients.* The Panel was not able to locate nor is it aware of any data demonstrating the safety and effectiveness of the following ingredients when used as OTC corn and callus remover active ingredients. The Panel, therefore, classifies these ingredients as Category II for this use, and they will not be discussed further in this document.

Acetic acid, glacial (glacial acetic acid)
Allantoin (5-ureidohydantoin)
Ascorbic acid
Belladonna (extract) (alkaloids of belladonna)
Chlorobutanol
Diperodon hydrochloride
Ichthammol (ichthyol)
Iodine
Methylbenzethonium chloride
Methyl salicylate
Panthenol
Phenyl salicylate (salol)
Vitamin A

D. Referenced OTC Volumes

The "OTC Volumes" cited throughout this document include submissions made by interested persons in response to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179). All of the information included in these volumes, except for those deletions which are made in accordance with confidentiality provisions set forth in § 330.10(a)(2), will be put on public display after February 4, 1982, in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

II. General Discussion

In normal skin the cells in the stratum basale epidermidis (bottom layer of the epidermis) undergo mitotic division (cell reproduction) followed by the migration of maturing cells through the stratum spinosum (prickle cell layer) and the stratum granulosum (granular layer of the epidermis). The migration rate is equal to the continual surface shedding of these cells. Normal mitotic activity and subsequent shedding lead to complete replacement of epidermis in about 1 month. In the case of a callus, friction and pressure against the surface of the skin increase the shedding rate which leads to a faster mitotic activity of the basal cell layer. This increased activity in turn produces a thicker stratum corneum (outermost layer) as more cells reach the outer surface of the skin. When the friction or pressure is relieved, the mitotic activity returns to normal, causing remission and disappearance of the callus (Ref. *1*).

A corn and callus are similar in that each has a marked thickening (hyperkeratosis) of the top layer of the skin. Both corns and calluses are caused by long periods of pressure or friction against the skin, and the affected areas respond with a thickening of the skin which is sometimes painful. It is usually when the affected area becomes painful that advice and consultation are sought or an OTC product is purchased.

A callus is a thickening of the skin having no central core, as opposed to a corn which has a definite core (Refs. *2* and *3*). A callus has indefinite borders and ranges from a few millimeters to several centimeters in diameter. A callus is usually raised, off-white, and has a normal pattern of skin ridges on its surface. Calluses form on weight-bearing areas in addition to the skin covering joints (e.g., on the palms of the hands, the sides and soles of the feet). Calluses also provide protection. Because the callus does protect, a reduction of the callus should be cautiously attempted, and the shoe, stocking, or other irritant cause should be removed (Ref. *4*).

In a reference submitted to the Panel, all hyperkeratolytic lesions studied on the plantar (bottom) surface of the foot and on either side of the large toe were classified as calluses (Ref. *5*). All lesions occurring on any surface of a toe, except on the sides of the large toe, were called corns.

Corns can be hard or soft and are usually associated with an underlying bony prominence, which causes a thickening, and a more compact central core, which is usually painful. According to Popovich (Ref. *1*), a corn is a raised, yellowish-gray thickening and ranges from a few millimeters to one or more centimeters in diameter. The base of the corn is on the surface of the skin; the apex points inward and presses nerve endings in the skin, causing pain (Ref. *1*).

Hard corns are the most common form of corns and occur on the surfaces of the toe joints (Ref. *6*). They are shiny and polished (Ref. *1*).

Soft corns are whitish thickenings of the skin that are usually found on the webs between the fourth and fifth toes and are continually macerated by accumulated sweat.

An intermediate between hard and soft corns is the so-called "O-corn" which is hard-rimmed, soft in the center, and usually very painful (Ref. *4*).

Seed corns are tiny compact areas within calloused skin on the sole of the foot, particularly in the metatarsal area, and usually are without symptoms (Ref. *4*).

A neurovascular corn has a highly vascular core (i.e., contains a large amount of blood), is not responsive to treatment, may occasionally bleed, and usually develops along the side of the foot near the big toe (Ref. *4*).

The Panel recommends that OTC corn and callus remover drug products be used only on calluses and hard corns. For the treatment of corns other than those described as hard, the Panel recommends that a doctor be consulted.

Corns generally arise from poorly fitting shoes, improperly fitted hosiery, or orthopedic problems (Ref. *5*). Orthopedic problems include improper weight distribution, pressure, and the development of bunions (a swelling over the area of the ball of the great toe, with thickening of the overlying skin and the forcing of this toe toward the little toe) (Ref. *1*). Other conditions occurring on the feet, such as warts or tumors, may be mistaken for corns or calluses. The Panel, therefore, recommends that hyperkeratotic foot lesions which persist despite self-treatment should be evaluated by a doctor.

The Panel further recommends that OTC drug preparations for removing corns and calluses should not be used by diabetics and persons with poor circulation except on the advice and under the supervision of a doctor. These persons are more prone to infections which may result from injury to surrounding skin by the OTC corn and callus remover drug preparations or by mechanical attempts to remove the corn or callus. Acute inflammation and ulceration may also occur from overuse of OTC corn and callus remover drug products (Refs. *7* and *8*). The Panel also points out that these products should not be used on irritated skin or any area that is infected or reddened.

The Panel adopted the following definitions pertaining to corn and callus removers:

a. *Balm.* A soothing liquid or semisolid preparation.

b. *Collodion.* A solution of pyroxylin (nitrocellulose) in an appropriate nonaqueous solvent which, on application to the skin in a thin layer, leaves a transparent, cohesive film.

c. *Cream base.* A water-in-oil and oil-in-water preparation resulting in a semisolid vehicle.

d. *Emollient.* A bland, fatty, or oily substance which may be applied locally, particularly to the skin, to mucous membranes, or to abraded areas. The skin is rendered softer and more pliable.

e. *Foot salve.* An ointment intended for use on the feet.

f. *Keratolytic agent.* A peeling agent causing a loosening of the cells of the horny layer of the skin.

g. *Lubricant.* Any substance that decreases friction.

h. *Medicated disk.* A topical medication, usually incorporated in a skin-contact adhesive base, carried on a fabric, plastic, or other suitable backing cut to the size and shape appropriate to the lesion to be treated.

i. *Medicated pad.* A topical medication consisting of an appropriately-sized protective pad of fabric, plastic, or other suitable cushioning material in or on which the medication is carried.

j. *Medicated plaster.* A topical medication, usually incorporated in a skin-contact adhesive base, spread upon a fabric, plastic, or other suitable backing.

k. *Ointment base.* A single phase semisolid preparation for external application, which is readily applied to the skin and used primarily as a vehicle or base for the topical application of more active medicinal substances. It may also function as a protectant or emollient.

l. *Vehicle.* A substance utilizated as a carrier for active ingredients. For corn and callus remover active ingredients, it may be an ointment base, solvent, collodion, medicated pad, disk, or plaster.

References

(*1*) Popovich, N. G., "Foot Care Products," *in* "Handbook of Nonprescription Drugs," 5th Ed., American Pharmaceutical Association, Washington, pp. 361–365, 1977.

(*2*) Domonkos, A. N., "Andrews' Diseases of the Skin," 6th Ed., W. B. Saunders Co., Philadelphia, pp. 54–60, 1971.

(*3*) Potter, G. K., "Histopathology of Clavi," *Journal of the American Podiatry Association*, 63:57–66, 1973.

(*4*) Gibbs, R. C., "Skin Diseases of the Feet," Warren H. Green, Inc., St. Louis, pp. 44–62, 1974.

(*5*) Arndt, K. A., "Manual of Dermatologic Therapeutics with Essentials of Diagnosis," 2d Ed., Little, Brown, and Co., Boston, pp. 46–49, 1978.

(*6*) "Stedman's Medical Dictionary," 23d Ed., The Williams and Wilkins Co., Baltimore, 1976, s.v. "corn."

(*7*) Rasmussen, J. E., and A. A. Fisher, "Allergic Contact Dermatitis to a Salicylic Acid Plaster," *Contact Dermatitis*, 2:237–238, 1976.

(*8*) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, p. 909, 1977.

III. Categorization of Data

A. Category I Conditions

These are conditions under which active ingredients used for corn and callus removal are generally recognized as safe and effective and are not misbranded.

1. *Category I ingredient—Salicylic acid.* The Panel concludes that salicylic acid is safe and effective for OTC use as a corn and callus remover when used within the dosage limits stated below.

Salicylic acid, also known as 2-hydroxybenzoic acid and *o*-hydroxybenzoic acid, is found in nature in wintergreen leaves and in the bark of the sweet birch. It is synthesized by heating sodium phenolate with carbon dioxide under pressure. Salicylic acid is

a lipid-soluble drug; 1 gram (g) dissolves in approximately 460 milliliters (mL) water or 15 mL boiling water, 2.7 mL alcohol, 3 mL acetone, 42 mL chloroform, 3 mL ether, 135 mL benzene, 52 mL turpentine, 60 mL glycerin, or 80 mL of fats or oils which makes salicylic acid compatible with a variety of pharmaceutical vehicles (Ref. *1*).

a. *Safety.* Salicylic acid and its derivatives are a widely used group of compounds. They are used as analygesics (pain relievers), antipyretics (fever reducers), keratolytics (peeling agents), rubefacients (agents that cause reddening of the skin), and anti-inflammtory agents. Whether the salicylates are administered orally, rectally, intravenously, or cutaneously, systemic absorption occurs. When salicylates are administered in a toxic dose, the potential side effects are nausea, decreased ability to hear, tinnitus (ringing in the ears), confusion, metabolic disturbances, hallucinations, and, in some extreme cases, death. These toxic reactions are collectively known as salicylism. However, the Panel is unaware of any report of salicylism resulting from the topical use of salicylic acid as a corn and callus remover.

Salicylic acid, when used topically in concentrations of 1 percent and higher, depending on the vehicle, is keratolytic on normal skin and should be applied carefully to hyperkeratotic areas of skin to avoid damage to adjacent healthy skin. It softens and destroys the outer layer of skin by increasing endogenous hydration (water concentration) in this area. This action probably results from lowering the pH and causes the cornified epithelium (horny skin) to swell, soften, and then shed. Necrosis (cell death) of the normal skin has been associated with overuse of salicylic acid (Ref. *2*).

A primary dermal irritation study (Ref. *3*) using a 14-percent concentration of salicylic acid in both acetone collodion and collodion vehicles was performed using the standard Draize Irritation Test on six albino New Zealand rabbits. The procedure for using both test solutions was the same. Application of 0.5 mL of the test material was made to clipped areas of intact and abraded skin. Following application of the test material, the entire trunk of each animal was covered with an impermeable occlusive wrapping. The wrapping and test material were removed and discarded at the end of 24 hours. The skin was examined at 24 and 72 hours following application.

On a scale of 0 to 5, the results of the study showed that 14 percent salicylic acid in acetone collodion gave a primary irritation index of 0.25 (potential for slight irritation, rarely irritating to people, no warning required). Fourteen-percent salicylic acid in collodion gave a primary irritation index of 1.0 (potential for mild irritation, possibly irritating to some people under occlusive wrap conditions, usually no warning required).

A midwestern research department in podiatric medicine conducted two investigations to determine the safety of OTC corn removers containing salicylic acid (Ref. *4*). The first retrospective investigation in September 1976 used completed outpatient medical records for the same year 1974 as a data base. The second investigation, conducted for one week in September 1977, was aimed at the collection of specific and current information on this subject through in-depth interviews. A specifically designed questionnaire was employed as the instrument of the survey and was conducted by a team of doctors on a cross section of the population of Chicago.

The results of the first investigation showed that, of the 3,165 patients who visited the foot clinic in 1974, 2,140 (67.6 percent) were identified as having corns and calluses. A team of researchers carefully examined the clinical histories of each record. A specific search was made for instances where the use of corn removers containing salicylic acid could have been the cause of the clinic visit in 1974. No cases were recorded.

The results of the patient interview survey showed that, out of a total of 953 patients who visited the clinic during the week of the survey, 604 (63.4 percent) had been diagnosed as having corns and calluses. Seventy-two (12 percent) of those 604 patients gave histories of self-medication through the application of corn removers containing salicylic acid. None of the users of such products complained of ever having an adverse reaction which became so severe, in the judgment of the patient, as to necessitate treatment by a doctor. The researchers concluded that there was a complete absence of serious side effects in the cases studied as a result of self-treatment with corn removers containing salicylic acid. This conclusion, in addition to the history of repeated use of such products by many of the patients seen, indicated to the researchers that the application of corn removers containing salicylic acid was safe.

b. *Effectiveness.* Salicylic acid is commonly used by the consumer in OTC preparations for its peeling action in the treatment of hyperkeratotic conditions such as corns and calluses. It is usually formulated in flexible collodion, plasters, disks, or pads.

Flexible collodion contains pyroxylin, in a mixture of ether and alcohol, and plasticizers (camphor and castor oil). Pyroxylin is a nitrocellulose derivative which, after evaporation of the volatile solvents, remains on the skin as an insoluble water-repellant film that adhers better than an aqueous system (Ref. *5*). Flexible collodion is highly flammable and therefore must be stored at room temperature away from heat and must be kept away from fire or flame. Care must also be taken to keep the bottle tightly capped to avoid rapid evaporation of the product and inhalation of the volatile solvents which may cause hypnotic or other undesirable effects.

Collodion, plaster, disk, and pad dosage forms are advantageous because they are adherent and assure contact of the medication with the affected area (Ref. *6*). They also prevent moisture evaporation from the skin, and thereby facilitate penetration of the active ingredient into the affected area resulting in sustained local action of the drug.

Moisture is essential for salicylic acid to exert its action and for maceration and desquamation of epidermal tissue to take place. For that reason, soaking the feet for 15 to 30 minutes and drying before applying the medication aids the keratolytic action of salicylic acid.

A double-blind study was conducted to determine the safety and effectiveness of medicated disks containing 40 percent salicylic acid for the removal of corns and calluses (Ref. *7*). Of the 73 male and female subjects recruited for the study, 54 met the baseline requirements, and 51 completed the study. Subjects were selected for the study if they had at least two lesions, either corns or calluses.

The lesions were classified, graded clinically, measured in size, and rated for pain sensation. Lesions were grouped into paris. Treatments of active drug and placebo were randomly assigned and applied in a double blind fashion. Of the 52 corns and 68 calluses studied, 26 corns and 34 calluses were treated with medicated disks, and the remaining one-half were treated with placebo disks. A total of five applications including the initial application were made in 11 days (at 48- and 72-hour intervals). During each visit the disk was removed, the lesions evaluated, and another disk applied.

The results of the study showed that 19 of the 26 (73 percent) corns treated with the active drug were completely removed as opposed to 1 of 26 (4 percent) treated with the placebo, which was a significant difference. In

considering calluses, 5 of the 34 (15 percent) treated with the active ingredient showed complete removal of the calluses after 11 days as opposed to none in the placebo group. This test statistically demonstrated the effectiveness of the active treatment.

It was impossible to perform this test under truly double-blind conditions because the active formulation produced a characteristic white maceration on normal skin, while the placebo treatment produced only whitening without maceration. This difference could be observed by both the evaluator and the subject.

The study showed that when complete removal of the corn or callus occurred, the freshly exposed areas were red but only slightly tender to touch, and that this redness was not an indication of irritation, but was due to the normal vascular characteristics of freshly exposed skin. It was concluded that the active ingredient was as safe for use on corns and calluses as was the placebo.

The Panel agrees that complete removal of corns and calluses is not always essential because partial removal may provide needed comfort. Therefore, the Panel considers it safer to restrict the application of OTC disks, pads, or plasters to five treatments over a period of not more than 14 days rather than to prolong self-treatment.

A 2-week study with 100 subjects was performed to evaluate the effectiveness of salicylic acid 13.60 percent combined with zinc chloride 2.18 percent in a collodion and castor oil vehicle for the treatment of corns (Refs. *8* and *9*). At the beginning of the study and at all subsequent interviews, the subjects were examined by one consulting dermatologist. The examination consisted of the classification of the location, number, size, and severity, as well as the degree of pain of each subject's corns.

The subjects were randomly divided into 2 equal groups of 50 each. Group I was instructed to apply test medication "X" and test medication "Y" to their corns. Group II was instructed to apply test medication "A" and test medication "B" to their corns. The test medications were coded as follows: "A"—salicylic acid 13.60 percent and 2.18 percent zinc chloride in collodion; "B"—salicylic acid 13.60 percent in a cream base; "X"—proprietary corn and callus remover, salicylic acid concentration unknown; "Y"—salicylic acid 64.5 percent in petrolatum.

The subjects in Group I used test medication "X" on 56 corns and test medication "Y" on 54 corns. The subjects in Group II used test medication "A" on 53 corns and test medication "B" on 53 corns.

The applicants applied the test medications twice daily, once in the morning and once in the evening for 4 days. At the end of the fourth day they were to soak the feet in warm water for 30 minutes, dry the feet, and reapply the test medication. The subjects were told to return to the research laboratory to be reexamined by the consulting dermatologist after using the medication for 7 consecutive days.

At the end of the first week of the study, neither group had obtained 100 percent relief (complete removal of the corn). At the end of the second week of the study, the results showed that 16 percent of the subjects using test medication "X" obtained complete relief, 7.4 percent using test medication "Y" obtained complete relief, 47 percent using test medication "A" obtained complete relief, and 1.9 percent using test medication "B" obtained complete relief.

Based on the current literature, submitted data which includes the results of well-controlled clinical studies, and its own clinical expertise and experience, the Panel concludes that salicylic acid is safe and effective as a keratolytic agent for the treatment of hard corns and calluses at concentrations of 12 to 40 percent in pads, plasters, and disks, and at concentrations of 12 to 17.6 percent in a collodion vehicle. The Panel further concludes that if the hard corn or callus shows no improvement after 2 weeks of treatment, the patient should see a doctor.

For products containing salicylic acid in a collodion vehicle, directions must ensure that the salicylic acid be kept away from the surrounding skin preferably by encircling the corn or callus with a ring of petrolatum. The vehicle used and the accompanying directions must ensure that the salicylic acid is applied only to the corn or callus and is not applied to surrounding normal skin. The Panel cannot recommend the use of salicylic acid in an ointment vehicle for OTC use on corns and calluses because of a lack of data on both safety and effectiveness and classifies salicylic acid formulated in an ointment vehicle as Category II.

The Panel cannot recommend a concentration of salicylic acid which would be safe and effective for removal of soft corns because of insufficient data on both safety and effectiveness and recommends that studies for the treatment of soft corns be undertaken.

c. *Dosage.* Topical dosage is 12 to 40 percent salicylic acid in pads, plasters, and disks, or 12 to 17.6 percent in a collodion vehicle.

d. *Labeling.* The Panel recommends Category I labeling for corn and callus remover active ingredients. (See part III. paragraph A.2. below—Category I labeling.)

References

(*1*) Windholz, M., editor, "The Merck Index," 9th Ed., Merck and Co., Inc., Rahway, NJ, p. 1080, 1976.

(*2*) Strakosch, E. A., "Studies on Ointments, II. Ointments Containing Salicylic Acid," *Archives of Dermatology and Syphilology,* 47:16–26, 1943.

(*3*) OTC Volume 160283.

(*4*) OTC Volume 16256.

(*5*) Dittert, L. W., editor, "Sprowls' American Pharmacy," 7th Ed., J. B. Lippincott Co., Philadelphia, p. 167, 1974.

(*6*) Ansel, H. C., "Introduction to Pharmaceutical Dosage Forms," 2d Ed., Lea and Febiger, Philadelphia, pp. 328–329, 1976.

(*7*) OTC Volume 160293.

(*8*) OTC Volume 160003.

(*9*) OTC Volume 160133.

2. *Category I labeling.* The Panel recommends the following labeling for Category I corn and callus remover active ingredients:

a. *Indications.* "For the removal of hard corns and calluses."

b. *Directions*—(1) *For active ingredients formulated in a collodion vehicle.* "Cleanse feet thoroughly with soap. Soak in warm water for 15 to 30 minutes and dry feet thoroughly. Circle corn or callus with a ring of petrolatum to protect surrounding skin. Apply product one drop at a time to sufficiently cover each hard corn or callus only; let dry. Repeat this procedure daily until the corn or callus is removed or partially removed to provide comfort. Do not use medication for more than 14 days."

(2) *For active ingredients formulated in a pad, plaster, or disk dosage form.* "Cleanse feet thoroughly with soap. Soak in warm water for 15 to 30 minutes and dry feet thoroughly. Cut pad, plaster, or disk exactly to cover the corn or callus. Apply the pad, plaster, or disk. Remove pad, plaster, or disk after 48 hours and soak feet for 15 to 30 minutes. If the corn or callus is not soft enough to be removed, repeat the procedure. Do not exceed five treatments over a 14-day period."

c. *Warnings.* (1) "Do not use this product if you are a diabetic or have poor blood circulation because serious complications may result."

(2) "Do not use on irritated skin or on any area that is infected or reddened."

(3) "If discomfort persists, see your doctor."

(4) "Care should be used to avoid contact of product with skin surrounding corn and callus."

(5) "Do not use this product on soft corns."

(6) *For any products containing collodion.* (i) "Highly flammable, keep away from fire or flame."

(ii) "Store at room temperature away from heat."

(iii) "Keep bottle tightly capped."

(iv) "Avoid inhaling vapors."

(v) "If product gets into the eye, flush with water to remove film and continue to flush with water 15 more minutes."

B. Category II Conditions

These are conditions under which active ingredients used for corn and callus removal are not generally recognized as safe and effective or are misbranded.

1. *Category II ingredients.* These ingredients are discussed elsewhere. (See part I. paragraph C.3. above—Other ingredients.)

2. *Category II labeling.* The Panel has examined the submitted labeling claims for corn and callus remover drug products and has classified the following claims as Category II because they are not supported by scientific data:

a. "You are about to make your feet more confortable."

b. "You have just purchased one of the finest foot aids available."

c. "This special liquid preparation helps remove corns quickly."

d. "Walk easy, walk soft."

e. "Other uses for * * * corn pads, chafing, tender spots on sole of foot, instep ridges."

f. "Make walking more pleasurable for you."

g. "Sure to stay in place."

h. "Dissolves corn or callus away."

i. "Lifts off corns." or "Loosens corns."

j. "Absolutely painless."

C. Category III Conditions.

These are conditions for which the available data are insufficent to permit final classification at this time.

1. *Category III ingredients.*

Phenoxyacetic acid
Zinc chloride

a. *Phenoxyacetic acid.* The Panel concludes that phenoxyacetic acid is safe, but there are insufficient data available to determine its effectiveness as an OTC corn and callus remover active ingredient when used within the dosage limits stated below.

Phenoxyacetic acid is also known as phenoxyethanoic acid. It is prepared from phenol and monochloroacetic acid. It has a molecular weight of 152.4. One g is soluble in about 75 mL water; it is freely soluble in alcohol, ether, and benzene (Ref. *1*). Phenoxyacetic acid is not as strong an acid as salicylic acid (K value of 1.06×10^{-3} at 25° C) (Ref. *2*).

(1) *Safety.* A two-phase study was conducted to compare the local toxic effects of phenoxyacetic acid and salicylic acid (Ref. *3*). The experiment was conducted for 30 days on the skin of rabbits to determine the long-term effects and for 3 days on the skin of rats to determine the short-term effects.

Tests ointments of phenoxyacetic acid and salicylic acid were prepared in concentrations of 0.1, 0.3, 1, 5, 10, and 20 percent, and each concentration was applied to the shaved, clipped abdomen and ear of four rabbits. The abdomen was covered by an occlusive bandage. The treated ear was left uncovered. At 2-day intervals the test sites were examined and test preparations reapplied. This procedure was followed for 30 days. At the end of 30 days final inspection of the treated areas was made, the animals were sacrificed, and the tissues were examined histologically.

The results of the first phase of this study showed that both phenoxyacetic acid and salicylic acid, when applied to sensitive rabbit skin in high concentrations (up to 20 percent) for long periods of time (30 days), act as primary irritants. On the basis of both gross and histological evidence, the two preparations appeared to be similar in their irritating effects.

The second phase of the study compared both the relative activity and irritating effects of phenoxyacetic acid with salicylic acid on the skin of adult rats.

Test ointments of phenoxyacetic acid and salicylic acid were prepared in concentrations of 5, 10, 20, and 40 percent. Each concentration was applied to the backs of three white rats after the hair had been closely cut, and the site was then covered with an occlusive wrap. Once a day the skin was inspected. One animal from each concentration group was sacrificed daily, and portions of treated skin were examined for signs of gross irritation.

The results of phase two of the study showed that in concentrations of 5 percent, the onset of the keratolytic effect was seen in 3 days with phenoxyacetic acid. With concentrations of 10 to 40 percent, the onset of activity of phenoxyacetic acid was reduced to 2 days.

With salicylic acid in concentrations of 10 percent, the onset of the keratolytic effect was seen in 3 days. With concentrations of 20 to 40 percent, the onset of activity of salicylic acid was reduced to 2 days.

Concentrations above 20 percent of both salicylic acid and phenoxyacetic acid did not decrease the time of onset of activity or increase signs of irritation.

On the basis of the similar effects of the phenoxyacetic acid and salicylic acid in both phases of the test, the researchers concluded that phenoxyacetic acid could be expected to be no more irritating to hyperkeratotic human skin than salicylic acid in similar concentrations. Salicylic acid has been determined by the Panel to be safe for such use. (See part III. Paragraph A.1. above—Category I ingredient—Salicylic acid.)

In a study performed on both men and women with corns and calluses, test preparations were applied using 40 percent phenoxyacetic acid in 30 percent silicone fluid and 40 percent salicylic acid in 30 percent silicone fluid (Ref. *3*). Sixty-two corns and 62 calluses were treated with phenoxyacetic acid, and 36 corns and 47 calluses were treated with salicylic acid.

The medications were incorporated into identical standard corn and callus pads. At the beginning of the experiment the feet of each patient were carefully examined and detailed records prepared. Experimental pads were then placed on the lesions and were left on for 72 hours. At the end of this period, the pads were removed at the clinic, and the sites examined.

Throughout the clinical study no case of primary irritation due to phenoxyacetic acid was noted. Evidence of irritation was noted in three patients with salicylic acid

The conclusions drawn by the researcher was that phenoxyacetic acid was safe for consumer use as an OTC corn and callus active ingredient because of the lack of occurrence of primary irritation.

(2) *Effectiveness.* Two studies were conducted in 1948 to compare the effectiveness of 40 percent salicylic acid to the effectiveness of 40 percent phenoxyacetic acid contained in one type of corn pad (Ref. *3*). In the first study 62 corns and 62 calluses were treated with phenoxyacetic acid, and 36 corns and 47 calluses were treated with salicylic acid.

The results of the study showed that phenoxyacetic acid was 95.1 percent effective in the treatment of corns, while salicylic acid was 72.2 percent effective. Phenoxyacetic acid was 77.4 percent effective, and salicylic acid was 74.5 percent effective in the treatment of calluses.

In the second study, 33 corns were treated with a plaster containing 40 percent phenoxyacetic acid, and 33 additional corns were treated with a plaster containing 40 percent salicylic acid. The plasters were allowed to remain on the corns for 72 hours. If a second application was necessary, a second plaster was applied and allowed to remain for 72 hours. The final results were satisfactory (either complete or partial removal) to 76 percent of the subjects using plasters with phenoxyacetic acid and to 79 percent of subjects using plasters with salicylic acid. However, the method used in evaluating the "activity" of phenoxyacetic acid and salicylic acid in these tests is open to question. The method of scoring depended on the extent to which the corn could be removed by the patient after 72 hours of treatment. The effectiveness of the product, therefore, depended first upon the dexterity and the vigor used by the patient in removing the corn, and second upon the ability of the observer to decide when the core of the corn had been removed.

The Panel concludes that there are insufficient data to establish that phenoxyacetic acid is effective as an OTC corn and callus remover active ingredient.

(3) *Proposed dosage.* Topical dosage is 40 percent phenoxyacetic acid in pads, plasters, or disks.

(4) *Labeling.* The Panel recommends Category I labeling. (See part III. paragraph A.2. above—Category I labeling.)

References

(1) Windholz, M., editor, "The Merck Index," 9th Ed., Merck and Co., Inc., Rahway, NJ, p. 943, 1976.

(2) Heilbron, I., and H. M. Bunbury, "Dictionary of Organic Compounds," Volume 4, Oxford University Press, New York, p. 2663, 1965.

(3) OTC Volume 160294.

b. *Zinc chloride.* The Panel concludes that zinc chloride is safe, but there are insufficient data available to determine its effectiveness as an OTC corn and callus remover active ingredient when used within the dosage limits stated below.

Zinc chloride occurs as a white or nearly white, odorless substance taking various forms such as a crystalline powder, porcelain-like masses, or fused sticks or pencils. It has a molecular weight of 136.29, and a density of about 2.907. It melts at about 290° C and boils at 732° C. One g dissolves in 0.5 mL water, in about 1.5 mL alcohol at 25° C, in 0.25 mL of 2 percent hydrochloric acid, in 2 mL glycerin, and is fairly soluble in acetone and soluble in ether. An aqueous solution of 10 percent zinc chloride has a pH of about 4 and is acid to litmus (Refs. *1* and *2*).

Zinc chloride is chemically produced by reacting metallic zinc or zinc oxide with hydrochloric acid and evaporating the solution to a dry state (Refs. *1, 2,* and *3*).

(1) *Safety.* Zinc chloride has been safely used as a caustic, astringent, antibacterial, antiperspirant, and a tooth desensitizer (Refs. *1, 4, 5,* and *6*).

One study was performed to determine the primary irritation index of 2.2 percent zinc chloride in collodion (Ref. *5*). The test was conducted on six albino New Zealand rabbits, three male and three female. The test method was essentially that of the standard Draize Irritation Test. Applications of 0.5 mL of the test material were made on clipped areas of intact and abraded skin. The abrasions were only deep enough to penetrate the outer layer.

Following application of the test material, the entire trunk of each animal was covered with an impermeable occlusive wrapping. The wrappings were removed 24 hours after the application of the test material. The test sites were individually examined and scored separately at 24 and 72 hours. The results gave a primary irritation index of 1.60 (a potential for mild irritation which may be possibly irritating to some people under occlusive wrap conditions).

Based on the current literature and its own clinical expertise and experience, the Panel concludes that zinc chloride is safe as an OTC corn and callus remover active ingredient.

(2) *Effectiveness.* Zinc chloride applied as a paste in a concentration of 30 to 40 percent destroys tissues. Mohs (Ref. *7*) reported that zinc chloride was used to destroy external malignant lesions. Layers of dead tissue were excised after each application until normal tissue was reached.

In low concentrations (2.2 percent) zinc chloride, like most of the other metallic salts, is not strong enough for use as a caustic (Ref. *4*).

The Panel is not aware of any data available on zinc chloride as a single active ingredient for use as an OTC corn or callus remover, but it is a component of a reviewed combination. (See part III. paragraph D. 3. below—Category III combination.)

The Panel concludes there are insufficient data to establish the effectiveness of zinc chloride as an OTC corn and callus remover active ingredient.

(3) *Proposed dosage.* Topical dosage is 2.2 percent zinc chloride in collodion.

(4) *Labeling.* The Panel recommends Category I labeling. (See part III. paragraph A.2. above—Category I labeling.)

References

(1) Harvey, S. C., "Topical Drugs," *in* "Remington's Pharmaceutical Sciences," 15th Ed., Edited by A. Osol et al., Mac Publishing Co., Easton, PA, p. 719, 1975.

(2) Wade, A., and J. E. F. Reynolds, editors, "Martindale. The Extra Pharmacopoeia," 27th Ed., The Pharmaceutical Press, London, p. 221, 1977.

(3) Windholz, M., editor, "The Merck Index," 9th Ed., Merck and Co., Inc., Rahway, NJ, p. 1307, 1976.

(4) Soine, T. O., and C. O. Wilson, "Rogers' Inorganic Pharmaceutical Chemistry," 8th Ed., Lea and Febiger, Philadelphia, pp. 410–413, 1967.

(5) OTC Volume 160283.

(6) Sonneland, J., "The 'inoperable' Breast Carcinoma, A Successful Result using Zinc Chloride Fixative," *The American Journal of Surgery,* 124:391–393, 1972.

(7) Mohs, F. E., "Chemosurgical Treatment of Melanoma; Microscopically Controlled Method of Excision," *Archives of Dermatology and Syphilology,* 62:269–279, 1950.

2. *Category III labeling.* None.

D. Combination Policy

The Panel has reviewed and concurs with the rationale expressed in the combination drug policy for OTC products as set forth in 21 CFR 330.10(a)(4)(iv):

> An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

The Panel classified the combinations of active ingredients submitted to it as follows:

1. *Category I combinations.* None.

2. *Category II combinations—Salicylic acid and local anesthetics.* The Panel concludes that salicylic acid is safe and effective. (See part III. paragraph A.1. above—Category I ingredient—Salicylic acid.) However, the Panel concludes that pain from keratolytic action of salicylic acid on subcutaneous tissue and developing infections may be masked by local anesthetic used in combination with salicylic acid so that the consumer would not be alerted to potential danger. Such combinations are therefore considered unsafe.

3. *Category III combination—Salicylic acid and zinc chloride.* The Panel concludes that salicylic acid is safe and effective. (See Part III. paragraph A.1. above—Category I ingredient—Salicylic acid.) However, there is no evidence to establish that zinc chloride contributes to the effectiveness of the combination of salicylic acid and zinc chloride as a corn and callus remover. This combination has been discussed elsewhere. (See part III. paragraph C.1.b. above—Zinc chloride.) The Panel is also concerned about the possible formation of zinc salicylate in this combination. The Panel recommends that chemical stability tests be conducted as part of any Category III testing. Salicylic acid is not effective when incorporated in a zinc oxide paste because of the formation of zinc salicylate which is pharmacologically inactive (Ref. *1*).

Reference

(*1*) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, p. 909, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under 21 CFR 5.11 (see 46 FR 26052; May 11, 1981), the agency advises in this advance notice of proposed rulemaking that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations would be amended by adding in Part 358, new Subpart F, to read as follows:

PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart F—Corn and Callus Remover Drug Products

Sec.

358.501 Scope.
358.503 Definitions.
358.510 Corn and callus remover active ingredients.
358.550 Labeling of corn and callus remover drug products.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704).

Subpart F—Corn and Callus Remover Drug Products

§ 358.501 Scope.

(a) An over-the-counter corn and callus remover drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 358.503 Definitions.

As used in this subpart:

(a) *Corn and callus remover drug product.* A topical agent used for the removal of hard corns and calluses.

(b) *Collodion.* A solution of pyroxylin (nitrocellulose) in an appropriate nonaqueous solvent which, on application to the skin in a thin layer, leaves a transparent, cohesive film.

(c) *Medicated disk.* A topical medication, usually incorporated in a skin-contact adhesive base, carried on a fabric, plastic, or other suitable backing cut to the size and shape appropriate to the lesion to be treated.

(d) *Medicated pad.* A topical medication consisting of an appropriately sized protective pad of fabric, plastic, or other suitable cushioning material in or on which the medication is carried.

(e) *Medicated plaster.* A topical medication, usually incorporated in a skin-contact adhesive base, spread upon a fabric, plastic, or other suitable backing.

§ 358.510 Corn and callus remover active ingredients.

(a) Salicylic acid 12 to 40 percent in pads, plasters, and disks.

(b) Salicylic acid 12 to 17.6 percent in collodion.

§ 358.550 Labeling of corn and callus remover drug products.

(a) *Statement of identify.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "corn and callus remover."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "indications" that is limited to the following phrase: "For the removal of hard corns and calluses."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing any ingredient identified in § 358.510.* (i) "Do not use this product if you are a diabetic or have poor blood circulation because serious complications may result."

(ii) "Do not use on irritated skin or on any area that is infected or reddened."

(iii) "If discomfort persists, see your doctor."

(iv) "Care should be used to avoid contact of product with skin surrounding corn and callus."

(v) "Do not use this product on soft corns."

(2) *For any products containing collodion.* (i) "Highly flammable, keep away from fire or flame."

(ii) "Store at toom temperature away from heat."

(iii) "Keep bottle tightly capped."

(iv) "Avoid inhaling vapors."

(v) "If product gets into the eye, flush with water to remove film and continue to flush with water 15 more minutes."

(d) *Directions*—(1) *For products containing salicylic acid identified in § 358.510(a).* "Cleanse feet thoroughly with soap. Soak in warm water for 15 to 30 minutes and dry feet thoroughly. Cut pad, plaster, or disk exactly to cover the corn or callus. Apply the pad, plaster, or disk. Remove pad, plaster, or disk after 48 hours and soak feet for 15 to 30 minutes. If corn or callus is not soft enough to be removed, repeat the procedure. Do not exceed five treatments over a 14-day period."

(2) *For products containing salicylic acid identified in § 358.510(b).* "Cleanse feet thoroughly with soap. Soak in warm water for 15 to 30 minutes and dry feet thoroughly. Circle corn or callus with a ring of petrolatum to protect surrounding skin. Apply product one drop at a time to sufficiently cover each hard corn or callus only; let dry. Repeat this procedure daily until corn or callus is removed or partially removed to provide comfort. Do not use medication for more than 14 days."

Interested persons may, on or before April 5, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this advance notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments replying to comments may also be submitted on or before May 5, 1982. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 23, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: December 17, 1981.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-4 Filed 1-4-82; 8:45 am]

BILLING CODE 4160-01-M

federal register

Tuesday
January 5, 1982

Part XIII

Department of Agriculture

Food and Nutrition Service

Food Stamp Program; AFDC/Food Stamp Consolidation Demonstration Project; Final Rule

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 282

[Amdt. No. 199]

Food Stamp Program: AFDC/Food Stamp Consolidation Demonstration Project

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: Section 17(b)(1) of the 1977 Food Stamp Act authorizes the Secretary to waive requirements of the Act to the degree necessary to conduct demonstration projects designed to test program changes that might improve program administration or benefit delivery. However, such waivers may not lower or further restrict the income or resource standards or benefit levels provided under Sections 5 and 8 of the Act. Under the authority of this provision, the Department is granting the following waivers to certain Food Stamp Program requirements to enable the Department of Health and Human Services (DHHS) to conduct a demonstration project involving increased coordination between the Aid to Families with Dependent Children (AFDC) Program and the Food Stamp Program. This project, hereafter referred to as the AFDC/Food Stamp Consolidation Project, will test the effectiveness of modifying certain requirements of both programs in order to reduce administrative complexity and cost. It is hoped that minimizing differences between these two similar programs will assist State welfare agencies in administering both of them more efficiently.

For the most part, the Food Stamp Program requirements waived are rules which define and govern the treatment of income and resources. For the purpose of this demonstration, the food stamp regulations specified in this rulemaking are changed to more closely agree with AFDC procedures which will be used during the project.

EFFECTIVE DATE: October 1, 1981.

FOR FURTHER INFORMATION CONTACT: Marilyn Carpenter, Chief, Program Research and Analysis Branch, Program Development Division, Family Nutrition Programs, Food and Nutrition Service, United States Department of Agriculture, Washington, D.C. 20250; 202–447–8332. The Final Impact Statement describing the options considered in developing this final rule and the impact of implementing each option is available upon request from Ms. Carpenter.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed in relation to the requirements of Executive Order 12291, and it has been determined that the rule is not major as defined by that order. This rule will have an effect on the economy of less than $100 million and will not cause a major increase in costs or prices for consumers, individual industries, Federal, state or local government agencies, or geographic regions. While it is difficult to predict in monetary figures the effects of this demonstration project, the sponsoring agencies anticipate a savings in administrative costs for both Federal and State agencies. Given that the project will operate in only three States, those savings will not amount to $100 million. The Department has further determined that the rule will not have an adverse effect on competition, employment, investment, productivity, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. The experimental changes in assistance program policies and procedures have no foreseeable effects on private enterprises here or abroad. Therefore, the rule is classified as not major.

The rule has also been reviewed in relation to the requirements of the Regulatory Flexibility Act of 1980 (Pub. L. No. 96–354, 94 Stat. 1164, Sept. 9, 1980). G. William Hoagland, Administrator, Food and Nutrition Service (FNS), has certified that this action does not have a significant economic impact on a substantial number of small entities. The regulations have no impact whatsoever on small organizations. The rules establish alternatives to standard Food Stamp Program procedures, which will be tested in three States. The primary impact will be on State governments and individual recipients. To the extent that county governments operate the Food Stamp Program within States, they may be affected. However, the project is intended to simplify administration of the Food Stamp and AFDC Programs and thus any effects should be positive. There should not be significant economic costs in conjunction with this project.

The Department of Agriculture has also determined, in accordance with 5 U.S.C. 553(d)(3), that good cause exists for making this rule effective earlier than thirty days after publication and for declaring there to be a retroactive effective date of October 1, 1981. This action is necessary in order for the Food Stamp Program changes to comply with the implementation schedule that has been established by DHHS and the participating State agencies.

The AFDC/Food Stamp Consolidation Project was originally announced in the **Federal Register** on May 14, 1980 (45 FR 31924), when DHHS published a notice of its intention to conduct a demonstration project to test methods for improving coordination between the programs. The notice stated that DHHS would provide funds and waivers to offer the opportunity to test AFDC definitions of income and resources more in line with Food Stamp Program definitions. Interested States were requested to submit proposals for the design and operating procedures for such an experiment. On the basis of the proposals received, DHHS authorized projects in South Carolina, Vermont, and Michigan. (The Michigan project will operate only in Berrien County and the Redford District Office of Wayne County.) After being notified by DHHS of their acceptance as demonstration sites, the three sponsor States submitted to FNS requests for food stamp waivers needed for their separate project designs.

Optional Project Procedures

On July 31, 1981, the Department published a proposed rule (at 46 FR 39153) which added a new paragraph 7 CFR 282.18, providing waivers to a number of Food Stamp Program requirements in the Act and regulations needed for operation of this demonstration project. Due to a pressing DHHS implementation schedule, there was a 30-day comment period on the rule. Between publication and the end of the comment period, the Department received written comments from 16 parties. These included seven State agencies, five FNS regional offices, three public interest groups, and a State employment security agency. Michigan also submitted requests for six additional waivers due to general revisions in both programs that are scheduled for implementation in October. (Michigan will be delaying implementation of the demonstration project until January 1982 as a result of the October changes.)

In writing this final rule, FNS considered all the comments received and is making some minor changes in the regulations as a result of these comments. Two additional waivers are being added based on Michigan's requests. A discussion of the major comments appears in this preamble. For a fuller understanding of the project's background and the individual Food

Stamp Program waivers being granted for its operation—especially those that are unchanged from the proposed rulemaking—readers may wish to refer to the preamble of the proposed rule.

Eight commenters strongly supported the principle of consolidation. Two State agencies stated their enthusiasm for this project without reservation. They noted their own difficulties with program variations and were encouraged by this step toward coordination. Four other State agencies acknowledged their support but questioned whether the proposed waivers do much to achieve consolidation. One of these agencies desired to be considered for participation if the project were expanded, but still felt that the waivers may cause additional confusion by merely reducing rather than eliminating program differences. Two other State agencies stated that the proposed waivers contribute very little to real program uniformity and appear unlikely to have a significant impact on overall processing of AFDC and Food Stamp applications for a single family. Both thought, for instance, that resource limits would remain different. One State agency recommended a test which would use uniform eligibility criteria and a single eligibility process, including at a minium a single budgeting process. The other agency suggested a number of changes in the project to make it a more thorough test of the concept of consolidation, including revisions to proposed procedures and addition of waivers regarding income and resource exclusions and program terminology. Specific reference was made to the Intergovernmental Eligibility Simplification Project as a good resource for expanding this project. A third State recommended allowing States to use their AFDC standards to administer the Food Stamp Program.

Two FNS regional offices also suggested additional waivers. One recommended adopting the AFDC disregard of interest income under $5 per month. Another suggested uniform timeframes for fair hearings, or possibly holding joint AFDC/Food Stamp fair hearings, and the use of uniform timeframes for initial processing.

While the published waivers may appear modest to some, FNS is not significantly expanding the project's scope. It should first be noted that the published waivers do not reflect the entire scope of the project since they do not set forth the changes to be made in AFDC procedures to bring them closer to Food Stamp Program procedures. For instance, AFDC resource limits are in fact being changed to conform with food stamp limits in all three sponsor States. Second, a prohibition in the Food Stamp Act of 1977 against instituting demonstration project procedures that would lower or restrict income or asset limits constrains this agency's ability to make sweeping changes that would improve coordination but in the process lower or restrict such standards. See 7 U.S.C. 2026(b)(1). Many requests for waivers, including four of the most recently submitted, had to be disallowed due to this statutory limitation. Additionally, FNS has chosen not to adopt the suggestions offered by the non-participating commenters. The State agencies have largely designed their own projects and chosen the items they wish to consolidate. Since no States have requested changes in the treatment of interest income or various administrative timeframes, FNS is not offering those waivers at this time.

One regional office supported the concept of consolidation, but thought that the additional exclusions from income contradicted the demonstration project authority in the Food Stamp Act of 1977 by lowering the income standards. The legislative history on demonstration projects (H.R. Rep. No. 95–464, 95 Cong., 1st sess., 363 (1977)) makes it clear that it is not allowable to institute procedures that restrict income or resource standards or benefit levels more than general procedures do. Examples in the report of unacceptable project waivers include imposition of a ceiling on the value of a home and the inclusion of housing subsidies as income. None of the proposed waivers would restrict or lower income or asset limits in this way. The additional income exclusions would actually have more income disregarded and thus are legal under demonstration provisions.

Two public interest organizations expressed concern about this project's impact on participants. One group opposed the project altogether, fearing it to be a clear step toward a massive consolidation of income-assistance programs under block grants. This commenter urged that the programs be kept separate and cited the importance of the distinction between Food Stamps and "welfare" to target populations. This project was not designed to be a forerunner of block grant consolidation, but to be a rational effort at coordinating the programs for more effective administration. The other group felt that the regulations contained insufficient guarantees that no optional procedure would be instituted if it adversely affected the eligibility or benefits of any participant. This commenter desired a firm recognition of participants' rights within the regulations. Language has been added in section (d) of the regulations to affirm that no procedure will be implemented if it would lower or restrict income or asset limits required by the Act. FNS wishes to emphasize that the consideration of effects on participants has been a high priority throughout the design of the Food Stamp Program component of this project. Many requested waivers, which would have had adverse effects on income and resource standards, were, in fact, rejected during the negotiation process with the States.

There were several additional comments on project regulations and operations. One public interest group objected to the shortened comment period and urged USDA to retain the 60-day standard comment period whenever changes are being made that will affect recipients. FNS fully acknowledges the importance of public comment but at times finds compelling reasons to shorten the comment period, as in this case. One regional office emphasized the need for an effective date of October 1, 1981 in order that the adoption of a consolidated AFDC/Food Stamp Manual will coincide with the project implementation schedule of DHHS. FNS is aware of the implementation schedule and the effective date for project operations is October 1.

Two regional offices requested clarifications on quality control measures to be used during the demonstration. Baseline quality control information will be collected before implementation and compared with post-test quality control samples in South Carolina and Vermont. Special desk review audits will also be performed to enhance standard quality control data. Additional technical guidance on quality control procedures is being provided to the affected regional offices.

One public interest organization questioned the rationale of allowing optional project procedures rather than instituting them in all sites, believing data comparability will be damaged by variations among the sites. Flexibility is being permitted largely due to a DHHS determination that the concept of integration can be tested without complete uniformity. The effects of the majority of the individual changes cannot be evaluated independently, but the project will examine the major effects of improved coordination. The most effective evaluative tool to test the project's outcome—experimental and control sites—will be used in Michigan.

FNS is adding three provisions to the final rule in response to requests from the State of Michigan. Two of these concern work registration procedures. The other provision grants categorical eligibility for food stamps to AFDC households, if it is demonstrated that the AFDC gross income limits in the affected project areas will not exceed the Food Stamp Program's gross income limits. FNS is rescinding one waiver contained in the proposed rulemaking that exempted AFDC recipients from voluntary quit rules. Paragraphs governing the other potential procedures have been renumbered accordingly but have not been otherwise changed from the proposed rulemaking unless noted.

The first added provision removes the five day time limit contained in § 273.7(c)(2) for sending work registration forms to the State Employment Security Agency in cases when a food stamp application is approved but an AFDC application is pending. This change would enable the Food Stamp Office to hold these registration forms until a determination is made on the applicant's receipt of AFDC and accompanying WIN responsibilities. This procedural change removes the need for fully work registering applicants and then deregistering them when they are declared eligible for WIN.

Currently, § 273.7(b)(iv) exempts from work registration a parent or other caretaker who is responsible for caring for a child 12 years of age or less. The second addition to the final rule in response to a request from Michigan would provide that exemption only to persons caring for children 6 years or younger. This provision is contained in the 1981 Farm Bill, recently passed by Congress. The bill contains an additional clause that would accept inadequate child care for children 6 to 12 as good cause for refusing a job. This modification is being included in the final rule for this project.

The third additional waiver enables these States to use AFDC income and assets eligibility tests to determine eligibility for food stamps, as long as it is demonstrated that the gross income limits for AFDC eligibility do not exceed Food Stamp Program gross income limits. Under this waiver, applicants found eligible for AFDC would automatically be eligible for food stamps. Categorical eligibility would save time and eliminate much of the paperwork an eligibility worker now handles, largely because differences in the treatment of assets and gross income could be ignored when determining eligibility at intake and redetermination. It would in no way disadvantage any person eligible to receive food stamps. Separate allotment calculations would still be performed for both programs, so no benefits would be lost due to categorical eligibility. All income pertinent to each program would be considered in calculating allotments. Further, any case that does not meet all the requirements for AFDC eligibility would be required to be processed according to standard Food Stamp Program rules effective for the project area. This safeguard will assure that income and resource standards will not be lowered by this experimental change and that no food stamp client will be treated more harshly because of it.

Changes in the process of determining eligibility for both programs that were made by the Omnibus Reconciliation Act of 1981 (Pub. L. 97–35, enacted August 13, 1981) have enabled this waiver to be granted. While previously a number of separate deductions for each program were subtracted from total gross income before an applicant's income level was judged against the allowable income limits, total non-excluded gross income is now the basis for eligibility. This means that more comparable levels of income are now considered in the initial test for each program, although a few types of income are counted for Food Stamp Program purposes but excluded from AFDC gross income considerations and the limits themselves are not identical. Pub. L. 97–35 also applied restrictions to the treatment of earned income for AFDC purposes that will prevent categorical eligibility from re-establishing significant inequities in eligibility criteria such as those which led to the repeal of categorical eligibility in the Food Stamp Act of 1977 (Pub. L. No. 95–113, 91 Stat. 958, September 29, 1977). Because of these stricter income rules in the AFDC program, this waiver is expected to result in little or no increase in costs for the Food Stamp Program.

FNS is removing the waiver that would exempt, from the 60-day disqualification period, persons receiving AFDC benefits at the time they voluntarily quit a job. The proposed rule extended the exemption, which is currently available to persons certified for the Food Stamp Program at the time of a quit, to households certified for the AFDC program at the time of a quit in order to simplify treatment of AFDC recipients applying for food stamps. The 1981 Farm Bill, however, contains a provision to remove this exemption for persons already certified for the Food Stamp Program to make treatment of applicants and participants equitable in this regard. It was determined that rescinding this waiver would result in a more reasonable research approach than proceeding to expand an exemption that will soon be eliminated altogether by law. The sections of the regulations that extended this exemption to AFDC recipients have thus been removed.

Two comments were received on the proposed waiver which would exempt from the Food Stamp Program work registration requirement those AFDC recipients declared exempt from the Work Incentive (WIN) Program requirements under Title IV of the Social Security Act. One State agency noted its support for this change. This waiver further stipulated that a person who loses a WIN exemption without beginning participation in that program will be subject to food stamp work requirements. One commenter requested that timely, written notification of the work registration requirement be provided to prevent disqualification due to misunderstanding. FNS is not adding this requirement to the regulatory language since other means are available for communicating with the client about this requirement. If the loss of a WIN exemption is due to a loss of AFDC benefits, the client would report this change of income and the applicability of the work registration requirements would be reviewed at that time. If the loss of the WIN exemption results in no loss of benefits, clients can be registered for work at the time of their next recertification for benefits, as permitted in § 273.7(b)(2)(ii).

One commenter requested clarification on the purpose and scope of the revised procedures for obtaining social security numbers (SSN's) for applicants who do not have them at the time of application. This waiver of § 273.6(b) would enable State agencies to require an applicant to permit State agency staff to make an application for an SSN on his/her behalf. The provision eliminates the need for the client to provide verification of application or the number itself at a later date, since the Social Security Administration would directly contact the State agency with that information. It is anticipated that this will be less burdensome to applicants. Most importantly, the procedure will conform with AFDC requirements in some States. The commenter believed the regulations established separate procedures for applicants who need SSNs but are unable to provide them, applicants over 18, and children receiving income. In reality, there is no distinction between these groups of people or their

requirements. A paragraph heading which appears to have misled this commenter is being removed to clarify this section.

Of the three proposed changes in treatment of resources, only the change in determining the resource value of a licensed vehicle received comment. This waiver would remove the requirement that any licensed vehicle be evaluated for equity value but would still require determination of the fair market value of all licensed vehicles not completely excluded as resources. That value over $4500 would be applied to the Congressionally-set resource limit. Unlicensed vehicles would be evaluated for equity value with that full amount counted toward the resource limit. Three commenters stated that this waiver would still not result in unified procedures. They recommended the $4500 limit be eliminated and other necessary changes made to develop one method of handling vehicles for both programs. FNS is not revising this waiver for two reasons. First, adopting the AFDC procedures for vehicles in each State would result in lowering resource standards, which cannot be done under the law. Second, though very few recipients own expensive vehicles, FNS is retaining the $4500 limit to protect program integrity. Thus, the proposed waivers on vehicle resource calculation, jointly-held resources, and payments designated for restoration of a home damaged in a disaster are made final in this rule.

Several comments addressed the procedural changes for handling certain types of income. Two commenters supported the exclusion of additional portions of educational loans and scholarships. Clarifications were requested on the waivers concerning rental income and excludable irregular income.

It was proposed that the criteria for determining whether rental income is considered earned or unearned be made less specific to accord with AFDC regulations. Current Food Stamp Program rules count rental income as earned only if a household member is engaged in managing the property an average of 20 hours per week. The proposed waiver would eliminate the 20-hour quota for a more general requirement that a household member assume responsibility for management, which may include custodial functions.

The waiver further states that rental income will be generally considered unearned if a third party is employed to manage the property. One commenter stated that this definition still differs from AFDC regulations. Another requested clarification of the degree of activity necessary for income to be considered earned and generally found unsatisfactory the distinction between management by a household member and management through a third party to decide the degree of activity. FNS is revising the regulatory language to clarify that the existence of third party management which leaves the household with no specific responsibilities will mean that rental income will be treated as unearned, which is similar to AFDC rules.

Two options were offered to State agencies for determining excludable irregular or infrequent income. The first option would account for inflation by increasing the allowable exclusion from $30 per quarter to $25 per month (a total of $75 per quarter). The other option was offered in response to one State's explanation that the difference between programs was not in the amount of the dollar limit but the limit itself. The second option defines excludable irregular or infrequent income as income which is not received "on a periodic basis, making its receipt infrequent or irregular to the point it cannot be reasonably anticipated and which has no substantial effect on the calculation of benefits." One commenter objected to the second optional definition, requesting that a factual example be provided to explain its necessity and that "substantial effect" be further explained. This second option will give eligibility workers more flexibility in determining whether infrequent income would be excluded; in a State which chooses to adopt this option, reported income exceeding $25 per month but recognized as non-recurring can be disregarded for both programs. Because this option is intended to provide greater flexibility, no dollar limit will be set to explain "substantial effect." Eligibility workers in States adopting the second option will be instructed to use the same criteria in judging how to handle infrequent income for Food Stamp Program purposes as they do now for AFDC purposes.

Besides the clarification on the policy of handling rental income, no other changes are being made in the proposed regulations on income exclusions. Thus, the regulations on exclusion of educational loans and scholarships, income of children under 18 years of age, irregular income, and payments to members of some Indian tribes under Pub. L. 92–254, 86 Stat. 64, Mar. 18, 1972 are being made final as they were proposed.

One commenter supported the waiver of § 273.9(d)(5)(ii) which would allow States to develop a shelter insurance standard to be added onto the standard utility deduction. The commenter noted this modification would eliminate tedious verification and supported the nationwide application of a shelter insurance standard. Consideration will be given to the applicability of all project waivers for standard use. For now, this waiver is made final as it was proposed.

The only other change to the proposed regulations concerns the table to be used in the first optional procedure for use in calculating, for purposes of income exclusion, the allowable cost of doing business in a non-commercial boarding house. Current regulations at § 273.11(b)(1)(i) state that the cost of doing business can either be considered as (1) the cost of the Thrifty Food Plan for a household size equal to the number of boarders or (2) the actual documented cost of providing room and meals, if the actual cost exceeds the Thrifty Food Plan amount. The first option provided in the proposed rule would permit an increase in the "cost of doing business" exclusion by using separate standard costs for room and board. The room costs would be $43 per person in the boarder group, and the standard board costs would continue to be the cost of the Thrifty Food Plan. One commenter called attention to the inaccuracy of the Thrifty Food Plan amounts contained in the table published in the proposed rulemaking. These amounts have been revised in the schedule which is published in the final regulations. Another commenter found both this option and the change in the way business costs are calculated more cumbersome than current procedures. The commenter recommended the procedures not be changed or that States use AFDC methods to compute room/board income. Since the participating States suggested the changes, no further modifications are being made at this time. The two optional procedures to be used for determining room/board income are being made final as they were proposed.

FNS is thus waiving the following requirements of the Act and regulations in Vermont, Michigan and South Carolina, under demonstration authority given in Section 17(b)(1) of the Food Stamp Act of 1977. While these specific waivers were not uniformly requested by all the States, each State may choose to implement any or all of them, subject to prior FNS notification and approval.

Therefore, 7 CFR Part 282 is amended as follows:

PART 282—DEMONSTRATION, RESEARCH AND EVALUATION PROJECTS

1. In Part 282, § 282.18 is added to read as follows:

§ 282.18 AFDC/Food Stamp Consolidation Demonstration Project.

(a) *General.* Section 17(b) of the Food Stamp Act of 1977 authorizes the Secretary to conduct on a trial basis experimental projects that might increase the efficiency of the program and to waive requirements of the Act to the degree necessary to conduct such projects, so long as resource and income limits for eligibility and benefit level are not lowered or further restricted. These regulations establish variations to the Food Stamp Program operating procedures which shall apply during the course of the demonstration project, hereafter referred to as the AFDC/Food Stamp Consolidation Project. In this project, certain requirements for both the Food Stamp Program and the Aid to Families with Dependent Children (AFDC) Program will be modified for closer program coordination.

(b) *Purpose.* The purpose of the AFDC/Food Stamp Consolidation Project is to test the effects of a number of program changes, particularly in defining resources and income, which are designed to simplify eligibility and benefit calculations for households applying for both programs. This project is part of a series of ongoing attempts to improve the management of administrative resources. This project is intended to test whether closer coordination between these two programs, which serve overlapping caseloads, will reduce error rates and administrative costs in both programs.

(c) *Areas of operation.* The project, which is being primarily sponsored by the Department of Health and Human Services (DHHS), will operate in the States of Vermont, South Carolina, and in Berrien County and the Redford District of Wayne County, Michigan. Certain Food Stamp Program requirements, as set forth in paragraphs (d) and (e) of this section, may be waived in these areas of operation.

(d) *Statutory requirements to be waived.* For the limited purpose of permitting operation of this project, the following requirements of the Act are waived and modified as explained. The three States participating in the project, and only these States, may avail themselves of any or all of the waivers and elect to use the corresponding substitute procedures set out in paragraphs (f) through (u) of this section. Project operators at the State level shall have the authority to develop, subject to FNS approval, whatever procedures are necessary to project operations. No optional requirement will lower or further restrict income or resource standards or benefit levels as established in Sections 5 and 8 of the Act. The effective dates of waivers shall be publicized at the project sites. Other requirements may be waived as the Secretary deems necessary consistent with the limitations on the waiver authority provided in the Act. Any such waivers shall be published in the **Federal Register.**

(1) *Sec. 5(b) Uniform national standards.* The requirement for uniform national standards may be waived to the extent necessary to allow operation of this project.

(2) *Sec. 5(d) Exclusions from income.* Definitions of funds excluded from consideration as income within section 5(d) shall be expanded. The definitions that may be modified are those for irregular income in Section 5(d)(2); educational loans and scholarships in section 5(d)(3); and a dependent child's earnings in section 5(d)(7). Judgment payments to members of certain Indian tribes shall be specified as one of the Federal payments excluded from consideration as income for food stamp purposes, as set forth in section 5(d)(10). These modifications are explained in detail in paragraphs (f) through (t) of this section.

(3) *Sec. 6(d)(2)(A) Work registration exemptions.* The exemption from the food stamp work registration requirement which is granted to persons subject to and complying with a work registration requirement under Title IV of the Social Security Act, as amended (42 U.S.C. 602), may be extended to persons who are exempt from the Title IV requirement.

(e) *Regulatory requirements to be waived.* All current Food Stamp Program regulations (7 CFR Parts 270 through 282) shall govern the operation of this project, except the following paragraphs, which may be waived at the option of the participating project authority: 273.6(a) (2) and (3) and (b)(1) through (3); 273.7(b)(1) (iii) and (iv); 273.7(c)(2); 273.8(d); 273.8(e)(7); 273.8(h) (2) through (5); 273.9(b)(1)(ii); 273.9(c)(2); 273.9(c)(3); 273.9(c)(7); 273.9(d)(6)(i); 273.10(e)(2)(i)(B); and 273.11(b)(1)(ii) (A) and (B). The three States participating in this project may elect to use the appropriate substitute procedures, as set forth within paragraphs (f) through (t) of this section, as agreed upon by the State and FNS.

(f) *Optional project procedure: Social security numbers.* (1)(i) If any household member(s) required to provide the State agency with an SSN is unable to do so prior to certification or recertification, that member shall be allowed to participate only if she/he consents to have the State agency file an application with the Social Security Administration (SSA) in his/her behalf and provides the necessary verification for such application. The State agency shall be responsible for completing the application and will receive validation of the new number when it is issued.

(ii) If any household member(s) required to provide an SSN who is unable to provide one refuses to consent to having the State agency apply for an SSN in his/her behalf, and can show no good cause for this refusal, that individual shall be disqualified from participation, in accordance with paragraph (c) of § 273.6. This disqualification shall last until the individual obtains an SSN or until she/he consents to have the State agency apply to the SSA on his/her behalf for an SSN.

(2)(i) For those individuals who provide SSN's prior to certification, recertification or at any office contact, the State agency shall record the SSN and verify it in accordance with § 273.2(f)(1)(v).

(ii) For those individuals required to have an SSN who do not have one, the State agency shall offer to, and complete a Form SS–5, to obtain a SSN, at the household's request. To complete Form SS–5, the State agency must document the verification of identity, age, and citizenship or alien status as required by SSA and forward the SS–5 to SSA. The State agency shall follow the same procedures for applicants who do not know if they have an SSN or who are unable to find their SSN.

(g) *Optional project procedure: WIN exemptions from work registration.* A household member subject to and participating in the Work Incentive Program (WIN) under Title IV of the Social Security Act is exempt from food stamp work registration requirements. Additionally, those AFDC household members who are determined exempt from the WIN Program will be considered exempt from the food stamp work registration requirements. If such a person loses his/her WIN Program exemption and does not participate in the WIN Program, she/he shall be required to comply with the food stamp work registration requirements as a condition of continuing eligibility. If the exemption claimed is questionable, the State agency shall be responsible for verifying the exemption.

(h) *Optional project procedure: Caretaker exemption from work*

registration. A parent or other household member who is responsible for the care of a dependent child under 6 or an incapacitated person is exempt from food stamp work registration requirements. The unavailability of adequate child care for children from 6 to 12 shall be considered good cause for refusing employment. If the child has its sixth birthday within a certification period, the individual shall fufill the work registration requirement as part of the next scheduled recertification process, unless the parent or caretaker qualifies for another exemption.

(i) *Optional project procedures: Transmittal of certain work registration forms to the SESA.* Upon reaching a determination that an applicant or a member of the applicant's household is required to register, the State agency shall explain to the applicant the work registration and job search requirements, his or her rights and responsibilities, and the consequences of failure to comply. The State agency shall provide work registration forms to the applicant for each household member required to register for employment, and permit the applicant to complete the form for those members in accordance with paragraph (a) of § 273.7. Household members are considered to have registered when an identifiable work registration form is submitted to the State agency. An identifiable work registration form shall contain those items necessary for partial entry into the Employment Service Automated Reporting System (ESARS): the applicant's name, address, phone number, social security number (or some other identifying number when a social security number is not available), the expiration date of the household's certification period, an indication of exemption from job search, and any other information agreed upon by the State agency and SESA in their operating agreements. The State agency and SESA must agree before any information in the last category can be specifically required. If the registrant is an instream migrant and seasonal farmworker, or if the State agency knows that the registrant would otherwise be exempt from job search under the provisions of paragraph (f)(1)(ii)(c) of § 273.7, the State agency shall also indicate this on the registration form. The State agency shall not forward work registration forms to SESA until the household is certified, so that the SESA will not have to expend unnecessary efforts on applicants who are subsequently denied rather than certified for food stamps. The State agency shall forward the completed work registration form to the SESA having jurisdiction over the area where the registrant resides no later than five days after the date of household certification, unless a PA application is still pending at that time. In these cases, the State agency shall forward the completed form to the appropriate SESA within five days after the PA decision is made if such decision does not remove the food stamp work registration requirement.

(j) *Optional project procedure: Jointly owned resources.* Only a pro rata share of the value of resources owned jointly by separate households shall be considered available to each household, unless it can be demonstrated by the applicant household that such resources are inaccessible to that household. If the household can demonstrate that it has access to less than a pro rata portion of the resource, the value of that lesser portion of the resource shall be counted toward the household's resource level. The resource shall be considered totally inaccessible to the household if the resource cannot practically be subdivided and the household's access to the value of the resource is dependent on the agreement of a joint owner who refuses to comply.

(k) *Optional project procedure: Exclusion of disaster payments.* Non-government hazard insurance payments designated for the restoration of a home damaged in a disaster shall be excluded as a resource if there is a clear contract to restore the damaged home.

(l) *Optional project procedure: Handling of licensed and unlicensed vehicles.* (1) Licensed vehicles not exempt under subparagraph (1) of § 273.8(h) shall be individually evaluated for fair market value. That portion of their value which exceeds $4,500 shall be attributed in full toward the household's resource level, regardless of any encumbrances on the vehicle.

(2) Unlicensed vehicles, which are not exempted completely by § 273.8(e) (3), (4), or (5), shall be individually evaluated for equity value. Their equity value shall be attributed in full toward the household's resource level.

(m) *Optional project procedure: Definition of rental income.* The gross income from a self-employment enterprise, including the total gain from the sale of any capital goods or equipment related to the business, excluding the costs of doing business as provided in paragraph (c) of § 273.9, shall be considered earned income. Ownership of rental property shall be considered a self-employment enterprise. Rental income shall be deemed earned if a member of the household assumes responsibility for property management, which may include custodial functions. If a third party is employed to manage the property and no household member has any specific responsibilities for property management, the income shall generally not be considered earned (such as where rental properties are in the hands of rental agencies and the check is forwarded to the recipient). Payments from a roomer or boarder shall also be considered self-employment income.

(n) *Optional project procedure: Exclusion of irregular income.* Irregular income, defined in either of the following ways, shall be excluded from household income:

(1) Any income in the certification period which is received too infrequently or irregularly to be reasonably anticipated, but not in excess of $25 per month; or

(2) Any income in the certification period which is not received on a periodic basis, making its receipt infrequent or irregular to the point that it cannot be reasonably anticipated and which has no substantial effect on the calculation of benefits.

(o) *Optional project procedure: Exclusion of educational loans and scholarships.* Educational loans on which payment is deferred, grants, scholarships, fellowships, veterans' educational benefits, and the like to the extent that they are used for tuition, mandatory school fees, books, equipment, and transportation at an institution of higher education, including correspondence schools at that level, or a school at any level for the physically or mentally handicapped, are excluded from household income. Mandatory fees are those charged to all students or those charged to all students within a certain curriculum. Basic Educational Opportunity Grants are totally excluded as income.

(p) *Optional project procedure: Exclusion of earnings of a dependent child.* The earned income (as defined in paragraph (b)(1) of § 273.9) of children who are members of the household and who have not attained their 18th birthday shall be excluded as household income.

(q) *Optional project procedure: Exclusion of income excluded by other statute.* In addition to the funds listed in § 273.9(c)(10) which are excluded from income consideration by other Federal statutes, judgment payments to members of certain Indian tribes, as mandated in Pub. L. 92–254, shall be excluded from consideration as income

in calculating food stamp eligibility and benefits.

(r) *Optional project procedure: Standard shelter insurance deduction.* The State agency shall develop a method, subject to FNS approval, for establishing a standard utility allowance for use in calculating shelter costs of those households which incur certain utility costs separate and apart from their rent or mortgage payments. Households which do not incur any separate utility charges or which are billed separately for only telephone costs, water, sewerage, and garbage collection fees shall not be entitled to claim the standard utility allowance. The standard utility allowance may have a separate standard for each utility identified in paragraph (d)(4)(iii) of § 273.9 or it may be a single standard. If it is a single standard, the State shall include the cost of telephone service, water, sewerage, and garbage collection fees in the overall allowance, even though these utilities do not, by themselves, entitle the household to use the standard utility allowance. The State may elect to establish a shelter insurance deduction to be added to the standard utility deduction. If a household is not entitled to the standard utility allowance, it may claim actual utility expenses for any utility which it does pay separately. A household not claiming the utility standard deduction may claim the shelter insurance standard alone or the actual cost of the shelter insurance.

(s) *Optional project procedure: Categorical eligibility for applicants determined eligible for AFDC.* (1) Households applying for both the Food stamp and AFDC Programs in approved project areas in this demonstration project shall be considered automatically eligible for the Food Stamp Program if they are determined eligible for the AFDC program: *Provided,* That the State agency has submitted documentation that the potential gross income limits for AFDC households at 150 percent of the need standard do not exceed the Food Stamp Program gross income limits set forth in § 273.9(a)(1). Benefits shall be calculated according to standard procedures as set forth in § 273.10.

(2) For households applying for both programs in approved demonstration project areas which are determined ineligible for the AFDC program and for all other households not mentioned in paragraphs (A) and (C) of § 273.10(e)(2)(i), the State agency shall compare a household's gross income, as calculated in accordance with paragraph (e)(1)(i)(A) of § 273.10, to the monthly income eligibility standards defined in § 273.9(a)(1) for the appropriate household size to determine eligibility for the month. The State agency shall also apply to these applicant households the resource standards of eligibility as set forth in § 273.8 or as modified in other paragraphs of this section.

(t) *Optional project procedure: Boarders—determining the cost of doing business.* After determining the income received from the boarders, the State agency shall exclude that portion of the boarder payment which is a cost of doing business. The cost of doing business shall be equal to either of the following procedures provided that the amount allowed as a cost of doing business shall not exceed the payment the household receives from the boarder for lodging and meals:

(1) The cost of providing room and/or board for the number of people in the boarder group according to the table provided below. (The cost of board shall be equal to the Thrifty Food Plan amount for the number of people in the boarder group. The 2/3 board amount shall be allowed if only two meals per day are provided to the boarder group.) If the actual room/board payment is less than the standard, only the amount actually paid would be allowed.

NUMBER OF PEOPLE IN BOARDER GROUP

	1	2	3	4	5	6+
Room only	43	78	112	142	169	203
Board only	70	128	183	233	277	332
Room and board	113	206	295	375	446	535
2/3 board	47	85	122	155	185	221

(2) The actual documented cost of providing room and meals, or 50 percent of the gross payment received. If actual costs are used, only separate and identifiable costs of providing room and meals to boarders shall be excluded. If the boarder household resides in the same dwelling as the provider household, the cost of doing business may not exceed the difference between the actual total payment for an item and any public assistance (PA) allowances granted to the provider for that item.

Note: This regulation does not contain reporting and recordkeeping requirements subject to approval by OMB under the Paperwork Reduction Act.

(91 Stat. 958 (7 U.S.C. 2011–2027))

(Catalogue of Federal Domestic Program No. 10.551, Food Stamps)

Dated: December 28, 1981.

David B. Alspach,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 82-28 Filed 1-4-82; 8:45 am]

BILLING CODE 3410-30-M

federal register

Tuesday
January 5, 1982

Part XIV

Department of Education

Institutional Aid Programs

DEPARTMENT OF EDUCATION

34 CFR Parts 624, 625, 626 and 627

Institutional Aid Programs

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary of Education issues final regulations for the Institutional Aid Programs authorized by Title III of the Higher Education Act of 1965, as amended. The regulations implement the eligibility requirements and establish the application procedures and selection criteria for the Institutional Aid Programs established by the Education Amendments of 1980. The programs provide assistance to institutions of higher education and include: the Strengthening Program, the Special Needs Program, and the Challenge Grant Program.

EFFECTIVE DATES: Unless Congress takes certain adjournments, these regulations will take effect 45 days after publication in the **Federal Register**. If you want to know the effective date of these regulations, call or write the Department of Education contact person.

FOR FURTHER INFORMATION CONTACT: Dr. Claude Mayberry, Director, Institutional Aid Programs, Office of Postsecondary Education, U.S. Department of Education, L'Enfant Plaza, Post Office Box 23868, Washington, D.C. 20024. Telephone: (202) 245–9691.

SUPPLEMENTARY INFORMATION:

A. Background

Title III Institutional Aid Programs provide Federal financial assistance to help eligible institutions of higher education to solve problems that threaten their ability to survive and to stablize their management and fiscal operations so that they may achieve self-sufficiency. Beginning in fiscal year 1982, eligible institutions will be able to apply for funding under the following three new grant programs:

- *The Strengthening Program.*
- *The Special Needs Program.*
- *The Challenge Grant Program.*

These programs provide funds to plan, develop, and implement activities for: the development of academic programs and faculty; administrative management; acquisition of equipment for use in management of funds and academic programs; joint use of facilities such as libraries and laboratories; and student services.

Federal assistance under these programs may not be used to cover any general operating and maintenance expenses of grantees or to supplant what an institution would otherwise spend to carry out activities allowed under the programs. The purpose of these programs, as expressed in section 301 of the Higher Education Act, is to assist eligible institutions to carry out planning and development activities that will enable them to become viable, thriving institutions of higher education and, therefore, free from the need for continued assistance under Title III.

Thus, the Secretary provides the following:

- *Planning grants* to enable designated colleges and universities—including branch campuses that meet special eligibility requirements—to develop long-range plans for self-sufficiency if they do not already have acceptable long-range plans. Planning grants under the Strengthening Program may also be used to assist in the development of an application for a development grant.
- *Development grants* to enable designated institutions to implement their long-range plans.

In general, eligible recipients are institutions that are providing higher education to substantial numbers of students from low-income families and that do not yet have the capacity to carry out such activities as providing adequate management, improving academic programs and student services, or upgrading the quality of their faculty members.

Both two-year and four-year public and nonprofit private institutions of higher education are eligible for funding under all the programs. In addition, certain graduate schools and certain medical schools are eligible for funding under the Challenge Grant Program.

Both the Strengthening Program and Special Needs Program provide for grants to institutions in cooperative arrangements. A cooperative arrangement is an agreement under which two or more eligible institutions share or combine resources and otherwise cooperate in order to carry out the purposes of the Institutional Aid Programs more efficiently and effectively than if each institution were to conduct those activities separately.

B. Summary of Comments and Responses

A notice of proposed rulemaking was published in the **Federal Register** on July 20, 1981 (46 FR 37470–37482). Interested persons were given 60 days in which to comment. Comments were received from over 200 individuals, institutions, groups, and associations.

Most commenters were concerned with eligibility requirements in the statute and objected to the Department's interpretation that would have required an institution to meet each of three factors individually, rather than in the aggregate. As a result of comment, and with advice from members of Congress, a change in the regulations has been made. The Secretary will use a system of determining institutional eligibility that is similar to the system that was used in the past.

Under the Strengthening Program, points will be assigned on a scale of 1–100 for each criterion on the basis of the following factors: (1) The number of Pell grant recipients at the institution divided by the number of full-time equivalent (FTE) undergraduate students enrolled at that institution; (2) The total amount of the Pell grant awards received by students enrolled at the institution divided by the Pell grant recipients at that institution; and (3) Total educational and general (E&G) expenditures divided by the FTE undergraduate enrollment at that institution.

For the Special Needs Program points will be assigned to institutions on the basis of the following factors: (1) On a scale of 1–50 points, according to the number of recipients of need-based student aid at the institution divided by the number of FTE undergraduate students enrolled at that institution; (2) On a scale of 1–50 points according to the total amount of need-based assistance received by students at the institution divided by the recipients of such assistance at that institution; (3) On a scale of 1–100 points, according to the E&G expenditures at the institution divided by the FTE undergraduate student enrollment at that institution. For the purposes of the Special Needs Program, "need-based student aid programs" include the Pell Grant, Supplemental Educational Opportunity Grant, College Work-Study and National Direct Student Loan Programs.

Under each program, the number of points assigned to all three factors will be added together. All institutions with a point total above the minimum threshold established by the Secretary will satisfy these three factors. Thus, eligibility will be based on the total points received for the three factors combined, rather than for each factor separately.

The Secretary has the authority under the statute to waive the E&G expenditures requirement under certain conditions. However, any institution that seeks a waiver of the E&G requirement must meet a minimum threshold on the combined remaining factors (percentage of students receiving assistance and the average amount of that assistance). For example, an

institution applying for funds under the Strengthening Program that is granted a waiver of the E&G criterion will have to attain a minimum number of points out of the 200 available on criteria 1 and 2.

A summary of the other comments and the Secretary's responses to them is contained in the Appendix following the regulations.

Assessment of Educational Impact

In the notice of proposed rulemaking, the Secretary requested comments on whether the proposed regulations would require submission of information that is already being gathered by or is available from any other agency of authority of the United States.

Based on the absence of any comments on this matter and the Department's own review, the Secretary has determined that the regulations in this document do not require information that is already being gathered by or is available from any other agency or authority of the United States.

Invitation To Comment

To assist the Department in complying with the specific requirement of Executive Order 12291 and its overall requirements of reducing regulatory burden, public comment is invited on whether there may be further opportunities to reduce any regulatory burdens found in these regulations. Comments should be addressed to the contact person listed elsewhere in this document.

Citation of Legal Authority

A citation of statutory or other legal authority is placed in parenthese on the line following each substantive provision of these regulations.

(Catalog of Federal Domestic Assistance Number 84.031 Institutional Aid Programs)

Dated: December 29, 1981.

T. H. Bell,

Secretary of Education.

The Secretary revises Part 624 of Title 34 of the Code of Federal Regulations to read as follows:

PART 624—INSTITUTIONAL AID PROGRAMS—GENERAL PROVISIONS

Subpart A—General

Sec.

624.1 Institutional Aid Programs.
624.2 Eligible applicants.
624.3 Waiver of five-year requirement.
624.4 Eligible grantees.
624.5 Regulations that apply to the Institutional Aid Programs.
624.6 Definitions that apply to the Institutional Aid Programs.

Subpart B—What Kinds of Projects Does the Secretary Assist Under the Institutional Aid Programs?

624.10 Types of grants.
624.11 Planning grant.
624.12 Development grant.
624.13 Allowable activities.

Subpart C—How Does One Apply for a Grant?

624.20 Designation as an eligible applicant.
624.21 How to apply for a grant.
624.22 Long-range plan.
624.23 Applications for grants under cooperative arrangements.
624.24 Separate applications.

Subpart D—How Does the Secretary Make a Grant?

624.30 General evaluation of applications.
624.31 Selection criteria for planning grants.
624.32 Long-range plan to achieve self-sufficiency.
624.33 Selection criteria for development grants.
624.34 Grants under cooperative arrangements.

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624.40 Maintenance of eligibility.
624.41 Fiscal requirements.
624.42 Restrictions on the use of funds.

Subpart F [Reserved]

Subpart G—What Compliance Procedures Does the Secretary Use?

624.60 Failure to maintain eligibility.

Authority: Title III of the Higher Education Act of 1965, as amended (20 U.S.C. 1051–1069c).

Subpart A—General

§ 624.1 Institutional Aid Programs.

(a) The Institutional Aid Programs are designed to provide Federal funds for a limited period of time to assist eligible institutions of higher education to become self-sufficient by—

(1) Solving problems that threaten their ability to survive; and

(2) Stabilizing their management and fiscal operations.

(b) The Institutional Aid Programs consist of the following:

(1) The Strengthening Institutions Program (34 CFR Part 625), referred to in these regulations as the Strengthening Program.

(2) The Aid to Institutions with Special Needs Program (34 CFR Part 626), referred to in these regulations as the Special Needs Program.

(3) The Challenge Grant Program (34 CFR Part 627).

(20 U.S.C. 1051, 1057, 1060, and 1066)

§ 624.2 Eligible applicants.

(a) In order to apply for a grant under the Institutional Aid Programs, an institution of higher education or a branch campus must first be designated by the Secretary as an eligible institution.

(b) Before applying to the Secretary for designation as an eligible institution under § 624.20, the institution must satisfy basic eligibility requirements; that is, it must be an educational institution and—

(1) Admit as regular students persons who are—

(i) High school graduates;

(ii) The recognized equivalent of high school graduates; or

(iii) Beyond the age of compulsory school attendance in the State in which the institution is located and have the ability to benefit from the training offered by the institution;

(2) Be, and have been for five academic years preceding the academic year for which it seeks assistance, legally authorized in the State in which it is located to—

(i) Provide an educational program for which it awards a bachelor's degree; or

(ii) Be a junior or community college;

(3) Be, and have been for five academic years preceding the academic year for which it seeks assistance—

(i) Accredited by a nationally recognized accrediting agency or association; or

(ii) Making reasonable progress toward accreditation according to that accrediting agency or association; and

(4) Meet specific eligibility requirements for designation in 34 CFR 625.2, 626.2, or 627.2, as appropriate.

(c) If an institution changes its status from a junior or community college to an institution that awards bachelors' degrees or *vice versa*, it may satisfy the five-year requirements of paragraphs (b) (2) and (3) of this section by combining the periods of time it qualified as either type of institution.

(20 U.S.C. 1058, 1061, 1064, and 1141)

§ 624.3 Waiver of five-year requirement.

(a) At the request of an institution, the Secretary may waive for that institution all or part of the five-year requirements in paragraphs (b) (2) and (3) of § 624.2 if the Secretary determines that—

(1) The institution is located on an Indian reservation, or near an Indian reservation or a substantial population of Indians, and the waiver will substantially increase the higher educational opportunities appropriate to the needs of American Indians;

(2) The waiver will substantially increase higher educational opportunities for—

(i) Spanish-speaking people;

(ii) Individuals living in rural areas, whose needs are for the most part

unserved by other institutions of higher education; or

(iii) Individuals whose income is below the poverty level established by the United States Bureau of the Census (low-income individuals); or

(3) The institution has traditionally served substantial numbers of black students.

(b)(1) For purposes of paragraph (a)(1) of this section generally the Secretary considers "near" to mean within 50 miles. However, the Secretary reserves the right to consider each distance between an institution and an Indian reservation on a case-by-case basis, according to reasons stated by the applicant in its request for a waiver; and

(2) For the purposes of paragraph (a)(2)(ii) of this section "rural area" means an area that is not included in a standard metropolitan statistical area as defined by the United States Bureau of the Census.

(c) An institution requesting a waiver under this section shall submit to the Secretary a written statement that includes sufficient information and explanations as to why the Secretary should grant the waiver.

(20 U.S.C. 1067)

§ 624.4 Eligible grantees.

The Secretary awards a grant under the Institutional Aid Programs to—

(a) An institution the Secretary has designated as eligible; or

(b) Under the Strengthening Program or the Special Needs Program, two or more eligible institutions under a cooperative arrangement.

(20 U.S.C. 1057, 1060, 1064 and 1069)

§ 624.5 Regulations that apply to the Institutional Aid Programs.

The following regulations apply to the Institutional Aid Programs:

(a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR Part 75 (Direct Grant Programs) and 34 CFR Part 77 (Definitions) except for 34 CFR 75.128(a)(2) and 75.129(a), in the case of applications under cooperative arrangements.

(b) The regulations in this Part 624.

(c) The regulations in 34 CFR Parts 625, 626, or 627, as applicable.

(20 U.S.C. 1221e-3(a)(1), 1057, 1060, 1064)

§ 624.6 Definitions that apply to the Institutional Aid Programs.

(a) The following terms used in this part are defined in EDGAR, 34 CFR Part 77:

Applicant	Nonprofit
Application	Private
EDGAR	Project
Grant	Public
Grant period	Secretary
Grantee	State

(b) The following definitions apply specifically to the Institutional Aid Programs:

"Academic year" means a period of time, generally eight or nine months, in which a full-time student is expected to complete—

(1) The equivalent of at least two semesters, two trimesters, or three quarters at an institution using credit hours; or

(2) At least 900 hours training for each program at an institution using clock hours.

"Activity" means a specific component of a project for which Federal funds are requested.

"Base year" means a 12-month period identified by the Secretary through a notice in the **Federal Register**.

"Branch campus."

(1) This term means, in a university or college, a unit that is—

(i) Independent of the main campus; and

(ii) Geographically apart from the main campus of the university or college.

(2) The Secretary considers a branch campus to be independent of the university's or college's main campus if the branch campus—

(i) Is separately accredited;

(ii) Is permanent in nature;

(iii) Offers courses for credit and programs leading to an associate or bachelor's degree;

(iv) Is autonomous to the extent that it has its own faculty and administrative or supervisory organization; and

(v) Has its own budgetary and hiring authority.

"Comparable institutions" and "institutions that offer similar instruction" mean institutions that are being compared with an applicant institution and that fall within one of the following four categories:

(1) Four-year public institutions.

(2) Four-year non-profit private institutions.

(3) Public junior or community colleges.

(4) Nonprofit private junior or community colleges.

"Cooperative arrangement" means an agreement between two or more eligible institutions that share and combine resources and otherwise cooperate in order to carry out the purpose of the Institutional Aid Programs more effectively and efficiently than if each institution were to conduct those activities separately.

"Educational and general (E&G) expenditures" means the total amount expended by an institution of higher education for—

(1) Instruction;

(2) Research;

(3) Public service;

(4) Academic support including library expenditures;

(5) Student services;

(6) Institutional support;

(7) Scholarships and fellowships;

(8) Operation expenditures, and maintenance expenditures for physical plant; and

(9) Any mandatory transfers that the institution is required to pay by law.

"Full-time-equivalent (FTE)."

(1) This term means the sum of—

(i) The number of full-time students; and

(ii) The full-time equivalent of the number of part-time students enrolled at the institution.

(2) The Secretary determines the full-time equivalent of the number of part-time students in paragraph (1)(ii) of this definition by any method that yields the equivalent of—

(i) Adding the number of credit hours taken by all part-time students; and

(ii) Dividing that number by 12.

"General operating and maintenance expenses" means those costs that are generally recurrent or continuing in nature, such as costs of operating remedial programs, costs of classroom teaching, and costs of maintaining programs after the development period.

"Junior or community college" means an institution of higher education that provides an educational program—

(1) For which it does not award a bachelor's degree; but

(2)(i) That is of not less than two years' duration and is acceptable for full credit toward a bachelor's degree; or

(ii) That is a two-year program in engineering, mathematics, or the physical or biological sciences, designed to prepare a student to work as a technician or at the semiprofessional level in engineering, scientific, or other technological fields requiring the understanding and application of basic engineering, scientific, or mathematical principles of knowledge.

"Non-renewable grant" means a one-time-only, broad-purpose development grant designed to enable an institution or group of institutions to achieve self-sufficiency by the end of the grant period.

"Pell Grant" (formerly Basic Educational Opportunity Grant) means the grant awarded under Title IV–A–1 of the Higher Education Act of 1965, as amended (20 U.S.C. 1070a).

"Renewable grant" means a narrow-purpose development grant, for which an institution or group of institutions may reapply, designed to help an institution or group of institutions move toward self-sufficiency.

"Self-sufficient" means the point at which, in the determination of the Secretary, an institution should be viable, thriving, and able to survive without continued funding Under the Institutional Aid Programs.

"Strengthening Developing Institutions Program (SDIP)" means the program authorized under Title III of the Higher Education Act of 1965 before October 1, 1981.

(20 U.S.C. 1058, 1059, 1061, 1062, 1066, and 1069)

Subpart B—What Kinds of Projects Does the Secretary Assist Under the Institutional Aid Programs?

§ 624.10 Types of grants.

The Secretary awards two principal types of grants under the Institutional Aid Programs:

(a) Planning grants, as described in § 624.11.

(b) Development grants, as described in § 624.12.

(20 U.S.C. 1057, 1059, 1060, 1062, and 1064)

§ 624.11 Planning grant.

(a) Unless otherwise provided, a planning grant may be used for a project to develop—

(1) A long-range comprehensive development plan (long-range plan), as described in § 624.22;

(2) An application for a development grant; or

(3) A long-range plan and an application for a development grant.

(b) The Secretary does not consider awarding a planning grant to an institution that is receiving or has received another grant—whether a planning or a development grant—under the Institutional Aid Programs.

(c) The Secretary does not consider awarding a planning grant to develop a long-range plan to a cooperative arrangement unless the purpose of the grant is to develop a separate long-range plan for each of the participating institutions.

(20 U.S.C. 1057, 1059, 1060, 1062, and 1069)

§ 624.12 Development grant.

A development grant may be used for a project to implement portions of an applicant's long-range plan to enable it to move toward or achieve self-sufficiency.

(20 U.S.C. 1057, 1060, and 1066)

§ 624.13 Allowable activities

(a) The Secretary awards grants under the Institutional Aid Programs to assist eligible institutions to plan, develop, or implement activities that the Secretary determines are likely to enable the institution to become self-sufficient.

(b) The following types of development activities are allowable:

(1) Development of faculty.

(2) Management of funds and administrative management.

(3) Development and improvement of academic programs.

(4) Acquisition of equipment for use in strengthening management of funds and in strengthening academic programs.

(5) Joint use of facilities such as libraries and laboratories.

(6) Student services.

(c) The Secretary does not fund an activity for which a grantee is receiving or has received a grant under—

(1) Any Institutional Aid Program; or

(2) The SDIP, if that grant is scheduled to expire after September 30, 1982.

(20 U.S.C. 1057, 1059, 1060, 1062, 1066 and 1221e-3)

Subpart C—How Does One Apply for a Grant?

§ 624.20 Designation as an eligible applicant.

(a)(1) An institution that wishes to be designated as an eligible institution for a particular Institutional Aid Program must file with the Secretary a request for designation for that program, according to the instructions contained in a notice published in the **Federal Register.**

(2) The Secretary annually publishes a notice in the **Federal Register**—

(i) Requesting applications for eligibility; and

(ii) Indicating the base year for calculating whether an institution satisfies the eligibility criteria under 34 CFR 625.2 and 626.2. The Secretary uses the most recent base year for which reliable data are available. If necessary, the Secretary may establish a separate base year for each of the three criteria described in 34 CFR 625.2 or 626.2 depending on data availability.

(b) An institution that receives a grant for a grant period lasting more than one year shall include in its annual application for a continuation award the assurance described in § 624.40(b).

(20 U.S.C. 1058, 1061, and 1064)

§ 624.21 How to apply for a grant.

(a) *General.* In an application for either a planning grant or a development grant, an applicant shall—

(1) Explain how the grant will assist the institution to prepare for the critical financial and other problems facing it in this decade;

(2) If it is requesting funding for more than one activity—

(i) Identify those activities that would be a sound investment of Federal funds if funded separately;

(ii) Identify those activities that would be a sound investment of Federal funds only if funded along with other activities in the application; and

(iii) Rank the activities in order of preferred funding;

(3) If it is applying for a grant from more than one program under the Institutional Aid Programs, rank the applications in order of preferred funding;

(4) Submit all budgetary information the Secretary may require, including a separate detailed budget for each activity;

(5) Identify the policies and procedures it will use to ensure that any Federal funds it receives as a result of the application will be used to supplement—and not supplant—funds that would otherwise be available to carry out its long-range plan;

(6) Identify the fiscal control and accounting procedures necessary for proper disbursement of and accounting for any Federal funds it receives as a result of the application; and

(7) Provide assurance to the Secretary that it will comply with the restrictions on the use of funds specified in § 624.42 (a) through (g).

(b) *Development grant.* In an application for a development grant, an applicant shall—

(1) Include its long-range plan containing all the elements required in § 624.22;

(2) Provide information that fully addresses each component of each selection criterion in § 624.33;

(3) Identify the institutional goals in its long-range plan that each proposed development activity will help achieve; and

(4) If it is requesting a multi-year grant, explain why—

(i) A multi-year grant of that length is necessary; and

(ii) A single year grant would be inadequate.

(c) *Planning grant.* In an application for a planning grant, an applicant shall provide information that fully addresses each component of each selection criterion in § 624.31.

(20 U.S.C. 1066, 1069bm, and 1221e-3)

§ 624.22 Long-range plan.

(a) In its comprehensive long-range development plan (referred to in these regulations as the long-range plan), an

institution shall describe its strategy for achieving self-sufficiency by strengthening its—

(1) Academic quality; and

(2) Institutional management.

(b) The long-range plan must include—

(1) The institutional mission statement (that is, a broad statement of fundamental purpose that includes the social and intellectual aspirations of the institution);

(2) Long-range and short-range institutional goals;

(3) Measurable objectives for each major unit of the institution;

(4) Time frames to achieve institutional goals and unit objectives;

(5) Major resource requirements; and

(6) Strategies for evaluating the institution's success in achieving all aspects of its long-range plan.

(20 U.S.C. 1066)

§ 624.23 Applications for grants under cooperative arrangements.

(a) *General.* To apply for a grant under the Strengthening Program or the Special Needs Program, the participating institutions in a cooperative arrangement shall submit a single, collective application that includes—

(1) The information required in 34 CFR 624.21; and

(2) The names of the institutions participating in the cooperative arrangement.

(b) *Development grant.* The application for a development grant under a cooperative arrangement shall—

(1) Explain the relationship of the activities for which funding is requested to—

(i) The long-range plan of each participating institution; and

(ii) The activities each participating institution carried out or is carrying out under a renewable development grant, if any, awarded previously under the Strengthening Program;

(2) Explain the rationale for each participating institution's decision to request funds to carry out activities to achieve self-sufficiency as part of a cooperative arrangement rather than individually; and

(3) Identify the activities included in any other application the cooperative arrangement or any participating institution is submitting for funding in the same fiscal year under the Institutional Aid Programs.

(c) *Planning grant.* The application for a planning grant under a cooperative arrangement shall explain the rationale for each participating institution's decision to request funds to develop, as appropriate, its application or its long-range plan as part of a cooperative arrangement rather than individually.

(20 U.S.C. 1069)

§ 624.24 Separate applications.

If an institution wishes to apply in the same year for both a grant as an individual institution and a grant under a cooperative arrangement, the institution shall submit as an individual institution an application that is separate from the application the cooperative arrangement submits.

(20 U.S.C. 1066 and 1221e–3)

Subpart D—How Does the Secretary Make a Grant?

§ 624.30 General evaluation of applications.

(a) The Secretary evaluates an application for a planning grant on the basis of the criteria in § 624.31.

(b) The Secretary evaluates an application for a development grant on the basis of—

(1) The appropriate criterion in § 624.32 for assessing the long-range plan to achieve self-sufficiency; and

(2) The selection criteria in § 624.33.

(c)(1) The Secretary awards up to 100 points for the criteria in § 624.31 and up to 100 points for the criteria in § 624.33.

(2) The maximum possible score for each complete criterion is indicated in parentheses following the title of that criterion.

(3) In the case of criteria worth more than 10 possible points, the maximum possible score for each component of a criterion is indicated in parentheses following that component.

(d) The Secretary will not fund an application for a grant that receives less than 50 points for the criteria in § 624.31 or in §624.33

(20 U.S.C. 1221e–3)

§ 624.31 Selection criteria for planning grants.

The Secretary evaluates an application for a planning grant on the basis of the following criteria:

(a) *Plan of operation.* (Total: 50 points)

(1) The Secretary reviews each application for information that shows that the proposed project is likely to develop a high quality—

(i) Long-range plan providing for self-sufficiency;

(ii) Application; or

(iii) Long-range plan and application.

(2) The Secretary looks for information that shows—

(i) Measurable objectives appropriate to the purpose of the project (10 points); and

(ii) The quality of the project plan to achieve the objectives. The Secretary bases this assessment of quality on—

(A) The quality of the proposed strategy for developing the applicant's long-range plan or application (15 points);

(B) A realistic timetable for achieving each objective (5 points);

(C) The extent to which the applicant will use its own resources and personnel to achieve each objective (10 points); and

(D) The extent to which procedures described by the applicant in its application are likely to ensure effective administration of the proposed project (10 points).

(b) *Key personnel.* (Total: 30 points)

(1) The Secretary reviews each application for information that shows the quality of the key personnel the applicant will use to develop the long-range plan or application.

(2) The Secretary looks for information that shows—

(i) The extent to which the applicant involves its own personnel, students, and governing board members in the planning process (12 points);

(ii) The qualifications of the project director (6 points);

(iii) The role of each of the key personnel who will participate in the planning process as part of the project (6 points); and

(iv) The time that each person referred to in paragraphs (b)(2)(i) through (iii) of this section plans to commit to the project (6 points).

(c) *Budget and cost effectiveness.* (Total: 10 points)

(1) The Secretary reviews each application for information that shows that the project has an adequate budget that is cost effective.

(2) The Secretary looks for information that shows that costs are reasonable in relation to the objectives of the project.

(d) *Evaluation design.* (Total: 10 points)

(1) The Secretary reviews each application for information that shows the quality of the proposed evaluation design for the project.

(2) The Secretary looks for information that shows that—

(i) The methods of evaluation are appropriate for a planning process; and

(ii) The evaluation criteria are appropriate for determining success in achieving the objectives of the project.

(20 U.S.C. 1057, 1059, 1060, 1062, and 1221e–3)

§ 624.32 Long-range plan to achieve self-sufficiency.

(a) The Secretary reviews each application for a development grant for information that shows whether the applicant's long-range plan provides for self-sufficiency.

(1) In the case of an application for a renewable development grant, the Secretary looks for information that shows whether implementing the long-range plan is likely to result in that institution *moving toward self-sufficiency* by the end of the proposed grant period.

(2) In the case of an application for a non-renewable development grant, the Secretary looks for information that shows whether implementing the long-range plan is likely to result in that institution *becoming self-sufficient* by the end of the proposed grant period.

(b) In reviewing the applicant's long-range plan the Secretary looks for information showing that—

(1) The institution identifies the major problems or deficiencies that inhibit it from becoming self-sufficient and thriving; and

(2) The institution proposes effective strategies to overcome each problem or deficiency.

(c) The Secretary does not consider an application for a development grant unless the applicant's long-range plan meets the appropriate criterion in paragraph (a) of this section.

Note.—The Secretary does not assign points to this criterion. Rather, the Secretary reviews an application under §§ 624.31 or 624.33 if it meets the criterion and rejects it if it does not.

(20 U.S.C. 1057, 1059, 1060, 1064, 1066, and 1221e–3)

§ 624.33 Selection criteria for development grants.

(a) *Plan of operation.* (Total: 70 points)

(1) The Secretary reviews each application for information that shows the quality of the project's plan of operation.

(2) The Secretary looks for information that shows the following:

(i) The extent to which objectives for each activity are clear, specific, and measurable (10 points).

(ii) The quality of the project plan to achieve the objectives. The Secretary bases this assessment of quality on—

(A) The quality of the implementation strategy (a complete description of what the applicant plans to do and how the applicant plans to do it) for each activity (10 points);

(B) The extent to which achieving the objectives of the proposed activities in the project plan is likely to help the institution attain self-sufficiency (20 points);

(C) A realistic timetable for achieving the objectives of each activity (5 points);

(D) The extent to which the applicant will use its own resources and personnel to achieve each objective (15 points); and

(E) The extent to which procedures described by the applicant in its application are likely to ensure effective administration of the proposed project (10 points).

(b) Quality of key *personnel.* (Total: 10 points)

(1) The Secretary reviews each application for information that shows the quality of key personnel the applicant plans to use on the project.

(2) The Secretary looks for information that shows—

(i) The qualifications of the project director;

(ii) The qualifications of each of the key personnel to be used in the project; and

(iii) The time that each person referred to in paragraphs (c)(2) (i) and (ii) of this section plans to commit to the project.

(3) To determine the qualifications of a person, the Secretary considers evidence of past experience and training, in fields related to the objectives of the project, as well as other information that the applicant provides.

(c) *Budget and cost effectiveness.* (Total: 10 points)

(1) The Secretary reviews each application for information that shows that the project has an adequate budget that is cost effective.

(2) The Secretary looks for information that shows that costs are reasonable in relation to the objectives of the project.

(d) *Evaluation design.* (Total: 10 points)

(1) The Secretary reviews each application for information that shows the quality of the evaluation design for the project.

(2) The Secretary looks for information showing that proposed methods of evaluation are appropriate for the project and, to the extent possible, are objective and produce data that are quantifiable.

(20 U.S.C. 1057, 1060, and 1221e–3)

§ 624.34 Grants under cooperative arrangements.

(a) In considering applications from institutions that propose to carry out projects under a cooperative arrangement, the Secretary gives priority to those applications that the Secretary determines are—

(1) Geographically sound; and

(2) Economically sound.

(b) The Secretary determines that a cooperative arrangement is—

(1) Geographically sound based on the proximity of the participating institutions; and

(2) Economically sound if participating institutions demonstrate that each activity proposed in the application will be carried out more efficiently and effectively at less cost than would be possible if each participating institution were awarded a grant individually.

(c) The Secretary considers each participating institution in a cooperative arrangement to be a separate grantee for purposes of this part.

(20 U.S.C. 1069)

Subpart E—What Conditions Must a Grantee Meet?

§ 624.40 Maintenance of eligibility.

(a) A grantee under an Institutional Aid Program must maintain its eligibility under § 624.2(b) (1) through (3) of 34 CFR 627.2 (b), (c), or (d) as appropriate for the duration of the grant period.

(b) An institution that receives a grant for a grant period lasting more than one year must annually submit to the Secretary an assurance that it continues to meet eligibility requirements under § 624.2(b) (1) through (3) or 34 CFR 627.2 (b)(1)(i)–(iii), (c)(1)(i)–(iii), or (d)(1) as appropriate.

(20 U.S.C. 1058, 1061, and 1064)

§ 624.41 Fiscal requirements.

A grantee shall use Federal funds under the Institutional Aid Programs to supplement—and not supplant—funds the grantee would otherwise have available to plan, develop, or implement activities authorized under the Institutional Aid Programs.

(20 U.S.C. 1066)

§ 624.42 Restrictions on the use of funds.

A grantee may not use funds under any Institutional Aid Program for any of the following:

(a) Activities other than those in its approved application.

(b) Activities that are inconsistent with any State plan of higher education applicable to the institution.

(c) Activities that are inconsistent with a State plan for desegregation of higher education, if any, applicable to the institution.

(d) A school or department of divinity or any religious worship or sectarian activity.

(e) General operating and maintenance expenses.

(f) Indirect costs.

(g) Construction costs except for minor remodeling as part of an approved activity.

(20 U.S.C. 1066 and 1069b)

Subpart F [Reserved]

Subpart G—What Compliance Procedures Does the Secretary Use?

§ 624.60 Failure to maintain eligibility.

If an institution does not continue to meet the basic eligibility requirements under § 624.2(b) (1) through (3) or 34 CFR 627.2 (b)(1)(i)–(iii), (c)(1)(i)–(iii) or (d)(1) during the grant period, the Secretary terminates the grant.

(20 U.S.C. 1058, 1061, and 1064)

The Secretary adds a new Part 625 to Title 34 of the Code of Federal Regulations to read as follows:

PART 625—STRENGTHENING PROGRAM

Subpart A—General

Sec.

625.1 Strengthening Program.
625.2 Designation of eligibility.
625.3 Waiver of E&G requirement.
625.4 Regulations that apply to the Strengthening Program.

Subpart B—What Kinds of Grants Does the Secretary Award Under the Strengthening Program?

625.10 Types of grants under the Strengthening Program.
625.11 Allowable activities.

Subpart C—How Does One Apply for a Grant?

625.20 Limitations on applications.
625.21 Planning grants and development grants.

Subpart D—How Does the Secretary Make a Grant?

625.30 General rules.
625.31 Funding availability.

Authority: Sections 311–313 and 341–347 of Title III of the Higher Education Act of 1965 (20 U.S.C. 1057–1059 and 1066–1069c).

Subpart A—General

§ 625.1 Strengthening program.

The Strengthening Institutions Program (referred to in these regulations as the Strengthening Program) assists eligible institutions of higher education to become self-sufficient by providing funds to improve their academic quality and strengthen their planning, management, and fiscal capabilities.

(20 U.S.C. 1051 and 1057)

§ 625.2 Designation of eligibility.

(a) The Secretary designates an institution of higher education or a branch campus as eligible to be considered for a grant under the Strengthening Program if the Secretary determines that—

(1) In the academic year in which it applies for designation it satisfies the basic institutional eligibility requirements in 34 CFR 624.2;

(2) A substantial percentage of its full-time equivalent (FTE) undergraduate enrollment received Pell grants in the base year;

(3) The average Pell grant received by its students in the base year was high in comparison with the average Pell grant received by students at comparable institutions in that year; and

(4) The average educational and general (E&G) expenditure per FTE undergraduate student in the base year was less than the average E&G expenditure per FTE undergraduate student at institutions that offer similar instruction in that year.

(b) The Secretary groups comparable institutions and institutions that offer similar instruction for purposes of determining institutional eligibility.

(c) The Secretary assigns points to each of the three factors described in paragraphs (a) (2) through (4) of this section as follows:

(1) An institution may receive up to 100 points on the basis of the number of Pell grant recipients divided by the number of FTE undergraduate students enrolled at the institution. The points awarded reflect an institution's position on a scale of 1–100 when compared to the percent of Pell grant recipients enrolled at comparable institutions. (See the illustrative example in paragraph (c)(4) of this section.)

(2) An institution may receive up to 100 points on the basis of the total amount of the Pell grant awards that students received who were enrolled at the institution divided by the number of Pell grant recipients at that institution. The points awarded reflect an institution's position on a scale of 1–100 when compared to the average Pell grant award of students enrolled at comparable institutions. (See the illustrative example in paragraph (c)(4) of this section.)

(3) An institution may receive up to 100 points on the basis of its average E&G expenditure per FTE undergraduate student. Points are assigned to an institution in an inverse relationship to the average E&G expenditure per FTE undergraduate student at that institution. (See the illustrative example in paragraph (c)(4) of this section.)

(4) The Secretary assigns points for the three institutional eligibility criteria described in paragraphs (a) (2) through (4) of this section as follows:

(i) The Secretary develops a table by—

(A) Listing in rank order all comparable institutions nationwide and dividing them into 100 groups, from the highest value for each criterion to the lowest, with equal numbers of institutions in each group; and

(B) Identifying the range of values for each criterion that the institutions within each of the 100 groups possess.

(ii) The Secretary assigns a score from 1–100 for each of the range of values on the table.

(iii) The Secretary determines an applicant institution's score for each criterion by finding the range of values on the table that includes the applicant institution's value and assigning the score associated with that range of values.

(iv) For example, using the criterion in paragraph (a)(2) pertaining to percentage enrollment, all 2-year public institutions nationwide that enroll students receiving Pell grants in the base year would be listed in order of their percentage enrollment of Pell grant recipients from the highest percentage to the lowest and divided into 100 equal groups. If there are 1,000 such institutions, they would be placed in 100 groups with 10 institutions in each group. The percentage of Pell grant recipients enrolled at each of the 10 institutions in the top group is identified and the percent enrollment range for the group is determined. The range of percentage values for each of the remaining groups is similarly determined.

Consider the example provided in the following table. In the top group of institutions, between 99.6 and 100 percent of the student body receives Pell grants; in the next highest group of institutions the range of values is between 99.0 and 99.5 percent; in the lowest group of institutions the range is between 0.1 and 0.5 percent. An applicant institution would receive 100 points if its percentage of Pell grant recipients is between 99.6 and 100; 99 points if its percentage of Pell grant recipients is between 99.0 and 99.5; and 1 point if its percentage of Pell grant recipients is between 0.1 and 0.5. The same procedures apply when assigning points for each eligibility criterion. The Secretary adds the points for each of the three criteria. If the total is above the minimum that the Secretary announces in the **Federal Register** and the institution meets the basic institutional eligibility requirements in 34 CFR 624.2, then the institution is deemed eligible to apply for assistance.

STRENGTHENING PROGRAM

Point value	Range of values		
	Percent of FTE undergraduate enrollment receiving Pell grant awards	Average Pell grant award per recipient (in dollars)	Average E&G expenditure per FTE undergraduate student (in dollars)
100	99.6–100	1,600–1,750	1–600
99	99.0–99.5	1,550–1,599	601–750
98	98–98.9	1,500–1,549	
2	0.6–0.9	26–50	6,000–8,000
1	0.1–0.5	1–25	8,001+

Note.—The values in the explanation above are hypothetical and are not based on actual data.

(d)(1) In determining whether an institution satisfies the criteria in paragraphs (a) (2) through (4) of this section, the Secretary adds the points earned for each of the three factors. Thus, eligibility is based on the sum of the three factors combined rather than each factor taken separately.

(2) All institutions with a point total above the minimum threshold established by the Secretary satisfy the eligibility criteria in paragraphs (a) (2) through (4) of this section.

(e) Institutions receiving a waiver of the E&G criterion (see § 625.3) described in paragraph (a)(4) of this section must meet a minimum threshold established by the Secretary on the combined remaining eligibility factors described in paragraphs (a) (2) and (3) of this section. For example, to be eligible, an institution that is granted a waiver of the E&G criterion would have to obtain a minimum number of points out of the 200 points available on the criteria in paragraphs (a) (2) and (3) of this section.

(f) The Secretary establishes the minimum threshold for the combined points (as described in paragraphs (d)(1) and (2) of this section) to ensure that the pool of applicants for each type of grant will be at least twice as large as the pool of grantees.

(g) Through a notice in the **Federal Register** the Secretary annually—

(1) Publishes the tables the Secretary uses to assign points for each eligibility factor;

(2) Announces the total number of points an institution must receive to satisfy the eligibility factors described in paragraphs (a)(2) through (4) of this section; and

(3) Announces the total number of points an institution must receive to satisfy the eligibility factors described in paragraphs (a)(2) and (3) of this section if that institution requests a waiver of the factor in paragraph (a)(4) of this section.

(20 U.S.C. 1058 and 1221e–3)

§ 625.3 Waiver of E&G requirement.

(a) An institution may seek a waiver of the E&G requirement in § 625.2(a)(4) by submitting to the Secretary a written statement including information and an explanation as to why the Secretary should grant the waiver.

(b) The Secretary may waive the E&G requirement in § 625.2(a)(4) if the Secretary determines that—

(1) The institution's failure to comply with the requirement is caused by factors that distort that requirement with regard to that institution; and

(2) The institution's designation as an eligible institution for this program is consistent with the purposes of the program.

(c) Factors that the Secretary considers may distort an institution's E&G expenditures per FTE undergraduate student include, but are not limited to, the following:

(1) Low student enrollment.

(2) Size of the campus.

(3) Location in an unusually high cost of living area.

(4) High energy costs.

(5) An increase in State funding to that institution in order to comply with a desegregation plan for higher education.

(6) High cost professional training which is organized, budgeted, and conducted separately from regular graduate and undergraduate instruction, such as medical, dental, and legal programs.

(20 U.S.C. 1067 and House Report 96–1337, 96th Cong. 2d Sess. p. 161 (1980))

§ 625.4 Regulations that apply to the Strengthening Program.

The following regulations apply to the Strengthening Program:

(a) The regulations in 34 CFR Part 624.

(b) The regulations in this Part 625.

(20 U.S.C. 1221e–3, 1057–1059, and 1066–1069c)

Subpart B—What Kinds of Grants Does the Secretary Award Under the Strengthening Program?

§ 625.10 Types of grants under the Strengthening Program.

Under the Strengthening Program the Secretary awards—

(a) Planning grants;

(b) Renewable development grants for a period of one to three years; and

(c) Non-renewable development grants for a period of four to seven years.

(20 U.S.C. 1059)

§ 625.11 Allowable activities.

(a) Planning grants may be used for the purposes described in 34 CFR 624.11(a)(1) through (3).

(b) Development grants may be used to carry out any of the activities listed in 34 CFR 624.13(b) or other activities that promote self-sufficiency.

(20 U.S.C. 1051, 1057, and 1059)

Subpart C—How Does One Apply for a Grant?

§ 625.20 Limitations on applications.

(a) Regardless of whether an institution is applying for a grant individually or as part of a cooperative arrangement, it may not apply in the same fiscal year for a renewable (one-to-three-year) development grant and a non-renewable (four-to-seven-year) development grant.

(b) An institution that has received a non-renewable development grant—

(1) Under this part is ineligible to apply for any other grant under this part, either individually or as part of a cooperative arrangement; and

(2) Under the Aid to Institutions with Special Needs Program (Special Needs Program) or Challenge Grant Program may not apply for a renewable grant under this part, either individually or as part of a cooperative arrangement.

(c) An institution may not apply for a planning grant solely to prepare an application for a development grant under this part unless the institution submits a long-range plan containing all the elements described in 34 CFR 624.22.

(d)(1) Except as provided in paragraph (d)(2) of this section, an institution may not apply for a renewable development grant if the award of the grant results in the institution receiving funds from more than one renewable development grant during any fiscal year.

(2) An institution may apply for a renewable development grant even if the award of that grant would result in the institution receiving funds from two renewable development grants during any fiscal year, if one of the grants is awarded to a cooperative arrangement and the other is awarded individually.

(e)(1) Except as provided in paragraph (e)(2) of this section, an institution may not apply for a non-renewable development grant if it has received a non-renewable development grant under the Special Needs Program.

(2) An institution that has completed, or is in the final year, of a non-renewable development grant under the Special Needs Program may apply for a non-renewable development grant if the institution—

(i) Is otherwise eligible for a non-renewable development grant under this part; and

(ii) Demonstrates to the Secretary's satisfaction that unforeseeable circumstances prevented it from—

(A) Achieving or sustaining self-sufficiency; and

(B) Otherwise fulfilling the objectives of its previous development grant under the Special Needs Program.

(20 U.S.C. 1057 and 1059)

§ 625.21 Planning grants and development grants.

(a) In its application for a grant under this program an applicant shall—

(1) Indicate whether it is applying individually or under a cooperative arrangement for—

(i) A planning grant;

(ii) A renewable development grant; or

(iii) A non-renewable development grant; and

(2) Include the applicable information required under 34 CFR 624.21 and, if appropriate, § 624.23.

(b) If the application is for a planning grant, the applicant shall indicate whether it will use the grant to—

(1) Develop its long-range plan;

(2) Develop an application for a development grant; or

(3) Develop both a long-range plan and an application for a development grant.

(20 U.S.C. 1059 and 1066)

Subpart D—How Does the Secretary Make a Grant?

§ 625.30 General rules.

(a) Using the procedures in 34 CFR 624.30, the Secretary evaluates applications for—

(1) Planning grants on the basis of the criteria in 34 CFR 624.31; and

(2) Development grants on the basis of the criteria in 34 CFR 624.32 and 624.33.

(b) In the case of applications for development grants, the Secretary gives special consideration to applicants that propose to carry out the activities described in 34 CFR 624.13(b).

(20 U.S.C. 1057, 1066, and 1068)

§ 625.31 Funding availability.

(a) The Secretary makes available, for any fiscal year, the following:

(1) For awards to junior or community colleges, not less than 24 percent of the funds appropriated under this program.

(2) For awards for non-renewable development grants, not less than 25 percent of the funds appropriated under this program.

(b) Each year the Secretary announces through a notice in the **Federal Register**—

(1) The amount of funds that will be used to fund non-renewable development grants under this program; and

(2) The maximum amount of funds that the Secretary may award to a grantee that year for each type of grant available under this program.

(20 U.S.C. 1069c)

The Secretary adds a new Part 626 to Title 34 of the Code of Federal Regulations to read as follows:

PART 626—SPECIAL NEEDS PROGRAM

Subpart A—General

Sec.

626.1 Special Needs Program.
626.2 Designation of eligibility.
626.3 Waiver of E&G requirement.
626.4 Regulations that apply to the Special Needs Program.

Subpart B—What Kinds of Grants Does the Secretary Award Under the Special Needs Program?

626.10 Types of grants under the Special Needs Program.
626.11 Allowable activities.

Subpart C—How Does One Apply for a Grant?

626.20 Limitation on applications.
626.21 Planning grants and development grants.

Subpart D—How Does the Secretary Make a Grant?

626.30 General rules.
626.31 Funding availability.

Subpart E—What Conditions Must a Grantee Meet?

626.40 Cost sharing.

Authority: Sections 321–324 and 341–347 of Title III of the Higher Education Act of 1965 (20 U.S.C. 1060–1063 and 1066–1069c).

Subpart A—General

§ 626.1 Special Needs Program.

The Aid to Institutions with Special Needs Program (referred to in these regulations as the Special Needs Program) assists institutions of higher education to become self-sufficient by providing funds to improve their academic quality and strengthen their planning, management, and fiscal capabilities.

(20 U.S.C. 1051 and 1221e–3)

§ 626.2 Designation of eligibility.

(a) The Secretary designates an institution of higher education or a branch campus as eligible to be considered for a grant under the Special Needs Program if the Secretary determines that—

(1) In the academic year in which it applies for designation—

(i) It satisfies the basic institutional eligibility requirements in 34 CFR 624.2;

(ii) It has an enrollment of at least 100 full-time equivalent (FTE) students; and

(iii) In the case of a branch campus, it is located in a community different from that in which its parent institution is located.

(2) A substantial percentage of its FTE undergraduate enrollment received assistance under the need-based assistance programs (Pell Grant, Supplemental Educational Opportunity Grant, National Direct Student Loan, and College Work-Study Programs) in the base year;

(3) The average amount of need-based assistance received by its students in the base year was high in comparison with the average amount of assistance received by students under those programs at comparable institutions in that year; and

(4) The average educational and general (E&G) expenditure per FTE undergraduate student in the base year was less than the average E&G expenditure per FTE undergraduate student at institutions that offer similar instruction in that year.

(b) The Secretary groups comparable institutions and institutions that offer similar instruction for purposes of determining institutional eligibility.

(c) The Secretary assigns points to each of the three factors described in paragraph (a) (2) through (4) of this section as follows:

(1) An institution may receive up to 50 points on the basis of the number of recipients of need-based assistance divided by the number of FTE undergraduate students enrolled at the institution. The points awarded reflect an institution's position on a scale of 1–50 when compared to the percent of need-based assistance recipients enrolled at comparable institutions. (See the illustrative example in paragraph (c)(4) of this section.)

(2) An institution may receive up to 50 points on the basis of the total amount of need-based assistance received by students enrolled at the institution divided by the total number of recipients of need-based assistance enrolled at that institution. The points awarded reflect an institution's position on a scale of 1–50 when compared to the average amount of need-based assistance received by students at comparable institutions. (See the illustrative example in paragraph (c)(4) of this section.)

(3) An institution may receive up to 100 points on the basis of its average E&G expenditures per FTE undergraduate student. Points are assigned to an institution in an inverse relationship to the average E&G

expenditure per FTE undergraduate student at that institution. (See the illustrative example in paragraph (c)(4) of this section.)

(4) The Secretary assigns points for the three institutional eligibility criteria described in paragraphs (a)(2) through (4) of this section as follows:

(i) The Secretary develops a table by—

(A) Listing in rank order all comparable institutions nationwide that enroll students receiving need-based assistance in the base year and dividing them into 50 groups, from the highest value for each criterion to the lowest, with equal numbers of institutions in each group; and

(B) Identifying the range of values for each criterion that the institutions within each of the 50 groups possess.

(ii) The Secretary assigns a score for each of the range of values.

(iii) The Secretary determines an applicant institution's score for each criterion by finding the range of values on the table that includes the applicant institution's value and assigning the score associated with that range of values.

(iv) For example, using the criterion in paragraph (a)(2) of this section pertaining to percentage enrollment, all 2-year public institutions nationwide would be listed in order of their percentage enrollment of need-based aid recipients from the highest percentage to the lowest and divided into 50 equal groups. If there are 1000 such institutions, they would be placed in 50 groups with 20 institutions in each group. The percentage of need-based aid recipients enrolled at each of the 20 institutions in the top group is identified and the percent enrollment range for the group is determined. The range of percentage values for each of the remaining groups is similarly determined.

Consider the example provided in the following table. In the top group of institutions, between 99.0 and 100 percent of the student body receives need-based aid; in the next highest group of institutions the range of values is between 97.0 and 98.9 percent; in the lowest group of institutions the range is between 1.0 and 0.9 percent. An applicant institution would receive 50 points if its percentage of need-based aid recipients is between 99.0 and 100; 49 points if its percentage of need-based aid recipients is between 97.0 and 98.9; and 1 point if its percentage of need-based aid recipients is between 1.0 and 0.9. The same procedures apply when assigning points for each eligibility criterion. The Secretary adds the points for each of the three criteria. If the total is above the minimum that the Secretary announces in the **Federal Register** and the institution meets the basic institutional eligibility requirements in 34 CFR 624.2, then the institution is deemed eligible to apply for assistance.

SPECIAL NEEDS PROGRAM

Point score	Range of values		
	Percent of FTE undergraduate enrollment receiving need-based assistance	Average amount of need-based assistance per recipient (in dollars)	Average E&G expenditure per FTE undergraduate student (in dollars)[1]
50	99.0–100	3,500+	1–750
49	97.0–98.9	3,000–3,499	751–950
1	0.1–.9	1–100	8,001+

[1] When computing points for the E&G criterion, multiply the point score by 2 to obtain the proper score based on a scale of 1–100. For example, if the E&G expenditure of an applicant institution was $900, the applicant would earn 98 points (49 multiplied by 2).

Note.—The values in the explanation above are hypothetical and are not based on actual data.

(d)(1) In determining whether an institution satisfies the criteria in paragraphs (a)(2) through (4) of this section, the Secretary adds the points earned for each of the three factors. Thus, eligibility is based on the sum of the three factors combined rather than each factor taken separately.

(2) All institutions with a point total above the minimum threshold established by the Secretary satisfy the eligiblity criteria in paragraphs (a)(2) through (4) of this section.

(e) Institutions receiving a waiver of the E&G criterion (see § 626.3) described in paragraph (a)(4) of this section must meet a minimum threshold established by the Secretary on the combined remaining eligibility factors described in paragraphs (a)(2) and (3) of this section. For example, to be eligible, an institution that is granted a waiver of the E&G criterion will have to obtain a minimum number of points out the 100 points available on the criteria in paragraphs (a) (2) and (3) of this section.

(f) The Secretary establishes the minimum threshold for the combined points (as described in paragraphs (d) (1) and (2) of this section) to ensure that the pool of applicants for each type of grant will be at least twice as large as the pool of grantees.

(g) Through a notice in the **Federal Register** the Secretary annually—

(1) Publishes the tables the Secretary uses to assign points for each eligibility factor;

(2) Announces the total number of points an institution must receive to satisfy the eligibility factors described in paragraphs (a)(2) through (4) of this section; and

(3) Announces the total number of points an institution must receive to satisfy the eligibility factors described in paragraphs (a) (2) and (3) of this section if that institution requests a waiver of the factor in paragraph (a)(4) of this section.

(20 U.S.C. 1061 and 1221e–3)

§ 626.3 Waiver of E&G requirement.

(a) An institution may seek a waiver of the E&G requirement in § 626.2(a)(4) by submitting to the Secretary a written statement including information and an explanation as to why the Secretary should grant the waiver.

(b) The Secretary may waive the E&G requirement in § 626.2(a)(4) if the Secretary determines that—

(1) The institution's failure to comply with the requirement is caused by factors that distort that requirement with regard to that institution; and

(2) The institution's designation as an eligible institution for this program is consistent with the purposes of the program.

(c) For the purposes of paragraph (b)(1) of this section, factors that the Secretary considers may distort an institution's E&G expenditures per FTE undergraduate student include, but are not limited to, the following:

(1) Low student enrollment.

(2) Size of the campus.

(3) Location in an unusually high cost of living area.

(4) High energy costs.

(5) An increase in State funding to that institution in order to comply with a desegregation plan for higher education.

(6) High cost professional training which is organized, budgeted, and conducted separately from regular graduate and undergraduate instruction, such as medical, dental, and legal programs.

(d) For purposes of paragraph (b)(2) of this section, factors that the Secretary may also use in determining whether an institution's designation as an eligible institution is consistent with the needs of this program include whether the institution has—

(1) Extreme financial limitations requiring low faculty salaries, low cost of instruction for students, and low library expenditures;

(2) Little or no endowment, whether or not unrestricted;

(3) A high student-to-faculty ratio;

(4) A substantial percentage of students receiving need-based Federal student assistance;

(5) Limited library resources;

(6) A low percentage of faculty with earned doctoral degrees;

(7) Poor physical facilities and limited resources to maintain them;

(8) Little or no support from foundations, alumni, or corporations;

(9) Limited or no sponsored research or faculty publications;

(10) An inadequate development office and a limited capacity for long-range planning; and

(11) Poor or inadequate fiscal management and accounting procedures.

(20 U.S.C. 1061 and 1067, and House Report 96–1337, 96 Cong. 2d Sess. p. 161 (1980))

§ 626.4 Regulations that apply to the special needs program.

The following regulations apply to the Special Needs Program:

(a) The regulations in 34 CFR Part 624.

(b) The regulations in this Part 626.

(20 U.S.C. 1060–1063, 1066–1069c, and 1221e–3)

Subpart B—What Kinds of Grants Does the Secretary Award Under the Special Needs Program?

§ 626.10 Types of grants under the special needs program.

Under the Special Needs Program the Secretary awards—

(a) A planning grant for a period of one year; and

(b)(1) A non-renewable development grant for a period of one to five years; or

(2) If an institution previously received a planning grant under this program, a non-renewable development grant for a period of one to four years.

(20 U.S.C. 1062)

§ 626.11 Allowable activities.

(a) Planning grants may be used to develop a long-range plan as described in 34 CFR 624.11(a)(1).

(b) Development grants may be used to carry out the activities listed in 34 CFR 624.13(b).

(20 U.S.C. 1060 and 1062)

Subpart C—How Does One Apply for a Grant?

§ 626.20 Limitation on applications.

An institution that has received a non-renewable development grant under this part or under the Strengthening Program (34 CFR Part 625) may not apply for a grant under this part, either individually or as part of a cooperative arrangement.

(20 U.S.C. 1060, 1062 and 1221e–3)

§ 626.21 Planning grants and development grants.

In its application for a grant under this program, an applicant shall—

(a) Indicate whether it is applying individually or as part of a cooperative arrangement for—

(1) A planning grant; or

(2) A development grant;

(b) Include the applicable information required under 34 CFR 624.21; and

(c) In the case of an application for a development grant, provide assurances to the Secretary that it will have the fiscal resources to pay for its share of assistance beyond the second year.

(20 U.S.C. 1060, 1062, and 1066)

Subpart D—How Does the Secretary Make a Grant?

§ 626.30 General rules.

Using the procedures in 34 CFR 624.30, the Secretary evaluates applications for—

(a) Planning grants on the basis of the criteria in 34 CFR 624.31; and

(b) Development grants on the basis of the criteria in 34 CFR 624.32 and 624.33.

(20 U.S.C. 1060, 1066, and 1068)

§ 626.31 Funding availability.

(a) The Secretary makes available, for any fiscal year, the following:

(1) For awards to junior or community colleges with special needs, not less than 30 percent of the funds appropriated under this program.

(2) For awards to institutions with special needs that have historically served substantial numbers of black students, not less than 50 percent of the amount received by those institutions under the Strengthening Developing Institutions Program (SDIP) for fiscal year 1979. Fifty percent of the amount these institutions received under the SDIP for fiscal year 1979 is $27,035,000.

(b) The Secretary considers institutions that have historically served substantial numbers of black students to be those listed in the 1978 publication by the National Center for Education Statistics entitled *Traditionally Black Institutions of Higher Education: Their Identification and Selected Characteristics.*

(c) Each year the Secretary announces in a notice in the **Federal Register**—

(1) The amount of funds that will be used to fund non-renewable development grants under this program; and

(2) The maximum amount of funds that the Secretary may award to a grantee that year for each type of grant available under this program.

(20 U.S.C. 1069c)

Subpart E—What Conditions Must a Grantee Meet?

§ 626.40 Cost sharing.

The Secretary pays the entire cost of any grant for the first two years of assistance under this program. After that the Secretary pays—

(a) Ninety percent of the cost in the third year;

(b) Eighty percent of the cost in the fourth year; and

(c) Seventy percent of the cost in the fifth year.

(20 U.S.C. 1063)

The Secretary adds a new Part 627 to Title 34 of the Code of Federal Regulations to read as follows:

PART 627—CHALLENGE GRANT PROGRAM

Subpart A—General

Sec.

627.1 Challenge Grant Program.

627.2 Eligible applicants.

627.3 Regulations that apply to the Challenge Grant Program.

Subpart B—What Kind of Grant Does the Secretary Award Under the Challenge Grant Program?

627.10 Type of grant under the Challenge Grant Program.

627.11 Allowable activites.

Subpart C—How Does One Apply for a Grant?

627.20 General.

Subpart D—How Does the Secretary Make a Grant?

627.30 General rules.

627.31 Evaluation of applications for continuation awards.

Subpart E—What Conditions Must a Grantee Meet?

627.40 Matching requirements.

Authority: Sections 331–332 and 341–347 of the Title III of the Higher Education Act of 1965 (20 U.S.C. 1064–1069c).

Subpart A—General

§ 627.1 Challenge Grant Program.

The Challenge Grant Program provides Federal financial assistance as an incentive for eligible institutions of higher education to seek alternative sources of funding to become self-sufficient.

(20 U.S.C. 1051 and House Report 96–520, 96th Cong. 1st Sess., pp. 16–17, (1979))

§ 627.2 Eligible applicants.

(a) An institution of higher education or a branch campus is eligible to apply for a grant under the Challenge Grant Program if—

(1) The Secretary has designated it as an eligible insititution under the Strengthening Program (34 CFR 625.2) or Special Needs Program (34 CFR 626.2); or

(2) The Secretary has designated it as an eligible institution under paragraph (b), (c) or (d) of this section.

(b)(1) The Secretary designates an institution of higher education as eligible to be considered for a grant under this program if that institution—

(i) Does not award a bachelor's degree; but

(ii) Is, and has been for the five academic years preceding the academic year for which it seeks assistance, legally authorized by the State in which it is located to provide an educational program for which it awards a graduate or professional degree;

(iii) Satisfies the requirements of 34 CFR 624.2, other than the requirement of § 624.2(b)(2); and

(iv) Would have qualified as an eligible institution under 34 CFR 625.2 or 626.2 if—

(A) The requirement of 34 CFR 624.2(b)(2) were disregarded; and

(B) Calculations were based on need-based aid received by graduate level students, rather than undergraduate level students.

(2) "Comparable institutions" for purposes of paragraph (b) of this section as applied to determining eligibility under 34 CFR 625.2 or 626.2 means the types of institutions described in paragraph (b)(1) (i) and (ii) of this section.

(c)(1) the Secretary may designate an institution of higher education as eligible to be considered for a grant under this program if that institution—

(i) Is not a junior or community college; and

(ii) Does not award a bachelor's, graduate, postgraduate, or professional degree; but

(iii) Is, and has been for the five academic years preceding the academic year for which it seeks assistance, legally authorized by the State in which it is located to provide a medical education program;

(iv) Makes a substantial contribution to medical education opportunities for minorities and the economically disadvantaged;

(v) Satisfies the requirements of 34 CFR 624.2, other than the requirement of §624.2(b)(2); and

(vi) Would have qualified as an eligible institution under 34 CFR 625.2 or 626.2 based on the enrollment of students in its medical education program if the Secretary had waived the requirement of § 624.2(b)(2).

(2) "Comparable institutions" for purposes of paragraph (c) of this section as applied to determining eligibility under 34 CFR 625.2 or 626.2 means the types of institutions described in paragraph (c)(1) (i), (ii), and (iii) of this section.

(d) The Secretary designates an institution of higher education as eligible to be considered for a grant under this program if that institution—

(1) Provides a medical education program which—

(i) Leads to a doctor of medicine degree; or

(ii) Is not less than a two-year program fully acceptable toward such a degree;

(2) In the base year enrolled minority and educationally disadvantaged students constituting at least 35 percent of its full-time equivalent enrollment; and

(3) In fiscal year 1980 received a grant as a two-year medical school under section 788(a) of the Health Professions Education Assistance Act of 1976.

(e) The Secretary announces annually in a notice in the **Federal Register** the conditions, if any, under which the Secretary will waive the requirement of 34 CFR 624.2(b)(2) in the case of an institution applying for eligibility under paragraph (c) of this section.

(20 U.S.C. 1064)

§ 627.3 Regulations that apply to the Challenge Grant Program.

The following regulations apply to the Challenge Grant Program:

(a) Unless otherwise indicated, the regulations in 34 CFR Part 624.

(b) The regulations in this Part 627.

(c) Applicable provisions of 34 CFR Parts 625 and 626.

(20 U.S.C. 1221e-3(a)(1) and 1064)

Subpart B—What Kind of Grant Does the Secretary Award Under the Challenge Grant Program?

§ 627.10 Type of grant under the Challenge Grant Program.

(a) Under the Challenge Grant Program the Secretary awards a non-renewable development grant to an applicant for a period of up to five years.

(b) The Secretary does not award planning grants under this program.

(c) The Secretary may award a grant under this program to an institution that is simultaneously receiving a non-renewable development grant under the Strengthening Program or the Special Needs Program.

(20 U.S.C. 1064 and 1065)

§ 627.11 Allowable activities.

(a) If an institution qualifies for a grant on the basis of being designated by the Secretary as eligible under the Strengthening Program, as described in 34 CFR 625.2, it may use its grant to carry out the activities authorized under the Strengthening Program (see 34 CFR 625.11).

(b) If an institution qualifies for a challenge grant on the basis of being designated by the Secretary as eligible under the Special Needs Program, as described in 34 CFR 626.2, it—

(1) May use its grant to carry out the activities authorized under the Special Needs Program (see 34 CFR 626.11); and

(2) Must use those funds for the purpose of—

(i) Achieving greater financial independence; and

(ii) Eradicating the applicable conditions—

(A) Listed in 34 CFR 626.3(d); and

(B) Discussed in its application for funds, as required in § 627.20(a)(2).

(c) If an institution qualifies for a grant on the basis of being designated by the Secretary as eligible under this program under one of the criteria described in § 627.2(b), (c) or (d), it may use its grant to carry out those activities listed in 34 CFR 624.13(b).

(20 U.S.C. 1064 and 1065)

Subpart C—How Does One Apply for a Grant?

§ 627.20 General.

(a)(1)In its application for funding, an institution shall include the information required under 34 CFR 624.21 (a) and (b).

(2) In the case of an applicant that qualifies under this part on the basis of being designated an eligible institution under the Special Needs Program, the applicant shall discuss, in its application, those factors listed in 34 CFR 626.3(d) that are characteristic of its status as an institution with special needs.

(b) In its application for funding, an institution shall also include the following:

(1) Evidence that funds are available to the institution to match the funds it is requesting. The applicant may satisfy this requirement by—

(i) Providing a list of the source(s) and the amount of funds each source is contributing for each year of the grant period; and

(ii) Including a letter of intent from each source listed.

(2) An assurance that all matching funds will be—

(i) New funds previously unavailable to the institution from non-Federal

sources for activities allowable under the Challenge Grant Program; and

(ii) Used to carry out those portions of the institution's long-range plan for which funds may be used under this part.

(c) If an applicant is a public institution, it shall include in its application—

(1) The comments of the appropriate State agency responsible for higher education in its State; or

(2) A statement that the institution requested the State agency to comment and the agency failed to comment.

(20 U.S.C 1065,1066, and House Report 96–520, 96 Cong. 1st Sess., p. 16 (1979))

Subpart D—How Does the Secretary Make a Grant?

§ 627.30 General rules.

(a) Using the procedures in 34 CFR 624.30, the Secretary evaluates applications on the basis of the criteria in 34 CFR 624.32 and 624.33.

(b) Under this part the Secretary—

(1) Awards grants—

(i) To individual eligible institutions only;

(ii) For a period not to exceed the period for which matching funds, as described in § 627.40, are available to the applicant at the time its original application is submitted; and

(2) Gives preference in awarding grants to applications from institutions are receiving, or have received, grants under the Strengthening Program or Special Needs Program.

(20 U.S.C. 1065)

§ 627.31 Evaluation of applications for continuation awards.

In addition to the requirements in 34 CFR Part 75 (EDGAR) that pertain to the Secretary's evaluation of continuation award applications, the Secretary looks for evidence that an institution's matching funds are available at the time it submits its application.

(20 U.S.C. 1065)

Subpart E—What Conditions Must a Grantee Meet?

§ 627.40 Matching requirements.

A grantee must match the funds it receives under this program, on a dollar-for-dollar basis, with new funds that were previously unavailable to the applicant from non-Federal sources for activities allowable under the Challenge Grant Program.

(20 U.S.C. 1065)

Note.—This Appendix is included for information. It is not to be codified in the Code of Federal Regulations.

Appendix A—Summary of Comments and Responses

In the notice of proposed rule making published in the **Federal Register** on July 20, 1981 (46 FR 37470–37482), the Secretary invited comments on the proposed regulations to implement the three Institutional Aid Programs authorized by the Higher Education Act of 1965, as amended.

The following is a summary of the substantive public comments received and the Secretary's responses to these comments. The comments and responses are organized to the extent possible in the same order as the referenced sections are organized in these final regulations.

General Comments

Comment. A great number of comments concerned statutory requirements that were beyond the scope of the proposed regulations. These comments objected to: the use of the Pell grant factor as an eligibility criterion; the absence of a "grandfather" clause; the ineligibility of non-degree granting institution; double weighting of the Pell grant factor in the Strengthening Program; requiring an enrollment of at least 100 FTE students for eligibility for the Special Needs Program; the method of calculating educational and general expenditures; the definition of "full-time equivalent"; and the limitation to one non-renewable development grant under the Strengthening Program.

Other comments that pertained to statutory requirements included alternative methods of determining eligiblity such as, allowing a waiver of the Pell Grant requirement, or establishing an economic weighting system or cost of living allowance as eligibility qualifiers.

Response. All of the provisions referred to by the commenters are statutory requirements. They may not be changed by regulations.

Comment. Many commenters requested that the period of time allowed for public comments be extended and that public hearings be held.

Response. Public hearings were not held because of budgetary constraints faced by the Department. However, the Secretary recognized the need for extensive public comment on these proposed regulations and took the following action. The NPRM, accompanied by a cover letter requesting careful study of the proposed rules, was mailed to all FY 1980 Title III grantees, all FY 1981 Title III applicants, and all individuals, groups, or associations requesting information on the new program. In addition the comment period was set at 60 days, rather than the customary 45 days.

More than 200 comments were received. The comments covered virtually all aspects of the regulations. As a result the Secretary does not believe it is necessary to extend the comment period.

Comment. Some commenters recommended that the regulations establish a fixed base year for eligibility determinations. Others, who had no objection to a rolling base-year, felt that the base year should be more clearly defined.

Response. A change has been made. The definition of base year in § 624.6 has been revised to indicate that the Secretary will, in a notice published in the **Federal Register** indicate a base year that will be the most recent base year, i.e., 12 month period, for which reliable data are available.

Establishment of a fixed base year in the regulations would not allow the Secretary to evaluate the statutory eligibility characteristics of an institution using the most current available data without amending regulations.

Comment. Many comments were made in reference to the application review and approval process. The commenters focused on the qualifications and selection of outside readers, the role of the Title III professional staff, the criteria to be used for selecting grantees, the use of supplementary information, and the implementation of special performance requirements.

Response. No change has been made. These administrative procedures do not properly belong in Departmental regulations. However, the following explanation may be useful. The statute requires that applications be reviewed by panels of readers selected by the Secretary. The Secretary will select qualified readers who are highly skilled in institutional development from outside the Department to serve on the panels. These readers will review the applications using the criteria published in the regulations. Separate rank-order lists for development and planning grants under each of the Institutional Aid Programs will be prepared based on the points assigned by the readers. Applications from institutions that award bachelor's degrees will be ranked together with applications from junior and community colleges.

Using these rank-order lists separate funding-order slates are prepared for each program after taking into consideration the following—other

appropriate information from available sources, such as, existing public records, site visits, and external evaluation reports; applicable funding limitations in the regulations; and other funding priorities, as applicable, described in §§ 625.31, 626.31 or 627.30. Applications will be funded in descending order according to their placement on the funding-order slates.

Comment. Several commenters suggested substituting the method of determining eligibility contained in the regulations for the Strengthening Developing Institutions Program (SDIP) for the eligibility requirements contained in the NPRM.

Response. A change has been made. However, the procedure used to determine eligibility under the SDIP does not include all the factors the new law requires. Under the SDIP a formula was used to determine whether the applicant institution satisfied two of the statutory elements of the definition of a developing institution, namely, struggling for survival because of financial and other reasons, and isolated from the main currents of academic life. Under the Institutional Aid Programs, a similar *formula* will be used which will include the three factors described in the law—not merely the two used under the SDIP.

Comment. Many commenters asked whether the Fall quarter enrollment figures or cumulative full-year data would be used in computing the percentage of students receiving Pell grants and other need-based student assistance.

Response. Both full-year and fall quarter data will be used. Cumulative full-year student assistance data and fall quarter enrollment data for the designated base year must be used to compute the percentage of students receiving Pell grants and other need-based student assistance.

Comment. Many commenters objected to the provision limiting the number of students to be used in the computation of the percentage of student aid recipients to those who are at least half-time.

Response. A change has been made. The final rules require an institution to have a substantial percentage of its full-time equivalent (FTE) undergraduate enrollment receiving student aid rather than a substantial percentage of those eligible to apply for such aid actually receiving it. Therefore, students who are enrolled less than half-time may be proportionately counted.

Comment. Several commenters requested that eligibility requirements and procedures for eligibility determinations be arrived at well in advance of other final regulations so as to allow adequate time for notification of eligibility.

Response. No change is necessary. The Secretary will publish the data needed to determine eligibility annually in a separate notice in the **Federal Register**. This notice will be published well in advance of the deadline for submitting applications for funding.

Comment. One commenter asked whether an institution that awards both undergraduate and graduate degrees may receive funds under the Strengthening Program and Challenge Grant Program to support its *graduate* programs.

Response. No change is necessary. The regulations allow the graduate program of an eligible institution with both undergraduate and graduate programs to receive support under any of the Institutional Aid Programs.

Comment. Many commenters stated that the emphasis placed on institutions achieving self-sufficiency within the period of a non-renewable grant was contradictory to the statute which speaks only of increasing self-sufficiency. Other commenters asked whether the self-sufficiency requirement applies to all of the Institutional Aid Programs.

Response. The emphasis on achieving self-sufficiency, that is graduation from the need for continued aid under the Title III Program, is based on the Title III statute and its legislative history. All three programs—Strengthening, Special Needs, and Challenge Grant—provide for non-renewable grants. Further, the House and Senate Reports accompanying the Education Amendments of 1980 in its passage through the Congress clearly indicated an intention that institutions become self-sufficient and graduate from the Title III Program. If an institution believes that it is not likely to attain self-sufficiency during the period of a non-renewable grant, it should apply for a renewable grant which only requires that it be moving towards self-sufficiency.

Comment. Two commenters recommended that the regulations clarify the role of contractors (assisting agencies).

Response. No change has been made. It is no longer necessary to involve contractors in any phase of an application or grant. Neither the statute nor regulations require a grantee to purchase services from a contractor. However, any grantee may employ a contractor if it is necessary to achieve the objectives of one or more of the funded activities. The regulations that cover this type of arrangement are contained in EDGAR.

Comment. Several commenters were concerned that if an institution accepted a non-renewable grant for a shorter period of time than originally requested, it would not be able to reapply for funding to complete implementation of its long-range plan.

Response. No change has been made. An institution that accepts a non-renewable grant for less than the maximum number of years allowed cannot reapply later for another grant under that program. However, if an applicant institution determines that the size of the grant or the length of the grant period which is offered is insufficient to meet its objectives, it may decline the grant and reapply in a subsequent funding period for an award that it believes may be appropriate

Comment. A number of commenters recommended that the regulations stipulate the percentage of funds that will be set-aside for non-renewable grants.

Response. No change has been made. The Secretary will announce the proportion of the appropriated funds designated for non-renewable grants in the **Federal Register** in the annual Notice of Closing Date for grant applications.

Comment. One commenter inquired whether program funds could be transferred from one Institutional Aid Program to anther.

Response. The allocation of funds among the three programs is determined by statute. Transfers would upset the statutory allocation and are not permitted.

Comment. One commenter recommended that regulations applying to the program as a whole be distinguished from regulations pertaining to one of the three separate Institutional Aid Programs.

Response. A change has been made. Those portions of the general provisions (34 CFR Part 624) that refer to only one program have been placed under the appropriate program regulations.

Comment. Some commenters recommended that two-year colleges be treated separately in the funding process.

Response. No change has been made. The Secretary believes that the selection criteria for this program should be applied equally to all applicants since all applicants can apply equally for all available funds. Therefore, applications from both 2- and 4-year institutions will be rated on the same factors. However, the two-year college set-aside requirements will be taken into

consideration when developing the recommended funding slates for the Strengthening and Special Needs Programs.

Section 624.6 Definitions that apply to the institutional aid programs

Comment. A number of commenters requested a clearer definition of the term "self-sufficient".

Response. A change has been made. Self-sufficiency is now defined as the point at which, in the determination of the Secretary, an institution should be viable, thriving, and able to survive without funding from the Institutional Aid Programs. The term self-sufficient is synonymous with the concept of graduation from the program. Therefore, a grantee is self-sufficient or free from the need for additional Title III assistance at the end of its non-renewable development grant.

Section 624.10 Types of grants

Comment. Several commenters believed that categorizing grants as planning and development, did not provide for the actual implementation of program activities. They recommended that implementation grants also be awarded.

Response. No change is necessary. Implementing certain activities is an allowable part of a development grant.

Section 624.12 and 624.13 Development grant and allowable activities

Comment. One commenter asked whether the statement that funds cannot be used for duplicating activities that have previously been funded under the Institutional Aid Programs also pertains to activities previously supported under the SDIP.

Response. A change has been made. A new § 624.13(c) has been added to made it clear that the Secretary will not fund an activity for which an institution is receiving or has received funds under an Institutional Aid Program or a SDIP grant that is scheduled to expire after September 30, 1982.

Section 624.23 Applications for grants under cooperative arrangements

Comment. Several commenters suggested that the prohibition on duplication of effort in cooperative arrangements be extended to apply to all Institutional Aid Programs.

Response. A change has been made to make it clear that duplication of activities is not allowed under any Institutional Aid program. Section 624.23(b)(2) has been deleted because it duplicated § 624.12(b)(2) which applies to all development grants under the Institutional Aid Programs.

Section 624.30 General evaluation of applications

Comment. One commenter noted that the regulations do not specify a minimum point total that will be used to define a high-quality proposal, for example, 70 points.

Response. A change has been made. A new § 624.30(d) has been added which specifies that the Secretary will not fund an appliction that receives less than 50 points for the criteria in § § 624.31 or 624.33.

Section 624.32 Long-range plan to achieve self-sufficiency

Comment. Several commenters felt that there should be more Title III staff involvement in the review of long-range plans and applications. These commenters felt that staff members are more familiar with many of the potential applicant institutions than outside readers would be. Therefore, they would be able to use this knowledge in the award process.

Response. No change has been made since this is not a regulatory item. However, some explanation may be helpful. The statute requires that applications be reviewed by a panel of expert readers consisting of individuals selected by the Secretary. The Secretary only selects readers who have demonstrated they have expertise in solving the types of problems that have prohibited applicant institutions from achieving self-sufficiency.

Comment. A number of commenters asked whether each applicant must have a long-range plan. They also asked whether this plan would relate only to the implementation of activities covered by the grant.

Response. No change is necessary. Each institution applying for a development grant or a planning grant only to develop an application must have a long-range plan. The plan must cover the overall institutional goals and objectives through which the institution plans to achieve self-sufficiency by using its own funds, as well as Title III funds. If an institution submits an application under more than one Institutional Aid Program, it must submit the same long-range plan with each application.

Comment. One commenter recommended that an institution currently receiving an SDIP grant to develop a long-range plan which is not scheduled for completion by the deadline for submitting applications for development grants in fiscal year 1982 be allowed to submit such an application without a long-range plan.

Response. No change has been made. Such an institution has the option of accelerating the schedule for developing its long-range plan, or waiting until the plan is completed before submitting an application for a development grant in a subsequent fiscal year. The statute requires an applicant for a development grant to submit an acceptable long-range plan.

Comment. One commenter felt that the regulatory requirements will force a degree of uniformity on the institutional planning process that, in effect, constitutes unnecessary Federal intervention. The commenter felt that alternative documents, such as self-studies prepared for accrediting agencies, should be acceptable.

Response. No change has been made. The Secretary does not agree with the commenter's contention regarding Federal intervention. Applicants may use whatever documents or format they wish for their long-range plan as long as the required basic elements are included and the review criteria are addressed.

Comment. One commenter recommended that adequacy of the long-range plan be used along with other selection criteria, such as plan of operation and quality of key personnel, in the review process rather than be used as a preliminary disqualifier.

Response. No change is made. To apply for a development grant, an institution must show that it has the capability to move toward self-sufficiency by the end of the renewable grant period or will reach it by the end of the nonrenewable grant period. The long-range plan is the vehicle through which an institution will demonstrate whether it has developed the methods for achieving or moving towards this end. If it has not, it will not receive a development grant.

Comment. Several commenters asked whether a specific time-frame was required for a long-range plan and, if so, what it was?

Response. No change has been made. Neither the statute nor regulations stipulate a specific timeframe. However, the time frame of the plan must at least equal the period for which funds are being requested.

Comment. One commenter suggested changing "long-range plan to achieve self-sufficiency" to "strategic plan to move an institution toward becoming a viable, thriving institution of higher education" to make the language more in keeping with the intent of the statute. This commenter also suggested rewording the language relating to the long-range plan to stress the importance

of the strategic plan in the application review process.

Response. No change has been made. First, the Secretary believes that "long-range plan" is synonymous with a "strategic plan." Secondly, the Secretary believes the language in § 624.32(c) stressing the importance of the plan in the review process is clear.

Section 624.33 Selection criteria for development grants

Comment. One commenter recommended adding a criterion which would require an institution applying for any Institutional Aid grant to afford the appropriate State agency responsible for the coordination of postsecondary education the opportunity to review and comment upon the application.

Response. No change has been made. A public institution applying for a Challenge Grant is required to include in its application comments from the higher education agency in its State or a statement that the agency was given the opportunity but failed to comment. For each of the Institutional Aid Programs an applicant is required to certify that it will not use Title III funds for activities that are inconsistent with any State plan for higher education applicable to the institution. A state agency responsible for the coordination of postsecondary education should inform the Secretary if it finds that Title III funds are used by a grantee in a manner that is inconsistent with that State's plan for higher education.

Comment. Some commenters expressed concern that the quality of key personnel criterion requires them to commit personnel to the project in advance of any assurances that funds will be awarded.

Response. No change has been made. This criteria does not require an applicant to commit personnel. However, if personnel are known, their qualifications should be listed. If they are not known, then minimum qualifications prospective personnel must meet should be listed.

Section 624.34 Grants under cooperative arrangements

Comment. One commenter objected to the provision stipulating that there be no duplication of effort among institutions participating in a cooperative arrangement.

Response. A change has been made. This requirement, as revised (§ 624.34(b)(2)), is intended to prevent such instances of waste as institutions dividing funds to support separate but identical activities rather than engaging in a cooperative effort.

Comment. Some commenters expressed concern that the regulations, by considering participants in a cooperative arrangement as separate grantees, would discourage institutions from entering into cooperative arrangements.

Response. No change has been made. The regulations allow any institution that wishes to apply to choose the type of application that best suits its needs. Each recipient of Title III funds will be considered a grantee.

Section 624.40 Maintenance of eligibility

Comment. Some commenters objected to the requirement that an institution must maintain its eligibility for the duration of the grant period and must file annual assurances to that effect.

Response. No change has been made. The provision referred to in this section is required by statute. The Secretary must terminate funds to institutions that no longer meet basic institutional eligibility criteria.

Section 624.42 Restrictions on the use of funds

Comment. One commenter suggested that Challenge Grant funds, or matching private funds raised for a challenge grant, be used to supplement operational funds.

Response. No change has been made. Both Title III and non-Federal funds used to match Challenge Grant funds must be used to carry out approved activities. Therefore, they may not be used for general operating and maintenance expenses.

Comment. Several commenters objected to the provision which restricts Title III funds from being used for operating and maintenance expenses.

Response. No change has been made. The statute and its legislative history make it clear that Title III funds may not be used for operation and maintenance expenses, in spite of the fact that funds may have been used under the SDIP for these purposes.

Section 625.2/626.2 Designation of eligibility

Comment. Many commenters recommending changing the method of determining specific program eligibility. Recommendations included: changing the 35 percent figure used to define substantial percentage (most recommended lowering it to expand the eligibility pool, while some recommended raising it to 45 percent based on the colloquy on the Senate floor); and dropping the artificial system established in the proposed regulations that imposes separate absolute thresholds for each criterion and instead, rate all criteria together using a point system similar to that used under the SDIP. In addition, one commenter observed that when separate absolute thresholds are used to determine eligibility there is an adverse relationship created between the requirement that a substantial percentage of students receive financial assistance and the requirement that their average award be high in comparison with awards at comparable institutions.

Response. A change has been made. Rather than requiring an institution to satisfy each of the specific criteria in § 625.2(a) (2) through (4) or § 626.2(a) (2) through (4) separately, an institution must meet each of the three criteria in the aggregate using a point system similar to that used to determine eligibility under the SDIP to compare potentially eligible institutions. All institutions with a cumulative point score above the minimum threshold announced annually through a notice in the **Federal Register** will satisfy these specific criteria. Therefore, an institution may receive a relatively low number of points based on the size of its average award and still meet the minimum threshold based on the number of points it receives for the other two criteria.

Comment. One commenter recommended re-establishment of a bonus point system for the benefit of institutions serving large numbers of disadvantaged students.

Response. No change has been made. The bonus points awarded by the previous Title III program were done so as part of the application selection criteria. There is no statutory basis for establishing a new bonus point system.

Comment. One commenter asked what sanctions will be levied against an institution that submits falsified data.

Response. Submission of falsified data would be grounds for refusal to consider an application for a grant, or termination of a grant, as well as possible civil or criminal legal action.

Section 625.2 Designation of eligibility.

Comment. Several commenters expressed concern that the regulations did not stipulate the method that would be used to accomplish the double weighting of the Pell grant factor.

Response. A change has been made. The regulations detail the method used to double weight the Pell grant factor.

Section 625.10 Types of grants under the strengthening program.

Comment. One commenter asked whether an institution's application for a nonrenewable grant under the Strengthening Program could be funded as a renewable grant if the application was recommended for funding but insufficient funds for nonrenewable grants were available.

Response. No change has been made. When seeking funds for development activities, the statute requires an institution to apply for either a nonrenewable or renewable development grant. If an application for a nonrenewable grant is not funded, it may not be considered for funding as a renewable grant.

Section 625.20/626.20 Limitation on applications.

Comment. Two commenters objected to the provision that prohibits the four- to seven-year development grants under the Strengthening Program and the one- to five-year development grants under Special Needs Program from being renewed.

Response. No change has been made. The statute authorizing the Strengthening Program stipulates that the four- to seven-year development grants are nonrenewable. For the Special Needs Program, the Congressional reports clearly demonstrate that Congress intended that an institution be limited to a single development grant with a maximum of five years of funding in order to ensure that institutions graduate from financial dependence on Title III.

Section 625.30 General rules.

Comment. Several commenters asked for clarification of the provision that authorizes the Secretary to give special consideration to institutions that propose to carry out the allowable activities specified in 34 CFR 624.15.

Response. Applications of otherwise equal quality that contain the types of activities listed in § 624.15 will be ranked higher on the funding slate than applications that propose other types of activities.

Section 625.31/626.31 Funding availability.

Comment. One commenter urged that the percentage of funds set aside for junior and community colleges in the Strengthening Program and the Special Needs Program be considered a ceiling rather than a base.

Response. No change is necessary. It is clear from the statute that the percentage of funds allocated to junior and community colleges in each program are intended to be bases rather than ceilings.

Comment. Several commenters recommended that the Department inform potential grantees, in advance, of the actual amount of dollars that will be set aside for grants to junior and community colleges under the Strengthening Program and for grants to these institutions and historically black colleges under the Special Needs Program.

Response. One change has been made. The set-aside available to historically black institutions is contained in the regulations because it will not vary from year to year. The other set-asides are dependent on the level of Congressional appropriations. The Secretary will notify applicants of the various set-asides in the annual closing date notices for applications.

Comment. One commenter recommended that unused set-aside funds be used for general Title III funding rather than returned to the Treasury.

Response. No change has been made. There is no statutory authority for such an action.

Section 626.11 Allowable activities.

Comment. Several commenters objected to the fact that planning grants under the Strengthening Program can be used for developing a plan or an application, while planning grants awarded under the Special Needs Program can only be used to develop a long-range plan.

Response. No change has been made. The uses to which a planning grant may be put are specified in the statute. There is no statutory basis for allowing Special Needs planning grants to be used for developing applications.

Section 626.31 Funding availability

Comment. Several commenters offered alternative lists which could be used to identify historically black colleges.

Response. A change has been made. The Secretary will consider as institutions that have historically served substantial numbers of black students only those institutions listed in the 1978 National Center for Education Statistics (NCES) publication entitled: "Traditionally Black Institutions of Higher Education: Their Identification and Selected Characteristics." The Secretary considers this publication to be a stable and definitive list, based on historical criteria.

Comment. Several commenters recommended that institutions not included in the Secretary's list of historically black institutions be allowed to submit information to the Secretary that would show that they also could qualify as historically black.

Response. No change has been made. The Secretary believes that the definition of historically black institutions contained in the NCES publication referred to above is appropriate. The fact that an institution is not designated as historically black in no way precludes that institution from applying for or receiving Title III funds.

Comment. One commenter recommended that a portion of Title III funds be set aside for the exclusive use of private institutions.

Response. There is no statutory authority for such a set-aside.

Section 626.40 Cost sharing

Comment. Several commenters asked whether the institutional matching requirements could be met through in-kind contributions.

Response. Certain in-kind contributions are permissable if the matching contribution would qualify as a direct cost and allowable activity of the project. In-kind contributions analogous to general operating and maintenance expenses or indirect cost, such as space, fuel, and personnel not directly working under the grant, cannot be counted.

Section 627.2 Eligible applicants

Comment. Some commenters were concerned that the eligibility criteria in the proposed regulations did not comply with the law and permit schools that offered graduate degrees, but not bachelors degrees to be eligible for a Challenge Grant.

Response. The regulations follow the statute. Institutions that offer a graduate or professional degree but not a bachelor's degree will be eligible if they meet the eligibility criteria in §§ 625.2 or 626.2 and 627.2.

Section 627.11 Allowable activities

Comment. One commenter observed that under this section only institutions that had been designated as eligible for the Challenge Grant Program on the basis of being eligible for the Strengthening or Special Needs Programs would be able to carry out activities under a challenge grant.

Response. A change has been made. A new paragraph (c) has been added which stipulates that institutions designated as eligible by virtue of an alternative method set forth in § 627.2(b)–(d) may use challenge grant funds to carry out the activities listed in 34 CFR 624.13(b).

Comment. Several commenters objected to the fact that development offices appear to be denied the use of challenge grant funds.

Response. No change has been made. Challenge grant funds may be used to strengthen the operational capacity of development offices by, for example, training development officers. They may not be used to support specific development or fund raising activities because of the general prohibition on using Federal funds to raise money.

Comment. One commenter asked whether Challenge Grant funds may be used for the "College Endowment Funding Plan."

Response. Challenge grant funds may not be used for this purpose.

Section 627.20 General

Comment. Some commenters objected to the requirement that an institution have matching funds on hand at the time of application for a challenge grant and that these funds be from sources previously unavailable to the institution.

Response. A change has been made. An institution is only required to include in its application evidence that funds are available to match the funds it is requesting. In addition, the matching funds must be new funds, rather than funds from new sources, previously unavailable to the institution. The Secretary considers a letter of intent from the source of the matching funds to be satisfactory evidence.

Section 627.30 General rules

Comment. Many commenters asked how the provision requiring the Secretary to give preference to institutions that have received, or are receiving, Strengthening or Special Needs grants, will be implemented.

Response. Challenge grant applications of otherwise equal quality from institutions that have received, or are receiving Strengthening or Special Needs grants will be placed higher on the recommended funding slate than applications from institutions that have not received funds from these programs.

[FR Doc. 82-69 Filed 1-4-82; 8:45 am]

BILLING CODE 4000-01-M

federal register

Tuesday
January 5, 1982

Part XV

Department of the Interior

Office of Surface Mining Reclamation and Enforcement

Federal Programs to Regulate Coal Exploration Operations on Non-Federal and Non-Indian Lands in the States of Massachusetts, Michigan, and Rhode Island; Proposed Rules

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 921, 922, 937, and 939

Federal Programs to Regulate Coal Exploration Operations on Non-Federal and Non-Indian Lands in the States of Massachusetts, Michigan, Oregon, and Rhode Island

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rules.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM, or the Office), U.S. Department of the Interior, is proposing, and seeking comments on rules for the regulation of coal exploration operations on non-Federal and non-Indian lands in Massachusetts, Michigan, Oregon, and Rhode Island, in accordance with Sections 504 and 512 of the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act), 30 U.S.C. Sections 1254 and 1262, and 30 CFR Part 736. After OSM receives comments on the proposed rules, it will tailor them to each of the four States and issue separate final rules for each State. These final rules will amend 30 CFR Chapter VII, Subchapter T, by adding Part 921 for Massachusetts, Part 939 for Rhode Island, Part 922 for Michigan, and Part 937 for Oregon.

DATES: The comment period on each of these proposed Federal Coal Exploration Program rules will extend until February 4, 1982. Public hearings will be held in each of the four States on the following dates: Massachusetts on January 26, 1982, 1:00 p.m.–5:00 p.m., Michigan on January 28, 1982, 1:00 p.m.–5:00 p.m., Oregon on January 26, 1982, 7:00 p.m., and on January 28, 1982, 7:30 p.m., and in Rhode Island on January 27, 1982, 1:00 p.m.–5:00 p.m.

ADDRESSES: Written comments must be mailed or hand-delivered either to the Office of Surface Mining, Room 153, South Interior Building, 1951 Constitution Avenue, NW., Washington, D.C. 20240, or to the following appropriate OSM regional offices.

Comments pertaining to Massachusetts and Rhode Island may be sent to: Office of Surface Mining, Region I, 603 Morris Street, Charleston, WV 25301, (304) 342–8125.

Comments pertaining to Michigan may be sent to: Office of Surface Mining, Region III, Room 527, Federal Building and U.S. Courthouse, 46 East Ohio Street, Indianapolis, IN 46204, (317) 269–2600.

Comments pertaining to Oregon may be sent to: Office of Surface Mining, Wyoming State Office, Feden Building, 935 Pendell Blvd., Casper, Wyoming 82601, (307) 265–5550.

See Supplementary Information for the locations and times of the public hearings.

All written comments received and summaries of any meetings with representatives of OSM will be available for public review at the addresses listed above and those listed in "SUPPLEMENTARY INFORMATION".

FOR FURTHER INFORMATION CONTACT: James M. Kress, Federal Lands Specialist, Office of Surface Mining, U.S. Department of the Interior, South Interior Building, 1951 Constitution Avenue NW., Washington, D.C. 20240, (202) 343–5866.

SUPPLEMENTARY INFORMATION: This document contains proposed rules which are uniform for four States in which coal exploration is occurring—Massachusetts, Michigan, Oregon, and Rhode Island. Although a single version is being published for public comment, comment is sought on the proposed rules as they would apply to each of the four States. The final rulemaking will be separate for each of the four States.

Section 505(b) of the Act requires that State provisions continue in effect unless they are inconsistent with the Act. Therefore, comment is also solicited on provisions of State laws in each of the four States which have a bearing on the proposed program to regulate coal exploration activities. The Office will review the State statutes and regulations for each of the four States during the comment period in order to identify any provisions which set more stringent standards than are contained in these proposed rules.

Because the Director does not anticipate that mining operations will occur in Massachusetts, Michigan, Oregon, or Rhode Island in the near future, the Federal programs to be established for those States are proposed to be limited to the regulation of coal exploration. However, the Office would promulgate rules expanding the Federal program to regulate mining as well as exploration in any of the four States in advance of any proposed mining activity. Persons are invited to comment on the adequacy of establishing Federal programs for the States of Massachusetts, Michigan, Oregon, and Rhode Island to regulate coal exploration, but not mining. OSM solicits comments also on the likelihood and imminence of surface coal mining activity in any of these States, so that delays in developing a complete regulatory program can be avoided.

Background

Under Sections 501–503 of the Act and 30 CFR Part 731, States were provided the opportunity to submit programs for approval by the Secretary and thus achieve primacy for regulating coal exploration and surface coal mining and reclamation operations on non-Federal and non-Indian lands. Under Section 504 of SMCRA and 30 CFR 736.11, OSM must promulgate and implement a Federal program in each State that did not submit a program within the time provided in 30 CFR 731.12, and in which the Director reasonably expects coal exploration or surface coal mining and reclamation operations to exist on non-Federal and non-Indian lands at any time before June 1985. The time provided in 30 CFR 731.12 for submittal of State programs was extended to March 3, 1980, by the District Court for the District of Columbia. *In re: Permanent Surface Mining Regulation Litigation*, 13 ERC 1586 (August 22, 1979).

On May 16, 1980 (45 FR 32328–32331), OSM published an advance notice of intent to promulgate Federal regulatory programs for States with known surface coal mining and reclamation activities that did not submit programs by March 3, 1980. The notice stated that OSM was evaluating States with known coal reserves to determine whether coal exploration and surface coal mining and reclamation operations were occurring or reasonably expected to occur before June 1985. OSM has determined that coal exploration operations are occurring or may soon occur in four States which have not submitted programs: Massachusetts, Michigan, Oregon, and Rhode Island. Therefore, on July 21, 1980 (45 FR 48661–48662), OSM published notice of intent to promulgate Federal programs for these States.

The proposed rules would implement a permanent program to regulate coal exploration on non-Federal and non-Indian lands in each of these four States. Should the Director learn that coal exploration operations are expected to exist prior to 1985 on non-Federal and non-Indian lands in any other State, the Director will notify that State and the public.

Section 504(a) of SMCRA requires the implementation of permanent programs to regulate coal exploration and surface coal mining and reclamation operations in each State which fails to submit a State program. OSM promulgated permanent program regulations in 30 CFR Chapter VII which establish the minimum standards for the regulatory

program in each State and the procedures for developing, promulgating, and implementing such a program. The rules for the permanent program are found in 30 CFR Parts 700–707 and 730–865. Part 705 was published October 20, 1977 (42 FR 56064). Parts 795 and 865 (originally Part 830) were published December 13, 1977 (42 FR 62639). The other permanent program regulations were published at 44 FR 15312–15463 (March 13, 1979). Errata notices were published at 44 FR 15485 (March 14, 1979), 44 FR 49673–49687 (August 24, 1979), 44 FR 53507–53509 (September 14, 1979), and 44 FR 66195 (November 19, 1979), 45 FR 26001 (April 6, 1980), 45 FR 37818 (June 5, 1980), and 45 FR 47424 (July 15, 1980). Amendments to the rules have been published at 44 FR 60969 (October 22, 1979), as corrected at 44 FR 75143 (December 19, 1979), at 44 FR 75302 (December 19, 1979), 44 FR 77440–77447 (December 31, 1979), 45 FR 2626–2629 (January 11, 1980), 45 FR 25998–26001 (April 16, 1980), 45 FR 33926–33927 (May 20,1980), 45 FR 39446–39447 (June 10, 1980), 45 FR 52306–52324 (August 6, 1980), 45 FR 52375 (August 7, 1980), 45 FR 58780–58786 (September 4, 1980), 45 FR 76932–76935 (November 20, 1980), and 46 FR 41702 (August 17, 1981). Portions of these rules have been suspended, pending further rulemaking. See 44 FR 67942 (November 27, 1979), 44 FR 77447–77455 (December 31, 1979), 45 FR 6913 (January 30, 1980), and 45 FR 51547–51550 (August 4, 1980).

Representatives of industry, two States, and several environmental groups challenged the permanent regulatory program in the U.S. District Court for the District of Columbia. These suits were consolidated and heard in a single lawsuit entitled *In re: Permanent Surface Mining Regulation Litigation*, Civ. Action No. 79–1144. in response to the arguments raised in the challenges, the Secretary voluntarily suspended several permanent program regulations. These suspensions were announced in the **Federal Register** on November 27, 1979 (44 FR 67942), December 31, 1979 (44 FR 77447–77454), and January 30, 1980 (45 FR 6913). In two opinions the court remanded certain other regulations which had been challenged in the lawsuit. The opinions were issued on February 26, 1980, and May 16, 1980. OSM has considered the court's reasons for these suspensions and remands in drafting the proposed coal exploration program regulations. In some cases, OSM is proposing new language in the coal exploration program regulations, the basis for which is set forth below. The proposed language would not supersede, amend, or modify the permanent program rules in any way, although the proposals for these four States may differ from the permanent program rules. Major differences are explained in this discussion. If the Office promulgates new permanent program regulations, the coal exploration programs will be amended as appropriate. References to "9—" below indicate that each of the four programs covered by this rulemaking would include the section being referenced.

PROPOSED DISPOSITION OF SUSPENDED AND REMANDED NATIONAL PERMANENT PROGRAM REGULATIONS

Regulation	Topic	Extend of remand or suspension
30 CFR 701.11(d)(1) (i) and (ii)	Provided that if pre-existing structures met the Secretary's performance standards they may be exempted from the Secretary's reconstruction design requirements.	Suspended. The regulation was suspended insofar as it may be read to retain discretion in the regulatory authority not to grant an exemption from reconstruction of existing structures after making the findings in 30 CFR 786.21. (44 FR 67942 (1979).)

Proposed disposition: Proposed Rules 9—.701–11(b)(1)(i) and (ii) would provide that the Office shall grant an exemption from reconstruction requirements for existing structures after obtaining the information required by proposed Rules 9—.776 and making the findings required in 30 CFR 786.21. Proposed Rules 9—.701–11(b) (1)(i) and (ii) are based on a proposed national permanent program regulation published on February 6, 1980 (45 FR 8241). The preamble discussion of that proposed rule provides the rationale.

30 CFR 776.11(b)(3)	Regulation requires that written notice submitted by person intending to remove less than 250 tons must include a precise map at a scale of 1:24,000, or larger, of the exploration area.	Remanded. Section 512(a) of the Act requires notice to include only a description, not a map. (Court opinion, May 16, 1980, p. 54).

Proposed disposition: Proposed rule 9—776.11(b)(3) would reflect the court's interpretation.

30 CFR 776.11(b)(5) and 776.12(a)(6).	Regulation requires that operators explain their basis for entering the exploration area when the surface is owned by a person other than the operator.	Remanded. Section 512(a) of the Act provides no authority to require an operator to explain his basis for entering the land. (Court opinion, May 16, 1980, p. 54).

Proposed disposition: The proposed coal exploration program, §§ 9—.776–12(a) and 9—.776–11(b), would not require the submission of such information.

Availability of Copies

Copies of the proposed regulations are available for inspection and may be obtained at any of the OSM offices listed above.

Public Comment Period

The comment period on the proposed rule will extend to February 4, 1982. All written comments must be received at the appropriate address given in "ADDRESSES" by 5:00 p.m. on February 4, 1982. Comments received after that hour will not be considered or included in the administrative record for this rulemaking. The Office cannot insure that written comments delivered during the comment period to any location other than those specified above will be considered and included in the administrative record for this rulemaking.

OSM also invites public coment on the need to modify these rules for Massachusetts, Michigan, Oregon, and Rhode Island, taking into consideration:

1. Each State's soils, topography, climate, and biological, chemical, geological, hydrological, agronomic and other relevant physical conditions in accordance with Section 504(a) of SMCRA and 30 CFR 736.22(a)(1).

2. Any provision of any State law or regulation which provides for more stringent land use and environmental control and regulation of coal exploration operations than those otherwise provided by the Act and the permanent program rules in accordance with Section 505(b) of the Act and 30 CFR 736.22(a) and (b). Such provisions will be incorporated into the regulations creating the appropriate State-specific Federal coal exploration program. Such incorporation will provide better

continuity of existing operations during the transition from any State regulation to Federal regulation. It will also provide for better coordination with other State agencies which have responsibilities relating to the regulation of coal exploration operations. Adoption of provisions of State laws and regulations which establish more stringent standards as part of a program will result in OSM enforcement of those standards. All of the revisions to the permanent program regulations to incorporate provisions of existing State statutes and regulations will be identified by section in a detailed explanation within the preamble to the final State-specific program rules.

3. Provisions that are necessary to implement the requirements of 30 CFR 736.22(a)(2) regarding the Endangered Species Act of 1973, as amended (16 U.S.C. 531 *et seq.), the Fish and Wildlife Coordination Act, as amended (16 U.S.C. 661–666c), the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. 469a), the Clean Air Act, as amended (42 U.S.C. 7401 et seq.* and other relevant Federal laws imposing duties upon the Secretary.

4. Provisions of existing State statutes or regulations which provide standards equivalent to SMCRA and the permanent regulatory program rules contained in 30 CFR Chapter VII. Wherever practicable, OSM will incorporate into the specific rules for each of the four States any such provisions identified. Such incorporation will provide better continuity for existing operations during the transition from any State regulation to Federal regulation. It will also provide for better coordination with other State agencies which have responsbilities relating to the regulation of coal exploration operations. Adoption of provisions of State laws and regulations establish equivalent standards as part of a program will result in OSM enforcement of those standards. All of the variations from the standard permanent program regulations to incorporate provisions of existing State statutes and regulations will be identified by section in a detailed explanation within the preamble to the final State-specific program rules.

5. State statutes or regulations of the four States that are directly inconsistent with, or which interfere with, the purposes and requirements of the Act and the Federal program. Such statutes will be superseded by the rules promulgated under the Federal program in accordance with Section 504(g) of the Act and 30 CFR 736.23. Any such superseded State statutes and regulations will be specifically identified in the final rulemaking notice.

All written comments received by OSM will be available for public review at the addresses listed in "ADDRESSES" and those listed below:

For Massachusetts: Department of Environmental Quality Engineering, Division of Waterways, 100 Nashua Street, Room 534, Boston, Massachusetts 02114, Contact: Joseph Sinnot.

For Rhode Island: Rhode Island State Library, State House, Providence, Rhode Island 02903, Contact: Jean Nocera.

For Michigan: Geological Survey Division, Reclamation and Minning Control Unit Room, Division of Natural Resources, Stevens T. Mason Building, Allegon & Pine Streets, 4th Floor, Lansing, Michigan 48909, Contact: Thomas Segall.

For Oregon: State Librarian, Oregon State Library Building, Court Street, Salem, Oregon 97310.

Public Hearings

Public hearings will be held in each of the four States at the times and locations listed below. Individual testimony at the hearings will be limited to 15 minutes. The hearings will be transcribed. Filing of a written statement at the time of giving oral testimony would be helpful and would assist the court reporter. Whenever possible, submission of written statements in advance of the hearing dates to the person identified above under "FOR FURTHER INFORMATION CONTACT" would greatly assist the court reporter and OSM officials who will attend the hearings. Advance submissions will give OSM officials an opportunity to consider appropriate questions which could be asked to clarify or elicit more specific information from the person testifying.

Persons in the audience who have not been scheduled to speak but wish to do so will be heard after the scheduled speakers, if they are present when all scehduled speakers conclude.

Public hearings will be held at the following locations:

Michigan

Address and Date/Time

Stevens T. Mason Bulding, Allegon and Pine Streets, Fourth Floor, Geological Survey Division Conference Room, Lansing, Michigan 48909—January 28, 1982, 1 p.m.–5 p.m.

Massachusetts

John F. Kennedy Federal Building, Government Center, Room 307, Boston, Massachusetts 02203—January 26, 1982, 1 p.m.–5 p.m.

Rhode Island

Pastore Building, Room 215 L (Conference Room), Providence, Rhode Island—January 27, 1982, 1 p.m.–5 p.m.

Oregon

Federal Building, 1220 Southwest 3rd St., Room 335, Portland, Oregon 97204—January 26, 1982, 7 p.m.

Cloverleaf Hall, County Fairground, Wallowa County, Enterprise, Oregon—January 28, 1982, 7:30 p.m.

Public Meetings

Representatives of OSM will be available to meet between January 5, 1982, and February 4, 1982 at the request of any person or organization to receive advice and recommendations concerning the proposed regulations. The request may be made either at the appropriate Regional Office or the Washington office. OSM represntatives will be available for such meetings from 8:00 a.m. to 4:30 p.m. local time, Monday through Friday (excluding holidays) at the locations listed above. Summaries of meetings will be prepared and made promptly available for public review at the addresses listed above under "AVAILABILITY OF COPIES."

OMB Review

The recordkeeping and reporting requirements under the proposed rules are the same as those of the permanent program regulations, which were approved by the Office of Management and Budget under 44 U.S.C. 3507 and assigned clearance numbers as follows:

OMB Clearance Numbers

Part and Clearance No.

700—1029–0020
701—N/A
761—1029–0029
762—N/A
764—1029–0030
770—N/A
776—1029–0033
787—N/A
800—1029–0043
805—1029–0044
806—1029–0045
809—N/A
815—N/A
840—1029–0051
843—1029–0052
845—1029–0053

Forms for use in implementing the recordkeeping and reporting requirements of the program are being developed. All forms that will affect ten or more persons will be cleared with the

Office of Management and Budget, with accompanying notices in the **Federal Register**, in accordance with the requirements of 44 U.S.C. Chapter 35.

Content and Organization of the Program

The proposed rules are based on provisions of the permanent program regulations applicable to coal exploration as follows:

30 CFR Subchapter A—General.
30 CFR Subchapter G—Surface Coal Mining and Reclamation Operations Permits and Coal Exploration Systems Under Regulatory Programs.
30 CFR Subchapter K—Permanent Program Performance Standards.
30 CFR Subchapter L—Inspection and Enforcement.

The following types of variations from the model language would be made in these subchapters:

a. *Editorial changes.* Provisions that provide guidance for development of permanent regulatory programs other than Federal programs would be omitted except where they contain language critical to an understanding of subsequent provisions. Examples of such omissions include many of the sections entitled "Scope," "Applicability," and "Responsibility." Such sections would be retained because the initial Federal programs for Massachusetts, Michigan, Oregon, and Rhode Island would regulate coal exploration but not mining operations. Language modifications would be made throughout all Subchapters to make the proposed rules applicable to coal exploration operations only. Examples of such modifications include the substitution of "coal exploration" for "surface coal mining and reclamation," the use of "coal exploration approval" instead of "mining permit," and of "prospector" for "permittees." Provisions that apply only to approved State programs under Section 503 or the Federal lands program would also be deleted.

b. *Substantive revisions to procedures or standards.* Proposed substantive revisions to procedures or standards are discussed below to enable the reviewer to understand the rationale behind the proposed provisions and, where appropriate, alternatives considered by OSM.

c. *New procedures and standards.* Discussion is provided on proposed new procedures or standards developed by OSM which provide for discretion in implementing the permanent program regaulations. Also discussed are provisions for establishing compatibility with other Federal or State statutes or regulations. The numbering system of the permanent program regulations has been incorporated into the numbering system for the proposed programs. Program elements have been categorized under headings similar to the Subchapter titles. Subchapter T in 30 CFR Chapter VII has been established to include regulatory programs by State. Each State is assigned a separate part number. The proposed programs for Massachusetts, Michigan, Oregon, and Rhode Island would be assigned Parts 921, 922, 937, and 939, respectively. In addition to the proposed rules, the Federal regulatory programs for the four States would include:

30 CFR Subchapter P—Protection of Employees.
30 CFR Part 706—Restriction of Financial Interest of Federal Employees.

Those provisions are applicable to all regulatory programs under 30 CFR Chapter VII and would not be modified for application in any specific State.

Coal exploration on Federal lands is governed by Section 4 of the Federal Coal Leasing Amendments Act of 1975 (90 Stat. 1085, 30 U.S.C. 201(b)) and applicable regulations (43 CFR Part 3041) and is administered by the U.S. Geological Survey.

Many of the proposed general rules are identical to the provisions of the permanent program regulations. However, OSM intends to amend any rule in this proposal which is similar to a suspended rule in the national program regulation to adopt the new final permanent program rule when it becomes effective. The notices concerning those other proposed rule changes will indicate when the change is proposed to be incorporated in any of the Federal coal exploration programs. Comment is invited on the applicability of those provisions to the four States in accordance with the requirements of 30 CFR 736.22(a)(1), 736.22(a)(3) and 736.23(b), as described above.

This rulemaking is not the appropriate forum for seeking changes to the permanent program regulations. Comments submitted that are not relevant to the proposed rules will not be considered. Should a reviewer wish to suggest changes to the permanent program regulations, he or she may file a petition with the Director under 30 CFR 700.12, requesting a rulemaking for the issuance, amendment, or repeal of any regulation under the national permanent program regulations.

Detailed Discussion

General

Subparts 9—.701–4 through 9—.701–12 are similar to 30 CFR Subchapter A, General. The proposed rules would vary from the permanent program rules in the following respects:

Section 9—.701–4 would prescribe the authorities delegated by the Secretary to the Director in 30 CFR Part 736. That section also would reserve to the Secretary certain responsibilities and allows the Director to delegate certain responsibilities to other OSM officials. Delegations of responsibilities by the Director would be made through the OSM directives system and would be made available for public review at the Regional Offices and the Washington office at the addresses shown above. This differs in the sense that Subchapter A, General, of the permanent program regulations applies to the national permanent regulatory program and this section relates only to the authorities and sections for Federal and exploratory programs.

Section 9—.701–5 would contain all applicable definitions from 30 CFR 700.5 and 701.5. Some of the permanent program definitions would be dropped. Most, however, would be retained even though they may not be used in the coal exploration program because they will be needed when and if a complete Federal program is implemented.

The phrase "exploration area" would replace "permit area" in this proposal. As no permit for coal exploration is contemplated, "exploration area" is more descriptive of the land affected by the prospecting activities. The term also would be defined in § 9—.770–5. For the same reason, the term "prospector" would be used in place of "permittee" in Part 9—.843. Since no permits for coal exploration are contemplated in a Federal coal exploration program, "permittee" does not appropriately describe the person who conducts coal exploration activities.

The definition of road in these proposed rules would not include the references to different classes of roads which are contained in 30 CFR 701.5. Although these references have not been deleted from the permanent program definitions, they are now meaningless, because the road classification system was remanded by the District Court and suspended by the Secretary.

The references in § 9—.701.11(a) to the two-acre rule have been omitted in this rule. OSM does not believe that the two-acre rules applies to exploration operations. Section 528(2) of the Act does not mention exploration operations, and 30 CFR 700.11(b) applies only to surface coal mining and reclamation operations. Section 9—.701–11(a)(1) and (2) have been deleted as well. Coal removal as a part of highway construction or the extraction of other

minerals has no application in exploration operations. Section 9—.701–11(a) (1) and (2) have been deleted as well. Coal removal as a part of highway construction and the extraction of other minerals have no application in exploration operations.

Proposed § 9—.701–11(b) would provide that the regulatory authority "shall" grant an exemption from the design requirements where the requisite findings are made. This proposal differs from the February 6, 1980 proposed permanent program rule on existing structures (44 FR 8241–8245). Thus, the February 6, 1980 rule would, like the suspended rule, provide that the regulatory authority "may" grant the exemption. Although the intent of the February 6, 1980 proposed rule was to give operators a right to the exemption where the requisite findings are made, rather than giving the regulatory authority discretion not to grant the exemption under those circumstances, its wording would not make this clear. For purposes of greater clarity, proposed rule § 9—.701–11(b) would use the word "shall" instead of "may" the first time it appears in both paragraphs (1) and (2). However, this is not intended to allow the exemption to be granted without the requisite findings being made; it is simply to clarify that where the findings are made, the prospector is entitled to the exemption.

Section 9—.701–16 would note that the Federal exploration program for a State would terminate in accord with 30 CFR 736.16 upon approval of a State program for that State under 30 CFR Part 732.

Areas Unsuitable for Mining

Because petitions to designate areas unsuitable for coal mining cannot be accepted for a period of one year following the date of the implementation of a Federal program for a State (Sec. 504(a) of the Act), the regulations found at 30 CFR Subchapter F would simply be cross-referenced in these regulations. However, this would in no way restrict the petitioning process, since this exploration program would constitute a "Federal program" within the meaning of Section 504(a) of the Act. Therefore, the petitioning process will become available in each of these States one year after the effective date of the applicable Federal exploration program. The process will be the same as that used in State programs.

This approach would allow the Office to reduce the volume of regulations in this proposal. However, if a full Federal or a State program is promulgated in the future, a complete section on areas unsuitable for mining could be included. OSM solicits comments on whether this cross reference is adequate.

Coal Exploration Approvals

Proposed Subparts 9—.770, 776, and 787 would be similar to 30 CFR Subchapter G, Surface Coal Mining and Reclamation Operations Permits and Coal Exploration Systems. The following substantive variations from the permanent program regulations are proposed:

Section 9—.776.11 General requirements: Exploration affecting less than 250 tons. Language would be added under § 9—.776.11(b)(3), (b)(5), (b)(6), (b)(7), and (b)(8) to require the submission of additional information in the notice of intent where exploration will result in removal of less than 250 tons. The Office considers the additional information necessary to enable it and the public to identify the intended area of exploration on the ground, and to indicate all lands disturbed in exploration, including excavations, roads, and drill holes and the removal of necessary facilities and equipment.

Section 9—.776–12 General requirements: Exploration resulting in removal of more than 250 tons.

This Subsection, § 9—.776–12(b)(i), is designed to implement Sections 102(i) and 517 of the Act by providing for fully informed decisions on applications by the Office. The permanent program regulations allow the regulatory authority latitude to set the time limit within which a public notice of filing of the application shall be posted. This Subsection would set the time limit for posting such notice at one week after the Office has determined the application to be complete. The Office has proposed this time period because, until the application is determined to be complete, it can be changed by submission of additional information by the applicant. Once the application is determined to be complete, public notice should be afforded as soon as practicable.

Under § 9—.776–12(b)(3) of the permanent program regulation, any person with an interest which is or may be affected shall have the right to file written comments on the application within "reasonable" time limits. The proposed Subsection would set a time limit of 30 days for such written comment. The Office considered shorter and longer periods for submission of comments. A shorter period (10 days) would not allow sufficient public notice to comply with statutory mandates. A longer period (30–50 daya) could burden the processing of the application.

Section 9—.776–13 Applications: Approval or disapproval of exploration of more than 250 tons.

In § 9—.776–13(a), the regulatory authority has a reasonable time to act upon a completed application. This proposal would limit the time period to 60 days with no more than one extension of a maximum 30-day period. This period is based on an estimate of the time necessary to: (1) Determine whether the operation can comply with the performance standards of Part 815; (2) allow public participation; and (3) find that interests covered under the Endangered Species Act and the National Historic Preservation Act of 1966 will be adequately protected. The Office considered proposing a 30-day period and a 90-day period. The 30-day period was tentatively rejected as not allowing sufficient time to review the contents of the application and to have adequate public participation. The 90-day period was also tentatively rejected as imposing an undue delay on the applicant.

Since 30 CFR Part 788 would not be made a part of the Federal coal exploration system, a separate Subsection (c) would be added to § 9—.776–13 to incorporate the provisions of that part on review, revision, and renewal of approvals for exploration, and on transfer, sale, and assignment of rights granted under an exploration approval.

A Subsection (d) also would be added to establish a maximum duration of approval of 2 years, with an option for renewal for successive two-year periods upon reapplication. This subsection would set a time limit more in keeping with exploration activities. The permanent program regulations set longer periods for mining and reclamation permits because of the more extensive type of operation.

Performance Standards

Subpart 9—.815 would establish the same provisions, where applicable, as 30 CFR Subchapter K, Permanent Program Performance Standards. Because §§ 816.170 through 816.176, and 816.150 through 815.166 have been suspended, the prospector must meet the requirements of Sections 512(a) and 515(b) (17 and 18) of the Act. Where performance standards are based on the permanent program regulations, the latter are referred to rather than repeated in full text in this subpart. OSM requests comment on the adequacy of referring to these performance standards rather than printing their full text in this subpart.

Inspection and Enforcement

Proposed Subparts 9—.842 through 9—.845 would be similar to 30 CFR Subchapter L of the permanent program (Inspection and Enforcement Procedures). The proposed rules would vary from the permanent program rules in the following respects:

Language would be added to §§ 9—.842–16(b), 9—.843–13(c), and 9—.843–14(d) to assure that the State agencies having primary responsibilities for various aspects of exploration will receive copies of all required records, reports, inspection materials, or other information, including copies of show cause orders and notices of violation. This would be a courtesy to the State agencies. OSM considered not notifying the State agency, but felt that the State would not be recognized as an interested party in enforcement actions taken against explorations within its jurisdiction if copies were not provided. OSM also considered providing the State with copies of only specific enforcement actions, but felt that any separation would be arbitrary and would not recognize the State as an interested party.

This differs from the permanent program rules, in that under those rules copies of documents are provided to a State regulatory authority, if there is one. The proposed rules would ensure that State agencies having "primary responsibility" for various aspects of exploration would receive copies.

The proposed rules at § 9—.845 would provide the same civil penalty point system as that under the permanent program. The Office solicits comments concerning the usefulness of applying the point system in Federal coal exploration programs. Given the smaller risks of environmental degradation posed by exploration operations as compared with active mining, the point system may be unnecessarily burdensome to persons conducting exploration.

The OSM point system, a discussion of advantages of a point system compared to other civil penalty systems, and an alternative to the point system are described below.

OSM's assessment system includes: (1) Reviewing the facts surrounding each violation; (2) assigning points with respect to each of the four statutory assessment criteria; and (3) adding the points and converting the total to a dollar value. The assessment criteria with respect to which points are assigned are mandated by Section 518(a) of the Act and are more completely described in the OSM Assessment Manual.[1]

The principal advantages of a point system are that it provides a framework which allows any person who has access to the facts relevant to the violation to derive the same or a similar assessment as the person responsible for actually assessing the violation, and that it allows for gradations of penalties depending on factual situations. Thus, a point system is likely to be more accurate and objective than other systems for assessing penalties.

Another advantage of using OSM's point system to determine penalties is that it is familiar to coal mine operators. The Mine Safety and Health Administration (MSHA) has used a similar point system since 1974. There are two basic differences between OSM's system and MSHA's system: (1) OSM's system sets the dollar values of the points higher than MSHA's and (2) MSHA considers size of operation in determining the amount of the penalty. OSM does not consider size of operation because that is not one of the criteria listed in Section 518(a) of the Act, and the legislative history of the Act makes it clear that size cannot be used as a criterion in determining the amount of penalty. (MSHA is legislation specifically requires the agency to consider size in its assessment of penalties).

Point systems have been challenged in court and upheld. The Supreme Court in *Kleppe* v. *Delta Mining*, 423 U.S. 403, 408 n. 2 (1976), commented favorably on MSHA's use of a point system. The Court stated that use of the point system allowed anyone to see what consideration had been given to each assessment criterion. Prior to the use of the point system, MSHA's assessments had been criticized as being inconsistent and subjective. Further, the Comptroller General had criticized MSHA's assessment system, saying that the Comptroller was "unable to determine the adequacy of the consideration given the (assessment factors) and the basis for the penalties assessed in * * * sample cases." The application of a point system to the facts surrounding each violation results in more objective and consistent civil penalty assessments.

Inconsistent fines may result if assessment criteria are used without a point system. The amount of the penalty appropriate to any given set of facts is the subject of much debate. There is little agreement on what the "right" amount for a penalty is. Given the lack of agreement on size of penalties, a rational, objective system is very important.

One alternative to a point system which utilize the assessment factors listed in Section 518(a) of the Act might be a system whereby the civil penalty would be set at a fixed amount by type of violation, unless there were unusual factors in the specific case. For example, the standard civil penalty for failure to have all surface drainage pass through a sediment pond could be set at $500 unless the operator had been previously warned and had failed to heed the warning. Failure to heed the warning would indicate that the amount of the penalty should be raised. On the other hand, should the drainage area be very small, the amount of the penalty might be reduced. Such a system would give an operator little incentive to comply (voluntarily) with certain standards until the site was inspected, unless the operator could anticipate receiving a civil penalty for each violation. Thus, it might be necessary to set fixed civil penalties for virtually all violations. In order to provide guidance to assessors and conference officers under such a system an elaborate violations/penalties schedule would need to be developed. This could prove difficult for OSM to develop and more difficult still for operators to understand. A potential defect of this alternative is that it may not adequately ensure consideration of the four statutory criteria in Section 518(a). OSM solicits comment on this alternative or other alternatives to the point system.

Other Information

The Secretary has determined that this document is not a major rule and does not require a regulatory impact analysis under Executive Order 12291. The Secretary has also determined that this document will not have a significant economic effect on a substantial number of small entities and therefore does not require a regulatory flexibility analysis under Pub. L. 96–354. Furthermore, in accordance with Section 702(d) of the Act, neither an environmental impact statement nor an environmental assessment will be prepared.

Daniel N. Miller,

Assistant Secretary, Energy and Minerals.

OSM proposes to amend 30 CFR Chapter VII by adding Parts 921, 922, 937 and 939, each of which would contain the following provisions:

[1] OSM has contracted with a firm to make the Assessment Manual available to operators for a small charge. It is available from ACRA, Inc., 1000 Vermont Avenue, NW., Washington, D.C. 20005 (202) 347–9100. Amount of the penalty.

PART 9—[NAME OF STATE]

General

Subpart 9—.701—General

Sec.
9—.701–3 Authority and scope.
9—.701–4 Responsibility.
9—.701–5 Definitions.
9—.701–11 Applicability.
9—.701–12 Petitions to initiate rulemaking.
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Areas Unsuitable for Mining

9—.760 General.

Coal Exploration

Subpart 9—.770—General Requirements for Exploration

9—.770–4 Responsibilities.
9—.770–5 Definitions.
9—.770–12 Coordination with requirements under other laws.

Subpart 9—.776—General Requirements For Coal Exploration

9—.776–11 General requirements: Exploration affecting less than 250 tons.
9—.776–12 General requirements: Exploration affecting less than 250 tons.
9—.776–13 Applications: Approval or disapproval of exploration affecting more than 250 tons.
9—.776–14 Applications: Notice and hearing for exploration of more than 250 tons.
9—.776–15 Requirements for exploration operations.
9—.776–17 Public availability of information.

Subpart 9—.787—Administrative and Judicial Review of Decisions on Coal Exploration

9—.787–11 Administrative review.
9—.787–12 Judicial review.

Performance Standards

Subpart 9—.815—Performance Standards—Coal Exploration

9—.815–11 General responsibility of persons conducting coal exploration.
9—.815–13 Required documents.
9—.815–15 Performance standards for coal exploration.

Inspection and Enforcement Procedures

Subpart 9—.842—Federal Inspections

9—.842–11 Federal inspections.
9—.842–12 Citizens' requests for Federal inspections.
9—.842–13 Right of entry.
9—.842–14 Review of adequacy and completeness of inspections.
9—.842–15 Review of decision not to inspect or enforce.
9—.842–16 Availability of records.

Subpart 9—.843—Federal Enforcement

9—.843–11 Cessation orders.
9—.843–12 Notices of violation.
9—.843–13 Suspension or revocation of approvals.
9—.843–14 Service of notices of violations, cessation orders, and show cause orders.
9—.843–15 Informal public hearing.
9—.843–16 Formal review of citations.
9—.843–17 Lack of information.
9—.843–18 Inability to comply.
9—.843–19 Injunctive relief.

Subpart 9—.845—Civil Penalties

9—.845–11 How assessments are made.
9—.845–12 When penalty will be assessed.
9—.845–13 Point system for penalties.
9—.845–14 Determination of amount of penalty.
9—.845–15 Assessment of separate violations for each day.
9—.845–16 Waiver of use of formula to determine civil penalty.
9—.845–17 Procedures for assessment of civil penalties.
9—.845–18 Procedures for assessment conference.
9—.845–19 Request for hearing.
9—.845–20 Final assessment and payment of penalty.

Authority: Pub. L. 95–87, the Surface Mining Control and Reclamation Act of 1977, (30 U.S.C. 1201 *et seq.*)

General

Subpart 9—.701—General

§ 9—.701–3 Authority and scope.

(a) The Secretary is required by Sections 504(a) and 512 of the Surface Mining Control and Reclamation Act of 1977 (the Act) to prepare, promulgate, and implement a Federal coal exploration program for the State of (insert) because it failed to submit a program by March 3, 1980 in accordance with Section 504(a) of the Act, 30 CFR Part 736, and the July 25, 1979, and August 21, 1979, opinions of the District Court for the District of Columbia, *In re: Permanent Surface Mining Regulation Litigation*, 13 ERC 1447 and 1586.

(b) The following regulations apply to the Federal coal exploration program in the State of (insert):

(1) Subparts 9—.770, 9—.776 and 9—.787 regarding the requirements for coal exploration and the administrative and judicial review of decisions on exploration applications;

(2) Subpart 9—.815 regarding performance standards and design requirements which apply to coal exploration;

(3) Subparts 9—.842 through 9—.845 regarding inspection and enforcement and civil penalties under the program;

(4) 30 CFR Part 865 regarding protection of employees; and

(5) 30 CFR Part 706 on restriction of financial interests of Federal employees.

§ 9—.701–4 Responsibility.

(a) The Director of the Office of Surface Mining shall assume primary responsibility for the regulation of coal exploration (30 days after final rulemaking) on non-Federal and non-Indian lands in the State of (insert) in accordance with Sections 504 and 512 of the Act and 30 CFR Part 736. The Director has responsibility for: ensuring that every person who wants to conduct exploration operations files a notice of intention to explore; reviewing and approving coal exploration which removes more than 250 tons of coal from the earth in any one location and substantially disturbs the natural land surface; and, for ensuring adequate inspection and enforcement of all coal exploration operations for compliance with exploration approvals issued under this program, except where the primary responsibility has been retained by the Secretary as specified in this program. The Director may delegate all or any part of his responsibilities to any other official of the Office of Surface Mining.

§ 9—.701–5 Definitions.

As used in this part, the following terms have the specified meanings, except where otherwise indicated:

Acid drainage means water with a pH of less than 6.0 and in which total acidity exceeds total alkalinity, discharged from an area affected by coal exploration.

Acid-forming materials means earth materials that contain sulfide minerals or other materials which, if exposed to air, water, or weathering processes, from acids that may create acid drainage.

Act means the Surface Mining Control and Reclamation Act of 1977 (Pub. L. 95–87, 30 U.S.C. 1201 *et seq.*).

Adjacent area means lands located outside the area of exploration activity, where air, surface or ground water, fish, wildlife, vegetation or other resources protected by the Act may be adversely affected by coal exploration.

Agricultural activities means, with respect to alluvial valley floors, the use of any tract of land for the production of animal or vegetable life, where the use is enhanced or facilitated by subirrigation or flood irrigation associated with alluvial valley floors. These uses include, but are not limited to, the pasturing, grazing, or watering of livestock, and the cropping, cultivation, or harvesting of plants whose production is aided by the availability of water from subirrigation or flood irrigation. Those uses do not include agricultural practices which do not benefit from the availability of water from subirrigation or flood irrigation.

Agricultural use means the use of any tract of land for the production of animal or vegetable life. The uses

include, but are not limited to, the pasturing, grazing, and watering of livestock, and the cropping, cultivation, and harvesting of plants.

Alluvial valley floors means the unconsolidated stream-laid deposits holding streams with water availability sufficient for subirrigation or flood irrigation agricultural activities but does not include upland areas which are generally overlain by a thin veneer of colluvial deposits composed chiefly of debris from sheet erosion, deposits formed by unconcentrated runoff or slope wash, together with the talus, or other mass-movement accumlations, and windblown deposits.

Anthracite means coal classified as anthracite in ASTM Standard D 388–77. Coal classifications are published by the American Society of Testing and Materials under the title, *Standard Specification for Classification of Coals by Rank*, ASTM D 388–77, on pages 220 through 224. Table 1 which classifies the coal by rank is presented on page 223. This publication is hereby incorporated by references as it exists on the date of adoption of these regulations. Notices of changes made to this publication will be periodically published by the Office of Surface Mining in the Federal Register. This ASTM Standard is on file and available for inspection at the OSM Office, U.S. Department of the Interior, South Interior Building, Washington, D.C. 20240, at each OSM Regional Office, District Office, and Field Office. Copies of this publication may also be obtained by writing to the above locations. A copy of this publication will also be on file for public inspection at the Federal Register Library, 1100 L St. NW., Washington, D.C. Incorporation by reference provisions approved by the Director of the Federal Register, February 7, 1979. The Director's approval of this incorporation by reference expires on July 1, 1982.

Applicant means any person seeking approval from the Office to conduct coal exploration pursuant to this program.

Approximately original contour means that surface configuration achieved by backfilling and grading of the areas of exploration so that the reclaimed area, including any terracing or access roads, closely resembles the general surface configuration of the land prior to exploration and blends into and complements the drainage pattern of the surrounding terrain.

Aquifer means a zone, stratum, or group of strata that can store and transmit water in sufficient quantities for a specific use.

Arid and semiarid area means, in the context of alluvial valley floors, an area of the interior western United States, west of the 100th meridian west longitude, experiencing water deficits, where water use by native vegetation equals or exceeds that supplied by precipitation. All coalfields located in North Dakota west of the 100th meridian west longitude, all coalfields in Montana, Wyoming, Utah, Colorado, New Mexico, Idaho, Nevada, and Arizona, the Eagle Pass field in Texas, the eastern Oregon coal field and the Stone Canyon and the Ione fields in California are in arid and semirid areas.

Best technology currently available means equipment, devices, systems, methods, or techniques which will (a) prevent, to the extent possible, additional contributions of suspended solids to stream flow or runoff outside the area of exploration activity, but in no event result in contributions of suspended solids in excess of requirements set by applicable State or Federal laws; and (b) minimize, to the extent possible, disturbances and adverse impacts on fish, wildlife and related environmental values, and achieve enhancement of those resources where practicable. The term includes equipment, devices, systems, methods, or techniques which are currently available anywhere as determined by the Director, even if they are not in routine use. The term includes, but is not limited to, construction practices, siting requirements, vegetative selection and planting requirements, animal stocking requirements, scheduling of activities and design of sedimentation ponds in accordance with 30 CFR 816 and 817. The Director may determine the best technology currently available on a case-by-case basis.

Coal means combustible carbonaceous rock, classified as anthracite, bituminous, subbituminous, or lignite by ASTM Standard D 388–77, referred to and incorporated by reference in the definition of anthracite.

Coal exploration means the field gathering of: (a) Surface or subsurface geologic, physical, or chemical data by mapping, trenching, drilling, geophysical, or other techniques necessary to determine the quality and quantity of overburden and coal in an area; or (b) the gathering of environmental data to establish the conditions of an area before beginning surface coal mining and reclamation operations under the requirements of this part.

Combustible material means organic material that is capable of burning, either by fire or through oxidation, accompanied by the evolution of heat and a significant temperature rise.

Compaction means increasing the density of a material by reducing the voids between the particles and is generally accomplished by controlled placement and mechanical effort such as from repeated application of wheel, track, or roller loads from heavy equipment.

Cropland means land used for the production of adapted crops for harvest, alone or in a rotation with grasses and legumes, and includes row crops, small grain crops, hay crops, nursery crops, orchard crops, and other similar specialty crops.

Department means the Department of the Interior.

Director means the Director, Office of Surface Mining Reclamation and Enforcement, or the Director's representative.

Disturbed area means an area where vegetation, topsoil, or overburden is removed or upon which topsoil, spoil, or noncoal waste is placed by coal exploration operations. Those areas are classified as *disturbed* until reclamation is complete.

Diversion means a channel, embarkment, or other man-made structure constructed to divert water from one area to another.

Downslope means the land surface between the projected outcrop of the lowest coalbed being explored and a valley floor.

Embankment means an artificial deposit of material that is raised above the natural surface of the land and used to contain, divert, or store water, support roads or railways, or for other similar purposes.

Ephemeral stream means a stream which flows only in direct response to precipitation in the immediate watershed or in response to the melting of a cover of snow and ice, and which has a channel bottom that is always above the local water table.

Essential hydrologic functions means the role of an alluvial valley floor in collecting, storing, regulating, and making the natural flow of surface or ground water, or both, usefully available for agricultural activities by reason of the valley floor's topographic position, the landscape and the physical properties of its underlying materials. A combination of these functions provides a water supply during extended periods of low precipitation.

(a) The role of the valley floor in collecting water includes accumulating runoff and discharge from aquifers in sufficient amounts to make the water available at the alluvial valley floor greater than the amount available from direct precipitation.

(b) The role of the alluvial valley floor in storing water involves limiting the

rate of discharge of surface water, holding moisture in soils, and holding ground water in porous materials.

(c)(1) The role of the alluvial valley floor in regulating the natural flow of surface water results from the characteristic configuration of the channel flood plain and adjacent low terraces.

(2) The role of alluvial valley floor in regulating the natural flow of ground water results from the properties of the aquifers which control inflow and outflow.

(d) The role of the alluvial valley floor in making water usefully available for agricultural activities results from the existence of flood plains and terraces where surface and ground water can be provided in sufficient quantities to support the growth of agriculturally useful plants, from the presence of earth materials suitable for the growth of agriculturally useful plants, from the temporal and physical distribution of water making it accessible to plants throughout the critical phases of the growth cycle either by flood irrigation or by subirrigation, from the natural control of alluvial valley floors in limiting destructive extremes of stream discharge, and from the erosional stability of earth materials suitable for the growth of agriculturally useful plants.

Existing structure means a structure or facility used in connection with or to facilitate coal exploration operations for which construction began prior to the implementation of this Federal program.

Exploration area means, with respect to hydrology, the topographic and ground water basin surrounding the general vicinity of the proposed operations area, which is of sufficient size including areal extent and depth to include one or more watersheds containing perennial streams and ground water zones and to allow assessment of the probable cumulative impacts on the quality and quantity of surface and ground water systems in the basins.

Federal lands means any land, including mineral interests, owned by the United States, without regard to how the United States acquired ownership of the lands or which agency manages the lands. It does not include Indian lands. However, lands or mineral interests east of the 100th meridian west longitude owned by the United States and entrusted to or managed by the Tennessee Valley Authority are not subject to Sections 714 (surface owner protection) and 715 (Federal lessee protection) of the Act.

Federal program means a program established by the Secretary pursuant to Sections 504 and 512 of the Act to regulate coal exploration operations on non-Federal and non-Indian lands within a State in accordance wih the Act and 30 CFR Chapter VII.

Flood irrigation means, with respect to alluvial valley floors, supplying water to plants by natural overflow or the diversion of flows, so that the irrigated surface is largely covered by a sheet of water.

Fugitive dust means that particulate matter not emitted from a duct or stack which becomes airborne due to the forces of wind or coal exploration activities or both. During coal exploration operations it may include emissions from haul roads; wind erosion of exposed surfaces; emissions from reclamation operations; and emissions from other activities in which material is either removed, stored, transported, or redistributed.

Ground water means subsurface water that fills available openings in rock or soil materials to the extent that they are considered water saturated.

Half-shrub means a perennial plant with a woody base whose annually produced stems die back each year.

Highwall means the face of exposed overburden and/or coal in an open cut resulting from coal exploration.

Historically used for cropland means (a) lands that have been used for cropland for any 5 years or more out of the 10 years immediately preceding the acquisition, including purchase, lease, or option, of the land for the purpose of conducting or allowing through resale, lease or option the conduct of coal exploration and operations; (b) lands that the Office determines, on the basis of additional cropland history of the surrounding lands and the lands under consideration, that the exploration area is clearly cropland but falls outside the specific 5-years-in-10 criterion; or (c) lands that would likely have been used as cropland for any 5 out of the last 10 years immediately preceding such acquisition but for some fact of ownership or control of the land unrelated to the productivity of the land, in which case the regulations for prime farmland may be applied to include more years of cropland history only to increase the prime farmland acreage to be preserved.

Hydrologic balance means the relationship between the quality and quantity of water inflow to, water outflow from, and water storage in a hydrologic unit such as a drainage basin, aquifer, soil zone, lake, or reservoir. It encompasses the dynamic relationships among precipitation, runoff, evaporation, and changes in ground and surface water storage.

Hydrologic regime means the entire state of water movement in a given area. It is a function of the climate and includes the phenomena by which water first occurs as atmospheric water vapor, passes into a liquid or sold form, falls as precipitation, moves along or into the ground surface, and returns to the atmosphere as vapor by means of evaporation and transpiration.

Imminent danger to the health and safety of the public means the existence of any condition or practice, or any violation of an exploration approval or other requirements of the Act in a coal exploration operation, which could reasonably be expected to cause substantial physical harm to persons outside the approval area before the condition, practice, or violation can be abated. A reasonable expectation of death or serious injury before abatement exists if a rational person, subjected to the same condition or practice giving rise to the peril, would avoid exposure to the danger during the time necessary for abatement.

Impoundment means a closed basin, naturally formed or artificially built, which is dammed or excavated for the retention of water, sediment, or waste.

Indian lands means all lands, including mineral interests, within the exterior boundaries of any Federal Indian reservation, notwithstanding the issuance of any patent, and including rights-of-way, and all lands including mineral interests held in trust for or supervised by an Indian tribe.

Intermittent stream means—

(a) A stream or reach of a stream that drains a watershed of at least one square mile, or

(b) A stream or reach of a stream that is below the local water table for at least some part of the year, and obtains its flow from both surface runoff and ground water discharge.

Land use means specific uses or management-related activities, rather than the vegetation or cover of the land. Land uses may be identified in combination when joint or seasonal uses occur. Changes of land use or uses from one of the following categories to another shall be considered as a change to an alternative land use which is subject to approval by the Office.

(a) *Cropland.* Land used for the production of adapted crops for harvest, alone or in a rotation with grasses and legumes, and includes row crops, small grain crops, hay crops, nursery crops, orchard crops, and other similar specialty crops. Land used for facilities in support of cropland farming operations which is adjacent to or an integral part of these operations is also

included for purposes of these land use categories.

(b) *Pastureland or land occasionally cut for hay.* Land used primarily for the long-term production of adapted, domesticated forage plants to be grazed by livestock or occasionally cut and cured for livestock feed. Land used for facilities in support of pastureland or land occasionally cut for hay which is adjacent to or an integral part of these operations is also included.

(c) *Grazingland.* Includes both grasslands and forest lands where the indigenous vegetation is actively managed for grazing, browsing, or occasional hay production. Land used for facilities in support of ranching operations which are adjacent to or an integral part of these operations is also included.

(d) *Forestry.* Land used or managed for the long-term production of wood, wood fiber, or wood derived products. Land used for facilities in support of forest harvest and management operations which is adjacent to or an integral part of these operations is also included.

(e) *Residential.* Includes single- and multiple-family housing, mobile home parks, and other residential lodgings. Land used for facilities in support of residential operations which is adjacent to or an integral part of these operations is also included. Support facilities include, but are not limited to, vehicle parking and open space that directly relate to the residential use.

(f) *Industrial/Commercial.* Land used for—

(1) Extraction of transformation of materials for fabrication of products, wholesaling of products or for long-term storage of products. This includes all heavy and light manufacturing facilities such as lumber and wood processing, chemical manufacturing, petroleum refining, and fabricated metal products manufacture. Land used for facilities in support of these operations which is adjacent to or an integral part of that operation is also included. Support facilities include, but are not limited to, all rail, road, and other transportation facilities.

(2) Retail or trade of goods or services, including hotels, motels, stores, restaurants, and other commercial establishments. Land used for facilities in support of commercial operations which is adjacent to or an integral part of these operations is also included. Support facilities include, but are not limited to, parking, storage or shipping facilities.

(g) *Recreation.* Land used for public or private leisure-time use, including developed recreation facilities such as parks, camps, and amusement areas, as well as areas for less intensive uses such as hiking, canoeing, and other undeveloped recreational uses.

(h) *Fish and wildlife habitat.* Land dedicated wholly or partially to the production, protection or management of species of fish or wildlife.

(i) *Developed water resources.* Includes land used for storing water for beneficial uses such as stockponds, irrigation, fire protection, flood control, and water supply.

(j) *Undeveloped land or no current use or land management.* Land that is undeveloped or, if previously developed, land that has been allowed to return naturally to an undeveloped state or has been allowed to return to forest through natural succession.

Materially damage the quantity or quality of water means, with respect to alluvial valley floors, changes in the quality or quantity of the water supply to any portion of an alluvial valley floor where such changes are caused by coal exploration operations and result in changes that significantly and adversely affect the composition, diversity, or productivity of vegetation dependent on subirrigation, or which result in changes that would limit the adequacy of the water for flood irrigaion of the irrigable land acreage existing prior to mining.

Mulch means vegetation residues or other suitable materials that aid in soil stabilization and soil moisture conservation, thus providing micro-climatic conditions suitable for germination and growth.

Noxious plants means species that have been included on official State lists of noxious plants for the State in which the coal exploration operation occurs.

Office means the Office of Surface Mining Reclamation and Enforcement established under Title II of the Act.

Outslope means the face of the spoil or embankment sloping downward from the highest elevation to the toe.

Overburden means material of any nature, consolidated or unconsolidated, that overlies a coal deposit, excluding topsoil.

Perrenial stream means a stream or part of a stream that flows continuously during all of the calendar year as a result of groundwater discharge or surface runoff.

Permanent diversion means a diversion remaining after coal exploration operations are completed which has been approved for retention by the Office and other appropriate State and Federal agencies.

Person means any individual, any Indian tribe when conducting surface coal mining and reclamation operations on non-Indian lands, any partnership, association, society, joint venture, joint stock company, firm, company, corporation, cooperative or other business organization, and any agency, unit, or instrumentality of Federal, State or local government including any publicly owned utility or publicly owned corporation of Federal, State or local government.

Person having an interest which is or may be adversely affected or person with a valid legal interest shall include any person—

(a) Who uses any resource of economic, recreational, esthetic, or environmental value that may be adversely affectd by coal exploration or any related action of the Secretary, or

(b) Whose property is or may be adversely affected by coal exploration or any related action of the Secretary.

Precipitation event means a quantity of water resulting from drizzle, rain, snow, sleet, or hail in a limited period of time. It may be expressed in terms of recurrence interval. As used in these regulations, *precipitation event* also includes that quantity of water emanating from snow cover as snowmelt in a limited period of time.

Prime farmland means those lands which are defined by the Secretary of Agriculture in 7 CFR Part 657 (43 FR 4030, Jan. 3, 1978) and which have historically been used for cropland.

Prospector is a person conducting or proposing to conduct coal exploration.

Public office means a facility under the direction and control of a governmental entity which is open to the public on a regular basis during reasonable business hours.

Rangeland means land on which the natural potential (climax) plant cover is principally native grasses, forbs, and shrubs, valuable for forage. This land includes natural grasslands and savannahs, such as prairies, and juniper savannahs, such as brushlands. Except for brush control, management is primarily achieved by regulating the intensity of grazing and season of use.

Recharge capacity means the ability of the soils and underlying materials to allow precipitation and runoff to infiltrate and reach the zone of saturation.

Reclamation means those actions taken to restore explored land where exploration results in the removal of more than 250 tons to a postexploration land use approved by the Office, as required by this Part.

Recurrence interval means the interval of time in which a precipation event is expected to occur once, on the average. For example, the 10-year 24-hour precipitation event would be that

24-hour precipitation event expected to occur on the average once in 10 years.

Reference area means a land unit maintained under appropriate management for the purpose of measuring vegetative ground cover, productivity and plant species diversity that are produced naturally or by crop production methods approved by the Office. Reference areas must be prepresentative of geology, soil, slope, and vegetation in the approval area.

Regional Director means a Regional Director of the Office or a Regional Director's representative.

Regulatory authority means the Secretary when administering this Part.

Renewable resource lands means aquifers and areas for the recharge of aquifers and other underground waters, areas for agricultural or silvicultural production of food and fiber, and grazinglands.

Road means a surface right-of-way for purposes of travel by land vehicles used in coal exploration. A road consists of the entire area within the right-of-way, including the roadbed, shoulders, parking and side area, approaches, structures, ditches, surface and such contiguous appendages as are necessary for the total structure. The term includes access and land roads constructed, used, reconstructed, improved, or maintained for use in coal exploration, including use by coal hauling vehicles leading to transfer, processing, or storage areas.

Safety factor means the ratio of the available shear strength to the developed shear stress, or the ratio of the sum of the resisting forces to the sum of the loading or driving forces, as determined by accepted engineering practices.

Secretary means the Secretary of the Interior or the Secretary's representative.

Sedimentation pond means a primary sediment control structure designed, constructed and maintained in accordance with 30 CFR 816.46 and including but not limited to a barrier, dam, or excavated depression which slows down water runoff to allow sediment to settle out. A sedimentation pond shall not include secondary sedimentation control structures, such as straw dikes, riprap, check dams, mulches, dugouts and other measures that reduce overland flow velocity, reduce runoff volume or trap sediment, to the extent that such secondary sedimentation structures drain to a sedimentation pond.

Significant, imminent environmental harm to land, air or water resources means—

(a) An environmental harm is an adverse impact on land, air, or water resources including, but not limited to, plant and animal life.

(b) An environmental harm is imminent, if a condition, practice, or violation exists which—

(1) Is causing such harm; or,

(2) May reasonably be expected to cause such harm at any time before the end of the reasonable abatement time that would be set under Section 521(a)(3) of the Act, and is appreciable and not immediately reparable.

Slope means average inclination of a surface, measured from the horizontal, generally expressed as the ratio of a unit of vertical distance to a given number of units of horizontal distance (e.g., lv: 5th). It may also be expressed as a percentage or in degrees.

Soil horizons means contrasting layers of soil parallel or nearly parallel to the land surface. Soil horizons are differentiated on the basis of field characteristics and laboratory data. The three major soil horizons are—

(a) *A horizon.* The uppermost mineral layer, often called the surface soil. It is the part of the soil in which organic matter is most abundant, and leaching of soluble or suspended particles is typically the greatest.

(b) *B horizon.* The layer that typically is immediately beneath the A horizon and often called the subsoil. This middle layer commonly contains more clay, iron, or aluminum than the A or C horizons.

(c) *C horizon.* The deepest layer of soil profile. It consists of loose material or weather rock that is relatively unaffected by biologic activity.

Soil survey means a field or other investigation, resulting in a map showing the geographic distribution of different kinds of soils and an accompanying report that describes, classifies, and interprets such soils by use. Soil surveys must meet the standards of the National Cooperative Soil Survey as incorportate by reference in 30 CFR 785.17(b)(1).

Spoil means overburden that has been removed during coal exploration operations.

Stablize means to control movement of soil, spoil piles, or areas of disturbed earth by modifying the geometry of the mass, or by otherwise modifying physical or chemical properties, such as by providing a protective surface coating.

Steep slope means any slope of more than 20° or such lesser slope as may be designated by the Office after consideration of soil, climate, and other characteristic of a region or State.

Subirrigation means, with respect to alluvial valley floors, the supplying of water to plants from underneath or from a semi-saturated or saturated subsurface zone where water is available for use by vegetation. Subirrigation may be identified by:

(a) Diurnal fluctuation of the water table, due to the differences in night-time and daytime evapotranspiration rates;

(b) Increasing soil moisture from a portion of the root zone down to the saturated zone, due to capillary action;

(c) Mottling of the soils in the root zones;

(d) Existence of an important part of the root zone within the capillary fringe or water table of an alluvial aquifer; or

(e) An increase in streamflow or a rise in ground water levels, shortly after the first killing frost on the valley floor.

Substantially disturb means to impact significantly upon land, air, or water resources by such activities as blasting, mechanical excavation, drilling or altering coal or water exploratory holes, or wells, constructing roads and other access routes, and/or placing structures, excavated earth, or other debris on the surface of land.

Surface coal mining operations means—

(a) Activities conducted on the surface of lands in connection with a surface coal mine or, subject to the requirements of Section 516 of the Act, surface operations and surface impacts incident to an underground coal mine, the products of which enter commerce or the operations of which directly or indirectly affect interstate commerce. Such activities include excavation for the purpose of obtaining coal, including such common methods as contour, strip, auger, mountaintop removal, box cut, open pit, and area mining, the uses of explosives and blasting, and in situ distillation or retorting, leaching or other chemical or physical processing, and the cleaning, concentrating, or other processing or preparation, loading of coal for interstate commerce at or near the mine-site: *Provided,* These activities do not include the extraction of coal incidental to the extraction of other minerals, where coal does not exceed 16⅔ per centum of the tonnage of minerals removed for purposes of commercial use or sale, or coal exploration subject to Section 512 of the Act; *And provided further,* That excavation for the purpose of obtaining coal includes extraction of coal from coal refuse piles; and

(b) Areas upon which the activities described in paragraph (a) of this definition occur or where those

activities disturb the natural land surface. These area shall also include any adjacent the use of which is incidental to any such activities, all lands affected by the construction of new roads or the improvement or use of existing roads to gain access to the site of those activities and for haulage and excavation, workings, impoundments, dams, ventilation shafts, entryways, refuse banks, dumps, stockpiles, overburden piles, spoil banks, culm banks, tailings, holes or depressions, repair areas, storage areas, shipping areas, and other areas upon which are sited structures, facilities, or other property or material on the surface, resulting from or incident to those activities.

Surface coal mining and reclamation operations means surface coal mining operations and all activities necessary or incidental to the reclamation of such operations. This term includes the term surface coal mining operations.

Surface mining activities means those surface coal mining and reclamation operations incident to the extraction of coal from the earth by removing the materials over a coal seam, before recovering the coal, by auger coal mining, or by recovery of coal from a deposit that is not in its original geologic location.

Suspended solids or nonfilterable residue, expressed as milligrams per liter, means organic or inorganic materials carried or held in suspension in water which are retained by a standard glass fiber filter in the procedure outlined by the Environmental Protection Agency's regulations for waste water and analyses (40 CFR Part 136).

Temporary diversion means a diversion of a stream or overland flow during coal exploration operations which has not been approved by the Office postmining land use.

Topsoil means the A soil horizon layer of the three major soil horizons.

Toxic-forming materials means earth materials or wastes which, if acted upon by air, water, weathering, or microbiological processes, are likely to produce chemical or physical conditions in soils or water that are detrimental to biota or uses of water.

Toxic mine drainage means water that is discharged from active or abandoned mines or other areas affected by coal exploration, which contains a substance that through chemical action or physical effects is likely to kill, injure, or impair biota commonly present in the area that might be exposed to it.

Unconsolidated streamlaid deposits holding streams means, with respect to alluvial valley floors, all flood plains and terraces located in the lower portions of topographic valleys which contain perennial or other streams with channels that are greater than 3 feet in bankfull width and greater than 0.5 feet in bankfull depth.

Undeveloped rangeland means, for purposes of alluvial valley floors, lands where the use is not specifically controlled and managed.

Upland areas means, with respect to alluvial valley floors, those geomorphic features located outside the floodplain and terrace complex, such as isolated higher terraces, alluvial fans, pediment surfaces, landslide deposits, and surfaces covered with residuum, mud flows or debris flows, as well as highland areas underlain by bedrock and covered by residual weathered material or debris deposited by sheetwash, rillwash, or windblown material.

Valley fill means a fill structure consisting of any material other than coal waste and organic material that is placed in a valley where side slopes of the existing valley measured at the steepest point are greater than 20° or the average slope of the profile of the valley from the toe of the fill to the top of the fill is greater than 10°.

Water table means the upper surface of a zone of saturation, where the body of ground water is not confined by an overlying impermeable zone.

§ 9—.701–11 Applicability.

(a) This part applies to all coal exploration operations within the State of (insert) except exploration for coal on Indian or Federal lands.

(b) Each structure used in connection with or to facilitate a coal exploration operation shall comply with the performance standards and the design requirements of Subpart 9—.815 of this part, except that—

(1) An existing structure which meets the performance standards of Subpart 9—.815 of this part but does not meet the design requirements of Subpart 9—.815 of this part shall be exempted from meeting those design requirements by the Office. The Office may grant this exemption only as part of the coal exploration approval process after obtaining the information required by 30 CFR 9—.776.

(2) If the performance standards of 30 CFR Subchapter B are at least as stringent as the comparable performance standard of Subpart 9—.815 of this part, an existing structure which meets the performance standards of 30 CFR Subchapter B shall be exempted by the Office from meeting the design requirements of Subpart 9—.815 of this part. The Office may grant this exemption only as part of the coal exploration approval process after obtaining the information required by 30 CFR 9—.776.

(3) Where exploration will result in removal of more than 250 tons as required in § 9—.776–13, an existing structure which meets a performance standard of 30 CFR Subchapter B which is less stringent than the comparable performance standards of Subpart 9—.815 of this part or which does not meet a performance standard of Subpart 9—.815 of this part for which there was no equivalent performance standard in 30 CFR Subchapter B, shall be modified or reconstructed to meet the design standard of Subpart 9—.815 of this part pursuant to a compliance plan approved by the Office in the coal exploration approval after making the findings required by 30 CFR 786–21.

(4) An existing structure which does not meet the performance standards of 30 CFR Subchapter B and which the applicant proposes to use in connection with or to facilitate the coal exploration operation shall be modified or reconstructed to meet the design standards of Subpart 9—.815 of this part prior to issuance of the exploration approval.

(c)(1) Any person conducting coal exploration on non-Federal and non-Indian lands on or after the effective date of this part shall either file a notice of intention to explore or obtain approval of the Office as required by 30 CFR 9—.776.

(2) Two months after the effective date of this part, coal exploration performance standards in 30 CFR 9—.815 shall apply to coal exploration on non-Federal and non-Indian lands which substantially disturbs the natural land surface.

§ 9—.701–12 Petitions to initiate rulemaking.

The provisions of 30 CFR 700.12 provide the means by which petitions by the public to initiate rulemaking may be made.

§ 9—.701–13 Notice of citizen suits.

The provisions of 30 CFR 700.13 provide the means for giving notice of citizen suits.

§ 9—.701–14 Availability of records.

(a) Records required by the Act to be made available locally to the public shall be retained at the (name and address to be inserted).

(b) Other records or documents in the possession of the Office may be requested under 43 CFR Part 2, which

implements the Freedom of Information Act and the Privacy Act.

§ 9—.701-15 Computation of time.

(a) Except as otherwise provided, computation of time under this part is based on calendar days.

(b) In computing any period of prescribed time, the day on which the designated period of time begins is not included. The last day of the period is included unless it is a Saturday, Sunday, or legal holiday on which the Office is not open for business, in which event the period runs until the end of the next day which is not a Saturday, Sunday, or legal holiday.

(c) Intermediate Saturdays, Sundays, and legal holidays are excluded from the computation when the period of prescribed time is 7 days or less.

§ 9—.701-16 Termination of the program.

This program shall terminate upon approval of a State program for the State of (insert) under 30 CFR Part 732. The Federal program in the State of (insert) shall not be considered terminated until a State program for the State of (insert) has been approved by the Secretary in accordance with 30 CFR Part 732.

Areas Unsuitable for Mining

§ 9—.760— General.

Any person who intends to petition to designate an area unsuitable for mining should follow 30 CFR Part 764. Petitions may be filed one year after the effective date of this rule.

Coal Exploration

Subpart 9—.770—General Requirements for Exploration

§ 9—.770-4 Responsibilities.

(a) Persons seeking to conduct coal exploration must file a notice of intention or obtain approval of the Office as required under 30 CFR 9—.776 before commencing exploration.

(b) The Office shall review each application for exploration approval and petition for lands unsuitable, approve or disapprove each exploration application, and issue, condition, suspend, or revoke each exploration application.

§ 9—.770-5 Definitions.

As used throughout Subparts 9—.770, 9—.776 and 9—.787 of this part, except where otherwise indicated:

Applicant means a person who seeks to obtain exploration approval under Subparts 9—.770, 9—.776 and 9—.787 of this part.

Application for approval means the documents and other information filed with the Office under Subparts 9—.770 and 9—.776 of this part for the issuance of exploration approval.

Complete application means an application for exploration approval which contains all information required under the Act and Subparts 9—.770 and 9—.776 of this part.

Exploration approval means the approval required under Section 512 of the Act.

§ 9—.770-12 Coordination with requirements under other laws.

The Office shall, to avoid duplication, provide for the coordination of review and issuance of approvals for coal exploration with:

(a) Any other Federal or State permit process applicable to those operations including, at a minimum, permits required under the—

(1) Clean Water Act, as amended (33 U.S.C. Sec. 1251 *et seq.*);

(2) Clean Air Act, as amended (42 U.S.C. Sec. 7401 *et seq.*);

(3) Resource Conservation and Recovery Act (42 U.S.C. Sec. 3251 *et seq.*); and

(b) The requirements of any water quality management plans which have been approved by the Administrator of the United States Environmnental Protection Agency under Sections 208 or 303 (c) and (e) of the Clean Water Act, as amended (33 U.S.C. Sections 1288, 1313 (c) and (e)).

(c) The applicable requirements of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*); the Fish and Wildlife Coordination Act, as amended, (16 U.S.C. 661 *et seq.*); the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470 *et seq.*); Executive Order 11593; the Archeological and Historic Preservation Act of 1974 (16 U.S.C. 469 *et seq.*); the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4332); and the Clean Air Act (42 U.S.C. 7401 *et seq.*).

Subpart 9—.776—General Requirements for Coal Exploration

§ 9—.776-11 General requirements: Exploration affecting less than 250 tons.

(a) Any person who intends to conduct coal exploration during which less than 250 tons of coal will be removed from the area to be explored shall, prior to conducting the exploration, file with the Office a written notice of intention to explore.

(b) The notice shall include:

(1) The name, address, and telephone number of the person seeking to explore.

(2) The name, address, and telephone number of the representative who will be present at and responsible for conducting the exploration activities;

(3) A description sufficient to enable the Office to identify the location and size of areas at which exploration operations are to be conducted, access routes, the distance from the area or areas to a public road, and means of transportation used or proposed to be used;

(4) A statement of the period of intended exploration;

(5) A description of the practices proposed to be followed to protect the environment from adverse impacts as a result of the exploration activities.

(c) Any person who conducts coal exploration activities pursuant to this Section which substantially disturb the natural land surface shall comply with 30 CFR 9—.815.

(d) The Office shall, except as otherwise provided in § 9—.776-17, place such notices on public file and make them available for public inspection and copying.

§ 9—.776-12 General requirements: Exploration affecting more than 250 tons.

Any persons who intends to conduct coal exploration in which more than 250 tons of coal are to be removed from the area to be explored shall, prior to conducting the exploration, obtain the written approval of the Office, in accordance with the following:

(a) Contents of application for approval. Each application for approval shall contain, at a minimum, the following information:

(1) The name, address, and telephone number of the applicant;

(2) The name, address, and telephone number of the representative of the applicant who will be present at and be responsible for conducting the exploration;

(3) An exploration and reclamation operations plan, including—

(i) A narrative description of the proposed exploration area, describing surface topography; geological, surface water, and other physical features as described in paragraph (a)(5) of this section; vegetative cover; the distribution and important habitats of fish, wildlife, and plants, including but not limited to any endangered or threatened species listed pursuant to the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*); and districts, sites, buildings, structures, or objects listed or eligible for listing on the National Register of Historic Places;

(ii) A narrative description of the methods to be used to conduct coal exploration and reclamation, including, but not limited to, the types and uses of

equipment, drilling, blasting, road or other access route construction, and excavated earth and other debris disposal activities;

(iii) An estimated timetable for conducting and completing each phase of the exploration and reclamation;

(iv) The estimated amounts of coal to be removed and a description of the methods to be used to determine those amounts;

(v) A description of the measures to be used to comply with the applicalbe requirements of 30 CFR 9—.815;

(4) The name and address of the owner(s) of record of the surface land and of the subsurface mineral estate of the area to be explored; and

(5) A description of existing roads, occupied dwellings, and pipelines; proposed location of trenches, roads, and other access routes and structures to be constructed; the location of excavations to be conducted; water or coal exploratory holes and wells to be drilled or altered; earth or debris disposal areas; existing bodies of surface water; historic, topographic, cultural, and drainage features; and habitats of any endangered or threatened species listed pursuant to the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.).*

(b) Public notice and opportunity to comment. Public notice of the application and opportunity to comment shall be provided as follows:

(1) Within one week after the Office has determined the application to be complete, public notice of the filing of the application shall be posted by the applicant at the courthouse or other public office designated by the Regional Director in the vicinity of the proposed exploration area.

(2) The public notice shall state the name and business address of the person seeking approval, the date of filing of the application, the address to which written comments on the application may be submitted, the closing date of the comment period, and a description of the general area of exploration.

(3) Any person with an interest which is or may be adversely affected shall have the right to file written comments on the application within 15 days after the posting of the notice, as prescribed in paragraph (b)(1) of this section.

§ 9—.776-13 Applications: Approval or disapproval of exploration affecting more than 250 tons.

(a) The Office shall act upon a completed application for approval within 60 days. If additional time is necessary, the Office shall notify the applicant that the plan is being reviewed, but that more time, not to exceed an additional thirty days, is necessary to complete such review, setting forth the reasons why additional time is needed.

(b) The Office shall approve a complete application if it finds, in writing, that the applicant has demonstrated that the exploration and reclamation described in the application:

(1) Will be conducted in accordance with Subpart 9—.815.

(2) Will not jeopardize the continued existence of an endangered or threatened species listed pursuant to Section 4 of the Endangered Species Act of 1973 (16 U.S.C. 1533) or result in the destruction or adverse modification of critical habitat of those species; and

(3) Will not adversely affect cultural resources or districts, sites, buildings, structures, or objects listed or eligible to be on the National Register of Historic Places, unless the proposed exploration has been approved by both the Office and the agency with jurisdiction over such matters.

(c) Terms of approval. Each approval shall contain conditions necessary to ensure that the exploration and reclamation will be conducted in compliance with 30 CFR 9—.815.

(d) Approval shall be given for not to exceed 2 years. Approval may be renewed for successive two year periods upon reapplication.

(e) Except as otherwise provided in this section, review, revision, and renewal of approvals and transfer, sale, and assignment of rights granted by approvals shall be done in accordance with 30 CFR Part 788.

§ 9—.776-14 Applications: Notice and hearing for exploration of more than 250 tons.

(a) The Office shall notify the applicant and the appropriate local government officials, in writing, of its decision to approve or disapprove the application. If the application is disapproved, the notice to the applicant shall include a statement of the reason for disapproval. The Office shall provide public notice of approval or disapproval of each application, by publication in a newspaper of general circulation in the general vicinity of the proposed operations.

(b) Any person with interests which are or may be adversely affected by a decision of the Office pursuant to paragraph (a) of this section shall have the opportunity for administrative and judicial review as are set forth in 30 CFR 9—.787.

§ 9—.776-15 Requirements for exploration operations.

(a) All coal exploration and reclamation operations which substantially disturb the natural land surface or which remove more than 250 tons of coal over any period of time shall be conducted in accordance with the coal exploration requirements of this part and any conditions in the exploration approval.

(b) Any person who conducts any coal exploration in violation of the provisions of this subpart or Subpart 9—.815 of this Part shall be subject to the provisions of Subparts 9—.842 through 9—.845 of this Part.

§ 9—.776-17 Public availability of information.

(a) Except as provided in paragraph (b) of this section, all information submitted to the Office under this subpart shall be made available for public inspection and copying at (to be inserted).

(b)(1) The Office shall not make information available for public inspection, if the person submitting it requests in writing, at the time of submission, that it not be disclosed and the Office determines that the information is confidential and may be withheld under the Freedom of Information Act, 5 U.S.C. 552.

(2) The Office shall determine that information is confidential only if it concerns trade secrets or is privileged commercial or financial information which relates to the competitive rights of the person intending to conduct coal exploration.

(3) Information requested to be held as confidential under this Section shall not be made publicly available until after notice and opportunity to be heard is afforded to persons both seeking and opposing disclosure of the information.

Subpart 9—.787—Administrative and Judicial Review of Decisions on Coal Exploration

§ 9—.787-11 Administrative review.

(a) Within 30 days after the applicant is notified of the final decision of the Office concerning the application for coal exploration under 30 CFR 9—.776-14, the applicant, or any person with an interest which is or may be adversely affected, may request a hearing on the reasons for the final decision in accordance with this Section.

(b) The Office may, under such conditions as it may prescribe, grant such temporary relief as it deems appropriate, pending final determination of the proceeding, if:

(1) All parties to the proceeding have been notified and given an opportunity to be heard on a request for temporary relief;

(2) The person requesting that relief shows that there is a substantial likelihood that he or she will prevail on the merits of the final determination of the proceeding; and

(3) The relief is not to affect adversely the public health or safety, or cause significant, imminent environmental harm to land, air, or water resources; and

(4) The relief sought is not the issuance of exploration approval where an approval has been denied, in whole or in part, by the Office.

(c)(1) For the purpose of such hearing, the hearing authority may administer oaths and affirmations, subpoena witnesses, written, or printed materials, compel attendance of witnesses and production of written or printed materials, compel discovery, and take evidence, including, but not limited to, site inspections of the land to be affected and other coal exploration operations carried on by the applicant in the general vicinity of the proposed operations.

(2) A verbatim record of each public hearing required by this Section shall be made, and a transcript made available on the motion of any party or by order of the hearing authority.

(3) Ex parte contacts between representatives of the parties before the hearing authority and the hearing authority shall be prohibited.

(d) Within 30 days after the close of the record, the hearing authority shall issue and furnish the applicant and each person who participated in the hearing with the written findings of fact, conclusions of law, and order of the hearing authority with respect to the appeal.

(e) The burden of proof at such hearings shall be on the party seeking to reverse the decision of the Office.

§ 9—.787–12 Judicial review.

(a) Any applicant or any person with an interest which is or may be adversely affected and who has participated in the administrative proceedings as an objector shall have the right to appeal as provided in paragraph (b) of this section, if:

(1) The applicant or person is aggrieved by the decision of the hearing authority in an administrative review proceeding conducted pursuant to § 9—.787–11; or,

(2) Either the Office or the hearing authority for administrative review under § 9—.787–11 fails to act within time limits specified in the Subparts 9—.770 through 9—.787 of this part.

(b) The action of the Office or hearing authority identified in paragraph (a) of this section is subject to judicial review by the United States District Court for the district in which the coal exploration is or would be located, in the time and manner provided for in Section 526(a)(2) and (b) of the Act. The availability of such review shall not limit the operation of rights established in Section 520 of the Act.

Performance Standards

Subpart 9—.815—Performance Standards—Coal Exploration

§ 9—.815–11 General responsibility of persons conducting coal exploration.

(a) Each person who seeks to conduct coal exploration which substantially disturbs the natural land surface and in which 250 tons or less of coal are removed shall file the notice of intention to explore required under 30 CFR 9—.776–11 and shall comply with § 9—.815–15.

(b) Each person who conducts coal exploration which substantially disturbs the natural land surface and in which more than 250 tons of coal are removed in the area described by the written approval from the Office shall comply with the procedures described in the exploration and reclamation operations plan approved under 30 CFR 9—.776–12 and shall comply with § 9—.815–15.

§ 9—.815–13 Required documents.

Each person who conducts coal exploration which substantially disturbs the natural land surface and which removes more than 250 tons of coal shall, while in the exploration area, possess written approval of the Office for the activities granted under 30 CFR § 9—.776–12. The written approval shall be available for review by the authorized representative of the Office upon request.

§ 9—.815–15. Performance standards for coal exploration.

The following performance standards are applicable to coal exploration which substantially distrubs the natural land surface.

(a) Habitats of unique value for fish, wildlife, and other related environmental values and areas identified in 30 CFR 780.16(b) shall not be disturbed during coal exploration.

(b) The person who conducts coal exploration shall, to the extent practicable, measure important environmental characteristics of the exploration area during the operations, to minimize environmental damage to the area.

(c)(1) Vehicular travel on other than established roads shall be limited by the person who conducts coal exploration to that absolutely necessary to conduct the exploration. Travel shall be confined to roads during periods when excessive damage to vegetation or rutting of the land surface could result.

(2) Any new road in the exploration area shall be constructed to meet the requirements of the Office.

(3) Existing roads may be used for exploration in accordance with the following:

(i) All applicable Federal, State, and local requirements shall be met.

(ii) If the road is significantly altered for exploration, including, but not limited to, change of grade, widening, or change of route, or if use of the road for exploration contributes additional suspended solids to streamflow or runoff, then paragraph (g) of this section shall apply to all areas of the road which are altered or which result in such additional contributions.

(iii) If the road is significantly altered for exploration activities and will remain as a permanent road after exploration activities are completed, the person conducting exploration shall ensure that the requirements of 30 CFR 816.150 through 816.166, as appropriate, are met for the design, construction, alteration, and maintenance of the road.

(4) Promptly after exploration activities are completed, existing roads used during exploration shall be reclaimed either—

(i) To a condition equal to or better than their preexploration condition; or

(ii) To a condition required by the Office.

(d) If excavations, artificial flat areas, or embankments are created during exploration, these areas shall be returned to the approximate original contour promptly after such features are no longer needed for coal exploration.

(e) Topsoil shall be removed, stored, and redistributed on disturbed areas as necessary to assure successful revegetation or as required by the Office.

(f) Areas disturbed by coal exploration shall be revegetated by the person who conducts the exploration, or his or her agent. If more than 250 tons of coal are removed from the exploration area, all revegetation shall be in compliance with the plan approved by the Office and carried out in a manner that encourages prompt vegetative cover and recovery of productivity levels compatible with approved

postexploration land use and in accordance with the following:

(1) All disturbed lands shall be seeded or planted to the same seasonal variety native to the disturbed area. If both the preexploration and postexploration land uses are intensive agriculture, planting of the crops normally grown will meet the requirements of this paragraph.

(2) The vegetative cover shall be capable of stabilizing the soil surface to prevent erosion.

(g) With the exception of small and temporary diversions of overland flow of water around new roads, drill pads, and support facilities, no ephemeral, intermittent, or perennial stream shall be diverted during coal exploration activities. Overland flow of water shall be diverted in a manner that:

(1) Prevents erosion;

(2) To the extent possible using the best technology currently available, prevents additional contributions of suspended solids to streamflow or runoff outside the exploration areas; and

(3) Complies with all other applicable State or Federal requirements.

(h) Each exploration hole, borehole, well, or other exposed underground opening created during exploration must meet the requirements of 30 CFR 816.13, 816.14, and 816.15.

(i) All facilities and equipment shall be removed from the exploration area promptly when they are no longer needed for exploration, except for those facilities and equipment that the Office determines may remain to:

(1) Provide additional environmental quality data;

(2) Reduce or control the on- and off-site effects of the exploration activities; or

(3) Facilitate future surface mining and reclamation operations by the person conducting the approved exploration operations.

(j) Coal exploration shall be conducted in a manner which minimizes disturbance of the prevailing hydrologic balance, and shall include sediment control measures such as those listed in 30 CFR 816.45 or sedimentation ponds which comply with 30 CFR 816.46. The Office may specify additional measures which shall be adopted by the prospector.

(k) Toxic or acid-forming materials shall be handled and disposed of in accordance with 30 CFR 816.48 and 816.103. If specified by the Office, additional measures shall be adopted by the prospector.

(l) Permanent water impoundments may be permitted where the Office has determined that they comply with 30 CFR 816.49 and 816.56, 816.33 or 817.49, 817.56, and 817.133.

Inspection and Enforcement Procedures

Subpart 9—.842—Federal Inspections

§ 9—.842-11 Federal inspections.

(a) Authorized representatives of the Secretary shall conduct inspections of coal exploration operations as necessary:

(1) To develop or enforce this part;

(2) To enforce those requirements and permit conditions imposed under this part or 30 CFR Chapter VII or as provided in this section; and

(3) To determine whether any notice of violation or cessation order issued during an inspection authorized under this Section has been complied with

(b)(1) An authorized representative of the Secretary shall immediately conduct a Federal inspection to enforce any requirement of the Act, this part, or any condition of an exploration approval imposed under the Act or this part when the authorized representative has reason to believe, on the basis of information available to him or her (other than information resulting from a previous Federal inspection), that there exists a violation of the Act, this part, or any condition of an exploration approval, or that there exists any condition, practice or violation which creates an imminent danger to the health or safety of the public or is causing or can reasonably be expected to cause a significant, imminent environmental harm to land, air or water resources.

(2) An authorized representative shall have reason to believe that a violation, condition or practice exists if the facts alleged by the informant would, if true, constitute a condition, practice or violation referred to in paragraph (b)(1) of this section.

(c) The Office shall conduct periodic inspections of all coal exploration and reclamation operations required to comply in whole or part with the Act or this part including the collection of evidence with respect to every violation of any condition of the exploration approval or requirement of the Act or this Chapter.

(d) The inspections required under paragraph (c) of this section shall:

(1) Be carried out on an irregular basis so as to monitor compliance at all operations, including those which operate nights, weekends, or holidays;

(2) Occur without prior notice to the person being inspected or any of his agents or employees, except for necessary onsite meetings; and

(3) Include the prompt filing of inspection reports adequate to enforce the requirements of and to carry out the terms and purposes of this part any condition of an exploration approval imposed under this part and the Act.

§ 9—.842-12 Citizens' requests for Federal inspections.

(a) A citizen may request a Federal inspection under 30 CFR 9—842–11(b), by furnishing to an authorized representative of the Secretary a signed, written statement (or an oral report followed by a signed, written statement) giving the authorized representative reason to believe that a violation, condition, or practice referred to in 30 CFR 9—.842–11(b)(1) exists and setting forth a phone number and address where the citizen can be contacted.

(b) The identity of any person supplying information to the Office relating to a possible violation or imminent danger or harm shall remain confidential with the Office, if requested by that person, unless that person elects to accompany the inspector on the inspection, or unless disclosure is required under the Freedom of Information Act (5 U.S.C. Section 552) or other Federal law;

(c) If a Federal inspection is conducted as a result of information provided to the Office by a citizen as described in paragraph (a) of this section, the citizen shall be notified as far in advance as practicable when the inspection is to occur and shall be allowed to accompany the authorized representative of the Secretary during the inspection. Such person has a right of entry to, upon and through the coal exploration operation about which he or she supplied information, but only if he or she is in the presence of and is under the control, direction and supervision of the authorized representative while on the exploration area. Such right of entry does not include a right to enter buildings without consent of the person in control of the building or without a search warrant.

(d) Within 10 days of the Federal inspection or, if there is no inspection, within 15 days of receipt of the citizen's written statement, the Office shall send the citizen the following:

(1) If an inspection was made, a description of the enforcement action taken, which may consist of copies of the Federal inspection report and all notices of violation and cessation orders issued as a result of the inspection or an explanation of why no enforcement action was taken;

(2) If no Federal inspection was conducted, an explanation of the reason why; and

(3) An explanation of the citizen's right, if any, to informal review of the

action or inaction of the Office under 30 CFR 9—.842–15.

(e) The Office shall give copies of all materials in paragraphs (d)(1) and (2) of this section within the time limits specified in those paragraphs to the person alleged to be in violation, except that the name of the citizen shall be removed unless disclosure of the citizen's identity is permitted under paragraph (b) of this section.

§ 9—.842–13 Right of entry.

(a) Each authorized representative of the Secretary conducting a Federal inspection under 30 CFR 9—842–11:

(1) Shall have a right of entry to, upon, and through any coal exploration operation, without advance notice or a search warrant, upon presentation of appropriate credentials; and

(2) May, at reasonable times and without delay, have access to and copy any records, and inspecting any monitoring equipment or method of operation, required under the Act, this part, or any condition of an exploration approval imposed under the Act or this part.

(b) No search warrant shall be required with respect to any activity under paragraph (a) of this section except that a search warrant may be required for entry into a building.

§ 9—.842–14 Review of adequacy and completeness of inspections.

Any person who is or may be adversely affected by a surface coal exploration operation may notify the Office in writing of any alleged failure on the part of the Office to make adequate and complete or periodic Federal inspections as provided in 30 CFR 9—.842–11 (b)(1), (c) and (d). The notification shall include sufficient information to create a reasonable belief that 30 CFR9—.842–11 (b)(1), (c) and (d) are not being complied with and to demonstrate that the person is or may be adversely affected. The Office shall within 15 days or receipt of the notification determine whether 30 CFR9—.842–11 (b)(1), (c) and (d) are being complied with, and if not, shall immediately order a Federal inspection to remedy the noncompliance. The Office shall also furnish the complainant with a written statement of the reasons for such determination and the actions, if any, to remedy the noncompliance.

§9—.842–15 Review of decision not to inspect or enforce.

(a) Any person who is or may be adversely affected by a coal exploration operation may ask the Office to review informally an authorized representative's decision not to inspect or take appropriate enforcement action with respect to any violation alleged by that person in a request for Federal inspection under 30 CFR9—.842–12. The request for review shall be in writing and include a statement of how the person is or may be adversely affected and why the decision merits review.

(b) The Office shall conduct the review and inform the person, in writing, of the results of the review within 30 days of his or her receipt of the request. The person alleged to be in violation shall also be given a copy of the results of the review, except that the name of the citizen shall not be disclosed unless confidentiality has been waived or disclosure is required under the Freedom of Information Act or other Federal law.

(c) Informal review under this Section shall not affect any right to formal review under Section 525 of the Act or to a citizen's suit under Section 520 of the Act.

§ .842.16 Availability of records.

(a) Copies of all records, reports, inspection materials, or information obtained by the Office under Title V of the Act or this part shall be made immediately available to the public in the area of exploration so that they are conveniently available to residents of that area, except that Office may refuse to make available:

(1) Investigatory records complied for law enforcement purposes to the extent allowed under the Freedom of Information Act (5 U.S.C. Section 552(b)); and

(2) Information not required to be made available under § 9—.776–17 or 30 CFR 786.15.

(b) Copies of documents and information required to be made available under paragraph (a) of this section shall be provided to the (insert title of State agency(ies)) responsible for (insert State statute or regulation).

Subpart 843—Federal Enforcement

§ 9—.843–11 Cessation orders.

(a)(1) An authorized representative of the Secretary shall immediately order a cessation of coal exploration or of the relevant portion thereof, if he finds, on the basis of any Federal inspection, any condition or practice or any violation of the Act, this part, or an exploration approval issued under this part, which:

(i) Creates an imminent danger to the health or safety of the public; or

(ii) Is causing or can reasonbly can be expected to cause significant, imminent environmental harm to land, or water resources.

(2) If the cessation ordered under paragraph (a)(1) of this section will not completely abate the imminent danger or harm in the most expeditious manner physically possible, the authorized representative of the Secretary shall impose affirmative obligations on the person to whom it is issued to abate the conditions, practice, or violation. The order shall specify the time by which abatement shall be accomplished and may require, among other things, the use of existing or additional personnel and equipment.

(b)(1) An authorized representative of the Secretary shall immediately order a cessation of coal exploration operations, or of the relevant portion thereof, when a notice of violation has been issued under § 9—.843–12(a) and the person to whom it was issued fails to abate the violation within the abatement period fixed or subsequently extended by the authorized representative.

(2) A cessation order issued under this paragraph shall require the person to whom it is issued to take all steps the authorized representative of the Secretary deems necessary to abate the violations covered by the order in the most expeditious manner physically possible.

(c) A cessation order issued under paragraphs (a) or (b) of this section shall be in writing, signed by the authorized representative who issues it, and shall set forth with reasonable specificity: (1) The nature of the violation; (2) the remedial action or affirmative obligation required, if any, including interim steps, if appropriate; (3) the time established for abatement, if appropriate, including the time for meeting any interim steps; and (4) a reasonable description of the portion of the coal exploration operation to which it applies. The order shall remain in effect until the condition, practice or violation has been abated or until vacated, modified or terminated in writing by an authorized representative of the Secretary.

(d) Reclamation operations and other activities intended to protect public health and safety and the environment shall continue during the period of any order unless otherwise provided in the order.

(e) An authorized representative of the Secretary may modify, terminate or vacate a cessation order for good cause, and may extend the time for abatement if the failure to abate within the time previously set was not caused by lack of diligence on the part of the person to whom it was issued.

(f) An authorized representative of the Secretary shall terminate a cessation order, by written notice to the person to

whom the order was issued, when he determines that all conditions, practices or violations listed in the order have been abated. Termination shall not affect the right of the Office to assess civil penalties for those violations under subpart 9—.845 of this part.

§ 9—.843–12 Notices of violation.

(a) An authorized representative of the Secretary shall issue a notice of violation if, on the basis of any Federal inspection, he finds a violation of the Act, this part, or any conditions of an exploration approval imposed under the Act or this part, which does not create an imminent danger or harm for which a cessation order must be issued under § 9—.843–11.

(b) A notice of violation issued under this Section shall be in writing, signed by the authorized representative who issued it, and shall set forth with reasonable specificity: (1) The nature of the violation; (2) The remedial action required, which may include interim steps; (3) A reasonable time for abatement, which may include time for accomplishment of interim steps; and (4) A reasonable description of the portion of the coal exploration operation to which it applies.

(c) An authorized representative of the Secretary may extend the time set for abatement or for accomplishment of an interim step, if the failure to meet the time previously set was not caused by lack of diligence on the part of the person to whom it was issued. The total time for abatement under a notice of violation, including all extensions, shall not exceed 90 days from the date of issuance, except upon a showing by the prospector that it is not feasible to abate the violation within 90 calendar days due to one or more of the circumstances in paragraph (f) of this section. An extended abatement date pursuant to this section shall not be granted when the prospector failure to abate within 90 days has been caused by a lack of diligence or international delay by the prospector in completing the remedial action required.

(d) If the person to whom the notice was issued fails to meet any time set for abatement or for accomplishment of an interim step, the authorized representative shall issue a cessation order under § 9—.843–11(b).

(e) An authorized representative of the Secretary shall terminate a notice of violation by written notice to the person to whom it was issued, when he determines that all violations listed in the notice of violations have been abated. Termination shall not affect the right of the Office to assess civil penalties for those violations under Subpart 9—.845 of this part.

(f) Circumstances which may qualify a surface coal mining operation for an abatement period of more than 90 days are:

(1) Where the prospector of an ongoing permitted operation has timely applied for an diligently pursued an exploration approval renewal or other necessary approval of designs or plans but such approval has not been or will not be issued within 90 days after a valid approval expires or is required for reasons not within the control of the prospector;

(2) Where there is a valid judicial order precluding abatement within 90 days as to which the prospector has diligently pursued all rights of appeal and as to which he or she has no other effective legal remedy;

(3) Where the prospector cannot abate within 90 days due to a labor strike;

(4) Where climatic conditions preclude abatement within 90 days, or where, due to climatic conditions, abatement within 90 days clearly:

(i) Would cause more environmental harm than it would prevent; or

(ii) Requires action that would violate safety standards established by statute or regulation under the Mine Safety and Health Act.

(g) Whenever an abatement time in excess of 90 days is permitted, interim abatement measures shall be imposed to the extent necessary to minimize harm to the public or the environment.

(h) If any of the conditions in paragraphs (f) (1)–(4) of this section exist, the prospector may request the authorized representative to grant an abatement period exceeding 90 days. The authorized representative shall not grant such an abatement period without the concurrence of the Director or his or her designee and the abatement period granted shall not exceed the shortest possible time necessary to abate the violation. The prospector shall have the burden of establishing by clear and convincing proof that he or she is entitled to an extension under the provisions of paragraphs (c) and (f) of this section. In determining whether or not to grant an abatement period exceeding 90 days the authorized representative may consider any relevant written or oral information from the prospector or any other source. The authorized representative shall promptly and fully document in the file his or her reasons for granting or denying the request. The inspector's immediate supervisor shall review this document before concurring in or disapproving the extended abatement date and shall promptly and fully document the reasons for his or her concurrence or disapproval in the file.

(i) Any determination made under paragraph (h) of this section shall be in writing and shall contain a right of appeal to the Office of Hearings and Appeals in accordance with 43 CFR 4.1281 and the regulations at 43 CFR Part 4.

(j) No extension granted under paragraph (h) of this section may exceed 90 days in length. Where the condition or circumstance which prevented abatement within 90 days exists at the expiration of any such extension, the prospector may request a further extension in accordance with the procedures of paragraph (h) of this section.

§ 9—.843–13 Suspension or revocation of approvals.

(a)(1) Except as provided in paragraph (b) of this section, the Director shall issue an order to a prospector requiring him or her to show cause why approval to conduct coal exploration under the Act should not be suspended or revoked, if the Director determines that a pattern of violations of any requirements of the Act, this Part, or any condition for approval required by the Act exists or has existed, and that the violations were caused by the prospector willfully or through unwarranted failure to comply with those requirements or conditions. Willful violation means an act or omission which violates the Act, this part, or any exploration approval condition required by the Act, or this part, committed by a person who intends the result which actually occurs. Unwarranted failure to comply means the failure of the prospector to prevent the occurrence of any violation of the approval or any requirement of the Act, due to indifference, lack of diligence, or lack of reasonable care, or the failure to abate any violation of such approval or the Act, due to indifference, lack of diligence, or lack of reasonable care. Violations by any person conducting coal exploration on behalf of the prospector shall be attributed to the prospector, unless the prospector establishes that they were acts of deliberate sabotage.

(2) The Director may determine that a pattern of violations exists or has existed, based on two or more Federal inspections of the exploration activities within any 12-month period, after considering the circumstances, including:

(i) The number of violations, cited on more than one occasion, of the same or

related requirements of the Act, this part, or the approval;

(ii) The number of violations, cited on more than one occasion, of different requirements of the Act, this part, or the approval; and

(iii) The extent to which the violations were isolated departures from lawful conduct.

(3) The Director shall determine that a pattern of violations exists, if he finds that there were violations of the same or related requirements of the Act, this part, or the approval during three or more Federal inspections of the approval area within any 12-month period.

(4)(i) In determining the number of violations within any 12-month period, the Director shall consider only violations issued as a result of a Federal inspection carried out during enforcement of this Part.

(ii) The Director may consider violations issued as a result of inspections in determining whether to exercise his discretion under paragraph (a)(2) of this section.

(b) The Director may decline to issue a show cause order, or may vacate an outstanding show cause order, if he finds that, taking into account exceptional factors present in the particular case, it would be demonstrably unjust to issue or to fail to vacate the show cause order. The basis for this finding shall be fully explained and documented in the record of the case.

(c) At the same time as the issuance of the order, the Director shall:

(1) File a copy of the order to show cause with the Office of Hearings and Appeals and provide a copy to the (insert State agency) responsible for (insert State law or regulation).

(2) If practicable, publish notice of the order, including a brief statement of the procedure for intervention in the proceeding, in a newspaper of general circulation in the area of the coal exploration.

(3) Post the notice at the regional, district or field office closest to the area of the coal exploration activities.

(d) If the prospector files an answer to the show cause order and requests a hearing under 43 CFR Part 4, a public hearing shall be provided as set forth in that part. The Office of Hearings and Appeals shall give thirty days' written notice of the date, time and place of the hearing to the Director, the prospector, the (insert State agency) and any intervenor. Upon receipt of the notice, the Director shall publish it, if practicable, in a newspaper of general circulation in the area of the coal exploration and shall post it at the regional, district, or field office closest to those operations.

(e) Within sixty days after the hearing, and within the time limits set forth in 43 CFR Part 4, the Office of Hearings and Appeals shall issue a written determination as to whether a pattern of violations exists and, if appropriate, an order. If the Office of Hearings and Appeals revokes or suspends the exploration approval the prospector shall immediately cease coal exploration on the approval area and shall:

(1) If the exploration approval is revoked, complete reclamation within the time specified in the order; or

(2) If the exploration approval is suspended, complete all affirmative obligations to abate all conditions, practices or violations, as specified in the order.

(f) Whenever a prospector fails to abate a violation contained in a notice of violation or a cessation order within the abatement period set in the notice or order or as subseqently extended, the Director shall review the prospector's history of violations to determine whether a pattern of violations exists pursuant to this section, and shall issue an order to show cause as appropriate pursuant to 30 CFR 9—.845.15(b)(2).

§ 9—.843-14 Service of notices of violations, cessation orders, and show cause orders.

(a) A notice of violation or cessation order shall be served on the person to whom it is directed or his designated agent promptly after issuance, as follows:

(1) By tendering a copy of the notice of violation or cessation order to the designated agent or to the individual who, based upon reasonable inquiry by the authorized representative, appears to be in charge of the coal exploration operation referred to in the notice or order. If no such individual can be located at the site, a copy may be tendered to any individual at the site who appears to be an employee or agent of the person to whom the notice or order is issued. Service shall be complete upon tender of the notice or order and shall not be deemed incomplete because of refusal to accept.

(2) As an alternative to paragraph (a)(1) of this section, service may be made by sending a copy of the notice or order by certified mail or by hand to the person to whom it is issued or his designated agent. Service shall be complete upon tender of the notice or order or of the mail and shall not be deemed incomplete because of refusal to accept.

(b) A show cause order may be served on the person to whom it is issued in either manner provided in paragraph (a) of this section.

(c) Designation by any person of an agent for service of notices and orders shall be made in writing to the appropriate regional, district or field office of the Office.

(d) The Office shall furnish copies of notices and orders to the (insert State agency) responsible for (insert State law or regulation) promptly after their issuance. The office may furnish copies to any person having an interest in the coal exploration, or the exploration approval area, such as the owner of the fee, a corporate officer of the entity conducting coal exploration.

§ 9—.843-15 Informal public hearing.

(a) Except as provided in paragraphs (b) and (c) of this section, a notice of violation or cessation order which requires cessation of exploration, expressly or by necessary implication, shall expire within 30 days after it is served unless an informal public hearing has been held within that time. The hearing shall be held at or reasonably close to the exploration site so that it may be viewed during the hearing or at any other location acceptable to the Office and the person to whom the notice or order was issued. The Office of Surface Mining office nearest to the exploration site shall be deemed to be reasonably close to the exploration site unless a closer location is requested and agreed to by the Office. Expiration of a notice or order shall not affect the Driector's right to assess civil penalties with respect to the period during which the notice or order was in effect. No hearing will be required where the condition, practice or violation in question has been abated, or the hearing has been waived.

(b) A notice of violation or cessation order shall not expire as provided in paragraph (a) of this section if the informal public hearing has been waived or if, with the consent of the person to whom the notice or order was issued, the informal public hearing is held later than 30 days after the notice or order was served. For purposes of this paragraph:

(1) The informal public hearing will be deemed waived if the person to whom the notice or order is issued:

(i) Is informed, by written notice served in the manner provided in paragraph (b)(2) of this section, that he will be deemed to have waived an informal public hearing unless he requests one within 30 days after service of the notice or order, and

(ii) Fails to request an informal public hearing within that time.

(2) The written notice referred to in paragraph (b)(1)(i) of this section shall be delivered to such person by an authorized representative or sent by certified mail to such person no later than five days after the notice or order is served on such person.

(3) The person to whom the notice or order is issued shall be deemed to have consented to an extension of the time for holding the informal public hearing if his request is received on or after the 21st day after service of the notice or order. The extension of time shall be equal to the number of days elapsed after the 21st day.

(c) The Office shall give as much advance notice as is practicable of the time, place, and subject matter of the informal public hearing to:

(1) The person to whom the notice or order was issued;

(2) Any person who filed a report which led to that notice or order; and

(3) The (insert State agency(ies)) that enforce(s) (insert other State statutes or regulations).

(d) The Office shall also post notice of the hearing at the regional, district or field office closest to the exploration site, and publish it, where practicable, in a newspaper of general circulation in the area of the exploration.

(e) Section 554 of Title 5 of the United States Code, regarding requirements for formal adjudicatory hearings, shall not govern informal public hearings. An informal public hearing shall be conducted by a representative of the Office, who may accept oral or written arguments and any other relevant information from any person attending.

(f) Within five days after the close of the informal public hearing, the Office shall affirm, modify, or vacate the notice or order in writing. The decision shall be sent to—

(1) The person to whom the notice or order was issued;

(2) Any person who filed a report which led to the notice or order; and

(3) The (insert State agency(ies)) that enforce (insert other State statutes or regulations).

(g) The granting or waiver of an informal public hearing shall not affect the right of any person to formal review under Sections 518(b), 521(a)(4), or 525 of the Act.

(h) The person conducting the hearing for the Office shall determine whether or not the exploration site should be viewed during the hearing. In making this determination the only consideration shall be whether a view of the exploration site will assist the person conducting the hearing in reviewing the appropriateness of the enforcement action or the required remedial action.

§ 9—.843–16 Formal review of citations.

(a) A person issued a notice of violation or cessation order under 30 CFR 9—.843–11 or 9—.843–12, or a person having an interest which is or may be adversely affected by the issuance, modification, vacation or termination of a notice or order, may request review of that action by filing an application for review and request for hearing, under 43 CFR Part 4, within 30 days after receiving notice of the action.

(b) The filing of an application for review and request for a hearing under this Section shall not operate as a stay of any notice or order, or of any modification, termination or vacation of either.

§ 9—.843–17 Lack of information.

No notice of violation, cessation order, show cause order, or order revoking or suspending an approval may be vacated because it is subsequently determined that the Office did not have information sufficient under *Response.* § 9—.842–11(b)(1) to justify an inspection.

§ 9—.843–18 Inability to comply.

(a) No cessation order or notice of violation issued under this subpart may be vacated because of inability to comply.

(b) Inability to comply may not be considered in determining whether a pattern of violations exists.

(c) Unless caused by lack of diligence, inability to comply may be considered only in mitigation of the amount of civil penalty under Subpart 9—.845 of this part and of the duration of the suspension of an approval under § 9—.843–13(e).

§ 9—.843–19 Injunctive relief.

The Office may request the Attorney General of the United States to institute a civil action for relief, including a permanent or temporary injunction, restraining order or any other order, in the district court of the United States for the district in which the coal exploration is located or in which the person to whom the notice of violation or order has been issued has his principal office, whenever that person or his or her agent, in violation of the Act, this part, or any condition of an exploration approval imposed under the Act, or this part:

(a) Violates or fails or refuses to comply with any order or decision of the Secretary or an authorized representative of the Secretary under the Act or this part;

(b) Interferes with, hinders or delays the Secretary or an authorized representative of the Secretary in carrying out the provisions of the Act or this part;

(c) Refuses to admit an authorized representative of the Secretary to an exploration site;

(d) Refuses to permit inspection of an exploration area by an authorized representative of the Secretary;

(e) Refuses to furnish any required information or report;

(f) Refuses to permit access to or copying of any required records; or

(g) Refuses to permit inspection of monitoring equipment.

Subpart 9—.845—Civil Penalties

§ 9—.845–11 How assessments are made.

The Office shall review each notice of violation and cessation order issued under Subpart 9—.843 of this part in accordance with the assessment procedures described in §§ 9—.845–12, 9—.845–13, 9—.845–14, 9—.845–15, and 9—.845–16 to determine whether a civil penalty will be assessed, the amount of the penalty, and whether each day of a continuing violation will be deemed a separate violation for purposes of the total penalty assessed.

§ 9—.845–12 When penalty will be assessed.

(a) The Office shall assess a penalty for each cessation order.

(b) The Office shall assess a penalty for each notice of violation, if the violation is assigned 31 points or more under the point system described in § 9—.845–13.

(c) The Office may assess a penalty for each notice of violation assigned 30 points or less under the point system described in § 9—.845–13. In determining whether to assess a penalty, the Office shall consider the factors listed in § 9—.845–13(b).

§ 9—.845–13 Point system for penalties.

(a) The Office shall use the point system described in this section to determine the amount of the penalty and, in the case of notices of violations, whether a mandatory penalty should be assessed as provided in § 9—.845.12(b).

(b) Points shall be assigned as follows:

(1) *History of previous violations.* The Office shall assign up to 30 points based on the history of previous violations. One point shall be assigned for each past violation contained in a notice of violation. Five points shall be assigned for each violation (but not a condition or practice) contained in a cessation order. The history of previous violations, for

the purpose of assigning points, shall be determined and the points assigned with respect to a particular coal exploration operation. Points shall be assigned as follows:

(i) A violation shall not be counted, if the notice or order is the subject of pending administrative or judicial review or if the time to request such review or to appeal any administrative or judicial decision has not expired, and thereafter it shall be counted for only one year;

(ii) No violation for which the notice or order has been vacated shall be counted; and

(iii) Each violation shall be counted without regard to whether it led to a civil penalty assessment.

(2) *Seriousness.* The Office shall assign up to 30 points based on the seriousness of the violation, as follows:

(i) *Probability of occurrence.* The Office shall assign up to 15 points based on the probability of the occurrence of the event which a violated standard is designed to prevent. Points shall be assessed according to the following schedule:

Probability of occurrence—Points

None—0
Insignificant—1–4
Unlikely—5–9
Likely—10–14
Occurred—15

(ii) *Extent of potential or actual damage.* The Office shall assign up to 15 points, based on the extent of the potential or actual damage, in terms of area and impact on the public or environment, as follows:

(A) If the damage or impact which the violated standard is designed to prevent would remain within the coal exploration area, the Office shall assign zero to seven points, depending on the duration and extent of the damage or impact.

(B) If the damage or impact which the violated standard is designed to prevent would extend outside the coal exploration area, the Office shall assign eight to fifteen points, depending on the duration and extent of the damage or impact.

(iii) *Alternative.* In the case of a violation of an administrative requirement, such as a requirement to keep records, the Office shall, in lieu of paragraphs (b)(2) (i) and (ii) of this section, assign up to 15 points for seriousness, based upon the extent to which enforcement is obstructed by the violation.

(3) *Negligence.* (i) The Office shall assign up to 25 points based on the degree of fault of the person to whom the notice or order was issued in causing or failing to correct the violation, condition, or practice which led to the notice or order, either through act or omission. Points shall be assessed as follows:

(A) A violation which occurs through no negligence shall be assigned no penalty points for negligence;

(B) A violation which is caused by negligence shall be assigned 12 points or less, depending on the degree of negligence;

(C) A violation which occurs through a greater degree of fault than negligence shall be assigned 13 to 25 points, depending on the degree of fault.

(ii) In determining the degree of negligence involved in a violation and the number of points to be assigned, the following definitions apply:

(A) No negligence means an inadvertent violation which was unavoidable by the exercise of reasonable care.

(B) Negligence means the failure of a prospector to prevent the occurrence of any violation of his or her approval or any requirement of the Act or this Chapter due to indifference, lack of diligence, or lack of reasonable care, or the failure to abate any violation of such approval or the Act due to indifference, lack of diligence, or lack or reasonable care.

(C) A greater degree of fault than negligence means reckless, knowing, or intentional conduct.

(iii) In calculating points to be assigned for negligence, the acts of all persons working on the coal exploration area shall be attributed to the person to whom the notice or order was issued, unless that person establishes that they were acts of deliberate sabotage.

(4) *Good faith in attempting to achieve compliance.* (i) The Office shall add points based on the degree of good faith of the person to whom the notice or order was issued in attempting to achieve rapid compliance after notification of the violation. Points shall be assigned as follows:

Degree of good faith—Points

Rapid compliance: −1 to −10.
Normal compliance: 0.

(ii) The following definitions shall apply under paragraph (b)(4)(i) of this section:

(A) *Rapid compliance* means that the person to whom the notice or order was issued took extraordinary measures to abate the violation in the shortest possible time and that abatement was achieved before the time set for abatement.

(B) *Normal compliance* means the person to whom the notice or order was issued abated the violation within the time given for abatement.

(iii) If the consideration of this criterion is impractical because of the length of the abatement period, the assessment may be made without considering this criterion and may be reassessed after the violation has been abated.

§ 9—.845–14 Determination of amount of penalty.

The Office shall determine the amount of any civil penalty by converting the total number of points assigned under 30 CFR 9—.845–13 to a dollar amount, according to the following schedule:

Points	Dollars	Points	Dollars
1	20		
2	40		
3	60		
4	80		
5	100		
6	120		
7	140		
8	160		
9	180		
10	200		
11	220		
12	240		
13	260		
14	280		
15	300		
16	320		
17	340		
18	360		
19	380		
20	400		
21	420		
22	440		
23	460		
24	480		
25	500		
26	600		
27	700		
28	800		
29	900		
30	1,000		
31	1,100		
32	1,200		
33	1,300		
34	1,400		
35	1,500		
36	1,600		
37	1,700		
38	1,800		
39	1,900		
40	2,000		
41	2,100		
42	2,200		
43	2,300		
44	2,400		
45	2,500		
46	2,600		
47	2,700		
48	2,800		
49	2,900		
50	3,000		
51	3,100		
52	3,200		
53	3,300		
54	3,400		
55	3,500		
56	3,600		
57	3,700		
58	3,800		
59	3,900		
60	4,000		
61	4,100		
62	4,200		
63	4,300		
64	4,400		
65	4,500		
66	4,600		
67	4,700		
68	4,800		
69	4,900		

Points	Dollars	Points	Dollars
70 and above 70	5,000		

§ 9—.845–15 Assessment of separate violations for each day.

(a) The Office may assess separately a civil penalty for each day from the date of issuance of the notice of violation or cessation order to the date set for abatement of the violation. In determining whether to make such an assessment, the Office shall consider the factors listed in § 9—.845–13 and may consider the extent to which the person to whom the notice or order was issued gained any economic benefit as a result of a failure to comply. For any violation which continues for two or more days and which is assigned more than 70 points under § 9—.845–13(b), the Office shall assess a civil penalty for a minimum of two separate days.

(b) In addition to the civil penalty provided for in Paragraph (a), whenever a violation contained in a notice of violation or cessation order has not been abated within the abatement period set in the notice or order or as subsequently extended pursuant to Section 521(a) of the Act, a civil penalty of not less than $750 shall be assessed for each day during which such failure to abate continues, except that:

(1)(i) If suspension of the abatement requirements of the notice or order is ordered in a temporary relief proceeding under Section 525(c) of the Act, after a determination that the person to whom the notice or order was issued will suffer irreparable loss or damage from the application of the requirements, the period permitted for abatement shall not end until the date on which the Office of Hearings and Appeals issues a final order with respect to the violation in question; and

(ii) If the person to whom the notice or order was issued initiates review proceedings under Section 526 of the Act with respect to the violation, in which the obligations to abate are suspended by the court pursuant to Section 526(c) of the Act, the daily assessment of a penalty shall not be made for any period before entry of a final order by the court;

(2) Such penalty for the failure to abate a violation shall not be assessed for more than 30 days for each such violation. If the prospector has not abated the violation within the 30-day period, the Office shall take appropriate action pursuant to Sections 518(e), 518(f), 521(a)(4), or 521(c) of the Act within 30 days to ensure that abatement occurs or to ensure that there will not be a recurrence of the failure to abate.

§ 9—.845–16 Waiver of use of formula to determine civil penalty.

(a) The Director, upon his own initiative or upon written request received within 15 days of issuance of a notice of violation or a cessation order, may waive the use of the formula contained in § 9—.845–13 to set the civil penalty, if he or she determines that, taking into account exceptional factors present in the particular case, the penalty is demonstrably unjust. However, the Director shall not waive the use of the formula or reduce the proposed assessment on the basis of an argument that a reduction in the proposed penalty could be used to abate violations, this part, or any condition of any exploration approval. The basis for every waiver shall be fully explained and documented in the records of the case.

(b) If the Director waives the use of the formula, he or she shall use the criteria set forth in § 9—.845–13(b) to determine the appropriate penalty. When the Director has elected to waive the use of the formula, he or she shall give a written explanation of the basis for the assessment made to the person to whom the notice or order was issued.

§ 9—.845–17 Procedures for assessment of civil penalties.

(a) Within 15 days of service of a notice or order, the person to whom it was issued may submit written information about the violation to the Office and to the inspector who issued the notice of violation or cessation order. The Office shall consider any information so submitted in determining the facts surrounding the violation and the amount of the penalty.

(b) The Office shall serve a copy of the proposed assessment and of the worksheet showing the computation of the proposed assessment on the person to whom the notice or order was issued, by certified mail, within 30 days of the issuance of the notice or order. If the mail is tendered at the address of that person set forth in the sign required under 30 CFR 816.11, or at any address at which that person is in fact located, and he or she refuses to accept delivery of or to collect such mail, the requirements of this paragraph shall be deemed to have been complied with upon such tender.

(c) Unless a conference has been requested, the Office shall review and reassess any penalty if necessary to consider facts which were not reasonably available on the date of issuance of the proposed assessment because of the length of the abatement period. The Office shall serve a copy of any such reassessment and of the worksheet showing the computation of the reassessment in the manner provided in paragraph (b) of this section, within 30 days after the date the violation is abated.

§ 9—.845–18 Procedures for assessment conference.

(a) The Office shall arrange for a conference to review the proposed assessment or reassessment, upon written request of the person to whom the notice or order was issued, if the request is received within 15 days from the date the proposed assessment or reassessment is mailed.

(b)(1) The Office shall assign a conference officer to hold the assessment conference. The assessment conference shall not be governed by Section 554 of Title 5 of the United States Code, regarding requirements for formal adjudicatory hearings. The assessment conference shall be held within 60 days from the date of issuance of the proposed assessment or the end of the abatement period, whichever is later.

(2) The Office shall post notice of the time and place of the conference at the regional, district or field office closest to the exploration site at least 5 days before the conference. Any person shall have a right to attend and participate in the conference.

(3) The conference officer shall consider all relevant information on the violation. Within 30 days after the conference is held, the conference officer shall either:

(i) Settle the issues, in which case a settlement agreement shall be prepared and signed by the conference officer on behalf of the Office and by the person assessed; or

(ii) Affirm, raise, lower, or vacate the penalty.

(4) An increase or reduction of a proposed civil penalty assessment of more than 25 percent and more than $500 shall not be final and binding on the Secretary, until approved by the Director or his designee.

(c) The conference officer shall promptly serve the person assessed with a notice of his or her action in the manner provided in § 9—.845–17(b) and shall include a worksheet if the penalty has been raised or lowered. The reasons for the conference officer's action shall be fully documented in the file.

(d)(1) If a settlement agreement is entered into, the person assessed will be deemed to have waived all rights to further review of the violation or penalty in question, except as otherwise expressly provided for in the settlement

agreement. The settlement agreement shall contain a clause to this effect.

(2) If full payment of the amount specified in the settlement agreement is not received by the Office within 30 days after the date of signing, the Office may enforce the agreement or rescind it and proceed according to paragraph (b)(3)(ii) of this section within 30 days from the date of the rescission.

(e) The conference officer may terminate the conference when he determines that the issues cannot be resolved or that the person assessed is not diligently working toward resolution of the issues.

(f) At formal review proceedings under Section 518, 521(a)(4), and 523 of the Act, no evidence as to statements made or evidence produced by one party at a conference shall be introduced as evidence by another party or to impeach a witness.

§ 9—.845–19 Request for hearing.

(a) The person charged with the violation may contest the proposed penalty or the fact of the violation by submitting a petition and an amount equal to the proposed penalty or, if a conference has been held, the reassessed or affirmed penalty to the Office of Hearings and Appeals (to be held in escrow as provided in paragraph (b) of this section) within 30 days from receipt of the proposed assessment or reassessment or 15 days from the date of service of the conference officer's action, whichever is later. The fact of the violation may not be contested, if it has been decided in a review proceeding commenced under § 9—.843–16.

(b) The Office of Hearings and Appeals shall transfer all funds submitted under paragraph (a) of this section to the Office, which shall hold them in escrow pending completion of the administrative and judicial review process, at which time it shall disburse them as provided in § 9—.845–20.

§ 9—.845–20 Final assessment and payment of penalty.

(a) If the person to whom a notice of violation or cessation order is issued fails to request a hearing as provided in § 9—.845–19, the proposed assessment shall become a final order of the Secretary and the penalty assessed shall become due and payable upon expiration of the time allowed to request a hearing.

(b) If any party requests judicial review of a final order of the Secretary, the proposed penalty shall continue to be held in escrow until completion of the review. Otherwise, subject to paragraph (c) of this section, the escrowed funds shall be transferred to the Office in payment of the penalty, and the escrow shall end.

(c) If the final decision in the administrative and judicial review results in an order reducing or eliminating the proposed penalty assessed under this subpart, the Office shall within 30 days of receipt of the order refund to the person assessed all or part of the escrowed amount, with interest from the date of payment into escrow to the date of the refund at the rate of 6 percent or at the prevailing Department of the Treasury rate, whichever is greater.

(d) If the review results in an order increasing the penalty, the person to whom the notice or order was issued shall pay the difference to the Office within 15 days after the order is mailed to such person.

[FR Doc. 81–37065 Filed 12–31–81; 8:45 am]

BILLING CODE 4310–05–M

federal register

Tuesday
January 5, 1982

Part XVI

Department of Labor

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

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 on construction projects 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 Secretary of Labor's Order No. 24–70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's Orders 12–71 and 15–71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination 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 subsequent to its publication date shall be made a part of 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.

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 Secretary of Labor's Order No. 24–70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's Orders 13–71 and 15–71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing general wage determination decisions, as hereby modified, and/or superseded 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.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Office of Government Contract Wage Standards, Division of Government Contract Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Determination Decision.

Modifications to General Wage Determination Decisions

The numbers of the decisions being modified and their dates of publication in the **Federal Register** are listed with each State.

Arizona: AZ81–5142	Aug. 14, 1981.
Colorado:	
CO81–5148	Sept. 4, 1981.
CO81–5145	Sept. 4, 1981.
CO81–5146	Sept. 4, 1981.
CO81–5147	Sept. 4, 1981.
Idaho: ID81–5157	Oct. 9, 1981.
Oregon: OR81–5127	July 6, 1981.
Tennessee: TN81–1314	Dec. 18, 1981.
Washington: WA81–5163	Dec. 4, 1981.
Utah: UT81–5156	Oct. 2, 1981.

Supersedeas Decisions to General Wage Determination Decisions

None.

Signed at Washington, D.C. this 31st day of December 1981.

Dorothy P. Come,

Assistant Administrator, Wage and Hour Division.

BILLING CODE 4510-27-M

DECISION NO. AZ81-5142 - Mod. #5
(46 FR 41299-August 14, 1981)
Statewide, Arizona

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Bricklayers; Stonemasons:					
Northern Area:					
Zone A	$15.18	$1.07	$1.50		.18
Zone B	16.39	1.07	1.50		.18
Zone C	17.15	1.07	1.50		.18
Zone D	17.91	1.07	1.50		.18
Zone E	18.52	1.07	1.50		.18
Zone F	19.73	1.07	1.50		.18
Drywall Tapers:					
Zone A	13.79	.60	.50		.10
Zone B	14.79	.60	.50		.10
Zone C	16.29	.60	.50		.10
Lathers:					
Area 1	14.325	1.00			.06
Area 2	14.32	1.00			.06
Plumbers:					
Excluding Hoover Dam:					
Zone 1	18.34	1.20	1.35		.23
Zone 2	18.74	1.20	1.35		.23
Zone 3	19.19	1.20	1.35		.23
Zone 4	21.34	1.20	1.35		.23
Sheet Metal Workers:					
Area 1:					
Zone 1	17.39	1.10	1.92		.13
Zone 2	18.64	1.10	1.92		.13
Zone 3	21.39	1.10	1.92		.13
Area 2:					
Zone A	16.74	1.20	1.92		.07
Zone B	17.96	1.20	1.92		.07
Zone C	20.61	1.20	1.92		.07

DECISION NO. CO81-5148 - Mod. #4
(46 FR 44616-September 4, 1981)
Las Animas, Otero, and Pueblo Counties, Colorado

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Plumbers:					
Zone 1: 0 to 15 miles from Post Office	$16.22	$1.00	$1.50		.10
Zone 2: 15 to 20 miles from Post Office	16.79	1.00	1.50		.10
Zone 3: 20 to 40 miles from Post Office	17.22	1.00	1.50		.10
Zone 4: 40 miles and over from Post Office	18.245	1.00	1.50		.10
Sheet Metal Workers	15.96	3%+.90	1.76		.10

DECISION NO. CO81-5145 - Mod. #5
(46 FR 44602-September 4, 1981)
Adams, Arapahoe, Boulder, Clear Creek, Denver, Douglas, Eagle, Elbert, Gilpin, Grand, Jefferson, Lake, Larimer, Morgan, Park, Summit, and Weld Counties, Colorado

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Sheet Metal Workers	$15.96	3%+.90	$1.76		.17
Tile Layers:					
Elbert, Lake, and Park Counties	13.31	.85	.70		

DECISION NO. CO81-5146 - Mod. #4
(46 FR 44607-September 4, 1981)
El Paso County, Colorado

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Plumbers; Pipefitters	$14.80	$ 1.00	$1.50	$1.60	.10
Sheet Metal Workers	15.96	3%+.90	1.76		.17
Tile Setters	13.31	.85	.70		

DECISION NO. CO81-5147 - Mod. #4
(46 FR 44611-September 4, 1981)
Delta, Garfield, Gunnison Mesa, Montrose, and Pitkin Counties, Colorado

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Sheet Metal Workers	$15.96	3%+.90	$1.76		.17

Modification Page 3

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION NO. ID81-5157 - Mod #4 (46 FR 50223 - October 9, 1981) Statewide Idaho					
CHANGE:					
BRICKLAYERS; STONEMASONS; and MARBLE SETTERS:					
Area 6	$14.35	.90	.75		
ELECTRICIANS:					
Area 1:					
Electricians	19.85	.95	3%+1.00		.02
Cable Splicers	20.25	.95	3%+1.00		.02
Area 3:					
Electricians; Technicians	15.65	1.00	3%+1.00		1%
Cable Splicers	17.22	1.00	3%+1.00		1%
SOFT FLOOR LAYERS:					
Area 3	12.37	.69	.50		
TERRAZZO WORKERS and TILE SETTERS:					
Area 6	12.65	.90	.75		
DECISION NO. OR81-5127 - Mod #7 (46 FR 35019 - July 6, 1981) Statewide Oregon					
CHANGE:					
ELECTRICIANS:					
Area 2:					
Electricians	$19.82	.95	3%+1.30		.10
Lead Cable Splicers	20.81	.95	3%+1.30		.10
Area 6:					
Electricians	19.06	.90	3%+2.00		.17
Cable Splicers	20.98	.90	3%+2.00		.17
ROOFERS:					
Area 2:					
Roofers	16.85	.80	1.40		.10
Handling of irritating material (Coal tar, Epoxy)	17.10	.80	1.40		.10
Handling of irritating material (Coal tar, Epoxy) in a confined area	17.35	.80	1.40		.10

Modification Page 4

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION NO. TN81-1314 - MOD. #1 (46 FR 61815 - December 18, 1981) Statewide, Tennessee					
Change:					
Description of Work:					
To Read:					
Heavy Construction Projects (except Hamilton County), Highway Construction Projects					
DECISION NO. WA81-5163 - Mod. #2 (46 FR 59457 - December 4, 1981) Statewide Washington					
CHANGE:					
ELECTRICIANS:					
Area 1:					
Electricians	18.95	.95	3%+1.30		.02
Cable Splicers	19.35	.95	3%+1.30		.02
Area 2:					
Electricians	19.82	.95	3%+1.30		.10
Cable Splicers	20.81	.95	3%+1.30		.10
Area 3:					
Electricians	19.70	.95	3%+1.85		.05
Cable Splicers	21.67	.95	3%+1.85		.05
ROOFERS:					
Area 6:					
Roofers	16.85	.80	1.40		.10
Handling of irritating material (Coal tar, Epoxy)	17.10	.80	1.40		.10
Handling of irritating material (Coal tar, Epoxy) in a confined area	17.35	.80	1.40		.10

DECISION NO. UT81-5156 - Mod. #4

(46 FR 48870-October 2, 1981)

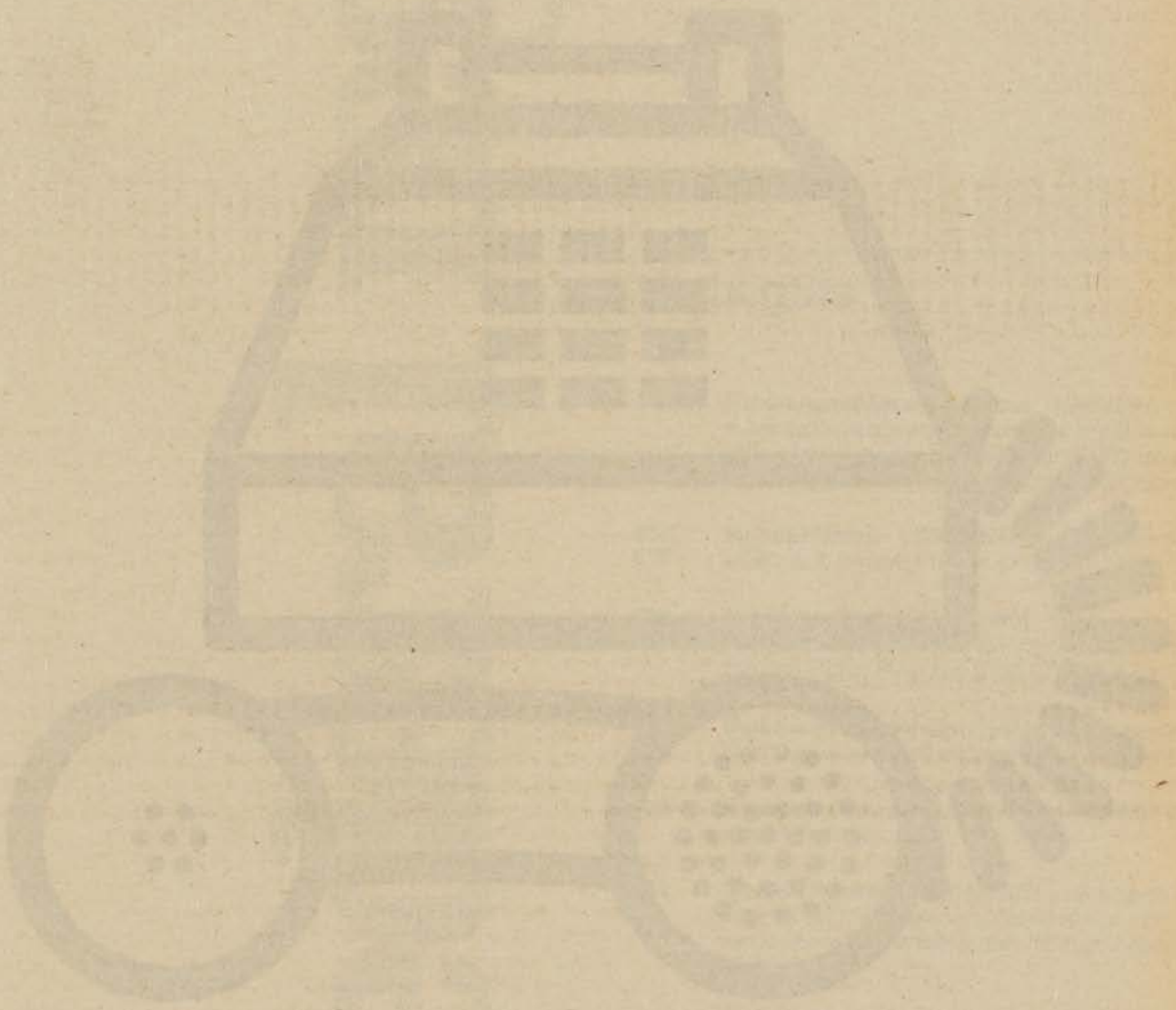
Statewide, Utah

Change:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Electricians:					
Area 2:					
Zone 1:					
Zone 1A:					
Electricians; Technicians	$15.65	$1.00	3%+1.00		8/10%
Cable Splicers	16.75	1.00	3%+1.00		8/10%
Zone 1B:					
Electricians; Technicians	16.40	1.00	3%+1.00		8/10%
Cable Splicers	16.95	1.00	3%+1.00		8/10%
Zone 1C:					
Electricians; Technicians	17.15	1.00	3%+1.00		8/10%
Cable Splicers	17.65	1.00	3%+1.00		8/10%
Zone 2:					
Electricians; Technicians	19.65	1.00	3%+1.00		8/10%
Cable Splicers	20.15	1.00	3%+1.00		8/10%
Painters:					
Area 2:					
Brush; Roller	12.90	.61	.60		.02
Brush (swing stage); Brush (steel and bridge); Spray	13.20	.61	.60		.02
Sandblaster, Steeplejack	13.20	.61	.60		.02
Spray (swing stage); Spray (swing stage); Sandblaster (swing stage)	13.45	.61	.60		.02
Wallcovering Hanger	13.15	.61	.60		.02

[FR Doc. 82-140 Filed 1-4-82; 8:45 am]

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