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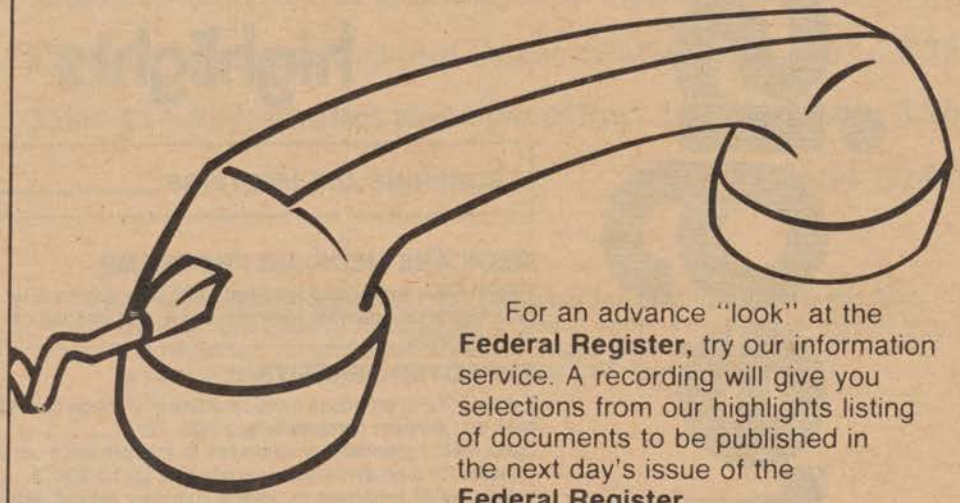

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rules and regulations

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

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

[6325-01]

Title 5—Administrative Personnel

CHAPTER I—CIVIL SERVICE COMMISSION

PART 213—EXCEPTED SERVICE

National Foundation on the Arts and the Humanities

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: The titles of two positions of Humanist Administrator in the Office of State Programs, National Endowment for the Humanities, are changed to Director and Deputy Director, Division of State Programs, to reflect additional duties resulting from upgrading of the office to divisional level.

EFFECTIVE DATE: August 11, 1978.

FOR FURTHER INFORMATION CONTACT:

Michael Sherwin, 202-632-4533.

Accordingly, 5 CFR 213.3282(b)(5) is amended as set out below:

§ 213.3282 National Foundation on the Arts and the Humanities.

* * * * *

(b) *National Endowment for the Humanities* * * *

(5) Until September 30, 1980, one Director, one Deputy Director, and five Humanist Administrators, Division of State Programs.

(5 U.S.C. 3301, 3302; EO 10577, 3 CFR 1954-1958 Comp., p. 218.)

UNITED STATES CIVIL SERVICE COMMISSION.
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc. 78-23571 Filed 8-24-78; 8:45 am]

[3410-30]

Title 7—Agriculture

CHAPTER II—FOOD AND NUTRITION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER A—CHILD NUTRITION PROGRAMS

[Amdt. 3]

PART 226—CHILD CARE FOOD PROGRAM

Two Percent Audit Funds

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: The Department is issuing this amendment in order to implement a provision of Section 14 of Pub. L. 95-166, enacted on November 10, 1977. That provision and this amendment provide for funds to be made available to State agencies which administer the Child Care Food Program to be used to conduct audits of participating child care institutions.

EFFECTIVE DATE: August 25, 1978.

FOR FURTHER INFORMATION CONTACT:

Henry S. Rodriguez, Acting Director, Child Care and Summer Programs Division, Food and Nutrition Service, USDA, Washington, D.C. 20250, 202-447-8211.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget Circular A-102 provides that, prior to fiscal year 1978, audits of grantees must be conducted on a "reasonable frequency" basis. It further provides that, beginning with fiscal year 1978, such audits must be carried out at least once every 2 years. In recognition of the added financial burden this latter, more specific requirement would place on State agencies administering the program, provision was made in Pub. L. 95-166 to make funds available to help defray related costs. It was determined that the amount should be equal to 2 percent of program funds used by the individual State agency in the second fiscal year prior to the year in which the money would be made available.

In addition, the Department understands the legislative intent in this regard to include the use of the funds provided hereunder for administrative reviews of participaing institutions. The regulatory amendment so provides, with the stipulation that the State agency satisfy its audit requirement before using these funds for reviews.

Finally, it should be noted that in accordance with section 7(e) of the Child Nutrition Act of 1966, as amended by Pub. L. 95-166, funds which are allocated to the States for the current fiscal year shall be carried over into fiscal year 1979 and used for audits and reviews conducted during that year.

This amendment is nondiscretionary because of the legislative mandate. For this reason, it is made without proposed rulemaking and a public participation procedure.

Accordingly, part 226 is amended as follows:

1. In § 226.4, paragraph (d) is added as follows:

§ 226.4 Payment of food assistance funds to States.

* * * * *

(d) Within 15 days after issuance of this amendment, and on the first day of each fiscal year following the issuance of this amendment, the Secretary shall make available by Letter of Credit to each State agency an amount equal to two percent of the program reimbursement paid to institutions within the State during the second fiscal year preceding the fiscal year in which these funds are made available for the purpose of conducting audits of institutions participating in the program in accordance with § 226.27(f). Funds available to each State in fiscal year 1978 that are not obligated or expended in fiscal year 1978 shall remain available for obligation and expenditure by that State in fiscal year 1979. For fiscal year 1979, and the succeeding fiscal year, the Secretary shall establish a date by which each State shall submit to the Secretary a plan for the disbursement of funds under this section for each such year, and the Secretary shall reallocate any unused funds as evidenced by such plans, to other States as the Secretary deems appropriate.

In § 226.27, paragraph (f) is added as follows:

§ 226.27 Management evaluations and audits.

* * * * *

(f) In conducting audits for any fiscal year the State agency shall use the funds provided for in § 226.4(d) first to meet the fiscal audit requirements outlined in this section. Costs pertaining to such audits shall not be borne in whole or in part by the institution. Audits provided for herein shall be fiscal audits and shall be conducted in accordance with the Secretary's guidelines. After fulfilling the audit requirements, any remaining funds may be used by the State agency to conduct administrative reviews of program operations in institutions.

* * * * *

(Catalog of Federal Domestic Assistance Programs No. 10.558.)

NOTE.—The Food and Nutrition Service has determined that this document does not contain significant proposals requiring preparation of an economic impact statement under Executive Order 11821 and Office of Management and Budget Circular A-107.

Dated: August 17, 1978.

CAROL TUCKER FOREMAN,
Assistant Secretary.

[FR Doc. 78-23656 Filed 8-24-78; 8:45 am]

[3410-30]

PART 245—DETERMINING ELIGIBILITY FOR FREE AND REDUCED PRICE MEALS AND FREE MILK IN SCHOOLS

Racial Identification

AGENCY: Food and Nutrition Service, USDA.

ACTION: Interim rule.

SUMMARY: This interim regulation amends part 245 to provide that State agencies require school food authorities which will participate in the formal Department of Health, Education and Welfare (DHEW) Public School Civil Rights Survey, October 1978, to gather racial and ethnic data on applicants for free and reduced price meals served under the national school lunch program and school breakfast program. State agencies may allow such school food authorities the option of requesting the parents on the free and reduced price meal application to voluntarily self-identify their child's racial or ethnic identity.

DATE: This interim regulation will become effective upon signature, to be assured of consideration by the Department in the formulation of the final regulation, comments on this interim regulation must be postmarked by January 15, 1979.

ADDRESS: Comments should be sent to Margaret O'K. Glavin, Acting Director, School Programs Division, FNS, USDA, Washington, D.C. 20250, 202-447-8130.

FOR FURTHER INFORMATION CONTACT:

Margaret O'K. Glavin, Acting Director, School Programs Division, FNS, USDA, Washington, D.C. 20250, 202-447-8130.

SUPPLEMENTARY INFORMATION: Title VI of the Civil Rights Act of 1964 prohibits discrimination on the grounds of race, color, or national origin in programs receiving Federal assistance. The authority of the Attorney General to coordinate enforcement by Federal departments and agencies of title VI was defined in Executive Order 11764 of January 21, 1974. The Department of Justice developed regulations (28 CFR 42) to implement this authority. These regulations require the collection of data on the race and ethnicity of applicants for and recipients of Federal assistance. The major purposes of such data collection are to measure the accurual of program benefits to all eligible persons and to assure that benefits are equitable and are made available without regard to race, color, or national orgin.

The collection of racial and ethnic data to determine compliance with title VI is well founded both in regulations and in judicial precedent.

FNS collected racial and ethnic data for public schools until 1975 on the FNS form 87. The form was terminated at that time because it proved to be an effective data collection method. FNS has now entered into an agreement with DHEW to conduct a joint data collection activity, in an effort to satisfy requirements in this area and simultaneously to reduce unnecessary paperwork. This activity will be part of the formal DHEW Public School Civil Rights Survey beginning in the 1978-79 school year and will involve approximately 59,000 public schools. Pursuant to the agreement, records in survey schools will be reviewed to determine the racial and ethnic background of applicants for free or reduced price meals under the National School Lunch and School Breakfast Programs.

Therefore, the Department is amending 7 CFR Part 245 to provide for State agencies to require school food authorities of schools in the DHEW survey to develop procedures to gather information on the racial and ethnic identification of children for whom applications for free and reduced price meal benefits are filed. While visual surveys are the least intrusive method of collecting data on race and ethnicity of applicant children, State agencies may allow such school food authorities to request parents on the free and reduced price meal application to voluntarily self-identify the racial or ethnic identity of their child provided that the letter to parents and application contain the specific wording prescribed by these regulations which describes why the data is being collected. Parental response to such a request is purely voluntary. In no event will failure to respond on the part of the applicant affect the child's eligibility for free or reduced price meal benefits.

COMMENT PERIOD

Comments are invited from State agency and local school personnel and the general public, and are especially encouraged from those persons directly affiliated with schools participating in the survey.

Commentors should address their remarks to the provisions and other areas of concern contained in these interm regulations and indicate whether they are associated with schools participating in the survey. While these regulations must be implemented in the 1978-79 school year to conform to other regulatory requirements, comments will be especially helpful to the Department in assessing the provision prior to the development of final program regulations.

All written submissions received will be made available for public inspection at the School Programs Division, Food and Nutrition Service, during regular business hours (8:30 a.m. to 5 p.m., Monday through Friday) (7 CFR 1.27(b)).

Accordingly, part 245 is amended by adding a new § 245.13 "Special responsibilities of State agencies."

§ 245.13 Special responsibilities of State agencies.

(a) State agencies shall require school food authorities of schools selected for participation in the Department of Health, Education, and Welfare Public School Civil Rights Survey to gather information on the race and ethnicity of children for whom applications for free and reduced price meals are filed.

(b) To comply with the provisions of § 245.13(a) above, State agencies at their discretion may permit such school food authorities the option of requesting parents on application forms to voluntarily self-identify the race or ethnicity of their child for whom application is being made. Parents' provision of this information is purely voluntary and failure to provide this information will not affect the eligibility for benefits of the child for whom application is made. School food authorities shall develop alternative means of providing racial and ethnic data for applicants when such information is not voluntarily provided by parents on the application.

(c) School food authorities in such

survey schools which are granted the option by the State agency and wish to request that the parents voluntarily self-identify the race or ethnicity of their children on the application form shall include the following statement on the letter to parents: "A survey is being conducted in your school to collect racial and ethnic data on applicants. This information is voluntary and will not affect your child's eligibility. This information is being collected to be sure everyone receives school meals on a fair basis, without regard to race, color, or national origin." Such schools shall also include the following statement on the application: "Please check in the space provided the racial or ethnic identity of your child(ren). This information is voluntary and will not affect your child's eligibility. This information is being collected only to be sure that everyone receives school meals on a fair basis, without regard to race, color, or national origin." Schools which provide for racial and ethnic identification data collection of applicants by means other than parental self-identification need not include the above statements on the application or parental letter

(d) Participation in the survey shall not affect reimbursement or individual eligibility for program participation or benefits. The data collected shall be confidential and shall be used solely to determine the equitable distribution of benefits without regard to race, color, or national origin.

(Catalog of Federal Domestic Assistance No. 10.555.)

NOTE.—The Food and Nutrition Service has determined that this document does not contain major proposals requiring preparation of an economic impact statement under Executive Order 11821 and OMB Circular A-107.

Dated: August 22, 1978.

CAROL TUCKER FOREMAN,
Assistant Secretary.

[FR Doc. 78-23947 Filed 8-24-78; 8:45 am]

[3410-02]

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

[Lemon Regulation 160]

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation establishes the quantity of fresh California-Arizona lemons that may be shipped to market during the period August 27–September 2, 1978. Such action is needed to provide for orderly marketing of fresh lemons for this period due to the marketing situation confronting the lemon industry.

EFFECTIVE DATE: August 27, 1978.

FOR FURTHER INFORMATION CONTACT:

Charles R. Brader, 202-447-6393.

SUPPLEMENTARY INFORMATION: *Findings.* Pursuant to the marketing agreement, as amended, and Order No. 910, as amended (7 CFR part 910), regulating the handling of lemons grown in California and Arizona, effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), and upon the basis of the recommendations and information submitted by the Lemon Administrative Committee, and upon other information, it is found that the limitation of handling of lemons, as hereafter provided, will tend to effectuate the declared policy of the act.

The committee met on August 22, 1978, to consider supply and market conditions and other factors affecting the need for regulation and recommended a quantity of lemons deemed advisable to be handled during the specified week. The committee reports the demand for lemons continues good on 165's and larger, and easier on 200's and smaller.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the FEDERAL REGISTER (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation is based and the effective date necessary to effectuate the declared policy of the act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

§ 910.460 Lemon Regulation 160.

Order. (a) The quantity of lemons grown in California and Arizona which may be handled during the period August 27, 1978, through September 2, 1978, is established at 250,000 cartons.

(b) As used in this section, "handled" and "carton(s)" mean the same as defined in the marketing order.

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

Dated: August 23, 1978.

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

[FR Doc. 78-24277 Filed 8-24-78 11:36 am]

[3410-02]

PART 926—TOKAY GRAPES GROWN IN SAN JOAQUIN COUNTY, CALIF.

Expenses and Rate of Assessment

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation authorizes expenses and rate of assessment for the 1978-79 fiscal period to be collected from handlers to support activities of the Industry Committee which locally administers the marketing order for Tokay grapes grown in San Joaquin County, Calif.

DATES: Effective April 1, 1978, through March 31, 1979.

FOR FURTHER INFORMATION CONTACT:

Charles R. Brader, 202-447-6393.

SUPPLEMENTARY INFORMATION: *Findings.* Pursuant to marketing order 926, as amended (7 CFR Part 926), regulating the handling of Tokay grapes grown in San Joaquin County, Calif., effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), and upon the basis of the recommendations and information submitted by the Industry Committee established under the order, and upon other information, it is found that the expenses and rate of assessment, as hereafter provided, will tend to effectuate the declared policy of the act.

§ 926.218 Expenses and rate of assessment.

(a) Expenses that are reasonable and likely to be incurred by the Industry Committee during fiscal year April 1, 1978, through March 31, 1979, will amount to $116,856.50.

(b) The rate of assessment for said year payable by each handler in accordance with § 926.46 is fixed at $0.10 per No. 38L grape lug (as specified in § 1380.19 of the regulations of the

California Department of Food and Agriculture) or equivalent quantity of Tokay grapes.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the FEDERAL REGISTER (5 U.S.C. 553), as the order requires that the rate of assessment for a particular fiscal year shall apply to all assessable Tokay grapes handled from the beginning of such year which began April 1, 1978. To enable the Industry Committee to meet fiscal obligations which are now accruing, approval of the expenses and assessment rate is necessary without delay. Handlers and other interested persons were given an opportunity to submit information and views on the expenses and rate of assessment at an open meeting of the committee. It is necessary to effectuate the declared purposes of the act to make these provisions effective as specified.

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

Dated: August 21, 1978.

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

[FR Doc. 78-23913 Filed 8-24-78; 8:45 am]

[3410-02]

[Area No. 2]

PART 948—IRISH POTATOES GROWN IN COLORADO

Handling Regulation

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation requires fresh market shipments of potatoes grown in Colorado—Area No. 2 to be inspected and meet minimum grade, size, and maturity requirements. The regulation will promote orderly marketing of such potatoes and keep less desirable qualities and sizes from being shipped to consumers.

EFFECTIVE DATE: September 1, 1978.

FOR FURTHER INFORMATION CONTACT:

Charles R. Brader, Deputy Director, Fruit and Vegetable Division, AMS, U.S. Department of Agriculture, Washington, D.C. 20250, telephone 202-447-6393.

SUPPLEMENTARY INFORMATION: Marketing agreement No. 97 and order No. 948, both as amended, regulate the handling of potatoes grown in designated counties of Colorado Area No. 2. It is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674). The Colorado Area No. 2 Potato Committee, established under the order, is responsible for its local administration.

Notice of proposed rulemaking was published in the July 25, 1978, FEDERAL REGISTER (43 FR 32139) inviting comments by August 9, 1978. None was received.

This regulation is based upon recommendations for regulations made through October 31, 1978, made by the committee at its public meeting in Monte Vista, Colo., on June 22, 1978.

The grade, size, maturity, and inspection requirements specified herein are similar to those issued during past seasons. They are necessary to prevent potatoes of low quality or less desirable sizes from being distributed to fresh market outlets. They will benefit consumers and producers by standardizing and improving the quality of the potatoes shipped from the production area.

Exceptions are provided to certain of these requirements to recognize special situations in which such requirements would be inappropriate or unreasonable.

Shipments are permitted to certain special purpose outlets without regard to the grade, size, maturity, and inspection requirements, provided that safeguards are met to prevent such potatoes from reaching unauthorized outlets. Certified seed is exempt because requirements for this outlet differ greatly from those for fresh market. Shipments for use as livestock feed likewise are exempt. Since no purpose would be served by regulating potatoes used for charity purposes, such shipments are exempt. Potatoes for most processing uses are exempt under the legislative authority for this part.

Findings. After consideration of all relevant matter presented, including the proposal set forth in the aforesaid notice which was recommended by the Colorado Area No. 2 Potato Committee, established pursuant to said marketing agreement and order, it is hereby found that the handling regulation, as hereinafter set forth, will tend to effectuate the declared policy of the act.

It is hereby further found that good cause exists for not postponing the effective date of this section until 30 days after its publication in the FEDERAL REGISTER (5 U.S.C. 553) in that (1) shipments of potatoes grown in the production area will begin on or about the effective date specified herein, (2) to maximize benefits to producers, this regulation should apply to as many shipments as possible during the marketing season, and (3) compliance with this regulation, which is similar to that in effect during previous marketing seasons, will not require any special preparation on the part of persons subject thereto which cannot be completed by the effective date hereof.

The regulation is as follows:

§ 948.380 Handling regulation.

During the period September 1, 1978, through October 31, 1978, no person shall handle any lot of potatoes grown in Area No. 2 unless such potatoes meet the requirements of paragraphs (a), (b), and (c) of this section, or unless such potatoes are handled in accordance with paragraphs (d) and (e), or (f) of this section.

(a) *Minimum grade and size requirements.*—(1) *Round varieties.* U.S. No. 2, or better grade, 2-inches minimum diameter.

(2) *Long varieties.* U.S. No. 2, or better grade, 1⅞-inch minimum diameter.

(3) *All varieties.* Size B, if U.S. No. 1, or better grade.

(4) *All varieties for export.* One and one-half inch minimum diameter.

(b) *Maturity (skinning) requirements.*—(1) *Russet Burbank and Red McClure varieties.* For U.S. No. 2 grade not more than "moderately skinned" and for other grades not more than slightly skinned."

(2) *All other varieties.* Not more than "moderately skinned."

(c) *Inspection.* (1) No handler shall handle any potatoes for which inspection is required unless an appropriate inspection certificate has been issued with respect thereto and the certificate is valid at the time of shipment. For purposes of operation under this part it is hereby determined pursuant to § 948.40(d) that each inspection certificate shall be valid for a period not to exceed 5 days following the date of inspection as shown on the inspection certificate.

(2) No handler may transport or cause the transportation by motor vehicle of any shipment of potatoes for which an inspection certificate is required unless each shipment is accompanied by a copy of the inspection certificate applicable thereto and the copy is made available for examination at any time upon request.

(d) *Special purpose shipments.* (1) The grade, size, maturity, and inspection requirements of paragraphs (a), (b), and (c) of this section and the assessment requirements of this part shall not be applicable to shipments of potatoes for:

(i) Livestock feed;

(ii) Relief or charity; or

(iii) Canning, freezing, and "other processing" as hereinafter defined.

(2) The grade, size, maturity, and inspection requirements of paragraphs

(a), (b), and (c) of this section shall not be applicable to shipments of seed pursuant to § 948.6 but such shipments shall be subject to assessments.

(e) *Safeguards.* Each handler of potatoes which do not meet the grade, size, and maturity requirements of paragraphs (a) and (b) of this section and which are handled pursuant to paragraph (d) of this section for any of the special purposes set forth therein shall:

(1) Prior to handling, apply for and obtain a certificate of privilege from the committee;

(2) Furnish the committee such reports and documents as requested, including certification by the buyer or receiver as to the use of such potatoes; and

(3) Bill each shipment directly to the applicable processor or receiver.

(f) *Minimum quantity.* For purposes of regulation under this part, each person may handle up to but not to exceed 1,000 pounds of potatoes without regard to the requirements of paragraphs (a), (b), and (c) of this section, but this exemption shall not apply to any shipment which exceeds 1,000 pounds of potatoes.

(g) *Definitions.* The terms "U.S. No. 1," "U.S. No. 2," "Size B," "slightly skinned," and "moderately skinned" shall have the same meaning as when used in the U.S. Standards for Potatoes (7 CFR 2851.1540-2851.1566), including the tolerances set forth therein. The term "other processing" has the same meaning as the term appearing in the act and includes, but is not restricted to, potatoes for dehydration, chips, shoestrings, starch, and flour. It includes only that preparation of potatoes for market which involves the application of heat or cold to such an extent that the natural form or stability of the commodity undergoes a substantial change. The act of peeling, cooling, slicing, dicing, or applying material to prevent oxidation does not constitute "other processing." Other terms used in this section shall have the same meaning as when used in Marketing Agreement No. 97, as amended, and this part.

(h) *Applicability to imports.* Pursuant to section 8e of the act and §980.1, Import regulations (7 CFR 980.1), Irish potatoes of the red-skinned round type, except certified seed potatoes, imported into the United States during the period September 1, 1978, through October 31, 1978, shall meet the minimum grade, size, quality, and maturity requirements specified in paragraphs (a) and (b) of this section.

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

Dated August 21, 1978, to become effective September 1, 1978.

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

[FR Doc. 78-23914 Filed 8-24-78; 8:45 am]

[3410-07]

CHAPTER XVIII—FARMERS HOME ADMINISTRATION, DEPARTMENT OF AGRICULTURE

SUBCHAPTER J—LOAN AND GRANT PROGRAMS (GROUP)

PART 1933—LOAN AND GRANT PROGRAMS (GROUP)

Subpart A—Community Facility Loans

INTERIM RULE

AGENCY: Farmers Home Administration, USDA.

ACTION: Interim rule.

SUMMARY: The Farmers Home Administration amends its regulations regarding contracts for construction on projects financed with loans and/or grants. The amendment would permit the contractor to furnish a bank letter of credit or a cash bond as surety for contract completion. The intent is to permit an alternate form of surety in those cases where a contractor is unable to obtain a performance payment bond or the cost of a bond would be exorbitant because of the nature of the project. This action is taken because of an administrative decision.

EFFECTIVE DATE: August 25, 1978. However, comments must be received on or before September 25, 1978.

ADDRESSES: Submit written comments to the Chief, Directives Management Branch, Farmers Home Administration, USDA, Room 6316, Washington, D.C. 20250. All written comments made pursuant to this notice will be available for public inspection at the address given above.

FOR FURTHER INFORMATION CONTACT:

Mr. John Bowles, 202-447-7667.

SUPPLEMENTARY INFORMATION: FmHA amends § 1933.18(a)(9)(ii)(F)(*3*) of Subpart A, Part 1933, Chapter XVIII, Title 7 in the Code of Federal Regulations. This amendment prescribes two additional forms of contract surety. There have been cases where contractors have been unable to obtain performance and payment bonds because surety companies had little or no experience with the particular type of construction projects. There have been other cases where bonds were obtainable but at an exorbitant cost. The amendment permits a qualified contractor to give a cash deposit in escrow or use a letter of credit as surety for contract completion. The use of surety other than performance and payment bonds will require prior approval by the national office for each case. It is the policy of the Department that rules relating to public property, loans, grants, benefits, or contracts shall be published for comment, notwithstanding the exception in 5 U.S.C. 553 with respect to such rules. This amendment, however, is being published effective on an interim basis since the amendment relieves a restriction and since any delay in implementing this amendment would be contrary to the public interest by preventing some qualified contractors from bidding on publicly financed projects. Comments made pursuant to this notice will be considered in the development of the final rule. Therefore, § 1933.18(a)(9)(ii)(F)(*3*) is amended as follows:

§ 1933.18 Appendix B—Community facilities—Planning, bidding, contracting, constructing.

(a) * * *

(9) Procurement, bidding, and contract. * * *

(ii) * * *

(F) * * *

(*3*) In all contracts for construction or facility improvement awarded in excess of $100,000, the borrower shall require bonds, a bank letter of credit, or cash deposit in escrow, assuring performance and payment of 100 percent of the contract cost. The use of surety other than performance and payment bonds will require concurrence by the national office after submission of a suitable justification by the State director together with the proposed form of escrow agreement or letter of credit. Such requests will be limited to those types of projects, where the contractor is unable to obtain a bond or the cost would be exorbitant. For contracts of lesser amounts the borrower may require such surety. When a performance and payment bond is not provided, contractors will furnish evidence of payment in full for all materials, labor, and any other items procured under the contract. Form FmHA 424-10, "Release by Claimants," and form FmHA 424-9, "Certificate of Contractor's Release," may be obtained at the local FmHA office and used for this purpose. The United States, acting through the Farmers Home Administration, will be named as coobligee on all surety unless prohibited by State law.

* * * * *

(7 U.S.C. 1989; delegation of authority by the Secretary of Agriculture, 7 CFR 2.23;

delegation of authority by Assistant Secretary for Rural Development, 7 CFR 2.70.)

Dated: August 9, 1978.

GORDON CAVANAUGH,
Administrator,
Farmers Home Administration.

[FR Doc. 78-23916 Filed 8-24-78; 8:45 am]

[7535-01]

Title 12—Banks and Banking

CHAPTER VII—NATIONAL CREDIT UNION ADMINISTRATION

PART 701—ORGANIZATION AND OPERATIONS OF FEDERAL CREDIT UNIONS

Final Rule—Loan Origination Fees

AGENCY: National Credit Union Administration.

ACTION: Final rule.

SUMMARY: This rule amends the National Credit Union Administration's real estate lending regulation and establishes limits on loan origination fees that Federal credit unions may charge to borrowers. Permitting originating fees (commitment fees, processing fees, administrative fees) will allow Federal credit unions to recover the additional costs of originating real estate loans.

EFFECTIVE DATE: This regulation is to be effective September 25, 1978.

ADDRESS: National Credit Union Administration, 2025 M Street NW., Washington, D.C. 20456.

FOR FURTHER INFORMATION CONTACT:

Robert M. Fenner, Assistant General Counsel, Office of General Counsel, or Thomas C. Buckman, Examination and Insurance, at the above address, telephone 202-632-4870 (Mr. Fenner) or 202-254-8760 (Mr. Buckman).

SUPPLEMENTARY INFORMATION: With the amendment of the Federal Credit Union Act (12 U.S.C. 1751, et seq.; hereafter "the Act") by Pub. L. 95-22, Federal credit unions received the authority to grant long-term real estate loans with maturities up to 30 years. Pursuant to this authority the Administration promulgated the real estate lending regulation which became effective May 8, 1978. The Administration announced on April 7, 1978, that it proposed to amend the real estate lending regulation to prohibit loan origination fees and to require written notification where the possibility of a refund exists (i.e., in the event of early payment of a mortgage loan which has included "front-end" charges). Public comment was invited to be received on or before May 8, 1978. Thirty-five comments were received, the majority of which were in opposition to the proposed amendment to the real estate lending regulation. In response to the public comments the Administration has made various changes in the proposed amendment.

LOAN ORIGINATION FEES

Credit unions traditionally have not assessed origination fees in connection with consumer loans to their members. In keeping with this tradition, the proposed regulation would have prohibited such fees in connection with real estate loans. The vast majority of commentors objected to this proposal, noting: (i) That the costs of originating mortgage loans are substantially greater than those for other consumer loans, and (ii) certain insured and guaranteed loan programs regulate contract interest rates and origination fees in a way that creates a practical necessity of assessing the fees in order for Federal credit unions to be competitive with other lenders.

In response to the public comments the Administration has determined that within certain limits Federal credit unions will be allowed to assess loan origination fees in order to recoup the additional costs of originating real estate loans. It is not the intent of the Administration that loan origination fees be used by Federal credit unions to increase income. Accordingly, the Administration has determined to allow loan origination fees within specified limits (one-half of 1 percent of the loan amount except in the case of insured or guaranteed loans the loan origination fee may equal 1 percent of the loan amount). However, it is not the Administration's intent to encourage the assessment of such fees.

The Administration will carefully monitor Federal credit union practices in this regard, to assure that origination fees are assessed in a manner which reflects actual origination costs. Also, Federal credit union borrowers are protected by the statutory 1 percent per month ceiling on the effective interest rate (inclusive of any origination fees or other service charges) on all Federal credit union loans.

PREPAYMENT REBATE

If a Federal credit union assesses origination fees or other service charges on mortgage loans, these charges must not cause the effective interest rate to exceed the statutory ceiling—1 percent per month "inclusive of all service charges." In the event of prepayment of a loan with origination fees or other "front-end" service charges, the Federal credit union must consider the impact of the prepayment upon the effective rate and make a rebate (or adjust the amount of the final payment) if necessary to stay within the 1-percent ceiling.

The proposed amendment would have required that Federal credit unions provide affected borrowers with a written notice of this potential rebate. A majority of the commentors objected to the written notice, citing the cumulative impact of such requirements upon both the creditor's paperwork burden and the volume and complexity of disclosures. Also, to the extent that the front-end charges are elements of the "finance charge" within the meaning of the Federal Truth in Lending Act and regulation Z, disclosure of the method of rebate of unearned charges (in the event of prepayment) is already required by § 226.8(b)(7) of regulation Z. For these reasons, the Administration has determined to dispense with the written notice proposal.

It should be understood that Federal credit unions are nonetheless required to make a rebate or adjustment in appropriate cases, and that the Administration will monitor compliance with this requirement through its examination process.

Finally regarding the subject of rebates, the Administration's staff hopes to issue specific guidelines in the near future concerning compliance with the above noted truth in lending requirement.

LAWRENCE CONNELL,
Administrator.

AUGUST 18, 1978.

(Sec. 107, 91 Stat. 49 (12 U.S.C. 1757); sec. 120, 73 Stat. 635 (12 U.S.C. 1766); sec. 209, 84 Stat. 1104 (12 U.S.C. 1789).)

Accordingly 12 CFR 701.21-6 is amended as follows:

(1) Paragraph (c)(6) is added to the regulation to read as follows:

* * * * *

(c) * * *

(6) A Federal credit union shall not charge a loan origination fee in excess of one-half of 1 percent of the loan amount except that the loan origination fee charged on an insured or guaranteed loan may equal up to 1 percent of the loan amount if authorized pursuant to law or regulation of the insuring or guaranteeing agency.

[FR Doc. 78-23917 Filed 8-24-78; 8:45 am]

[4110-03]

Title 21—Food and Drugs

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

SUBCHAPTER C—DRUGS: GENERAL

[Docket No. 78N-0109]

PART 201—LABELING

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 314—NEW DRUG APPLICATIONS

Prescription Drug Dispensing Container Requirements

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule requires the manufacturer of a prescription drug product to include information on the drug label telling the pharmacist the type of dispensing container needed to maintain the identity, strength, quality, and purity of the drug product. This brief description of the proper container, e.g., light-resistant, well-closed, or tight, is not required on drug products intended to be dispensed in the manufacturer's original container.

EFFECTIVE DATE: Compliance with this regulation may begin immediately. The regulation is effective for all products introduced or delivered for introduction initially into interstate commerce on or after August 27, 1979.

FOR FURTHER INFORMATION CONTACT:

Robert D. Bradley, Bureau of Drugs HFD-30, Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-5220.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of August 26, 1974, (39 FR 30844), the Commissioner of Food and Drugs proposed to amend § 1.106 (21 CFR 1.106, now 21 CFR 201.100, as recodified in the FEDERAL REGISTER of March 22, 1977 (42 FR 15553)) and § 314.1 (21 CFR 314.1) to include, as part of the prescription drug product label, information directed to the pharmacist about the type of container to be used in dispensing the drug product to the patient. The proposed requirements were scheduled for implementation in July 1975 to be concurrent with the implementation of the United States Pharmacopeia (U.S.P.) and the National Formulary (N.F.) standards for tightness of seal (well-closed or tight). The effective date of these standards was delayed until April 1, 1977 to ensure availability of appropriate containers. The Commissioner is allowing additional time before implementing the labeling requirements because of concern over the availability of prescription containers and because some manufacturers may need additional time to determine the proper prescription container and to make corresponding labeling changes.

The Commissioner advises, however, that the compendial standards for tightness of seal are in effect, and compliance with these requirements is necessary at this time in accordance with section 502(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(g)). These standards apply to both the containers used by the manufacturers and the containers used by pharmacists for dispensing certain compendial drugs. Manufacturers have always been required to package drug products in containers that protect the contents until the expiration date or, if no expiration date is shown, throughout the period of normal shelf life until the container is opened. The Commissioner believes that the manufacturer's original container will exceed the specifications for tightness of seal as defined in the official compendia.

Prior to the compendial standards for tightness of container seals, no official standards and test procedures were established for determining whether dispensing containers for prescription drugs met the requirements for specified types of containers as defined in the U.S.P. and N.F. The standards for tightness caused the container manufacturing industry to develop a new container to meet these requirements. Because of concern over the availability of these prescription containers to the pharmacist, on March 9, 1977 the Food and Drug Administration (FDA) recommended that enforcement action under the tight-container requirement be withheld if spot shortages occurred. However, there were no reports of shortages; therefore, on July 18, 1977, FDA withdrew its recommendation.

The Food and Drug Administration received 23 responses to the proposal from drug and container manufacturers, pharmaceutical associations, government agencies, hospitals, and interested professionals. The substantive comments received and the Commissioner's conclusions concuring them are discussed below.

1. Many of the comments stated that the proposed regulations would require the pharmacist to maintain a costlier inventory of several types of prescription drug containers, e.g., tight containers and well-closed containers in both child-resistant and non-child-resistant form, and made of both clear and light-resistant materials, in both glass and plastic. One comment stated that if one manufacturer designates one type of container for a multisource drug and another manufacturer specifies a different container for the same drug, then the pharmacist would be required either to stock duplicate containers or to ignore the instructions of one manufacturer.

The Commissioner does not believe that this regulation alone will significantly affect a pharmacist's inventory of prescription drug product containers. Monographs for many compendial drug products already specify container types to be used in packaging and storing a drug product, e.g., light-resistant container, tight container, and well-closed container. Because these packaging and storage requirements apply to prescription drug products, the pharmacist must already maintain a complete inventory of containers to meet these compendial requirements for dispensing compendial drug products. For a noncompendial drug product, manufacturers should, if possible, use terminology defined in an official compendium to describe a suitable container for dispensing the product. The Commissioner does not believe that noncompendial drug products would require any types of dispensing containers different from those required for compendial drug products. This regulation, therefore, does not increase the types of containers a pharmacist needs to stock. Furthermore, existing stocks of dispensing containers do not become obsolete because not all drug products require the tight containers; in many instances, stocks of older containers will meet the less rigid well-closed container requirements.

The Commissioner realizes that manufacturers of similar drugs may require different types of prescription containers, because storage conditions for a drug product are based on the manufacturer's stability studies. The requirements set forth by this regulation would enable a pharmacist to select the correct dispensing container in these instances.

2. Several comments questioned the feasibility of using a tight container in conjunction with child-protective packaging. The comments stated that because most containers with caps for child-protective packaging do not seal, greater air moisture movement occurs with continued use. In addition, most of these caps have an inner lining of porous, sponge-foam plastic so that a tight seal may not be possible.

The Commissioner advises that tight containers are in use, including tight containers with child-proof caps. While many of the prescription drug

containers for child-protective packaging that were in use at the time of the proposal did not meet the requirements of a tight container, the Commissioner has found that suitable containers are now available. Further, as stated previously, the U.S.P. and N.F. container standards became effective on April 1, 1977, and no shortages have since been reported.

3. One comment stated that when a manufacturer markets a prescription drug intended to be dispensed to the patient in the manufacturer's original container, the labeling should indicate whether the container is child resistant.

The Poison Prevention Packaging Act of 1970 and the implementing regulations contained in part 1700 of title 16 of the Code of Federal Regulations (16 CFR part 1700) require oral prescription drugs to be in child-protective packaging when dispensed to a patient. Therefore, a statement indicating whether or not such a package is child resistant would not be useful. Further, the pharmacist is obligated to dispense oral prescription drugs in child-protective packaging unless otherwise directed by the physician, by the patient, or specifically exempted by the regulations, e.g., oral contraceptives, nitroglycerin, and nitrosorbide.

4. Two comments recommended that the regulations provide exemptions for any manufacturer's package that complies with poison prevention packaging requirements.

The Commissioner does not agree with this comment. He believes that each dispensed drug product, whether or not it is dispensed in a child-resistant container, must be stored in a container that will maintain the identity, strength, quality, and purity of the drug product. He believes that this comment may have been prompted by the fact that few child-resistant containers met the tight-seal requirement at the time this regulation was proposed. This situation has changed. The temporary lack of child-resistant containers was a primary reason that the U.S.P. and N.F. delayed the implementation of the container requirements until April 1, 1977. There now are sufficient child-resistant containers that also meet the tight-seal requirements.

5. Several comments requested that FDA provide a reasonable period of time for compliance. Some comments thought that special containers would be available only after a reasonable transition period. One comment stated that because packaging that is both tight fitting and child protective is not available, dispensing pharmacists would be required to break the law when dispensing certain drug products. Comments also requested a reasonable transition period to allow drug manufacturers to exhaust present label inventory and make the necessary modifications in new labeling.

The Commissioner notes that the concern over possible shortage was limited to tight containers. Since the U.S.P. and N.F. requirements became effective on April 1, 1977, which is almost 2 years after the originally scheduled effective date, FDA has not received any reports of shortages of containers. As previously mentioned, FDA had recommended that enforcement action be withheld if shortages occurred, but because none were reported, FDA recommended that compendial requirements for prescription containers be enforced. The requirement that manufacturers label prescription drugs to designate the proper container will not significantly increase the demand for tight containers; most prescribed drugs are subject to container standards as provided by a U.S.P. or N.F. monograph.

The Commissioner is, however, allowing sufficient time before implementing the labeling requirements for prescription containers so that manufacturers can exhaust their label inventory and devise new labeling.

6. Several comments were concerned that the container requirements would be costly to both the container industry and the consumer. One comment stated that at the time the N.F. proposed the tight container standards for drug packaging, no plastic vials (either child-resistant or regular type) could have met the levels for moisture vapor transmissions, and 80 percent of the containers were of styrene vials. Therefore, to meet the requirements by July 1975, as originally planned, massive replacement of these vials would be necessary. A container manufacturer's analysis of the top 200 drug products dispensed in 1973 indicated that over 70 percent would require tight containers. It was then thought desirable for the pharmacist to stock only "tight" containers, but this action would create a demand for about 1.6 billion capsule and 1.9 billion tablet containers per year. Another container manufacturer stated that in 1975, only its wide-mouth powder jars and glass capsule bottles that closed with continuous threaded closures could meet the tight container requirements, and they represented only about 5 percent of their styrene vial sales. Further, the comment stated that to meet the tight container requirements, replacement in tools, machines, new buildings, and ancillary production equipment would require 2 to 3 years to implement. In addition, a capital investment of $1.5 million to $3 million would be involved. Another manufacturer estimated that the cost of the vial would be increased from 30 percent to 100 percent, and this cost would have to be passed to the consumer. Two national container manufacturers' associations estimated that the new capital investment necessary for the container industry to achieve full compliance would exceed $14 million. That total represented new manufacturing equipment, write-off of some existing machinery, plant requirements, and new closure capacity. These two comments stated that the impact to the consumer and container industry would be moderated if an appropriate transition period were adopted.

The Commissioner believes that the stay until April 1, 1977, granted by the U.S.P. and N.F. in implementing their container requirements, has lessened the burden that would have been imposed on drug and container manufacturers if these requirements had been imposed at an earlier date. Sufficient containers complying with the compendial standards are now available. The Commissioner, while not disputing the economic impact figures presented by the container manufacturers, believes that the additional 2-year transition period provided for container manufacturers to meet the demands for the various containers for drugs other than official compendial drugs has been more than reasonable. Neither the inflationary impact that would be imposed upon container manufacturers nor the total impact to industry, government, and consumers is considered a major economic impact as defined in Executive Orders 11821 and 11949, OMB Circular A-107, and guidelines issued by the Department of Health, Education, and Welfare.

7. One comment contends that the scope of the proposed regulation should be expanded to cover over-the-counter (OTC) drugs, cosmetics, notions, and sundries to preserve their identity, strength, quality, and purity, on the theory that all are stored together in a pharmacy and in the home medicine chest. The example was given that a non-prescription drug normally requiring only a well-closed container may be significantly affected by extraneous vapors from a highly efflorescent or volatile item stored beside it.

The Commissioner does not agree with this comment. A labeling requirement indicating the type container to use would not serve a useful purpose, because OTC drugs and cosmetics are normally sold in the manufacturer's original package. With respect to OTC drugs, good manufacturing practice regulations require these products to be packaged to preserve the products' original identity, strength, quality, and purity. Likewise, manufacturers of cosmetics would use the most suitable container for their products.

8. Two comments indicated that the regulation failed to differentiate between prescription drugs dispensed by a pharmacist and those administered by a licensed practitioner. One of the Comments recommended that proposed § 201.100(b) be reworded to explain the difference. One comment stated that pharmacists would not need to know the type of container in which to dispense a drug product such as an anesthetic used in surgical settings or a topical fluoride used by a dentist.

The Commissioner concludes that the regulation does distinguish between drugs dispensed by a pharmacist and those drugs usually administered by a licensed practitioner. The last sentence of § 201.100(b) says that the statement specifying the type of container to be used is not required for unit-dose or unit-of-use packaging or any other packaging format in which medication is dispensed in the manufacturer's original package. A package containing an injectable product, for example, would not need the statement. Therefore, these comments are not accepted.

9. Three comments were concerned with the practice of unit-of-use and single-dose packaging. They stated that hospital pharmacists, in particular, have been packaging drugs in single-unit doses with increased frequency over the last few years. The comments stated that pharmacists do not have readily available information about the permeability of unit-of-use or single-dose containers. One comment stated that single-unit containers are sometimes kept for as long as 5 weeks.

The Commissioner advises that this rule does not apply to single-unit or unit-of-use containers. If a manufacturer markets a drug in a unit-of-use or single-unit package that is intended to be distributed to the patient in the manufacturer's original package, the manufacturer is required to use a container that will maintain the strength, identity, and purity of the packaged drug. If the hospital pharmacist repackages a drug into unit-of-use or single-unit containers, that person should also use containers or packaging materials appropriate for the particular drug. A statement in the drug labeling about the type of container to be used for repackaging the drug, even though intended for the pharmacist dispensing the drug in a multiple-unit container, will aid the hospital pharmacist in selecting the proper packaging material.

10. Some comments suggested a money savings by not requiring container specifications on drug products that are stable even if subjected to stresses of moisture, heat, and light. One comment recommended that only drugs with stability problems require container specifications.

The Commissioner rejects these suggestions. If the labeling does not include container specifications, the pharmacist cannot always be assured that the manufacturer considered the necessity of such specifications. The integrity of most, if not all, drugs may be compromised by dispensing in unsatisfactory containers; thus, it is neither appropriate nor readily feasible to identify drugs with known stability or handling problems and apply container specifications only to them.

11. One comment expressed the opinion that the regulations would provide container directions to pharmacists when the original container is inappropriate for dispensing. The comment stated that the wording "is dispensed" in § 201.100(b) implies that the package must be dispensed to be exempt from the requirement, despite the fact that the package was designed and is suitable for use as a patient package. It was suggested that the wording be changed to show that container directions are not required for prescription drugs whose original package is designed and suitable for dispensing to patients without repackaging.

The Commissioner concludes that the intent of the regulation as proposed is the same as that recommended in this comment. To avoid confusion, the Commissioner accepts this comment and has revised this provision accordingly.

12. One comment recommended that liquids be exempt from the labeling requirement, because a liquid is usually dispensed in an amber-colored glass bottle with a screw top and would automatically meet the requirements for light resistance and tight seal.

The Commissioner does not agree with this recommendation. If liquids were exempt from the container specification requirement, the pharmacist might attribute the absence of such a statement to a lack of importance in choosing the appropriate container. With container specifications directly on the manufacturer's label, the pharmacist can more readily determine which container is appropriate.

13. One comment stated that manufacturers of drug products have long been responsible for proper packaging and labeling of their products but have little control over subsequent repackaging and storage by pharmacists. The comment, therefore, saw no practical benefit from the proposed label requirement and suggested that it would be more effective to establish pharmaceutical grade container specifications that would be developed, implemented, identified, and guaranteed by the container manufacturer.

Both phamacists and drug manufacturers are responsible for packaging a drug product in accordance with packaging requirements specified in the monographs for drug products recognized in the official compendia. In the absence of compendial specifications, the pharmacist often has little or no information on which to base the selection of a suitable container. For this reason, FDA considers it appropriate to require that such information be available to the pharmacist for all drugs. As stated in the preamble to the proposal, the Commissioner believes that the manufacturer of a drug product is the person best able to imform the pharmacist of what constitutes a suitable container for that product. The label statement directed to the pharmacist, as required by this regulation, is therefore considered necessary to enable the pharmacist to select a container for dispensing a drug product that is adequate to maintain the product's original identity, strength, quality, and purity.

14. One comment recommended the standardization of a phamaceutical grade multiple-dose container line of bottles, vials, and closures that would satisfy basic light-resistance, weight, and tight-closure characteristics for most oral preparations. Other comments suggested urging pharmacists to use only tight containers, and one comment stated that the burden to show adequate stability in anything less than a tight container should rest upon whoever proposes to dispense or recommend dispensing in anything less.

The Commissioner advises that this regulation does not preclude a pharmacist from dispensing drug products in containers having specifications of higher quality than that designated by the manufacturer. The Commissioner believes that the suggestion to use only tight containers may simplify the pharmacist's job; however, FDA lacks the authority to require that drug containers exceed actual packaging needs of the drug involved. Because the Commissioner believes that the types of containers needed for noncompendial drugs do not differ greatly from those already required to be used by a pharmacist for compendial drugs, this regulation does not impose any additional burden on pharmacists in maintaining an adequate inventory of dispensing containers.

15. Several comments indicated that the pharmacist is the person best able to select an appropriate container in certain situations. One comment questioned the statement from the proposal that the manufacturer is most able to determine the best prescription container for a particular product and pointed out that pharmacists have years of professional training to equip

them in making dispensing decisions. Further, the comment stated that the manufacturer's original container is an excellent reference source as to the type of container to be used for the drug. Therefore, the pharmacist would be able to make a comparison in selecting a container that would not unreasonably jeopardize the purity and quality of the drug product. Several comments stated that the proposal failed to consider prescriptions that are to be consumed immediately or in a matter of hours and that the pharmacist would be most able to select the proper container in this situation.

While not disputing a pharmacist's expertise or judgment, the Commissioner contends that manufacturers are best able to recommend the appropriate prescription container for a particular product. Because manufacturers are required to do stability studies on the product, they already have available much of the data needed to determine the proper prescription container. It would be extremely difficult to predict the time within which it would be permissible for a product requiring tight closure to be dispensed instead in a well-closed container. Further, there is no assurance that a product will be entirely used within a prescribed time. With regard to the pharmacist comparing a container to the manufacturer's original container, such a comparison would provide some information as to the type of closure needed, but it would not be necessarily adequate. Manufacturers package their products to assure their integrity, through seals or other means, to protect the products under varying condition of storage and handling. The Commissioner therefore maintains that the pharmacist should give careful attention to the manufacturer's directions for container selection.

16. One comment stated that the discretionary language about the type of container to be used could vitiate the U.S.P. container program.

The Commissioner disagrees with this comment. If a drug is subject to a U.S.P. or N.F. monograph, the statement in the labeling specifying the type of container to be used has to be consistent with any wording in the monograph. Therefore, this regulation is consistent with the U.S.P.'s container program. In the case of drugs not subject to a U.S.P. or N.F. monograph, the manufacturer's statement directs the pharmacist to use a type of container that is specified for that particular drug.

17. Five comments suggested that labeling statements specifying appropriate containers should not be required until the level of required protection is known and subject to drug monographs, or until some other specific determination has been made that requirements such as a tight container are needed. One comment recommended that the regulation require the labeling statement for only those drugs that need special handling, protection, or storage when dispensed to a patient and which are not subject to compendial storage requirements specifying the type of container.

The Commissioner believes that for proper enforcement of the act, prescription drug products must be labeled to specify the appropriate container to assure that they are dispensed in a manner that provides maximum protection to the consumer. The U.S.P. and N.F. contain monographs specifying containers for many drug products. For drug products not subject to an official monograph, the manufacturer can determine the proper container. A container cannot be specified unless stability data are available. The manufacturer should know the type of container necessary to maintain the stability of its product. If the manufacturer fails to identify the appropriate container for a drug product, the pharmacist has no assurance that the proper container was considered. Whether the drug is recognized in an official compendium should not be a basis for determining the need for the container statement.

18. One comment suggested that labeling requirements specifying appropriate prescription containers could be best enforced under the Consumer Product Safety Act.

The Commissioner disagrees with this comment. The Food and Drug Administration, not the Consumer Product Safety Commission, has the authority to require drug manufacturers and pharmacists to package prescription drugs in containers that maintain the identity, strength, quality, and purity of the drug. Under section 502 of the act, a drug is misbranded if it it does not comply with the packaging requirements of paragraphs (g), (h), and (p); and under section 501(a)(2)(B) of the act, a drug is adulterated if it is not manufactured under current good manufacturing practice.

19. One comment suggested recording § 201.100(b) to show that the manufacturer's directions about containers are merely for informational purposes and do not have to be followed by the pharmacist. Another comment was concerned that if the manufacturer's directives were followed in all instances, it would frustrate the pharmacist's professional capabilities and would not benefit the patient; if, however, the pharmacist chose not to follow the manufacturer's "suggestion," the pharmacist would be exposed to an increased risk of liability.

The container statement is more than a suggestion to the pharmacist. Section 503(b) of the act does not exclude compendial drug products from the labeling and packaging requirements of section 502(g). The products are misbranded if they are not packaged in the specified containers. Moreover, the pharmacist should be aware that a manufacturer's directive for a particular type of container is derived from research demonstrating that such a container is suitable for the drug product. The Commissioner believes that readily available container specifications will be more of a benefit than a problem because they will save the pharmacist time. The Commissioner fails to understand how providing pharmacists with packaging information frustrates or adversely reflects upon the professional training of the pharmacist.

20. Two comments objected to the wording "Dispense (name of drug product) in containers which (statement of specifications which clearly enable the dispensing pharmacist to select an adequate container)". The comment interpreted this statement as allowing, or even mandating, drug manufacturers to prescribe particular materials, dimensions, or other specifications for drug containers.

It is not the intent of the regulation to require a statement specifying the particular materials or dimensions for drug containers. The statement of specification is intended to be a statement by the manufacturer that indicates the type of container to be used for the drug, e.g., well-closed, tight, light-resistant. A drug whose stability is critical enough to require the type of detail mentioned by the comment should be packaged for dispensing from the manufacturer's original container.

21. One comment stated that all drugs should be required to show an expiration date or date of manufacture on the immediate container because, for container specifications to be effective, the pharmacist must know the age of the drug.

The Commissioner maintains that expiration dates should be on all prescription drugs and included such a requirement in the proposed current good manufacturing practice regulations published in the FEDERAL REGISTER of February 13, 1976. It is expected that a final order regarding this proposal will be published soon.

22. Three comments stated that this regulation would further crowd the wording on labels, resulting in other important information being less discernible. One comment recommended that a universal container code should be devised, such as "Storage A" (or B, C, D, E, etc.), so that the label could fulfill this requirement but not crowd the present wording. Two comments recommended against repeating the name of the drug in the directions

specifying the type of container to be used.

The proposal for a code system to signify the type of dispensing container to be used is a novel idea. The Commissioner is not certain of its value or feasibility, and invites comments concerning such a system. No action will be taken on this comment at this time.

The Commissioner does not believe that the brief statement specifying the type of container would crowd the wording in existing labels to such an extent that it would compromise other information on the label. If the immediate container is too small or otherwise unable to accommodate a label and still have enough space to bear all other required information, the regulations provide for alternative methods for placement of this information. To save space, however, the Commissioner is deleting from the requirements for container specifications a requirement that the name of the drug be stated.

23. One comment recommended that the required container dispensing information be permitted anywhere in the labeling. It was stated that such a statement on the label was unnecessary and would distract the pharmacist from other information on the label.

The Commissioner concludes that it is particularly important that the container information be placed on the immediate container label of any drug product large enough to bear such a statement. Small packages are often stored in an outer package on the pharmacist's shelf and the container information is readily available, either on the outer package or on an insert. If the package is so small that it would be exempted from having other mandatory statements on the label, the pharmacist would automatically refer to the accompanying labeling. By contrast, drugs packaged in larger immediate containers are often stored only in the manufacturer's original container and the pharmacist dispenses therefrom. In these cases, the only readily available container information would have to be on the label.

The potential environmental effects of this action have been carefully considered, and the FDA has concluded that the action will not significantly affect the quality of the human environment. This action is one of a type for which the agency has determined that the preparation of an environmental impact statement is not required, except in rare and unusual circumstances (21 CFR 25.1(f)(12)). Accordingly, the preparation of an environmental impact analysis report for this action is not required under 21 CFR 25.1(g).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 701(a), 1050–1053 as amended, 1055 (21 U.S.C. 352, 355, 371(a))), and under authority delegated to the Commissioner (21 CFR 5.1), chapter I of title 21 of the Code of Federal Regulations is amended as follows:

1. In part 201 by amending § 201.100 by revising paragraph (b)(6) and adding a new paragraph (b)(7) to read as follows:

§ 201.100 Prescription drugs for human use.

* * * * *

(b) * * *

(6) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug.

(7) A statement directed to the pharmacist specifying the type of container to be used in dispensing the drug product to maintain its identity, strength, quality, and purity. Where there are standards and test procedures for determining that the container meets the requirements for specified types of containers as defined in an official compendium, such terms may be used. For example, "Dispense in tight, light-resistant container as defined in the National Formulary". Where standards and test procedures for determining the types of containers to be used in dispensing the drug product are not included in an official compendium, the specific container or types of containers known to be adequate to maintain the identity, strength, quality, and purity of the drug products shall be described. For example, "Dispense in containers which (statement of specifications which clearly enable the dispensing pharmacist to select an adequate container)": *Provided, however,* That in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, but which are packaged within an outer container from which they are removed for dispensing or use, the information required by paragraph (b) (2), (3), (5), and (7) of this section may be contained in other labeling on or within the package from which it is to be dispensed; the information referred to in paragraph (b)(1) of this section may be placed on such outer container only; and the information required by paragraph (b)(6) of this section may be on the crimp of the dispensing tube. The information required by this paragraph (b)(7) is not required for prescription drug products packaged in unit-dose, unit-of-use, on other packaging format in which the manufacturer's original package is designed and intended to be dispensed to patients without repackaging.

* * * * *

2. In part 314:

a. Section 314.1(c)(2) is amended by adding a new item 4.g. in form FD-356H to read as follows:

§ 314.1 Applications.

* * * * *

(c) * * *

(2) * * *

FD-356H * * *

* * * * *

4. * * *

g. If the drug is limited in its labeling to use under the professional supervision of a practitioner licensed by law to administer it, its label shall bear a statement directed to the pharmacist specifying the type(s) of container(s) to be used in dispensing the drug to maintain its identity, strength, quality, and purity so as to be in conformance with the provisions of § 201.100(b) (21 CFR 201.100(b)).

* * * * *

b. Section 314.8 is amended by adding new paragraph (a)(5)(xi) to read as follows:

§ 314.8 Supplemental applications.

(a) * * *

(5) * * *

(xi) Change in the label to provide for a statement directed to the pharmacist specifying the type(s) of container(s) to be used in dispensing the drug to maintain its identity, strength, quality, and purity.

* * * * *

Effective date: Compliance with this regulation may begin immediately. The regulation is effective for all products introduced or delivered for introduction initially into interstate commerce on or after August 27, 1978.

In accordance with Executive Order 12044, the economic effects of this final rule have been carefully analyzed, and it has been determined that the final rule does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: August 18, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-23756 Filed 8-24-78; 8:45 am]

[4110-03]

SUBCHAPTER H—MEDICAL DEVICES

[Docket No. 77N-0255]

MEDICAL DEVICE LISTING

Final Rule

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document sets forth the procedures for the listing of medical devices under the Medical Devices Amendments of 1976. The rule establishes who must list devices, the times for listing, how devices must be listed, and other necessary procedural requirements.

EFFECTIVE DATE: October 10, 1978.

FOR FURTHER INFORMATION CONTACT:

Thomas V. Kelley, Bureau of Medical Devices (HFK-124), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7190.

SUPPLEMENTARY INFORMATION: The proposal upon which this final regulation is based was published in the FEDERAL REGISTER of September 30, 1977 (42 FR 52808), with corrections published October 7, 1977 (42 FR 54574), November 1, 1977 (42 FR 57137), and December 2, 1977 (42 FR 61287). Interested persons were given until November 29, 1977 to comment.

Eighteen comments were received on the proposal. The issues most often raised concerned the definition of a restricted device, the clarification of various other definitions, the requirements for maintenance of the historical file, and the requirement for semiannual updating.

The final regulation is being adopted substantially as proposed, although several changes have been made in response to the comments and to clarify the language of the regulation.

DEFINITIONS

1. Five comments objected to the definition of the term "restricted device" in proposed § 807.3(i) (21 CFR 807.3(i)). These comments stated that the Commissioner of Food and Drugs must designate restricted devices by regulations promulgated under section 520(e) of the act (21 U.S.C. 360j(e)) and could not, except by such regulations, designate all prescription devices under § 801.109 (21 CFR 801.109) as restricted devices.

The Commissioner maintains that the devices that were prescription devices under § 801.109 became restricted devices under section 520(e) of the act by operation of law on the date of enactment of the Medical Device Amendments of 1976.

The issue, however, has been under litigation. In three related cases, *Becton, Dickinson and Company* v. *Food and Drug Administration; United States* v. *Becton, Dickinson and Company,* and *In the Matter of Establishment Inspection of Bard-Parker Division of Becton, Dickinson and Company,* the U.S. District Court for the Northern District of New York ruled that FDA must issue regulations classifying devices as "restricted devices." 448 F. Supp. 776 (N.D. N.Y. 1978), appeal docketed, No. 78-6109 (2d Cir. June 5, 1978). The government is appealing that decision to the U.S. Court of Appeals for the Second Circuit.

Subsequent to the *Becton* decision, two other U.S. District Courts have ruled on the prescription/restricted device issue. In both cases, the courts declined to follow the *Becton* decision.

The U.S. District Court of the Central District of California sustained FDA's position that heart pacemakers, which previously were prescription devices, are now "restricted devices," and granted FDA access to related records. *In the Matter of the Establishment Inspection of American Technology, Inc.,* No. CV 78-1727-LEW (C.D. Cal., filed June 14, 1978).

The U.S. District Court for the District of Massachusetts granted a motion to quash an administrative warrant sought by FDA for records relating to endotracheal tubes on the basis that the warrant was too general. On the restricted device issue the Court held:

> I find, however, the device in question is a "restricted device" by reason of having been limited to use by prescription only prior to the enactment of 21 U.S.C. 360j [and] is covered by 21 CFR 801.109. I decline to follow *Becton, Dickinson* v. *FDA,* 448 F. Supp. 776 (N.D. N.Y., 1978).

In Re: Administrative Warrant Issued to the Food and Drug Administration on July 27, 1978 Regarding Portex, Inc. (D. Mass., filed July 28, 1978). The issue is pending also in two related cases before the U.S. District Court for the Western District of Missouri. *United States* v. *Sherwood Medical Industries, Inc., et al.* (No. 77-0890-CV-W-Z) and *In the Matter of Establishment Inspection of Sherwood Medical Industries, Inc.* (No. 77-0265-CV-W-Z). The definition of "restricted device" in § 807.3(i) is consistent with the Commissioner's position in those proceedings.

2. Two comments suggested the definitions of "representative sampling of advertisements" and "representative sampling of any other labeling" in proposed § 807.3 (k) and (l), respectively, need clarification because the phrase, "gives a balanced picture of," is confusing. One comment suggested that these definitions are unnecessary and that the Commissioner should be required to specify the nature of the advertisement and labeling material whenever the agency makes a specific request for labeling and advertisements.

The Commissioner agrees that the definitions need clarification. Therefore, the phrase, "a balanced picture of," has been deleted from § 807.3 (k) and (l) in the final regulation. However, the Commissioner rejects the suggestion that these definitions are unnecessary because they are needed to explain terms used in § 807.31(e) (2) and (3) of the final regulation (21 CFR 807.31(e) (2) and (3)). Section 510(j)(1) of the act (21 U.S.C. 360(j)(1)) requires only that a "representative sampling" of advertisements and labeling be submitted with device lists (Form FD-2892). Therefore, the Commissioner is not required to specify the nature of the advertisements and labeling to be submitted. Section 807.31, which allows owners or operators to maintain the advertisements and labeling in a historical file for their convenience, does not impose any additional legal requirements on the Commissioner to specify the nature of the advertisements and labeling. However, FDA requests for representative sampling of advertisements or any other labeling will, to the extent possible, specify the nature and the basis for the request to further aid the owner or operator in submitting advertisements and labeling.

3. One comment asked why labels and package inserts were excluded from the definition of "representative sampling of any other labeling" in proposed § 807.3(1). Another comment questioned how the labeling for an electronic instrument, which consists of nameplates, technical manuals (or instruction sheets), specification sheets, and advertisements relates to the terms "label," "package insert," and "any other labeling."

The Commissioner realizes that both the terms "label" and "package insert" are included within the term "labeling," as defined in section 201(m) of the act (21 U.S.C. 321(m)). Nevertheless, section 510(j)(1)(B)(ii) of the act provides that "the label and package insert * * * and a representative sampling of any other labeling" are required (see § 807.31(e)(3)). Thus, "any other labeling" includes written, printed, or graphic matter (other than the label or package insert) (1) upon any article or any of its containers and wrappers or (2) accompanying such article (e.g., specification sheets, maintenance manuals, technical manuals which do not give instructions for the use of the device, and catalogs).

In reference to the comment concerning electronic devices, the Commissioner notes that the definitions of "label" and "labeling" in section 201 (k) and (m) of the act, respectively, are controlling. To simplify greatly, a "label" is written information on, or attached to, a device; a "package insert" is any labeling accompanying the device that gives instructions for its use. ("Labeling" is a broad term encompassing both "label" and "package insert.") Therefore, for electronic devices, nameplates would be considered labels; technical manuals that include instructions for use or instruction sheets that accompany the device would be considered package inserts; and specification sheets would be "any other labeling"—other than labels or package inserts. Advertisements would not be "labeling" unless they accompany the device.

4. A new definition has been added to the final regulation. The term "material change" has been added to § 807.3 as paragraph (m) to clarify revised § 807.31(b). This is discussed further under the comments relating to proposed § 807.31.

WHO MUST LIST

5. One comment proposed that X-ray manufacturers be exempted from listing X-ray equipment and parts with the Bureau of Medical Devices because they are listed with the Bureau of Radiological Health.

The Commissioner rejects this proposal. Part 1002 of Title 21 of the Code of Federal Regulations (21 CFR Part 1002), governing records and reports issued under the authority of section 360A of the Public Health Service Act (42 U.S.C. 263i), provides for initial and annual reports to the Bureau of Radiological Health. However, the reports only provide information on operational characteristics of electronic products relating to radiation emission. The authority in section 510 of the act is much broader. It authorizes the Commissioner to require the submission of labeling (as set forth in § 807.31(a) and (b)) not merely information relating to electronic product radiation safety. In addition, firms must supply other information on Form FD-2892, e.g., classification name and number. Because the regulations issued under section 360A of the Public Health Service Act do not provide for the submission of information required by these regulations, the Commissioner concludes that owners or operators of firms producing equipment regulated by both the Bureaus of Radiological Health and Medical Devices must complete Form FD-2892 in its entirety. To eliminate duplication of requirements, the Bureau of Medical Devices will review initial and annual reports submitted to the Bureau of Radiological Health under part 1002 before contacting owners or operators for labeling and advertisements.

6. Section 807.20(a) (21 CFR 807.20(a)) provides that listing information may be submitted by the parent, subsidiary, or affiliate company for all the establishments under the control of one of these organizations when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments.

One comment suggested that this section be modified to provide that the listing information may be submitted by the parent, subsidiary, or affiliated company for all establishments "including foreign facilities."

The Commissioner concurs with the comment and has revised § 807.20(a) of the final regulation to include reference to foreign establishments. Section 807.40(b) has also been changed to permit a parent, subsidiary, or affiliate company of a foreign establishment to list and maintain the historical file on behalf of the foreign establishment.

7. One comment requested clarification as to whether registration and listing are required only for firms engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of "finished" devices. Also, the comment suggested that firms manufacturing or selling components of in vitro diagnostic products for use in systems manufactured by other firms, if required to register and list, should be required to submit labeling to the Food and Drug Administration for review to protect the public from exposure to products not in compliance with current in vitro diagnostic labeling regulations.

The Commissioner believes that § 807.20(a) as revised in this final regulation adequately specifies who must register and list. Under § 807.20(a), some owners or operators, in addition to those engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of "finished" devices, are required to list, e.g., owners or operators that (1) repackage or relabel a device, (2) manufacture components or accessories that are ready to be used for any intended health related purpose and are packaged or labeled for such health related purpose (e.g., blood fillers and hemodialysis tubing), or (3) manufacture devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient (e.g., a manufacturer of ophthalmic lens blanks). An owner or operator should review § 807.65 (21 CFR 807.65), which discusses exemptions from registration for device establishments. Any owner or operator who is exempt from registration is exempt from listing. In addition, any owner or operator is exempt from listing a particular device if the production of that device does not subject the owner or operator to the requirement of registration.

In response to the second comment, the Commissioner believes that § 807.31(e) will enable FDA to secure and to review labeling, when necessary, of firms manufacturing or selling components of in vitro diagnostic devices for use in systems manufactured by other firms. Accordingly, the Commissioner rejects the suggestion that this material be submitted routinely to FDA.

8. Two comments stated that manufacturers of devices that do not enter interstate commerce should be specifically exempted from the provisions of proposed § 807.20(a). These comments stated that the presumption of interstate commerce is rebuttable and that some devices do not enter commerce at all.

These comments raise the question of the applicablity of the regulation in two situations: (1) Where a device is not marketed at all, and (2) where it is manufactured and marketed only intrastate. The Commissioner advises with respect to the first situation that only those devices in commercial distribution (as defined in § 807.3(b)) must be listed. In response to the second issue, the Commissioner does not accept the implication in the comment that section 510 of the act applies only to devices that have been shown to move in interstate commerce. Section 510(b) of the act requires the annual registration of every establishment "in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device * * *." See also section 510(c) and (d) of the act relating to initial and additional registration. Similarly, section 510(h) of the act provides: "Every establishment in any State registered with the [FDA] * * * shall be subject to inspection * * *." Under section 510(j) of the act, of course, any establishment required to register may also be required to submit listing information.

The Commissioner notes that section 510 of the act specifically does not require a showing of movement in interstate commerce. Compare section 301(a) of the act (21 U.S.C. 331(a)) relating to the introduction of adulterated or misbranded devices into interstate commerce. When section 510 was initially enacted in 1962 (Pub. L. 87-781, Title III, § 302), Congress specifically made findings that the registration and inspection of intrastate esablishments were necessary because of their impact on interstate commerce.

See section 301 of Pub. L. 87-781. In enacting the Medical Device Amendments of 1976 (Pub. L. 94-295), Congress further expanded FDA's authority to regulate devices without regard to specific showings of movement in interstate commerce. See section 304(a)(2) of the act (21 U.S.C. 334(a)(2)), authorizing the seizure of any adulterated or misbranded device when and where found with no requirement to establish interstate commerce, and section 709 of the act (21 U.S.C. 379a), establishing a presumption of interstate commerce in other regulatory matters involving devices. Congress expressly stated its intention to expand FDA's intrastate authority over devices in House Report No. 94-853, Medical Device Amendments, February 29, 1976, at page 15.

9. Two comments suggested that the requirement in proposed § 807.20(a) "to submit a list of every device in commercial distribution" be modified to be consistent with the requirement in proposed § 807.22(b) (21 CFR 807.22(b)) that "devices having variations in physical characteristics such as size, package, shape, color, or composition should be considered to be one device, provided the variation does not change the function or intended use of the device." The comments noted that § 807.22(b) does not require the submission of a list including "every" device.

The Commissioner agrees with the comment and has revised § 807.20(a) by eliminating the word "every" and rephrasing the requirement to read: "to submit listing information for those devices in commercial distibution."

10. Section 807.20(a)(2) of the final regulation has been changed to eliminate duplicate listing by exempting an owner or operator who only manufactures devices according to another owner or operator's specifications for commercial distribution by the owner or operator initiating the specifications. As proposed, both parties would have been required to list the same product.

Time for Listing

11. Several comments objected to the imposition of the December 31, 1977 deadline for listing. These comments asserted that there was no requirement to list devices with FDA until FDA issued final device listing regulations.

The Commissioner notes that device listing is required by section 510(j) of the act and is not dependent on the issuance of a final regulation. In the Federal Register of December 28, 1976 (41 FR 56397), FDA gave notice that device listing requirements would be implemented in 1977. Form FD-2892 and the accompanying Device Listing Information and Instructions were sent to Medical Device Establishments in October 1977 to enable device listing by December 31, 1977. However, the Commissioner has determined that the regulation shall not become effective until October 10, 1978. This will allow ample time for submission of forms by owners or operators who did not receive a listing packet in time to list by December 31, 1977, or who did not have sufficient time for other reasons, such as contacting foreign suppliers or affiliates. Section 807.21 has been changed accordingly. The Commissioner believes that the effective date of October 10 1978, will alleviate the need of granting further extensions of time to submit the forms.

12. One comment suggested that the words "or as changes occur" be added to the last sentence of proposed § 807.21, which requires an owner or operator to "update its device listing information every June and December." This change will make § 807.21 consistent with 807.30(b), which requires an owner or operator to update its "device listing information during each June and December or, at its discretion, at the time the change occurs."

The Commissioner agrees with the comment and has changed § 807.21 by adding the phrase "or, at its discretion, at the time the change occurs."

How to Submit Listing

13. Two comments suggested that proposed § 807.25(f) be revised to allow the submission of computer-generated forms in lieu of the listing forms provided by FDA. The comments also suggested that FDA assign blocks of numbers so that registered establishments without access to a computer could preprint their forms with various repetitive information.

The Commissioner observes that proposed § 807.22(b) provides that tapes for computer input may be submitted if equivalent in all elements of information specified in Form FD-2892. The Commissioner would prefer the submission of computer tapes. However, should there be situations where it is not possible for the owner or operator to provide a computer tape compatible with FDA equipment, hard copy computer output would be accepted as equivalent to computer tapes, provided that review and approval is secured from FDA before submission in accordance with § 807.22(b).

Upon request to the Bureau of Medical Devices at the address given in § 807.22(a), FDA will provide blocks of numbers to be used as the document number by owners or operators who prefer to preprint their own listing forms.

14. One comment suggested that proposed § 807.22(c) be modified to indicate that the initial distributor of an imported device may submit device listing information on behalf of a foreign establishment if the initial distributor is: (1) A parent, subsidiary, or affiliate company of the foreign manufacturer where joint ownership and control exist, as provided in proposed § 807.20, or (2) the only domestic distributor of that foreign manufacturer and, in addition, submits to FDA a letter from the foreign establishment authorizing the initial distributor to list and maintain a historical file on the foreign establishment's behalf.

The Commissioner has reviewed the listing requirements for initial distributors and has made the following changes in the final regulation to clarify those requirements. Section 807.22(c) has been changed to require the initial distributor to submit form FD-2892 and to maintain the historical file for those imported devices (1) for which the specifications have been initiated or developed by the initial distributor or (2) which have been repackaged or relabeled by the initial distributor (see § 807.20(a) (1) and (2)). The listing requirements in § 807.22(c)(3) remain unchanged from proposed § 807.22(c) if the initial distributor did not initiate or develop the specifications for the device or repackage or relabel the device.

Section 807.40(b) (21 CFR 807.40(b)) has been changed to allow a parent, subsidiary, or affiliate company of the foreign manufacturer or an initial distributor, who is a sole initial distributor, to list and maintain the historical file for a foreign manufacturer upon meeting the other requirements in the paragraph. The Commissioner notes that the initial distributor may, in turn, distribute the product to multiple domestic distributors and still be authorized to list for the foreign establishment.

Information Required for Device Listing

15. One comment stated that the device listing information and instructions accompanying form FD-2892 contain terms that are not adequately defined and instructions that are unclear and confusing.

The Commissioner believes that the device listing information and instructions accompanying form FD-2892 give adequate directions for submitting listing information for most situations. The agency will provide detailed guidance in those situations where any owner or operator is confused as to the appropriate procedures to follow in listing devices. If many owners or operators need to have these instructions clarified, updated instructions will be provided at a later date.

16. One comment questioned the statutory authority for question 14 on form FD-2892. The question reads, "Is the device, as labeled, intended for distribution to and use by the general public?" The comment expressed concern that this information would be used to classify a device as a "restricted" device.

The Commissioner observes that section 510(j)(1) (A) and (B) (i) and (ii) of the act requires the submission of all labels for each listed device. If FDA required all labels to be submitted with form FD-2892, it could readily be discerned whether the device, as labeled, was intended for distribution to and use by the general public. Question 14 on form FD-2892 allows this information to be provided to FDA without requiring the submission of all labels, which would otherwise burden owners or operators with the additional costs of submitting all labels.

The agency will determine those devices that are restricted devices in accordance with section 520(e) of the act. This determination is not dependent on the answer to question 14. Also, the Commissioner notes that under section 510(j)(1)(D) of the act, FDA may require the submission of the basis for determining that a device is not a restricted device (see § 807.31(e)(5)).

17. One comment objected to the requirement in proposed § 807.25(f)(1) that the device be identified by a common or usual name. The comment stated that identifying a device by a common or usual name would require the addition of that name to the label in order to avoid misbranding under section 502(e)(2) of the act (21 U.S.C. 352(e)(2)). To relieve this problem, it was suggested that the term "common or usual name" on form FD-2892 be changed to "descriptive name."

The Commissioner notes that section 510(j) (1) and (2) (A), (B), and (C) of the act requires that upon initial listing, discontinuance, or a resumption of commercial distribution of a device, its established name, as defined in section 502(e) of the act, must be listed. In section 502(e)(4) of the act,

> * * * the term "established name" with respect to a device means (A) the applicable official name of the device designated pursuant to section 508, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.

Because no official names have been established for devices under section 508 of the act and few official names for devices are recognized in an official compendium, the common or usual name must be provided to satisfy the established name requirement of section 510(j) (1) and (2) (A), (B), and (C). The use of a "descriptive name" on form FD-2892 would not comply with the act.

The identification of a common or usual name on form FD-2892 does not change the requirement of section 502(e)(2) of the act that the established name appear on the label to avoid misbranding. However, the Commissioner does not intend to use the designation of the common or usual name on form FD-2892 to enforce section 502(e)(2) of the act because a change in the common or usual name does not require the updating of form FD-2892 (see § 807.30(b)(6) (21 CFR 807.30(b)(6))).

18. One comment suggested that the last phrase of proposed § 807.25(f)(1), which states "* * * that has not been included in any list of devices previously submitted on form FD-2892," be changed to read "* * * distribution that has not been included in any list of devices which have been previously submitted to FDA," because the present wording of the section suggests that more than one device can be included on a form FD-2892. The comment stated that this conflicts with proposed § 807.22(b), which states that "a separate form FD-2892 shall be submitted for each device or device class listed with the Food and Drug Administration."

The Commissioner does not believe that there is any conflict between the provisions of §§ 807.25(f)(1) and 807.22(b). The suggested change to the wording of § 807.25(f)(1) does not significantly change the meaning of that section and therefore is rejected. The Commissioner, however, agrees that only one device can be included on a form FD-2892.

19. One comment suggested that proposed § 807.25(f) (1) through (5) be modified to use the exact wording that appears on form FD-2892, thus permitting the reader of the regulation to know exactly what information has to be supplied even though he does not have a copy of form FD-2892.

The Commissioner agrees that, to the extent possible, all information to be submitted on form FD-2892 should be specified in the regulation. Section 807.25 has been changed accordingly. Section 807.25(f)(1) has been changed to specify that listing information shall state the classification number of the device. Section 807.25(f)(4) has been changed to specify that listing information shall state the establishment type of every domestic or foreign device establishment under joint ownership and control of the owner or operator at which the device is manufactured, repackaged, or relabeled (see paragraph 20 in this preamble). New § 807.25(f)(5) is added to specify that listing information shall state whether the device as labeled is intended for distribution to and use by the general public. New § 807.25(f)(6) has been added to specify that listing information shall state all other general information on form FD-2892. Proposed § 807.25(f)(5) (redesignated § 807.25(f) (7)) has been changed and allows descriptive information other than labeling to describe the intended use of a device when the owner or operator is unable to find an appropriate classification name for the device. A copy of form FD-2892 may be obtained by contacting FDA at the address indicated in § 807.22(a).

20. One comment questioned whether proposed § 807.25(f)(4) should be clarified by adding the words "domestic or foreign" before the words "device establishment."

The Commissioner agrees with the comment and has changed the final regulation accordingly. However, only those establishments under joint ownership and control of the owner or operator must appear on form FD-2892 (see paragraph 19 above).

Updating Device Listing

21. Three comments suggested that the filing of premarket notifications coupled with annual list updating would satisfy the requirement of semiannual list updating and ease the agency's administrative burden.

The Commissioner disagrees with the comment. Section 510(j)(2) of the act requires semiannual updating. In addition, certain information required under listing is not required under premarket notification. Therefore, the filing of premarket notifications coupled with annual list updating will not satisfy the statute. Also, the Commissioner believes that the time involved in submitting updated listing forms is minimal, because, for most devices, a form FD-2892 will be completed only at the time of initial listing.

22. One comment suggested that proposed § 807.30(b)(4), which requires updating device listing whenever there is any material change in any information previously submitted, be modified because the proposed language would require updating any supplemental sheets to form FD-2892, labeling supplied under proposed § 807.25(f)(5), or labeling, advertising, and other information required under proposed § 807.31. The comment indicated that the modification should make this section consistent with proposed § 807.22(b), proposed § 807.30(b) (1) and (2), and the device listing information and instructions accompanying form FD-2892.

Another comment suggested that to eliminate confusion, the word "material" in proposed § 807.30(b)(4) should be changed to "substantial." This com-

ment also suggested that proposed § 807.30 (a) through (c) be modified to use the exact language of form FD-2892.

The Commissioner notes that section 510(j)(2)(D) of the act requires an updated submission for any material change in any listing information submitted under section 510(j)(1), which states what information is required at the time of initial listing, and section 510(j)(2), which states what information is required after initial listing. Proposed § 807.30(b)(4) is consistent with sections 510(j)(2)(D) of the act and does require the updating of supplemental sheets to form FD-2892, labeling supplied under proposed § 807.25(f)(5) (now § 807.25(f)(7) in the final regulation), and labeling, advertisements, and other information required under § 807.31. However, the intent of proposed § 807.30(b)(4) was only to set forth the requirements for updating the listing information on form FD-2892. Therefore, to clarify the requirements for updating form FD-2892, proposed § 807.30 has been changed in its entirety to specify those changes to information required on form FD-2892 which must be updated and the information that must be included for each type of update specified in section 510(j)(2) (A) through (D) of the act.

Revised § 807.30(a) specifies that all changes must be made on form FD-2892. Revised § 807.30(b) reiterates the time when updating is required as indicated in § 807.21. Revised § 807.30(b)(1) specifies the information required when an owner or operator introduces into commercial distribution a device identified with a classification name not currently listed. Revised § 807.30(b)(2) specifies the information required when an owner or operator discontinues commercial distribution of all devices with the same classification name. Revised § 807.30(b)(3) specifies the information required when commercial distribution of a discontinued device is resumed. New § 807.30(b)(4) specifies the information required when a classification name for a previously listed device with multiple classification names has been added or deleted. New § 807.30(b)(5) specifies the information required when changes in block 6, 7, 12, 12a, 13, 13a, 14, 15, 16, or 17 of form FD-2892 occur. New § 807.30(b)(6) indicates which changes to the information required in § 807.25 do not require updating. Proposed § 807.30(c) has been deleted.

Section 807.30, as revised, is consistent with all other sections of the regulation and the information and instructions booklet accompanying form FD-2892 and does not refer to "material" changes.

The suggestion that the exact language of form FD-2892 be used is rejected as being unnecessary. Form FD-2892 and its accompanying device listing information and instructions may be obtained by contacting FDA at the address indicated in § 807.22(a).

23. One comment suggested that proposed § 807.30(b)(2), which requests that the owner or operator give the reason for discontinuing commercial distribution of a device, be deleted. The comment suggests that the reasons for discontinuing commercial distribution might constitute confidential commercial information, and that failure to furnish the reason under the optional terms of the proposed section might give rise to conjecture of a discreditable reason. The owner or operator should not be placed in this conflicting position.

The Commissioner has reevaluated this requirement. In light of the classification name approach to listing, the Commissioner agrees that such information would not be meaningful. The section is revised to delete the request for the reason(s) for discontinuance of commercial distribution.

ADDITIONAL LISTING INFORMATION

24. Two comments requested that a date be specified in § 807.31 from which maintenance of the historical file is required. Six comments stated that a time limit should be set for the retention of labeling and advertisements in the historical file. Some of the suggested time limitations included any reasonable, valid time period established by the manufacturer, 5 years after the labeling or advertisement has been introduced, or 1 year after the device has been discontinued.

The Commissioner concurs with the comments and has revised § 807.31(a) to specify the time from which owners or operators shall maintain labeling and advertisements in the historical file, which is the date of initial listing. Owners or operators shall maintain in the file labeling and advertisements in use on the date of initial listing and in use after October 10, 1978, but before the date of initial listing. Section 807.31(a) has also been changed to specify which labeling and advertisements must be retained in the historical file at the time of initial listing. (This change is discussed in paragraph 25 in this preamble.)

The Commissioner has established a time limit for retention of certain labeling and advertisements for discontinued devices in new § 807.31(c). Generally, the owner or operator may discard labeling and advertisements 5 years after the date of the last shipment of a discontinued device. However, if the device has an anticipated useful life of more than 5 years, the owner or operator must retain, in the historical file until the end of the anticipated useful life of the device, the labeling in use on the date of the last shipment and a representative sampling of all advertisements in use during the 12 months immediately preceding the last shipment of a restricted device. A retention period of 5 years after the last shipment of a discontinued device by an owner or operator was chosen because: (1) Devices can be marketed at the retail level long after discontinuance, (2) labeling and advertisements are used to promote the sale and indicate the use and effectiveness of the device even after it has been discontinued, and (3) commercial distribution of devices is sometimes resumed after discontinuance. A longer period is required for devices with a longer useful life because regulatory problems concerning labeling or advertisements may occur throughout the useful life of the device. The Commissioner has not established a time limit for the retention of labeling and advertisements for devices in commercial distribution because labeling and advertisements are relied upon by users of the device even after they have been discontinued by the manufacturer. If the need for a time limit on the retention of labeling and advertisements of devices in commercial distribution becomes necessary, the Commissioner will establish a time limit that is necessary to protect the public health.

25. One comment stated that section 510(j)(1)(B) (i) and (ii) of the act requires only a record or file of the labels and labeling in use at the time of initial listing. The comment states that to require more than a file of currently used labels and labeling clearly exceeds the scope, intent, and legislative history of section 510(j)(1)(B) (i) and (ii) of the act. Another comment asserted that many changes in labels, labeling, and advertising are typographical or otherwise inconsequential and the requirement to keep all labels, labeling, and advertisements would place an unnecessary burden on the owner or operator in the way of excessive and unproductive recordkeeping. This comment suggested that only significant, substantive changes in labels, labeling, and advertisements be retained

The Commissioner notes that section 510(j)(1) (A) and (B) (i) and (ii) of the act requires only that, upon initial listing, an owner or operator must submit: (1) A copy of all labeling for each unrestricted device subject to sections 514 or 515 of the act (see § 807.31(a)(1)); (2) a copy of all labeling and advertisements for each restricted device (see § 807.31(a) (2)); and (3) a copy of all labels, package inserts, and a representative sampling of any other labeling for each unrestricted

device that is not subject to sections 514 or 515 of the act (see § 807.31(a)(3)). However, section 510(j)(2)(D) of the act requires the submission of any material change in any information previously submitted under section 510(j)(1) (A) and (B) (i) and (ii) of the act. Therefore, the Commissioner rejects the contention that only a record or file of the labeling in use at the time of initial listing may be required. However, the Commissioner agrees that only "material changes" in labeling and advertisements retained under § 807.31(a) must be maintained in the historical file and has added new § 807.31(b) accordingly. (Proposed § 807.31(b) has been changed to § 807.31(e) in the final regulation.)

A definition of the term "material change" has been added in § 807.3(m) to aid owners and operators in complying with § 807.31(b). The Commissioner observes that a material change in the labeling or advertisements for a device may be evidence of a change in the device requiring a premarket notification under § 807.81(a)(3) (21 CFR 807.81(a)(3)).

Also, the Commissioner notes that the definition of "labeling" in section 201(m) of the act includes all "labels" and has shortened the phrase "labels and labeling" to "labeling" in the final regulation.

26. Two comments asserted that the cost of maintaining the historical file will become unjustifiably burdensome on manufacturers of devices in which every lot produced has its own insert with the label values for that lot, e.g., manufacturers of in vitro diagnostic calibrator devices. The comments suggested that labeling for a specific lot of product should only be retained for 6 months beyond the expiration date of the lot or 2 years after the date of initial distribution.

The Commissioner recognizes that, although there are some medical devices in which every lot produced has a unique label value (antisera, reference control sera, and calibration standards) and may be produced to the same specifications, the biological activity or known composition differs with each lot. For proper use, the specific activity or composition must be determined and made available to the user. However, for the purpose of maintaining the historical file, the labeling that contains the actual values is not required, Therefore, the definition of "material change" in § 807.3(m) excludes the labeling containing the actual values for each lot where the biological activity or known composition differs with each lot produced and the product is labeled accordingly. Nevertheless, the owner or operator must retain a copy of the labeling, as required under § 807.31(a), and any labeling to which a material change occurs, as required under § 807.31(b). For example, if value ranges are preprinted and specific values are added for each lot produced, only a copy of that labeling which includes the preprinted value ranges must be maintained.

27. Two comments suggested that proposed § 807.31(a) be modified to allow owners or operators who use separate or central facilities for the reproduction of labels, labeling, and advertisements to have those facilities maintain the historical file for the documents they reproduce. This would eliminate duplication of effort since these facilities retain a copy of all documents they reproduce.

The Commissioner agrees with the comment and has added new § 807.31(d) to allow the contents of the historical file to be maintained in more than one location under certain conditions set forth in that section.

28. One comment suggested that proposed § 807.31(b)(1) be modified to include a definition of "good cause" and to require that the Commissioner accompany any request under that section with an explanation of the reasons for such request.

The Commissioner disagrees with the suggestion to define "good cause" because each request under § 807.31 will be made on a case-by-case basis. However, proposed § 807.31(b)(1), which has been changed to § 807.31(e)(2) in the final regulation, requires that a request for all advertisements will, where feasible, be accompanied by an explanation of the basis for the request.

29. The Commissioner has changed proposed § 807.31(b) to § 807.31(e) in the final regulation and made the following changes in accordance with section 510(j)(1) of the act: New § 807.31(e)(1) requires that, upon request, all labeling for a device subject to sections 514 or 515 of the act shall be submitted to FDA in accordance with section 510(j)(1)(A) of the act. Proposed § 807.31(b)(1) has been changed to § 807.31(e)(2) and is discussed in paragraph 28 above. Proposed § 807.31(b)(2) has been changed to § 807.31(e)(3) and requires that, upon request, labeling for an unrestricted device that is not subject to sections 514 and 515 of the act shall be submitted to FDA in accordance with section 510(j)(1)(B)(ii). Proposed § 807.31(b)(3) has been changed to § 807.31(e)(4). New § 807.31(e)(5) requires that, upon request, a statement of the basis upon which the registrant has determined that the device is not a restricted device shall be submitted to FDA in accordance with section 510(j)(1)(D) of the act. Proposed § 807.31(b) (4) and (5) has been changed to § 807.31(e) (6) and (7), respectively.

NOTIFICATION OF REGISTRANT

30. One comment suggested that the phrase, "does not establish that the holder of the registration is legally qualified to deal in such devices and," be deleted from proposed § 807.35(c). The comment contends that the legal qualifications "to deal in such devices" are not related to these regulations.

The Commissioner disagrees with the comment. Section 807.35(c) states that the assignment of a device listing number does not establish any legal qualifications of the owner or operator to deal in such devices. This statement is correct. The suggested modification may imply by silence that an owner or operator with an assigned device listing number is legally qualified to deal in such devices.

PROCEDURES FOR FOREIGN ESTABLISHMENTS

31. One comment asserted that proposed § 807.40 (b), (c), and (d) should be deleted because: (1) The importer of record must supply the name of the foreign manufacturer of all devices being imported and the request for registration of the foreign manufacturer is merely duplication of paperwork, (2) there are formidable obstacles in requiring rather than requesting foreign manufacturers to list devices, (3) the main focus of FDA's enforcement will rest on the importer, and (4) the importer will bear the legal and financial burden for failure on the part of the foreign manufacturer to complete the listing requirements.

The Commissioner disagrees with the comment. Listing by foreign establishments is required by section 510(i) of the act. Section 807.40(b) has been changed to allow listing on behalf of the foreign establishment by a domestic establishment or the initial distributor as provided in that section. If the foreign establishment does not submit listing information and listing information is not submitted by a domestic establishment or by an authorized initial distributor under § 807.40(b), then the foreign establishment's products will be subject to detention.

32. One comment suggested that proposed § 807.40(b) be modified to limit the requirements on foreign establishments in proposed § 807.25 to only those foreign establishments who are not listed by a parent, subsidiary or affiliate, or an initial distributor.

The Commissioner believes that the revision of § 807.40(b) discussed in paragraph 14 above eliminates this problem. The requirement of § 807.25 remains with the foreign establishment. However, the requirement may be satisfied by a parent, subsidiary or

affiliate, or an initial distributor as provided in § 807.40(b).

33. Two comments suggested that proposed § 807.40(c) should be modified to allow the importation of a device after a premarket notification has been filed rather than after the device is listed. The comments asserted that the premarket notification should be sufficient until the device is required to be listed.

The Commissioner concurs and has changed § 807.40(c) to permit importation before listing. Although the device does not need to be listed before such importation begins, listing must be made at the next interval specified for updating device listing information in § 807.30(b). A premarket notification must be submitted before importation into the United States, if such notice would be required (see § 807.81).

34. One comment suggested modifying proposed § 807.40(c) to allow devices intended solely for investigational use to be imported or offered for import during the period ending on the 90th day after the date of promulgation of regulations prescribing the procedures and conditions required by section 520(g)(2) of the act.

The Commissioner does not believe that the regulation should be changed to reflect this interim period.

NOTE.—Interim final investigational device exemption regulations were published May 12, 1978 (43 FR 20726).

However, until final investigational device exemption regulations are published, a foreign device whose labeling identifies it as an investigational device can be imported without the product first being listed. The device will have to comply with investigational device exemption regulations whenever applicable. The Commissioner notes that investigational device exemption regulations are applicable for intraocular lenses.

GENERAL PURPOSE ARTICLES

35. In the course of implementing the listing procedures, FDA has received several inquiries from manufacturers of in vitro diagnostic products requesting guidance regarding the intent of § 807.65(c) which exempts from registration "a manufacturer of general purpose articles, such as chemical reagents or laboratory equipment whose uses are generally known by persons trained in their use and which are not labeled or promoted for medical uses." Copies of these inquiries are on file with the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. Many persons were of the opinion that, even though their in vitro diagnostic products were previously exempted from drug registration and listing, they would now be required to register and list these products with FDA since § 807.65(c) included the phrase "not labeled or promoted for medical uses." The persons inquiring believed that promoting the products for use in hospitals, clinical laboratories, etc., would, in itself, be interpreted as promotion for medical use.

In the case of in vitro diagnostic products, general purpose articles are those products that have general laboratory applications but whose uses are not solely in the collection, preparation, and examination of specimens taken from the human body. An in vitro diagnostic product which is a general purpose article must have a use or uses in other areas. Labeling for these products must not make reference to the application of the product in any specific dianostic procedure and must contain only product specifications and, when applicable, meet the labeling requirements of § 809.10(d) (21 CFR 809.10(d)). When appropriate, the labeling may also reference voluntary standards of purity, composition, calibration, etc., developed by organizations such as the American Chemical Society or National Bureau of Standards.

The sale of in vitro diagnostic products that are general purpose articles to clinical laboratories and other medical facilities where there is the probability of diagnostic use does not, in itself, mean that the products are "promoted for medical use." For example, generally a product will not be considered "promoted for medical use" if the labeling contains no reference to diagnostic use and the claims in the labeling do not differ from the claims in the promotional material provided to other types of facilities (i.e., industrial or educational) that also purchase and use the products.

In vitro diagnostic products that meet these requirements are general purpose articles and exempt from registration and listing under § 807.65(c). However, in vitro diagnostic products that are promoted and/or labeled as components or accessories to specific diagnostic systems are not considered general purpose articles. Therefore, they are medical devices subject to registration and listing as required by § 807.20.

ECONOMIC IMPACT

36. One comment stated that an inflation impact statement is necessary. Several other comments expressed concern with the cost of maintaining the historical file.

The Commissioner notes that a copy of the inflation impact assessment is on file with the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. Section 807.31 of the final regulation provides for limitations on the historical file that should reduce the cost of maintaining the file and allow compliance with section 510(j)(1) of the act. The Commissioner believes that the cost of maintaining the historical file will be less than the cost of requiring the industry to submit labeling and advertisements routinely along with device listing forms. If routine submission of labeling and advertisements were required, most owners or operators would keep a copy of the labeling and advertisements submitted for their own records. Under the historical file system, FDA will require actual submission of such information only when it is necessary to protect the public health.

NATIONAL HEALTH-RELATED ITEMS CODE

37. In the preamble to the proposed listing procedures, FDA announced that support for the National Health Related Items Code (NHRIC) as a system for the identification and numbering of marketed device packages compatible with other numbering systems such as the National Drug Code (NDC) and the Universal Product Code (UPC) would be limited.

The Commissioner observes that no comments were received on this announcement. Therefore, FDA will limit the support of the NHRIC system and no longer maintain the NHRIC data base. Although there is no requirement to place a NHRIC number on device labels, those labelers who wish to use the NHRIC system should contact FDA at the Bureau of Medical Devices, Device Registration and Listing Branch, HFK-124, 8757 Georgia Avenue, Silver Spring, Md. 20910, to obtain a labeler code and other information.

All labelers who participate in the system will be required to develop their own product code and perform any required maintenance to the number system such as adding new codes or deleting old product codes. Those labelers currently participating in the NHRIC system may continue to use the labeler codes assigned but are instructed to no longer submit update information to FDA.

Participants in the NHRIC system should display the NHRIC number prominently in the top third of the principal display panel of the immediate container and of any outside container labeling or wrapper. Owners, operators, and distributors of in vitro diagnostic products previously assigned NDC numbers may retain those numbers, but are required to change the prefix N or NDC to H or HRI as label revisions occur.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 301(p) and (q)(2), 501, 502, 508, 510, 519,

701(a), 52 Stat. 1042-1043 as amended, 1049-1050 as amended, 1055, 76 Stat. 789, 794 as amended, 86 Stat. 562 as amended, 90 Stat. 564-580 (21 U.S.C. 331 (p) and (q)(2), 351, 352, 358, 360, 360i, 371(a)) and under authority delegated to the Commissioner (21 CFR 5.1), Parts 207, 607, and 807 are amended as follows:

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

1. In Part 207, by amending § 207.65(i) by adding a sentence at the end of the paragraph, as follows:

§ 207.65 Exemptions for domestic establishments.

* * * * *

(i) * * * This paragraph does not exempt such persons from registration and listing for medical devices required under Part 807 of this chapter.

PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS

2. In Part 607, by amending § 607.65(e) by adding a sentence at the end of the paragraph, as follows:

§ 607.65 Exemptions for blood product establishments.

* * * * *

(e) * * * This paragraph does not exempt such persons from registration and listing for medical devices required under Part 807 of this chapter.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS OF DEVICES

3. The heading for Part 807 is revised as set forth above and Part 807 is amended as follows:

a. In Subpart A by amending § 807.3 by adding new paragraphs (i), (j), (k), (l), and (m) to read as follows:

§ 807.3 Definitions.

* * * * *

(i) "Restricted device" means a device for which the Commissioner, by regulation under § 801.109 of this chapter or otherwise under section 520(e) of the act, has restricted sale, distribution, or use only upon the written or oral authorization of a practitioner licensed by law to administer or use the device or upon such other conditions as the Commissioner may prescribe.

(j) "Classification name" means the term used by the Food and Drug Administration and its classification panels to describe a device or class of devices for purposes of classifying devices under section 513 of the act.

(k) "Representative sampling of advertisements" means typical advertising material that gives the promotional claims made for the device.

(l) "Representative sampling of any other labeling" means typical labeling material (excluding labels and package inserts) that gives the promotional claims made for the device.

(m) "Material change" includes any change or modification in the labeling or advertisements that affects the identity or safety and effectiveness of the device. These changes may include, but are not limited to, changes in the common or usual or proprietary name, declared ingredients or components, intended use, contraindications, warnings, or instructions for use. Changes that are not material may include graphic layouts, grammar, or correction of typographical errors which do not change the content of the labeling, changes in lot number, and, for devices where the biological activity or known composition differs with each lot produced, the labeling containing the actual values for each lot.

b. In subpart B by amending § 807.20, by revising the section heading, introductory text of paragraph (a), paragraph (a)(2), and paragraph (b), to read as follows:

§ 807.20 Who must register and submit a device list.

(a) An owner or operator of an establishment not exempt under section 510(g) of the act or subpart D of this part who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use is required to register and to submit listing information for those devices in commercial distribution, except that listing information may be submitted by the parent, subsidiary, or affiliate company for all the domestic or foreign establishments under the control of one of these organizations when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments. The term "device" includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. An owner or operator is required to register its name, places of business, and all establishments and to list the devices whether or not the output of the establishments or any particular device so listed enters interstate commerce. The registration and listing requirements shall pertain to any person who:

* * * * * *

(2) Manufactures for commercial distribution a device either for itself or for another person. However, a person who only manufactures devices according to another person's specifications, for commercial distribution by the person initiating specifications, is not required to list those devices.

* * * * *

(b) No registration or listing fee is required. Registration or listing does not constitute an admission or agreement or determination that a product is a device within the meaning of section 201(h) of the act.

c. By revising the section heading and text of § 807.21 to read as follows:

§ 807.21 Times for establishment registration and device listing.

An owner or operator of an establishment entering into, or currently engaged in, an operation defined in § 807.3(c) and not currently registered shall register the establishment by October 22, 1977, and submit device listing by October 10, 1978. An owner or operator of an establishment who has not previously entered into an operation defined in § 807.3(c) shall register within 30 days after entering into such an operation and submit device listing information at that time. An owner or operator of an establishment shall update its registration information annually between November 15 and December 31 and shall update its device listing information every June and December or, at its discretion, at the time the change occurs.

d. By revising the section heading and text of § 807.22, to read as follows:

§ 807.22 How and where to register establishments and list devices.

(a) The first registration of a device establishment shall be on form FD-2891 (Initial Registration of Device Establishments). Forms are obtainable on request from the Bureau of Medical Devices (HFK-124), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, or from the Food and Drug Administration district offices. Subsequent annual registration shall be accomplished on form FD-2891a (Registration of Device Establishment), which will be furnished by the Food and Drug Administration before November 15 of each year to establish-

ments whose registration for that year was validated under § 807.35(a). The completed form shall be mailed to the above-designated address before December 31 of that year.

(b) The initial listing of devices and subsequent June and December updatings shall be on form FD-2892 (Medical Device Listing). Forms are obtainable upon request as described in paragraph (a) of this section. A separate form FD-2892 shall be submitted for each device or device class listed with the Food and Drug Administration. Devices having variations in physical characteristics such as size, package, shape, color, or composition should be considered to be one device: *Provided*, The variation does not change the function or intended use of the device. In lieu of form FD-2892, tapes for computer input or hard copy computer output may by submitted if equivalent in all elements of information as specified in form FD-2892. All formats proposed for use in lieu of form FD-2892 require initial review and approval by the Food and Drug Administration.

(c) The listing obligations of the initial distributor within the United States of an imported device are satisfied as follows:

(1) For those imported devices for which the initial distributor has also initiated or developed the specifications, form FD-2892 shall be submitted and the historical file maintained by the initial distributor.

(2) For those imported devices for which the initial distributor repackages or relabels the device, form FD-2892 shall be submitted and the historical file maintained by the initial distributor.

(3) The initial distributor is not required to submit a form FD-2892 for those imported devices for which such distributor did not initiate or develop the specifications for the device or repackage or relabel the device. However, the initial distributor shall submit, for each device, the name and address of the foreign manufacturer. Initial distributors shall also be prepared to submit, when requested by the Food and Drug Administration, the proprietary name, if any, and the common or usual name of each device for which they are the initial distributors.

(4) The initial distributor shall update the information required by paragraphs (c) (1), (2), and (3) of this section at the intervals specified in § 807.30.

e. In § 807.25, by revising the section heading and by adding new paragraph (f), to read as follows:

§ 807.25 Information required or requested for establishment registration and device listing.

* * * * *

(f) Form FD-2892 is the approved form for providing the device listing information required by the act. This required information includes the following:

(1) The identification by classification name and number, proprietary name, and common or usual name of each device being manufactured, prepared, propagated, compounded, or processed for commercial distribution that has not been included in any list of devices previously submitted on form FD-2892.

(2) The Code of Federal Regulations citation for any applicable standard for the device under section 514 of the act or section 358 of the Public Health Service Act.

(3) The assigned Food and Drug Administration number of the approved application for each device listed that is subject to section 505, 507, or 515 of the act.

(4) The name, registration number, and establishment type of every domestic or foreign device establishment under joint ownership and control of the owner or operator at which the device is manufactured, repackaged, or relabeled.

(5) Whether the device, as labeled, is intended for distribution to and use by the general public.

(6) Other general information requested on form FD-2892, i.e., (i) if the submission refers to a previously listed device, as in the case of an update, the document number from the initial listing document for the device, (ii) the reason for submission, (iii) the date on which the reason for submission occurred, (iv) the date that the form FD-2892 was completed, (v) the owner's or operator's name and identification number.

(7) Labeling or other descriptive information (e.g., specification sheets or catalogs) adequate to describe the intended use of a device when the owner or operator is unable to find on the Food and Drug Administration list in the device listing package, an appropriate classification name for the device.

f. By adding new § 807.30 to read as follows:

§ 807.30 Updating device listing information.

(a) Form FD-2892 shall be used to update device listing information. The preprinted original document number of each form FD-2892 on which the device was initially listed shall appear in block 2 on the form subsequently used to update the listing information for the device and on any correspondence related to the device.

(b) An owner or operator shall update the device listing information during each June and December or, at its discretion, at the time the change occurs. Conditions that require updating and information to be submitted for each of these updates are as follows:

(1) If an owner or operator introduces into commercial distribution a device identified with a classification name not currently listed by the owner or operator, then the owner or operator must submit form FD-2892 containing all the information required by § 807.25(f).

(2) If an owner or operator discontinues commercial distribution of all devices in the same device class, i.e., with the same classification name, the owner or operator must submit form FD-2892 containing the original document number of the form FD-2892 on which the device class was initially listed, the reason for submission, the date of discontinuance, the owner or operator's name and identification number, the classification name and number, the proprietary name, and the common or usual name of the discontinued device.

(3) If commercial distribution of a discontinued device identified on a form FD-2892 filed under paragraph (b)(2) of this section is resumed, the owner or operator must submit on form FD-2892 a notice of resumption containing: the original document number of the form initially used to list that device class, the reason for submission, date of resumption, and all other information required by § 807.25(f).

(4) If one or more classification names for a previously listed device with multiple classification names has been added or deleted, the owner or operator must supply the original document number from the form FD-2892 on which the device was initially listed and a supplemental sheet identifying the names of any new or deleted classification names.

(5) Other changes to information on form FD-2892 will be updated as follows:

(i) Whenever a change occurs only in the owner or operator name (block 6) or number (block 7), e.g., whenever one company's device line is purchased by another owner or operator, it will not be necessary to supply a separate form FD-2892 for each device. In such cases, the new owner or operator must follow the procedures in § 807.26 and submit a letter informing the Food and Drug Administration of the original document number from form FD-2892 on which each device was initially listed for those devices affected by the change in ownership.

(ii) The owner or operator must also submit update information whenever changes occur to the responses to the questions in blocks 12, 12a, 13, 13a, and 14 on form FD-2892, or whenever establishment registration numbers, establishment names, and/or activities are added to or deleted from blocks 15, 16, and 17 of form FD-2892. The owner or operator must supply the original document number from the form FD-2892 on which the device was initially listed, the reason for submission, and all other information required by § 807.25(f).

(6) Updating is not required if the above information has not changed since the previously submitted list. Also, updating is not required if changes occur in proprietary names, in common or usual names (blocks 10 and 11 of form FD-2892), or to supplemental lists of unclassified components or accessories.

g. By adding new § 807.31 to read as follows:

§ 807.31 Additional listing information.

(a) Each owner or operator shall maintain a historical file containing the labeling and advertisements in use on the date of initial listing, and in use after October 10, 1978, but before the date of initial listing, as follows:

(1) For each device subject to section 514 or 515 of the act that is not a restricted device, a copy of all labeling for the device;

(2) For each restricted device, a copy of all labeling and advertisements for the device;

(3) For each device that is neither restricted nor subject to section 514 or 515 of the act, a copy of all labels, package inserts, and a representative sampling of any other labeling.

(b) In addition to the requirements set forth in paragraph (a) of this section, each owner or operator shall maintain in the historical file any labeling or advertisements in which a material change has been made anytime after initial listing.

(c) Each owner or operator may discard labeling and advertisements from the historical file as follows:

(1) Five years after the date of the last shipment of a discontinued device by an owner or operator,

(i) All labeling that was not in use at the time of the last shipment of the device may be discarded, and,

(ii) All advertisements may be discarded, except for a representative sampling of all advertisements in use during the 12 months immediately preceding the last shipment of a restricted device.

(2) All labeling that was in use at the time of the last shipment of a discontinued device and a representative sampling of all advertisements in use during the 12 months immediately preceding the last shipment of a restricted device may be discarded 5 years after the date of the last shipment of the device or at the end of the anticipated useful life of the device.

(d) Location of the file:

(1) Currently existing systems for maintenance of labeling and advertising may be used for the purpose of maintaining the historical file as long as the information included in the systems fulfills the requirements of this section, but only if the labeling and advertisements are retrievable in a timely manner.

(2) The contents of the historical file may be physically located in more than one place in the establishment or in more than one establishment provided there exists joint ownership and control among all the establishments maintaining the historical file. If no joint ownership and control exists, the registered establishment must provide the Food and Drug Administration with a letter authorizing the establishment outside its control to maintain the historical file.

(e) Each owner or operator shall be prepared to submit to the Food and Drug Administration, only upon specific request, the following information:

(1) For a device subject to section 514 or 515 of the act that is not a restricted device, a copy of all labeling for the device.

(2) For a device that is a restricted device, a copy of all labeling for the device, a representative sampling of advertisements for the device, and for good cause, a copy of all advertisements for a particular device. A request for all advertisements will, where feasible, be accompanied by an explanation of the basis for such request.

(3) For a device that is neither a restricted device, nor subject to section 514 of 515 of the act, the label and package insert for the device and a representative sampling of any other labeling for the device.

(4) For a particular device, a statement of the basis upon which the registrant has determined that the device is not subject to section 514 or 515 of the act.

(5) For a particular device, a statement of the basis upon which the registrant has determined the device is not a restricted device.

(6) For a particular device, a statement of the basis for determining that the product is a device rather than a drug.

(7) For a device that the owner or operator has manufactured for distribution under a label other than its own, the names of all distributors for whom it has been manufactured.

h. In § 807.35, by revising paragraph (c) to read as follows:

§ 807.35 Notification of registrant.

* * * * *

(c) Although establishment registration and device listing are required to engage in the device activities described in § 807.20, validation of registration and the assignment of a device listing number in itself does not establish that the holder of the registration is legally qualified to deal in such devices and does not represent a determination by the Food and Drug Administration as to the status of any device.

i. By revising the section heading and text of § 807.37 to read as follows:

§ 807.37 Inspection of establishment registration and device listings.

(a) A copy of the forms FD-2891 and FD-2891a filed by the registrant will be available for inspection in accordance with section 510(f) of the act, at the Bureau of Medical Devices (HFK-124), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office. Upon request, verification of registration number or location of a registered establishment will be provided.

(b)(1) The following information filed under the device listing requirements will be available for public disclosure:

(i) Each form FD-2892 submitted;

(ii) All labels submitted;

(iii) All labeling submitted;

(iv) All advertisements submitted;

(v) All data or information that has already become a matter of public knowledge.

(2) Requests for device listing information identified in paragraph (b)(1) of this section should be directed to the Bureau of Medical Devices (HFK-124), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910.

(3) Requests for device listing information not identified in paragraph (b)(1) of this section shall be submitted and handled in accordance with part 20 of this chapter.

j. In subpart C, by revising the section heading and text of § 807.40, to read as follows:

§ 807.40 Establishment registration and device listing for foreign manufacturers of devices.

(a) Foreign device establishments that export devices into the United States are requested to register in accordance with the procedures of sub-

part B of this part, unless exempt under subpart D of this part.

(b) Foreign device establishments that export devices into the United States, whether or not the establishment is registered, shall comply with the device listing requirements unless exempt from registration as stated in § 807.65. Those foreign owners or operators for which there exists joint ownership and control with a domestic establishment may have the domestic establishment submit listing information and maintain the historical file. A foreign owner or operator may authorize a domestic initial distributor to submit listing information when joint ownership and control does not exist, only if:

(1) The domestic distributor is the sole initial distributor for the foreign owner or operator's device; and

(2) The foreign owner or operator submits a letter to the Food and Drug Administration authorizing the initial distributor to list on its behalf and maintain the historical file.

(c) Except for a device imported or offered for import that has in effect an approved exemption for investigational use under section 520(g) of the act, a device may not be imported from a foreign device establishment into the United States unless it is listed at the interval specified for updating device listing information in § 807.30(b). The device listing information shall be in the English language.

(d) Foreign device establishments shall submit, as part of the device listing, the name and address of the establishment and the name of the individual responsible for submitting device listing information. Any changes in this information shall be reported to the Food and Drug Administration at the intervals specified for updating device listing information in § 807.30(b).

Effective date: This regulation shall be effective October 10, 1978.

(Secs. 301 (p) and (q)(2), 501, 502, 508, 510, 519, 701(a), 52 Stat. 1042-1043 as amended, 1049-1050 as amended, 1055, 76 Stat. 789, 794 as amended, 86 Stat. 562 as amended, 90 Stat. 564-580 (21 U.S.C. 331 (p) and (q)(2), 351, 352, 358, 360, 360i, 371(a)).)

Dated: August 16, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-23757 Filed 8-24-78; 8:45 am]

[4110-03]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 539—BULK ANTIBIOTIC DRUGS SUBJECT TO CERTIFICATION

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

Sterile Amoxicillin Trihydrate; Sterile Amoxicillin Trihydrate for Suspension

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The regulations are amended to reflect approval of a new animal drug application (NADA) filed by Beecham Laboratories. The NADA provides for safe and effective use of sterile amoxicillin trihydrate for suspension for treating certain bacterial infections in dogs and cats. In addition, the regulations are amended to provide for certification of the bulk sterile amoxicillin trihydrate used in the manufacture of sterile amoxicillin trihydrate for suspension.

EFFECTIVE DATE: August 25, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert A. Baldwin, Bureau of Veterinary Medicine (HFV-114), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: Beecham Laboratories, Division of Beecham, Inc., Bristol, Tenn. 37620, filed a NADA (55-091V) providing for use of sterile amoxicillin for suspension for treating dogs for certain bacterial infections of the respiratory tract, genitourinary tract, gastrointestinal tract, bacterial dermatitis, and soft tissues, and cats for certain infections of the upper respiratory tract, genitourinary tract, gastrointestinal tract, skin, and soft tissues. A companion application form 6, 62-015, provides for certification of the sterile amoxicillin trihydrate used in the manufacture of the drug.

In accordance with the freedom of information regulations and § 514.11(e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of the safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFA-305), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512 (i), (n), 82 Stat. 347, 350-351 (21 U.S.C. 360b (i), (n))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), parts 539 and 540 are amended as follows:

1. Part 539 is amended in subpart A by adding new § 539.3 to read as follows:

§ 539.3 Sterile amoxicillin trihydrate.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Amoxicillin trihydrate is the trihydrate form of D(−) *α*-amino-*p*-hydroxybenzyl penicillin. It is so purified and dried that:

(i) Its potency is not less than 900 micrograms and not nore than 1,050 micrograms of amoxicillin per milligram on an anhydrous basis.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) It passes the safety test.

(v) Its moisture content is not less than 11.5 percent and not more than 14.5 percent.

(vi) Its pH in an aqueous solution containing 2 milligrams per milliliter is not less than 3.5 and not more than 6.0.

(vii) Its amoxicillin content is not less than 90 percent on an anhydrous basis.

(viii) The acid-base titration concordance is such that the difference between the percent amoxicillin content when determined by nonaqueous acid titration and by nonaqueous base titration is not more than 6. The potency acid titration concordance is such that the difference between potency value divided by 10 and the percent amoxicillin content of the sample determined by the nonaqueous acid titration is not more than 6. The potency-base titration concordance is such that the difference between the potency value divided by 10 and the percent amoxicillin content of the sample determined by the nonaqueous base titration is not more than 6.

(ix) It is crystalline.

(x) It gives a positive identity test for amoxicillin trihydrate.

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5(b) of this chapter, this drug shall be labeled "amoxicillin".

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, pyrogens, safety, moisture, pH, amoxicillin content, concordance, crystallinity, and identity.

(ii) Samples required:

(*a*) For all tests except sterility: 10 packages, each containing approximately 600 milligrams.

(*b*) For sterility testing: 20 packages, each containing approximately 600 milligrams.

(b) *Tests and methods of assay*—(1) *Potency.* Use any of the following methods; however, the results obtained from the iodometric assay shall be conclusive:

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed portion of the sample in sufficient sterile distilled water to give a stock solution containing 1.0 milligram of amoxicillin per milliliter (estimated). Further dilute an aliquot of the stock solution with 0.1 *M* potassium phosphate buffer, pH 8.0 (solution 3) to the reference concentration of 0.1 microgram of amoxicillin per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter.

(iii) *Hydroxylamine colorimetric assay.* Proceed as directed in § 436.205 of this chapter.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter using the method described in paragraph (e)(2) of that section, except use medium C in lieu of medium A, medium F in lieu of medium E, and during the period of incubation shake the tubes at least once daily.

(3) *Pyrogens.* Proceed as directed in § 436.32(f) of this chapter, using a solution containing 20 milligrams of amoxicillin per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 2 milligrams per milliliter.

(7) *Amoxicillin content.* Proceed as directed in § 436.213 of this chapter, using both the titration procedures described in paragraph (e) (1) and (2) of that section. Calculate the percent amoxicillin content as follows:

(i) *Acid titration.*

Percent amoxicillin content=(A−B) (normality of lithium methoxide reagent) (365.4) (100) (100)/(weight of sample in milligrams) (100−*m*)

where:

A=Milliliters of lithium methoxide reagent used in titrating the sample.
B=Milliliters of lithium methoxide reagent used in titrating the blank.
m=Percent moisture content of the sample.

Difference=Potency in micrograms per milligram/10−percent amoxicillin content.

(ii) *Base titration.*

Percent amoxicillin content=(A−B) (normality of perchloric acid reagent) (365.4) (100) (100)/(weight of sample in milligrams) (100−*m*)

where:

A=Milliliters of perchloric acid reagent used in titrating the sample.
B=Milliliters of perchloric acid reagent used in titrating the blank.
m=Percent moisture content of the sample.

Difference=Potency in micrograms per milligram/10−percent amoxicillin content.

(8) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

(9) *Identity.* Proceed as directed in § 436.211 of this chapter, using a 0.5 percent potassium bromide disc prepared as described in paragraph (b)(1) of that section.

2. Part 540 is amended in subpart B by adding new § 540.203 to read as follows:

§ 540.203 Sterile amoxicillin trihydrate for suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sterile amoxicillin trihydrate for suspension is a dry mixture of amoxicillin trihydrate and one or more suitable and harmless buffer substances, stabilizers, suspending agents, and preservatives. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the labeled amount of amoxicillin. It is sterile. It is nonpyrogenic. It passes the safety test. Its moisture content is not less than 11.0 percent and not more than 14.0 percent. When reconstituted as directed in the labeling, its pH is not less than 5.0 and not more than 7.0. The amoxicillin trihydrate used conforms to the requirements of § 539.3 of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter, and in addition, this drug shall be labeled "sterile amoxicillin for suspension, veterinary".

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The amoxicillin trihydrate used in making the batch for potency, moisture, pH, amoxicillin content, concordance, crystallinity, and identity.

(*b*) The batch for potency, sterility, pyrogens, safety, moisture, and pH.

(ii) Samples required:

(*a*) The amoxicillin trihydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 12 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Reconstitute as directed in the labeling. Using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if the container is represented as a single-dose container or, if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Dilute the resultant solution with 0.1 *M* potassium phosphate buffer, pH 8.0 (solution 3), for the microbiological agar diffusion, assay, or distilled water for the iodometric assay, to give a stock solution of convenient concentration.

(ii) *Assay procedure.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 3 to the reference concentration of 0.1 microgram of amoxicillin per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with distilled water to the prescribed concentration.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(2) of that section, except use medium C in lieu of medium A, medium F in lieu of medium E, and during the period of incubation shake the tubes at least once daily.

(3) *Pyrogens.* Proceed as directed in § 436.32(f) of this chapter, using a solution containing 20 milligrams of amoxicillin per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using the solution obtained when the product is reconstituted as directed in the labeling.

(c) *Conditions of marketing*—(1) *Specifications.* Each vial contains 3 grams of amoxicillin activity as the trihydrate. It is reconstituted with sterile water for injection USP to the concentration of 100 or 250 milligrams per milliliter.

(2) *Sponsor.* See 000029 in § 510.600(c) of this chapter.

(3) *Conditions of use in dogs and cats*—(i) *Amount.* 5 milligrams per pound of body weight daily.

(ii) *Indications for use*—(*a*) Dogs: Use for the treatment of infections caused by susceptible strains of organisms as follows: Respiratory infections (tonsillitis, tracheobronchitis) due to *Staphylococcus aureus, Streptococcus* spp., *E. coli,* and *Proteus mirabilis;* genitourinary infections (cystitis) due to *Staphylococcus aureus, Streptococcus* spp., *E. coli,* and *Proteus mirabilis;* gastrointestinal infections (bacterial gastroenteritis) due to *Staphylococcus aureus, Streptococcus* spp., *E. coli,* and *Proteus mirabilis;* bacterial dermatitis due to *Staphylococcus aureus, Streptococcus* spp., and *Proteus mirabilis;* soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus aureus, Streptococcus* spp., *E. coli,* and *Proteus mirabilis.*

(*b*) Cats: Use for the treatment of infections caused by susceptible strains of organisms as follows: Upper respiratory infections due to *Staphylococcus aureus, Staphylococcus* spp., *Streptococcus* spp., *Hemophilus* spp., *E. coli, Pasteurella* spp., and *Proteus mirabilis;* genitourinary infections (cystitis) due to *Staphylococcus aureus, Streptococcus* spp., *E. coli, Proteus mirabilis,* and *Corynebacterium* spp.; gastrointestinal infections due to *E. coli, Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; skin and soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus aureus, Staphylococcus* spp., *Streptococcus* spp., *E. coli,* and *Pasteurella multocida.*

(iii) *Limitations.* Administer once daily for up to 5 days by intramuscular or subcutaneous injection. Treatment should be continued for 48 hours after the animal has become afebrile or asymptomatic. If no improvement is seen within 5 days, review the diagnosis and change therapy. As with all antibiotics, appropriate in vitro culturing and susceptibility testing of samples taken before treatment should be conducted. For use in dogs and cats only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date: This regulation is effective August 25, 1978.

(Sec. 512(i), (n), 82 Stat. 347, 350-351 (21 U.S.C. 360b(i), (n)).)

Dated: August 16, 1978.

LESTER M. CRAWFORD,
Director, Bureau of Veterinary Medicine.

[FR Doc. 78-23572 Filed 8-24-78; 8:45 am]

[4830-01]

Title 26—Internal Revenue

CHAPTER I—INTERNAL REVENUE SERVICE, DEPARTMENT OF THE TREASURY

SUBCHAPTER F—PROCEDURE AND ADMINISTRATION

[T.D. 7561; LR-265-74]

PART 301—PROCEDURE AND ADMINISTRATION

Annual Registration for Employee Retirement Benefit Plans

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document provides final regulations relating to the requirement that the plan administrator of an employee retirement benefit plan annually file information relating to plan participants who separate from service covered by the plan and are entitled to a retirement benefit under the plan, but are not paid this retirement benefit. This document also provides final regulations relating to the requirement that a plan administrator report certain changes in plan status, and to amounts imposed for failure to file with the Internal Revenue Service certain information required in connection with employee retirement benefit plans. Changes to the applicable tax law were made by the Employee Retirement Income Security Act of 1974 ("ERISA"). These regulations provide plan administrators and employers with the necessary guidance to comply with the law, and also affect plan participants who separate from service covered by an employee retirement benefit plan and are entitled to a retirement benefit under the plan.

DATES: The regulations relating to the reporting of the deferred vested retirement benefit of a separated plan participant are generally effective with respect to participants separating from service in plan years beginning after 1975. The regulations relating to the reporting of a change in plan status are also effective for plan years beginning after 1975. The regulations relating to amounts imposed for failure to file certain information with respect to employee benefit plans are generally effective for plan years beginning after September 2, 1974.

FOR FURTHER INFORMATION CONTACT:
Richard L. Johnson of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, D.C. 20224 (Attention: CC:LR:T:LR-265-74), 202-566-6358 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

BACKGROUND

On January 20, 1978, the FEDERAL REGISTER published proposed amendments to the procedure and administration regulations (26 CFR Part 301) under sections 6057, 6652 (e) and (f), and 6690 of the Internal Revenue Code of 1954 (43 FR 2892). A correction notice was published in the FEDERAL REGISTER on February 16, 1978 (43 FR 6812). The amendments were proposed to conform the regulations to section 1031 of the Employee Retirement Income Security Act of 1974 (88 Stat. 943) ("ERISA"). A public hearing was held on April 13, 1978. After consideration of all comments regarding the proposed amendments, those amendments are adopted as revised by this Treasury decision.

IDENTIFICATION OF SEPARATED PARTICIPANTS WITH DEFERRED VESTED RETIREMENT BENEFIT

ERISA requires that the plan administrator of an employee retirement benefit plan file with the Internal Revenue Service information relating to each plan participant who separates from service covered by the plan, is entitled to a deferred vested retirement benefit under the plan and is not paid this retirement benefit. The information required describes the nature, amount, and form of the benefit to which the participant is entitled, and is to be filed on schedule SSA ("Identification of Separated Participants With Deferred Vested Benefits") as an attachment to the annual return/report of employee benefit plan (form 5500 series). The description of the retirement benefit is also to be provided the participant.

The final regulations provided by this document differ in part from the proposed regulations. First, the final regulations provide that a plan to which more than one employer contributes is required to file schedule SSA starting with the first plan year beginning after 1977. Accordingly, the earliest required filing date for a plan to which more than one employer contributes is July 31, 1979. This is 1 year later than the date provided in the proposed regulations.

Under the proposed regulations, no information relating to the retirement benefit of a plan participant was required to be filed on schedule SSA if the participant is paid some or all of the benefit, forfeits the benefit or returns to service covered by the plan before the end of the plan year for which the schedule SSA is filed. The final regulations provide that no filing is required if such an event occurs before the date the schedule SSA is required to be filed, normally 7 months after the end of the plan year.

The final regulations provide that a plan administrator may, at its option, request that information relating to a plan participant's retirement benefit be deleted from Social Security Administration records if, after the information is filed on schedule SSA, the participant is paid some or all of the benefit or forfeits the benefit under the plan.

As described above, information relating to a participant's retirement benefit is not required to be filed on schedule SSA if the participant is paid only some of the benefit, and information previously filed may be deleted upon payment of only some of the benefit. The final regulations provide that if the participant is not paid all of the benefit, information relating to the benefit to which the participant remains entitled is required to be filed on the schedule SSA filed for the plan year following the plan year in which a portion of the benefit is last paid to the participant.

The final regulations clarify that a church or governmental plan is not required to file schedule SSA. In addition, certain other clarifying changes have been made in the final regulations.

Drafting Information

The principal author of these proposed regulations was Richard L. Johnson 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 regulation, both on matters of substance and style.

Adoption of Amendment to the Regulations

Accordingly, the proposed amendments are adopted with the changes set forth below:

Paragraph 1. Section 301.6057-1(a)(3) is revised by adding at the end thereof a new sentence to read: "The filing requirements described in this section and § 301.6057-2 (relating to notification of change in plan status) do not apply to a governmental or church plan described in section 414 (d) or (e)."

Par. 2. Section 301.6057-1(a)(5)(ii) is revised to read as follows:

§ 301.6057-1 Employee retirement benefit plans; identification of participant with deferred vested retirement benefit.

(a) *Annual registration statement* • • •

(5) *Time for reporting deferred vested retirement benefit* • • •

(ii) *Exception.* Notwithstanding subdivision (i), no information relating to the deferred vested retirement benefit of a separated participant is required to be filed on schedule SSA if, before the date such schedule SSA is required to be filed (including any extension of time for filing granted pursuant to section 6081), the participant (A) is paid some or all of the deferred vested retirement benefit under the plan, (B) returns to service covered by the plan, or (C) forfeits all of the deferred vested retirement benefit under the plan.

* * * * *

Par. 3. Section 301.6057-1(b)(2) is revised to read as follows:

§ 301.6057-1 Employee retirement benefit plans; identification of participant with deferred vested retirement benefit.

* * * * *

(b) *Plans to which more than one employer contributes* • • •

(2) *Time for reporting deferred vested retirement benefit*—(i) *In general.* In the case of a plan to which more than one employer contributes, information relating to the deferred vested retirement benefit of a plan participant must be filed no later than on the schedule SSA filed for the plan year within which the participant completes the second of two consecutive 1-year breaks in service (as defined in the plan for vesting percentage purposes) in service computation periods (as defined in the plan for vesting percentage purposes) which begin after December 31, 1974. At the option of the plan administrator, information relating to a participant's deferred vested retirement benefit may be filed earlier (that is, on the schedule SSA filed for the plan year in which the participant incurs the first 1-year break in service or, in the case of a separated participant, on the schedule SSA filed for the plan year in which the participant separates from service).

(ii) *Special rules.* For purposes of this subparagraph (1)—

(A) For the definition of the term "1-year break in service" in the case of a plan which uses the elapsed time method described in Department of Labor regulations for crediting service for vesting percentage purposes, see § 1.411(a)-6(c)(2).

(B) In the case of a plan which does not define the term "1-year break in service" for vesting percentage purposes, a plan participant shall be deemed to incur a 1-year break in service under the plan in any plan year within which the participant does not complete more than 500 hours of service covered by the plan.

(iii) *Transitional rule.* Notwithstanding subdivision (i), if the second consecutive 1-year break in service described in subdivision (i) is incurred in a plan year beginning before January 1, 1978, information relating to the participant's deferred vested retirement benefit is not required to be filed earlier than on the schedule SSA filed for the first plan year beginning after December 31, 1977.

(iv) *Exception.* Notwithstanding subdivision (i) or (iii) of this subparagraph, no information relating to a participant's deferred vested retirement benefit is required to be filed on schedule SSA if, before the date such schedule SSA is required to be filed (including any extension of time for filing granted pursuant to section 6081), the participant (A) is paid some or all of the deferred vested retirement benefit under the plan, (B) accrues additional retirement benefits under the plan, or (C) forfeits all of the deferred vested retirement benefit under the plan.

* * * * *

Par. 4. Section 301.6057-1(b)(3)(iii) is revised by deleting the second and third sentences and inserting in lieu thereof "If, in view of information provided either by the incomplete records or the plan participant, there is a significant likelihood that the plan participant is vested in a deferred retirement benefit under the plan, information relating to the participant must be filed on schedule SSA with the notation that the participant may be entitled to a deferred vested retirement benefit under the plan, but information relating to the amount of the benefit may be omitted".

Par. 5. Section 301.6057-1(c) is revised to read as follows:

§ 301.6057-1 Employee retirement benefits plans; identification of participant with deferred vested retirement benefit.

* * * * *

(c) *Voluntary filing*—(1) *In general.* The plan administrator of an employee retirement benefit plan described in paragraph (a)(3) of this section, or any other employee retirement benefit plan (including a governmental or church plan), may at its option, file on schedule SSA information relating to the deferred vested retirement benefit of any plan participant who separates at any time from service covered by the plan, including plan participants who separate from service in plan years beginning before 1976.

(2) *Deleting previously filed information.* If, after information relating to the deferred vested retirement benefit of a plan participant is filed on schedule SSA, the plan participant—

(i) Is paid some or all of the deferred vested retirement benefit under the plan, or

(ii) Forfeits all of the deferred vested retirement benefit under the plan,

the plan administrator may, at its option, file on schedule SSA (or such other form as may be provided for this purpose) the name and social security number of the participant with the notation that information previously filed relating to the participant's deferred vested retirement benefit should be deleted.

Par. 6. Paragraphs (d), (e) and (f) of § 301.6057-1 are redesignated (e), (f), and (g), respectively, and a new paragraph (d) is added to read as follows:

§ 301.6057-1 Employee retirement benefit plans; identification of participant with deferred vested retirement benefit.

* * * * *

(d) *Filing incident to cessation of payment of benefits*—(1) *In general.* As described in this section, no information relating to the deferred vested retirement benefit of a plan participant is required to be filed on schedule SSA if before the date such schedule SSA is required to be filed, some of the deferred vested retirement benefit is paid to the participant, and infor-

mation relating to a participant's deferred vested retirement benefit which was previously filed on schedule SSA may be deleted if the participant is paid some of the deferred vested retirement benefit. If payment of the deferred vested retirement benefit ceases before all of the benefit to which the participant is entitled is paid to the participant, information relating to the deferred vested retirement benefit to which the participant remains entitled shall be filed on the schedule SSA filed for the plan year following the last plan year within which a portion of the benefit is paid to the participant.

(2) *Exception.* Notwithstanding subparagraph (1) of this paragraph, no information relating to the deferred vested retirement benefit to which the participant remains entitled is required to be filed on schedule SSA if, before the date such schedule SSA is required to be filed (including any extension of time for filing granted pursuant to section 6081), the participant (i) returns to service covered by the plan, (ii) accrues additional retirement benefits under the plan, or (iii) forfeits the benefit under the plan.

Par. 7. Section 301.6057-1(d), redesignated as § 301.6057-1(e), is revised to read as follows:

§ 301.6057-1 Employee retirement benefit plans; identification of participant with deferred vested retirement benefit.

* * * * *

(e) *Individual statement to participant.* The plan administrator of an employee retirement benefit plan defined in paragraph (a)(3) of this section must provide each participant with respect to whom information is required to be filed on schedule SSA a statement describing the deferred vested retirement benefit to which the participant is entitled. The description provided the participant must include the information filed with respect to the participant on schedule SSA. The statement is to be delivered to the participant or forwarded to the participant's last known address no later than the date on which any schedule SSA reporting information with respect to the participant is required to be filed (including any extension of time for filing granted pursuant to section 6081).

Par. 8. Section 301.6057-1(e), redesignated as § 301.6057-1(f), is revised by deleting "paragraph (d)" where it appears therein and inserting in lieu thereof "paragraph (e)".

Par. 9. Section 301.6057-1(f)(2), redesignated as § 301.6057-(g)(2), is revised to read as follows:

§ 301.6057-1 Employee retirement benefit plans; identification of participant with deferred vested retirement benefit.

* * * * *

(g) *Effective dates.* * * *

(2) *Plans to which more than one employer contributes.* In the case of a plan to which more than one employer contributes, this section is effective for plan years beginning after December 31, 1977, and with respect to a participant who completes two consecutive one-year breaks in service under the plan in service computation periods beginning after December 31, 1974.

Par. 10. Section 301.6652-3(a) is revised by deleting "(determined without regard to any extension of time for filing)" where it appears in subparagraphs (4) and (5), and inserting in lieu thereof "(determined with regard to any extension of time for filing)".

Par. 11. Section 301.6652-3(e)(1)(ii) is revised as follows:

§ 301.6652-3 Failure to file information with respect to employee retirement benefit plan.

* * * * *

(e) *Effective dates*—(1) *Annual registration statement.* * * *

(ii) In the case of a plan to which more than one employer contributes, for plan years beginning after December 31, 1977, and with respect to participants who complete two consecutive 1-year breaks in service under the plan in service computation periods beginning after December 31, 1974.

* * * * *

Par. 12. Section 301.6690-1 is revised by deleting "§ 301.6057-1(d)" each place it appears therein and inserting in lieu thereof "§ 301.6057-1(e)".

This Treasury decision is issued under the authority contained in sections 6057 and 7805 of the Internal Revenue Code of 1954 (88 Stat. 943 and 68A Stat. 917; 26 U.S.C. 6057 and 7805).

JEROME KURTZ,
Commissioner of Internal Revenue.

Approved: August 17, 1978.

DONALD C. LUBICK,
Assistant Secretary of the Treasury.

PARAGRAPH 1. There is inserted in the appropriate place the following new sections:

§ 301.6057-1 Employee retirement benefit plans; identification of participant with deferred vested retirement benefit.

(a) *Annual registration statement*—(1) *In general.* Under section 6057(a), the plan administrator (within the meaning of section 414(g)) of an employee retirement benefit plan must file with the Internal Revenue Service information relating to each plan participant who separates from service covered by the plan and is entitled to a deferred vested retirement benefit under the plan, but is not paid this retirement benefit. Plans subject to this filing requirement are described in subparagraph (3) of this paragraph. Subparagraph (4) describes how the information is to be filed with the Internal Revenue Service. In the case of a plan to which only one employer contributes, the time for filing the information with respect to each separated participant is described in subparagraph (5). In the case of a plan to which more than one employer contributes the time for filing the information with respect to a participant is described in paragraph (b)(2). Paragraph (b) also provides other rules applicable only to plans to which more than one employer contributes.

(2) *Deferred vested retirement benefit.* For purposes of this section, a plan participant's deferred retirement benefit is considered a vested benefit if it is vested under the terms of the plan at the close of the plan year described in paragraph (a)(5) or (b)(4) (whichever is applicable) for which information relating to any deferred vested retirement benefit of the participant must be filed. A participant's deferred retirement benefit need not be a nonforfeitable benefit within the meaning of section 411(a) for the filing requirements described in this section to apply. Accordingly, information relating to a participant's deferred vested retirement benefit must be filed as required by this section notwithstanding that the benefit is subject to forfeiture by reason of an event or condition occurring subsequent to the close of the plan year described in paragraph (a)(5) or (b)(4) (whichever is applicable) for which information relating to any deferred vested retirement benefit of the participant must be filed.

(3) *Plans subject to filing requirement.* The term "employee retirement benefit plan" means a plan to which the vesting standards of section 203 of part 2 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (88 Stat. 854) apply for any day in the plan year. (For purposes of this section, "plan year" means the plan year as determined for purposes of the annual return required by section 6058(a)). Accordingly, a plan need not be a qualified plan within the meaning of section 401(a) to be subject to these filing requirements. A plan to which more than one employer contributes must file the report of deferred vested retirement benefits described in this section, but see paragraph (b) for special rules applicable to such a plan. The filing requirements described in this section and § 301.6057-2 (relating to notification of change in plan status) do not apply to a governmental or church plan described in section 414 (d) or (e).

(4) *Filing requirements.* Information relating to the deferred vested retirement benefit of a plan participant must be filed on schedule SSA as an attachment to the Annual Return/Report of Employee Benefit Plan (form 5500 series). Schedule SSA shall be filed on behalf of an employee retirement benefit plan for each plan year for which information relating to the deferred vested retirement benefit of a plan participant is filed under paragraph (a)(5) or (b)(2) of this sec-

tion. There shall be filed on schedule SSA the name and social security number of the participant, a description of the nature, form, and amount of the deferred vested retirement benefit to which the participant is entitled, and such other information as is required by section 6057(a) or schedule SSA and the accompanying instructions. The form of the benefit reported on schedule SSA shall be the normal form of benefit under the plan, or, if the plan administrator (within the meaning of section 414(g)) considers it more appropriate, any other form of benefit.

(5) *Time for reporting deferred vested retirement benefit*— (i) *In general.* In the case of a plan to which only one employer contributes, information relating to the deferred vested retirement benefit of a plan participant must be filed no later than on the schedule SSA filed for the plan year following the plan year within which the participant separates from service covered by the plan. Information relating to a separated participant may, at the option of the plan administrator, be reported earlier (that is, on the schedule SSA filed for the plan year in which the participant separates from service covered by the plan). For purposes of this paragraph a participant is not considered to separate from service covered by the plan solely because the participant incurs a break in service under the plan. In addition, for purposes of this paragraph, in the case of a plan which uses the elapsed time method described in Department of Labor regulations for crediting service for benefit accrual purposes, a participant is considered to separate from service covered by the plan on the date the participant severs from service covered by the plan.

(ii) *Exception.* Notwithstanding subdivision (i), no information relating to the deferred vested retirement benefit of a separated participant is required to be filed on schedule SSA if, before the date such schedule SSA is required to be filed (including any extension of time for filing granted pursuant to section 6081), the participant (A) is paid some or all of the deferred vested retirement benefit under the plan, (B) returns to service covered by the plan, or (C) forfeits all of the deferred vested retirement benefit under the plan.

(b) *Plans to which more than one employer contributes*—(1) *Application.* Section 6057 and this section apply to a plan to which more than one employer contributes with the modifications set forth in this paragraph. For purposes of section 6057 and this section, whether or not more than one employer contributes to a plan shall be determined by the number of employers who are required to contribute to the plan. Thus, for example, this paragraph applies to plans maintained by more than one employer which are collectively bargained as described in section 413(a), multiple-employer plans described in section 413(c) and the regulations thereunder, multiemployer plans described in section 414(f), and plans adopted by more than one employer of certain controlled and common control groups described in section 414 (b) and (c).

(2) *Time for reporting deferred vested retirement benefit*—(i) *In general.* In the case of a plan to which more than one employer contributes, information relating to the deferred vested retirement benefit of a plan participant must be filed no later than on the schedule SSA filed for the plan year within which the participant completes the second of two consecutive one-year breaks in service (as defined in the plan for vesting percentage purposes) in service computation periods (as defined in the plan for vesting percentage purposes) which begin after December 31, 1974. At the option of the plan administrator, information relating to a participant's deferred vested retirement benefit may be filed earlier (that is, on the schedule SSA filed for the plan year in which the participant incurs the first one-year break in service or, in the case of a separated participant, on the schedule SSA filed for the plan year in which the participant separates from service).

(ii) *Special rules*—For purposes of this subparagraph (1)—

(A) For the definition of the term "1-year break in service" in the case of a plan which uses the elapsed time method described in Department of Labor Regulations for crediting service for vesting percentage purposes, see § 1.411(a)-6(c)(2).

(B) In the case of a plan which does not define the term "1-year break in service" for vesting percentage purposes, a plan participant shall be deemed to incur a 1-year break in service under the plan in any plan year within which the participant does not complete more than 500 hours of service covered by the plan.

(iii) *Transitional rule.* Notwithstanding subdivision (i), if the second consecutive 1-year break in service described in subdivision (i) is incurred in a plan year beginning before January 1, 1978, information relating to the participant's deferred vested retirement benefit is not required to be filed earlier than on the schedule SSA filed for the first plan year beginning after December 31, 1977.

(iv) *Exception.* Notwithstanding subdivision (i) or (iii) of this subparagraph, no information relating to a participant's deferred vested retirement benefit is required to be filed on schedule SSA if, before the date such schedule SSA is required to be filed (including any extension of time for filing granted pursuant to section 6081), the participant (A) is paid some or all of the deferred vested retirement benefit under the plan, (B) accrues additional retirement benefits under the plan, or (C) forfeits all of the deferred vested retirement benefit under the plan.

(3) *Information relating to deferred vested retirement benefit*—(i) *Incomplete records.* Section 6057(a) and paragraph (a)(4) of this section require the filing on schedule SSA of a description of the deferred vested retirement benefit to which the participant is entitled. If the plan administrator of a plan to which more than one employer contributes maintains records of a participant's service covered by the plan which are incomplete as of the close of the plan year with respect to which the plan administrator files information relating to the participant on schedule SSA, the plan administrator may elect to file the information required by schedule SSA based only upon these incomplete records. The plan administrator is not required, for purposes of completing schedule SSA, to compile from sources other than such records a complete record of a participant's years of service covered by the plan. Similarly, if retirement benefits under the plan are determined by taking into account a participant's service with an employer which is not service covered by the plan, but the plan administrator maintains records only with respect to periods of service covered by the plan, the plan administrator may complete schedule SSA taking into account only the participant's period of service covered by the plan.

(ii) *Inability to determine correct amount of participant's deferred vested retirement benefit.* If the amount of a participant's deferred vested retirement benefit which is filed on schedule SSA is computed on the basis of plan records maintained by the plan administrator which—

(A) Are incomplete with respect to the participant's service covered by the plan (as described in subdivision (i)), or

(B) Fail to account for the participant's service not covered by the plan which is relevant to a determination of the participant's deferred vested retirement benefit under the plan (as described in subdivision (i)),

then the plan administrator must indicate on schedule SSA that the amount of the deferred vested retirement benefit shown therein may be other than that to which the participant is actually entitled because the amount is based upon incomplete records.

(iii) *Inability to determine whether participant vested in deferred retirement benefit.* Where, as described in subdivision (i), information to be reported on schedule SSA is to be based upon records which are incomplete with respect to a participant's service covered by the plan or which fail to take into account relevant service not covered by the plan, the plan administrator may be unable to determine whether or not the participant is vested in any deferred retirement benefit. If, in view of information provided either by the incomplete records or the plan participant, there is a significant likelihood that the plan participant is vested in a deferred retirement benefit under the plan, information relating to the participant must be filed on schedule SSA with the notation that the participant may be entitled to a deferred vested retirement benefit under the plan, but information relating to the amount of the benefit may be omitted. This subdivision (iii) does not apply in a case in which it can be determined from plan records maintained by the plan administrator that the participant is vested in a deferred retirement benefit. Subdivision (ii), however, may apply in such a case.

(c) *Voluntary filing*—(1) *In general.* The plan administrator of an employee retirement benefit plan described in paragraph (a)(3) of this section, or any other employee retirement benefit plan (including a governmental or chruch plan), may at its option, file on schedule SSA information relating to the deferred vested retirement benefit of any plan participant who separates at any time from service covered by the plan, including plan participants who separate from service in plan years beginning before 1976.

(2) *Deleting previously filed information.* If, after information relating to the deferred vested retirement benefit of a plan participant is filed on schedule SSA, the plan participant—

(i) Is paid some or all of the deferred vested retirement benefit under the plan, or

(ii) Forfeits all of the deferred vested retirement benefit under the plan, the plan administrator may, at its option, file on schedule SSA (or such other form as may be provided for this purpose) the name and social security number of the participant with the notation that information previously filed relating to the participant's deferred vested retirement benefit should be deleted.

(d) *Filing incident to cessation of payment of benefits*—(1) *In general.* As described in this section, no information relating to the deferred vested retirement benefit of a plan participant is required to be filed on schedule SSA if before the date such schedule SSA is required to be filed, some of the deferred vested retirement benefit is paid to the participant, and information relating to a participant's deferred vested retirement benefit which was previously filed on schedule SSA may be deleted if the participant is paid some of the deferred vested retirement benefit. If payment of the deferred vested retirement benefit ceases before all of the benefit to which the participant is entitled is paid to the participant, information relating to the deferred vested retirement benefit to which the participant remains entitled shall be filed on the schedule SSA filed for the plan year following the last plan year within which a portion of the benefit is paid to the participant.

(2) *Exception.* Notwithstanding subparagraph (1) of this paragraph, no information relating to the deferred vested retirement benefit to which the participant remains entitled is required to be filed on schedule SSA if, before the date such schedule SSA is required to be filed (including any extension of time for filing granted pursuant to section 6081), the participant (i) returns to service covered by the plan, (ii) accures additional retirement benefits under the plan, or (iii) forfeits the benefit under the plan.

(e) *Individual statement to participant.* The plan administrator of an employee retirement benefit plan defined in paragraph (a)(3) of this section must provide each participant with respect to whom information is required to be filed on schedule SSA a statement describing the deferred vested retirement benefit to which the participant is entitled. The description provided the participant must include the information filed with respect to the participant on schedule SSA. The statement is to be delivered to the participant or forwarded to the participant's last known address no later than the date on which any schedule SSA reporting information with respect to the participant is required to be filed (including any extension of time for filing granted pursuant to section 6081).

(f) *Penalties.* For amounts imposed in the case of failure to file the report of deferred vested retirement benefits required by section 6057 (a) and paragraph (a) or (b) of this section, see section 6652(e)(1). For the penalty relating to a failure to provide the participant the individual statement of deferred vested retirement benefit required by section 6057(e) and paragraph (e) of this section, see section 6690.

(g) *Effective dates.*—(1) *Plans to which only one employer contributes.* In the case of a plan to which only one employer contributes, this section is effective for plan years beginning after December 31, 1975, and with respect to a participant who separates from service covered by the plan in plan years beginning after that date.

(2) *Plans to which more than one employer contributes.* In the case of a plan to which more than one employer contributes, this section is effective for plan years beginning after December 31, 1977, and with respect to a participant who completes two consecutive 1-year breaks in service under the plan in service computation periods beginning after December 31, 1974.

§ 301.6057-2 Employee retirement benefit plans; notification of change in plan status.

(a) *Change in plan status.* The plan administrator (within the meaning of section 414(g)) of an employee retirement benefit plan defined in § 301.6057-1(a)(3) (including a plan to which more than one employer contributes, as described in § 301.6057-1(b)(1)) must notify the Internal Revenue Service of the following changes in plan status—

(1) A change in the name of the plan.

(2) A change in the name or address of the plan administrator,

(3) The termination of the plan, or

(4) The merger or consolidation of the plan with another plan or the division of the plan into two or more plans.

(b) *Notification.* A notification of a change in status described in paragraph (a) must be filed on the Annual Return/Report of Employee Benefit Plan (form 5500 series) for the plan year in which the change in status occurred. The notification must be filed at the time and place and in the manner prescribed in the form and any accompanying instructions.

(c) *Penalty.* For amounts imposed in the case of failure to file a notification of a charge in plan status required by section 6057(b) and this section, see section 6652(e)(2).

(d) *Effective date.* This section is effective for changes in plan status occurring within plan years beginning after December 31, 1975.

§ 301.6652 [Deleted]

PAR. 2. Section 301.6652 is deleted.

PAR. 3. There is added immediately after § 301.6652-2 the following new section:

§ 301.6652-3 Failure to file information with respect to employee retirement benefit plan.

(a) *Amount imposed*—(1) *Annual registration statement.* The plan administrator (within the meaning of section 414(g)) of an employee retirement benefit plan defined in § 301.6057-1(a)(3) is liable for the amount imposed by section 6652(e)(1) in each

case in which there is a failure to file information relating to the deferred vested retirement benefit of a plan participant, as required by section 6057(a) and § 301.6057-1, at the time and place and in the manner prescribed therefor (determined without regard to any extension of time for filing). The amount imposed by section 6652(e)(1) on the plan administrator is $1 for each participant with respect to whom there is a failure to file the required information, multiplied by the number of days during which the failure continues. However, the total amount imposed by section 6652(e)(1) on the plan administrator with respect to a failure to file on behalf of a plan for a plan year shall not exceed $5,000.

(2) *Notification of change in status.* The plan administrator (within the meaning of section 414(g)) of an employee retirement benefit plan defined in § 301.6057-1(a)(3) is liable for the amount imposed by section 6652(e)(2) in each case in which there is a failure to file a notification of a change in plan status, as described in section 6057(b) and § 301.6057-2, at the time and place and in the manner prescribed therefor (determined without regard to any extension of time for filing). The amount imposed by section 6652(e)(2) on the plan administrator is $1 for each day during which the failure to so file a notification of a change in plan status continues. However, the total amount imposed by section 6652(e)(2) on the plan administrator with respect to a failure to file a notification of a change in plan status shall not exceed $1,000.

(3) *Annual return of employee benefit plan.* [Reserved.]

(4) *Actuarial statement in case of mergers.* The plan administrator (within the meaning of section 414(g)) is liable for an amount imposed by section 6652(f) in each case in which there is a failure to file the actuarial statement described in section 6058(b) at the time and in the manner prescribed therefor (determined with regard to any extension of time for filing). The amount imposed by section 6652(f) on the plan administrator is $10 for each day during which the failure to file the statement with respect to a merger, consolidation or transfer of assets or liabilities continues. However, the amount imposed by section 6652(f) on the plan administrator with respect to a failure to file the statement with respect to a merger, consolidation or transfer shall not exceed $5,000.

(5) *Information relating to certain trusts and annuity and bond purchase plans.* Under section 6652(f) the amount described in this subparagraph is imposed in each case in which there is a failure to file a return or statement required by section 6047 at the time and in the manner prescribed therefor in § 1.6047-1 (determined with regard to any extension of time for filing). The amount is imposed upon the trustee of a trust described in section 401(a), custodian of a custodial account or issuer of an annuity contract, as the case may be (see § 1.6047-1(a)(1) (i) and (ii)). The amount imposed by section 6652(f) is $10 for each day during which the failure to file with respect to a payee for a calendar year continues. However, the amount imposed with respect to a failure to file with respect to a payee for a calendar year shall not exceed $5,000.

(b) *Showing of reasonable cause.* (1) No amount imposed by section 6652(e) shall apply with respect to a failure to file information relating to the deferred vested retirement benefit of a plan participant under section 6057(a), or a failure to give notice of a change in plan status under section 6057(b), if it is established to the satisfaction of the director of the internal revenue service center at which the information or notice is required to be filed that the failure was due to reasonable cause.

(2) No amount imposed by section 6652(f) shall apply with respect to a failure to file a return or statement required by section 6058 or 6047, or a failure to provide material items of information called for on such a return or statement, if it is established to the satisfaction of the appropriate district director or the director of the internal revenue service center at which the return or statement is required to be filed that the failure was due to reasonable cause.

(3) An affirmative showing of reasonable cause must be made in the form of a written statement setting forth all the facts alleged as reasonable cause. The statement must contain a declaration by the appropriate individual that the statement is made under the penalties of perjury.

(c) *Joint liability.* If more than one person is responsible for a failure to comply with sections 6057 (a) or (b) or section 6058 (a) or (b) or section 6047, all such persons shall be jointly and severally liable with respect to the failure.

(d) *Manner of payment.* An amount imposed under section 6652 (e) or (f) and this section shall be paid in the same manner as a tax upon the issuance of notice and demand therefor.

(e) *Effective dates*—(1) *Annual registration statement.* With respect to the annual registration statement described in section 6057(a), this section is effective—

(i) In the case of a plan to which only one employer contributes, for plan years beginning after December 31, 1975, with respect to participants who separate from service covered by the plan in plan years beginning after that date, and

(ii) In the case of a plan to which more than one employer contributes, for plan years beginning after December 31, 1977, and with respect to participants who complete two consecutive 1-year breaks in service under the plan in service computation periods beginning after December 31, 1974.

(2) *Notification of change in status.* With respect to the notification of change in plan status required by section 6057(b), this section is effective with respect to a change in status occurring within plan years beginning after December 31, 1975.

(3) *Annual return of employee benefit plan.* With respect to the annual return of employee benefit plan required by section 6058(a), this section is effective for plan years beginning after September 2, 1974.

(4) *Actuarial statement in case of mergers.* With respect to the actuarial statement required by section 6058(b), this section is effective with respect to mergers, consolidations or transfers of assets or liabilities occurring after September 2, 1974.

(5) *Information relating to certain trusts and annuity and bond purchase plans.* With respect to reports or statements required to be filed by section 6047 and the regulations thereunder, this section is effective with respect to calendar years ending after September 2, 1974.

PAR. 4. There is added in the appropriate place the following new section:

§ 301.6690-1 Penalty for fraudulent statement or failure to furnish statement to plan participant.

(a) *Penalty.* Any plan administrator required by section 6057(e) and § 301.6057-1(e) to furnish a statement of deferred vested retirement benefit to a plan participant is subject to a penalty of $50 in each case in which the administrator (1) willfully fails to furnish the statement to the participant in the manner, at the time, and showing the information required by section 6057(e) and § 301.6057-1(e), or (2) willfully furnishes a false or fraudulent statement to the participant. The penalty shall be assessed and collected in the same manner as the tax imposed on employers under the Federal Insurance Contributions Act.

(b) *Effective date.* This section shall take effect on September 2, 1974.

[FR Doc. 78-24010 Filed 8-24-78; 8:45 am]

[3410-11]

Title 36—Parks, Forests, and Public Property

CHAPTER II—FOREST SERVICE, DEPARTMENT OF AGRICULTURE

PART 223—SALE AND DISPOSAL OF TIMBER

National Forest Timber Sales; Contract Conditions

AGENCY: Forest Service, USDA.

ACTION: Final rule.

SUMMARY: This rule revises requirements for payment guarantees furnished in lieu of advance cash payments on national forest timber sales. The new rule will allow irrevocable letters of credit to be acceptable as payment guarantees.

EFFECTIVE DATE: August 25, 1978.

FOR FURTHER INFORMATION CONTACT:

George M. Leonard or Peter J. Wagner, Timber Management Staff, Forest Service, Department of Agriculture, P.O. Box 2417, Washington, D.C. 20013, 202-447-4051.

SUPPLEMENTARY INFORMATION: On May 10, 1978, the Secretary of Agriculture published a proposed rule (43 FR 20022) which would add irrevocable letters of credit to the list of acceptable sureties for payment bonds on national forest timber sales. The final rule is very similar to the proposed rule with one minor change which requires refunds to be made to the "current holder of the contract" rather than to "the original depositors."

SUMMARY OF COMMENTS

There were a total of five comments, all but one endorsing the proposed rule. One respondent opposed the rule as unnecessary and as allowing high risk entities to bid on future offerings. Several respondents favored the rule but suggested that refunds be made to the current holder of the contract rather than the original depositor. The final regulations reflect this suggestion.

Several respondents suggested wording changes which would have required the refund of "Advance payments found to be in excess of amounts due to the United States under the terms of this contract * * *." This addition would prevent the Government from exercising its rights to use deposits from other contracts when the contracts explicitly permit such use. This change would be to the disadvantage of the Government by weakening collection rights on sales where purchaser credit is being transferred. Therefore, this suggestion has not been used.

One respondent suggested adding negotiable securities as a form of acceptable payment guarantee. The proposed regulation is worded in a general way so negotiable securities will be permitted. Therefore, the proposed addition is unnecessary.

Therefore 36 CFR 223.3(e) is hereby modified to read:

§ 223.3 Contract conditions.

* * * * *

(e) Sale contracts shall provide that timber and forest products be paid for in advance of cutting, unless the contract authorizes the purchaser to furnish a payment guarantee satisfactory to the Forest Service. Advance payments found to be in excess of amounts due the United States shall be refunded to the current holder of the contract or to successors in interest. (90 Stat. 2959; 16 U.S.C. 472a.)

AUGUST 18, 1978.

M. RUPERT CUTLER,
Assistant Secretary.

[FR Doc. 78-23847 Filed 8-24-78; 8:45 am]

[6560-01]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER D—WATER PROGRAMS

[FRL 953-3]

PART 118—DETERMINATION OF HARMFUL QUANTITIES FOR HAZARDOUS SUBSTANCES

Effective Date of Regulations

AGENCY: Environmental Protection Agency.

ACTION: Deferral of effective date.

SUMMARY: On March 13, 1978, EPA published regulations under section 311 of the Clean Water Act to control the discharge of hazardous substances (43 FR 10474). On August 4, 1978, the District Court for the Western District of Louisiana declared certain portions of these regulations invalid, void, and unenforceable. Hazardous substances regulations under section 311 may, however, become effective in the future. EPA hereby defers the effective date of such regulations as they apply to discharges from railroad rolling stock until there are appropriate legal requirements for rail shippers to identify cargoes containing substances designated as hazardous under section 311.

Interested persons have pointed out that railroads must by law transport all shipments tendered to them in accordance with applicable legal requirements. Currently, there is no legal requirement that shippers identify their cargoes as containing substances designated as hazardous under section 311. Thus, railroad personnel may have no way of knowing whether a substance they are handling or carrying is subject to section 311's requirements. EPA is currently working with both the Department of Transportation and the Interstate Commerce Commission to expedite the development of appropriate legal requirements for shipper identification. When such requirements are developed, EPA will publish notice in the FEDERAL REGISTER announcing the effective date of the section 311 regulations as they apply to railroads.

FOR FURTHER INFORMATION CONTACT:

Kenneth M. Mackenthun, Director, Criteria and Standards Division (WH-585), Office of Water Planning and Standards, U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, 755-0100.

Dated: August 18, 1978.

JOHN T. RHETT,
Assistant Administrator for Water and Hazardous Materials.

[FR Doc. 78-23871 Filed 8-24-78; 8:45 am]

[6820-24]

Title 41—Public Contracts and Property Management

CHAPTER 101—FEDERAL PROPERTY MANAGEMENT REGULATIONS

SUBCHAPTER H—UTILIZATION AND DISPOSAL

[FPMR Amdt. H-112]

PART 101-44—DONATION OF PERSONAL PROPERTY

Subpart 101-44.2—Donations to Public Agencies and Nonprofit Educational and Public Health Activities

ELIGIBILITY

AGENCY: General Services Administration.

ACTION: Final rule.

SUMMARY: This directive amends the FPMR by adding a definition for the term "licensed," and by clarifying the meanings of certain other terms in an effort to assist State agencies in determining applicant eligibility for donation of surplus personal property.

EFFECTIVE DATE: August 25, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. John I. Tait, Director, Regulations and Management Control Division, Office of the Executive Director, Federal Supply Service, General Services Administration, Washington, D.C. 20406, 703-557-1914.

Section 101-44.207 is amended to revise paragraphs (a) (2), (3), (16), and (19) and add paragraph (a)(14.1) as follows:

§ 101-44.207 Eligibility.

* * * * *

(a) * * *

(2) "Approved" means recognition and approval by the State department of education, State department of health, or other appropriate authority where no recognized accrediting board, association, or other authority exists for the purpose of making an accreditation. For an educational institution or an educational program, approval must relate to academic or instructional standards established by the appropriate authority. An educational institution or program may be considered approved if its instruction and credits therefor are accepted by an accredited or State-approved institution, or if it meets the academic or instructional standards prescribed for public schools in the State; i.e., the organizational entity or program is devoted primarily to approved academic, vocational (including technical or occupational), or professional study and instruction, which operates primarily for educational purposes on a full-time basis for a minimum school year as prescribed by the State and employs a full-time staff of qualifed instructors. For a public health institution or program, approval must relate to the medical requirements and standards for the professional and technical services of the institution established by the appropriate authority. A health institution or program may be considered as approved when a State body having authority under law to establish standards and requirements for public health institutions renders approval thereto whether by accreditation procedures or by licensing or such other method prescribed by State law. In the absence of an official State approving authority for a public health institution or program or educational institution or program, the awarding of research grants to the institution or organization by a recognized authority such as the National Institutes of Health, the National Institute of Education, or by similar national advisory council or organization may constitute approval of the institution or program provided all other criteria are met.

(3) "Child care center" means a public or nonprofit facility where educational, social, health, and nutritional services are provided to children through age 14 or as prescribed by State law, and which is approved or licensed by the State or other appropriate authority as a child day care center or child care center.

* * * * *

(14.1) "Licensed" means recognition and approval by the appropriate State or local authority approving institutions or programs in specialized areas. Licensing generally relates to established minimum public standards of safety, sanitation, staffing, and equipment as they relate to the construction, maintenance, and operation of a health or educational facility, rather than to the academic, instructional, or medical standards for these institutions. Licensing may be required for educational or public health programs such as occupational training, physical or mental health rehabilitation services, or nursing care. Licenses frequently must be renewed at periodic intervals.

* * * * *

(16) "Museum" means a public or private nonprofit institution which is organized on a permanent basis essentially for educational or esthetic purposes and which, using a professional staff, owns or uses tangible objects, whether animate or inanimate; cares for these objects; and exhibits them to the public on a regular basis either free or at a nominal charge. As used in this section, the term "museum" includes, but is not limited to, the following institutions if they satisfy all other provisions of this section: Aquariums and zoological parks; botanical gardens and arboretums; museums relating to art, history, natural history, science, and technology; and planetariums. For the purposes of this section, an institution uses a professional staff if it employs full time at least one qualified staff member who devotes his or her time primarily to the acquisition, care, or public exhibition of objects owned or used by the institution. This definition of museum does not include any institution which exhibits objects to the public if the display or use of the objects is only incidential to the primary function of the institution. For example, an institution which is engaged primarily in the sale of antiques, objets d'art, or other artifacts and which incidentally provides displays to the public of animate or inanimate objects, either free or at a nominal charge, does not qualify as a museum.

* * * * *

(19) "Public health" means a program or programs to promote, maintain, and conserve the public's health by providing health services to individuals and/or by conducting research, investigations, examinations, training, and demonstrations. Public health services may include but are not limited to the control of communicable diseases, immunization, maternal and child health programs, sanitary engineering, sewage treatment and disposal, sanitation inspection and supervision, water purification and distribution, air pollution control, garbage and trash disposal, and the control and elimination of disease-carrying animals and insects.

* * * * *

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

Dated: August 11, 1978.

JAY SOLOMON,
Administrator of General Services.

[FR Doc. 78-23894 Filed 8-24-78; 8:45 am]

[1505-01]

Title 43—Public Lands: Interior

CHAPTER II—BUREAU OF LAND MANAGEMENT, DEPARTMENT OF THE INTERIOR

[Circular No. 2432]

PART 2920—SPECIAL LAND USE PERMITS

Rules for Visitor Use—Other Than Developed Recreation Sites

Correction

In FR Doc. 78-4761, appearing at page 7868 in the issue for Friday, February 24, 1978, on page 7870, immediately below the signature, the amendatory language for part 2920 was misprinted. The amendments to part 2920 should have read as follows:

PART 2920—SPECIAL LAND USE PERMITS

§ 2920.0-5 [Amended]

Subpart 2924 [Deleted]

1. Part 2920 is amended by deleting § 2920.0-5(e) and subpart 2924.

[4310-55]

Title 50—Wildlife and Fisheries

CHAPTER I—UNITED STATES FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

SUBCHAPTER B—TAKING, POSSESSION, TRANSPORTATION, SALE, PURCHASE, BARTER, EXPORTATION, AND IMPORTATION OF WILDLIFE

PART 20—MIGRATORY BIRD HUNTING

Early Seasons, Bag Limits, and Possession of Certain Migratory Game Birds in the Contiguous United States, Alaska, Hawaii, Puerto Rico, and the Virgin Islands; Correction

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Correction of final rule.

SUMMARY: This document corrects typographical errors in the season dates for mourning dove hunting in Texas, published by the Service on August 11, 1978.

EFFECTIVE DATE: August 25, 1978.

FOR FURTHER INFORMATION CONTACT:

John P. Rogers, Chief, Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, Washington, D.C., telephone 202-254-3207.

SUPPLEMENTARY INFORMATION: The amendments in this document correct typographical errors in the amendment to § 20.103(b) of Department of the Interior's regulations as published in the FEDERAL REGISTER at 43 FR 35902 on August 11, 1978 (FR Doc. 78-22600).

50 CFR part 20 is amended by revising § 20.103(b) as follows:

In the table for the central management unit at page 35902, August 11, 1978, the portion pertaining to mourning doves in the north zone of Texas that reads:

Texas: [3]	
North zone: Counties of Kinney, Val Verde, Terrell, Brewster, Presidio, Jeff Davis, Culberson, Hudspeth, and El Paso	
Shooting hours:	
12 noon until sunset.....	Sept. 2, 3, 9, 10.
½ hour before sunrise until sunset.	Sept. 23-Nov. 1. Jan. 6-Jan. 21.
Remainder of north zone:	
Shooting hours: ½ hour before sunrise until sunset.	Sept. 1-Oct. 21. Jan. 6-Jan. 14.

* * * * *

is corrected to read:

Texas: [3]	
North zone: Counties of Kinney, Val Verde, Terrell, Brewster, Presidio, Jeff Davis, Culberson, Hudspeth, and El Paso.	Sept. 1-Oct. 21. Jan. 6-Jan. 14.
Shooting hours:	
12 noon until sunset.....	Sept. 2, 3, 9, 10.
½ hour before sunrise until sunset.	Remainder of the season.
Remainder of north zone:	
Shooting hours: ½ hour before sunrise until sunset.	Sept. 1-Oct. 21. Jan. 6-Jan. 14.

* * * * *

AUTHORSHIP

The primary author of this document is Henry M. Reeves, Office of Migratory Bird Management, working under the direction of John P. Rogers, Chief.

ECONOMIC IMPACT REVIEW

The Service has determined that this document does not contain a major proposal requiring preparation of an economic impact statement under Executive Order 11949 and OMB Circular A-107.

Dated: August 22, 1978.

HARVEY K. NELSON,
Acting Director,
U.S. Fish and Wildlife Service.

[FR Doc. 78-23941 Filed 8-24-78; 8:45 am]

[4310-55]

PART 32—HUNTING

Ravalli National Wildlife Refuge, Mont.

AGENCY: U.S. Fish and Wildlife Service, Department of the Interior.

ACTION: Special regulations, migratory game bird.

SUMMARY: The Director has determined that the opening to migratory game bird hunting on the Ravalli National Wildlife Refuge is compatible with the objectives for which the area was established, will utilize a renewable natural resource, and will provide additional recreational opportunity to the public.

EFFECTIVE DATE: September 30, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert C. Twist, Refuge Manager, No. 5, Third Street, P.O. Box 257, Stevensville, Mont. 59870, 406-777-5552.

§ 32.12 Special regulations; migratory game birds; for individual wildlife refuge areas.

MONTANA

RAVALLI NATIONAL WILDLIFE REFUGE

The hunting of ducks, geese, coot and mergansers will be permitted on portions of the Ravalli National Wildlife Refuge during the regular migratory bird hunting season, from September 30, 1978 to December 31, 1978, and shall be in accordance with all applicable State and Federal regulations subject to the following additional special conditions:

1. All hunters must enter the public hunting area through appropriate check stations.

2. Hunters will be limited to 3 shells per duck of the daily bag limit, for a total of 21 shells per hunter per day.

3. Hunter selection for opening day and for the two following weekends will be made by a drawing held prior to opening day.

4. All hunters must set blind selection pointer to "taken" upon selecting a blind, and return blind selection pointer to "open" upon leaving the hunting area.

5. Placing blind selection pointer to "taken" determines the occupant of the blind.

6. During periods of high hunter demand, as determined by the Refuge Manager, hunters will be limited to one period only during a day:

Period No. 1: Start of shooting hours to 12 noon.

Period No. 2: 1 p.m. until close of shooting hours.

7. Hunters must be within 10 feet of designated blind sites while attempting to take and taking of waterfowl game birds.

8. Blind sites will be limited to five hunters each.

9. A designated area will be open to the taking of ducks, geese, coot and mergansers by means of falconry from the opening of the migratory waterfowl season through November 26, 1978. No firearms may be carried in this area.

10. The public hunting area will be closed to entry from 1 hour after sunset until 1½ hours before sunrise.

11. No fishing equipment of any type will be permitted on the public hunting area.

12. Boats are not permitted.

The hunting area is designated by signs and delineated on maps available at Refuge Headquarters, No. 5, Third Street, Stevensville, Mont., and from the Area Manager, U.S. Fish and Wildlife Service, Room 3035, Federal Building, 316 North 26th Street, Billings, Mont.

The provisions of these special regulations supplement the regulations which govern hunting on wildlife

refuge areas generally and which are set forth in Title 50, Code of Federal Regulations, Part 32, and are effective through June 30, 1979.

NOTE.—The U.S. Fish and Wildlife Service has determined that this document does not contain a major proposal requiring preparation of an economic impact statement under Executive Order 11949 and OMB Circular A-107.

ROBERT C. TWIST,
Refuge Manager, Ravalli National Wildlife Refuge, Stevensville, Mont.

AUGUST 18, 1978.

[FR Doc. 78-23952 Filed 8-24-78; 8:45 am]

[4310-55]

PART 32—HUNTING

Opening of Medicine Lake National Wildlife Refuge, Montana to Migratory Game Bird Hunting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Special regulation.

SUMMARY: The Director has determined that the opening to migratory game bird hunting of the Medicine Lake National Wildlife Refuge is compatible with the objectives for which the area was established, will utilize a renewable natural resource, and will provide additional recreation opportunity to the public.

DATES: September 1, 1978, through December 31, 1978.

FOR FURTHER INFORMATION CONTACT:

Jay R. Bellinger, Refuge Manager, Medicine Lake, Mont. 59247, telephone 406-789-2305.

SUPPLEMENTARY INFORMATION: Migratory game bird hunting is permitted on the Medicine Lake National Wildlife Refuge, Montana, only on the area designated by signs as being open to migratory game bird hunting. This area comprises 10,163 acres and is delineated on maps available at the refuge headquarters and from the office of the Area Manager, U.S. Fish and Wildlife Service, Federal Building, Room 3035, 316 North 26th Street, Billings, Mont. 59101.

§ 32.12 Special regulations; migratory birds; for individual wildlife refuge area.

Hunting shall be in accordance with all applicable State regulation subject to the following conditions:

1. Vehicle travel is permitted only on designated trails.

The provisions of this special regulation supplement the regulations which govern hunting on wildlife refuge areas generally which are set forth in Title 50 Code of Federal Regulations, Part 32. The public is invited to offer suggestions and comments at any time.

§ 32.22 Special regulations; upland game birds and jackrabbits; for individual wildlife refuge areas.

Upland game bird and jackrabbit hunting is permitted on the Medicine Lake National Wildlife Refuge, Montana, only on the areas designated by signs as being open to upland game hunting. These areas comprising 10,163 acres are delineated on maps available at the refuge headquarters and from the office of the Area Manager, U.S. Fish and Wildlife Service, Federal Building, Room 3035, 316 North 26th Street, Billings, Mont. 59101. Hunting shall be in accordance with all applicable State regulations subject to the following condition:

1. Vehicle travel is permitted only on designated trails.

The provisions of this special regulation supplement the regulation which govern hunting on wildlife refuge areas generally which are set forth in Title 50 Code of Federal Regulations, Part 32. The public is invited to offer suggestions and comments at any time.

§ 32.32 Special regulations; big game; for individual wildlife refuge areas.

Big game hunting is permitted on the Medicine Lake National Wildlife Refuge, Montana, only on the areas designated by signs as being open to big game hunting. These areas comprising 10,163 acres are delineated on maps available at the refuge headquarters and from the office of the Area Manager, U.S. Fish and Wildlife Service, Federal Building, Room 3035, 316 North 26th Street, Billings, Mont. 59101. Hunting shall be in accordance with all applicable State regulations subject to the following condition:

1. Unlimited vehicle travel is permitted only on county roads. In the hunting areas, vehicle travel is permitted only for the retrieval of deer on designated retrieval roads.

2. Horses may be used only for the retrieval of big game.

The provisions of this special regulation supplement the regulations which govern hunting on wildlife refuge areas generally which are set forth in Title 50 Code of Federal Regulations, Part 32. The public is invited to offer suggestions and comments at any time.

NOTE.—The U.S. Fish and Wildlife Service has determined that this document does not contain a major proposal requiring preparation of an economic impact statement under Executive Order 11949 and OMB Circular A-107.

JAY R. BELLINGER,
Refuge Manager.

AUGUST 8, 1978.

[FR Doc. 78-23949 Filed 8-24-78; 8:45 am]

[4310-55]

PART 32—HUNTING

Opening of National Elk Refuge, Wyoming to Big Game Hunting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Special regulation.

SUMMARY: The Director has determined that the opening to elk hunting at the National Elk Refuge is compatible with the objectives for which the area was established, will utilize a renewable natural resource, and will provide additional recreational opportunity to the public.

DATES: October 28, 1977, through December 8, 1978.

FOR FURTHER INFORMATION CONTACT:

John E. Wilbrecht, Refuge Manager, National Elk Refuge, P.O. Box C, Jackson, Wyo. 83001, 307-733-2627.

SUPPLEMENTARY INFORMATION: Public hunting of elk on the National Elk Refuge, Wyoming is permitted from October 28 through December 8, 1978, only on the area designated by signs as open to hunting. This open area, comprising 16,327 acres, is delineated on maps available at refuge headquarters, Jackson, Wyo. and from the Area Manager, U.S. Fish and Wildlife Service, Federal Building, Room 3035, 316 North 26th Street, Billings, Mont. 59101.

§ 32.32 Special regulations; big game; for individual wildlife refuge areas.

Hunting shall be in accordance with all applicable State regulations covering the hunting of elk subject to the following special conditions:

(1) A special permit is required in addition to a valid 1978 State elk hunting license. One hundred twenty special permits (for three hunt periods each week) shall be issued to applicants by drawing at refuge headquarters at 3 p.m. on Fridays, October 27, November 3, 10, 17, 24, and December 1, unless area 77 season closes earlier. Forty permits will be valid for Saturday and Sunday; forty permits valid Monday and Tuesday; forty permits valid Wednesday, Thursday, and Friday each week.

(2) Applicants for a special permit must have a hunter safety certifica-

tion or a current hunter safety instructor card.

(3) Persons successful in drawing a permit may not draw again in succeeding drawings; but may apply for unissued permits available after each drawing.

(4) Persons without permits may accompany special permit holders, but only permit holders are allowed to possess a firearm. Anyone entering hunt area must wear fluorescent orange exterior garments.

(5) Permits will be revoked in the event of a violation of refuge regulations and can result in denial of future privileges on the refuge.

(6) Access to the refuge is only through the main gate east of refuge headquarters in Jackson.

(7) Vehicles must be parked only in designated parking areas.

(8) All motorized travel is prohibited in the hunt area, except that vehicles will be permitted on designated trails after 4:15 p.m. to dark each day to facilitate retrieval of elk killed. Horses are permitted.

The provisions of this special regulation supplement the regulations which govern hunting on wildlife refuge areas generally which are set forth in Title 50 Code of Federal Regulations, Part 32. The public is invited to offer suggestions and comments at any time.

NOTE.—The U.S. Fish and Wildlife Service has determined that this document does not contain a major proposal requiring preparation of an economic impact statement under Executive Order 11949 and OMB Circular A-107.

JOHN E. WILBRECHT,
Refuge Manager.

AUGUST 4, 1978.

[FR Doc. 78-23950 Filed 8-24-78; 8:45 am]

proposed rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

[3410-05]

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service

Commodity Credit Corporation

[7 CFR Parts 728 and 1421]

1979 FEED GRAIN PROGRAM

Proposed Determinations Regarding Inclusion of Barley and Oats in Feed Grain Program, National Program Acreages, Program Allocation Factors, Set-Aside, Diversion Payments, Limitations on Planted Acreage, Loan and Purchase Levels, and Established (Target) Prices

NOTE.—This document originally appeared in the FEDERAL REGISTER for Wednesday, August 23, 1978. It is reprinted in this issue to meet requirements for publication on the Tuesday/Friday publication schedule assigned to the Agricultural Stabilization and Conservation Service. (See OFR Notice 41 FR 32914, August 6, 1976.)

AGENCY: Agricultural Stabilization and Conservation Service, Commodity Credit Corporation; Agriculture.

ACTION: Proposed rule.

SUMMARY: The Secretary of Agriculture proposes to make the following determinations with respect to the 1979 crops of corn, sorghum, barley, and oats: (a) Whether barley and oats should be included in the feed grain program; (b) The amount of the 1979 national program acreage; (c) The reduction from previous year's harvested acreage required, if any, to guarantee target price protection on total 1979 planted acreage; (d) Whether there should be a set-aside requirement and if so, the extent of such requirement; (e) Whether there should be a land diversion program, and if so, the extent of such diversion and level of payment; (f) If a set-aside or land diversion program is required, whether a limitation should be placed on planted acreage; (g) The loan and purchase levels for the 1979 crops of feed grains (corn, sorghum, barley, oats, and rye), and soybeans, including commodity eligibility, storage requirements, premiums and discounts; (h) established (target price); and (i) CCC minimum resale price and other related provisions necessary to carry out the loan, purchase, and payments programs.

Most of the above determinations are required to be made by the Secretary on or before November 15, 1978, in accordance with provisions in section 105A of the Agricultural Act of 1949, as amended.

DATES: This notice invites written comments on the proposed determinations. Comments must be received on or before October 10, 1978 to be assured of consideration.

ADDRESS: Acting Director, Production Adjustment Division, ASCS, USDA, Room 3630, South Building, P.O. Box 2415, Washington, D.C. 20013.

FOR FURTHER INFORMATION CONTACT: Orville I. Overboe (ASCS), 202-447-7987, Paul Meyers (ASCS), 202-447-8373.

SUPPLEMENTARY INFORMATION: The following determinations with respect to the 1979 crops of corn, sorghum, barley, and oats are to be made pursuant to section 105A of the Agricultural Act of 1949, as amended by the Food and Agriculture Act of 1977 (Pub. L. 95-113) hereafter referred to as the "Act", and with respect to the 1979 crop of soybeans pursuant to section 201 of the act.

PROPOSED DETERMINATIONS

a. *Whether barley and oats should be included in the feed grain program.* Corn and grain sorghum are required to be in the feed grain program; however, the Secretary has discretionary authority concerning the inclusion of barley and oats.

b. *National program acreage.* Section 105A(d)(1) of the act requires that the Secretary proclaim a national program acreage for each of the 1978 through 1981 crops of feed grains. The proclamation shall be made not later than November 15 of each calendar year. The national program acreage for each feed grain in the program shall be the number of harvested acres the Secretary determines (on the basis of a national average yield) will produce the quantity (less imports) that the Secretary estimates will be utilized domestically and for exports during the 1979-80 marketing year. The national program acreage may be adjusted by an amount the Secretary determines will accomplish a desired increase or decrease in carryover stocks.

The U.S. feed grain stock objective is set at 5.7 percent of world feed grain consumption, an amount judged to be our "fair" share of world feed grain stocks. Using this formula, our stock objective is approximately 41 million metric tons as of September 30, 1980. Estimates of the national program acreage required to meet this objective are requested from interested persons, together with appropriate explanatory material. Comments on the appropriate level of feed grain stocks are also requested.

c. *Voluntary reduction from previous year's harvested acreage.* Section 105A(d)(3) of the act provides that the 1979 crops of feed grain acreage eligible for payments shall not be reduced by application of an allocation factor (not less than 80 percent nor more than 100 percent) if producers reduce the acreage for any crop of feed grains planted for harvest on the farm from the previous year by at least the percentage recommended by the Secretary in his proclamation of the national program acreage.

The determination of the 1979 national program acreage simultaneously determines the reduction in acreage from 1978 to 1979 that will be required, if any, for a producer to qualify for target price protection on all acreage planted in 1979. Only if the national program acreage for 1979 is less than the national harvested acreage for 1978 will producers be required to reduce acreage in 1979 to be eligible for full target price protection on 100 percent of their acreage.

d. *Determine whether there should be a set-aside for 1979, and if so, the proportion of acreage to be set-aside.* Section 105A(f)(1) of the act provides that the Secretary shall provide for a set-aside of cropland if he determines that the total supply of feed grains will, in the absence of a set-aside, likely be excessive taking into account the need for an adequate carryover to maintain reasonable and stable supplies and prices in order to meet a national emergency. The Secretary is required to announce a set-aside program not later than November 15, 1978, for the 1979 feed grain crops. If a set-aside of cropland is in effect, then as a condition of eligibility for loans, purchases and deficiency and disaster payments, producers must set-aside and devote to conservation uses an acreage of cropland equal to the announced set-aside percentage times the acreage of feed grain crops planted for harvest in 1979.

Interested persons are encouraged to advise the Secretary on the need for a 1979 feed grain set-aside program and

the appropriate proportion of acreage to be set-aside if deemed necessary, taking into account the above factors.

e. *Determination of whether there should be a land diversion requirement and, if so, the extent of such diversion and level of payment.* Section 105A(f)(2) of the act authorizes the Secretary to make land diversion payments to producers of feed grains, whether or not a set-aside is in effect. Land diversion payments may be made if the Secretary determines they are necessary to assist in adjusting the total national acreage of feed grains to desired goals. If land diversion payments are made, producers will be required devote to approved conservation uses an acreage of cropland equal to the amount of such land diversion. Land diversion payment levels will be determined by the Secretary.

Land diversion payments may be established at a flat offer rate (specific rate per bushel times farm program yield) or through the submission of bids by producers.

If it is determined necessary to make land diversion payments in 1979, full consideration will be given to the procedure of submitting bids in determining appropriate payment rates as an alternative to the offer rate system. In determining the acceptability of bids, the Secretary would take into consideration the extent of the diversion to be undertaken and the productivity of the acreage being diverted. Interested persons are encouraged to address the need for the appropriate terms and conditions and the pros and cons of a land diversion program either in place of or in combination with a set-aside program for 1979.

f. *Limitation on planted acreage:* Section 105A(f)(1) of the act provides that the Secretary may limit the acreage planted to feed grains, if a set-aside is in effect. Such limitation is to be applied on a uniform basis to all feed grain producing farms. If a land diversion program is announced, 1979 plantings may be limited to a percentage of the previous year's acreage. Interested persons are invited to comment on the pros and cons of using these provisions.

g. *Loan and purchase levels.* (1) *Corn*—Section 105A(a)(1) provides that the Secretary shall make available to producers loans and purchases at such level, but at not less than $2 per bushel for the 1979 crop of corn, as he determines will encourage the exportation of feed grains and not result in excessive total stocks of feed grains in the United States: *Provided,* That if the Secretary determines that the average price of corn received by producers in the 1978 marketing year is not more than 105 percent of the level of loans and purchases for corn for the 1978 marketing year, the Secretary may reduce the level of loans and purchases of corn for the 1979 marketing year by an amount the Secretary determines necessary to maintain domestic and export markets for grains, except that the level of loans and purchases shall not be reduced by more than 10 percent in any year nor below $1.75 per bushel.

(2) *Other Feed Grains.* Section 105A(a)(2) provides the Secretary shall make available to producers loans and purchases for the 1979 crops of barley, oats, and rye at such level as the Secretary determines is fair and reasonable in relation to the level that loans and purchases are made available for corn, taking into consideration the feeding value of such commodity in relation to corn and other factors in section 401(b) of the act, and on each crop of grain sorghum at such level as the Secretary determines is fair and reasonable in relation to the level that loans and purchases are made available for corn, taking into consideration the feeding value and average transportation costs to market grain sorghums in relation to corn.

(3) *Soybeans.* Section 201(e) provides the price of the 1979 crop of soybeans shall be supported through loans and purchases at such levels as the Secretary determines appropriate in relation to competing commodities and taking into consideration domestic and foreign supply and demand factors.

h. *Established (target) price.* Section 105A(b)(1) (A), (B), and (D) provides that the Secretary shall make available to producers, as applicable, payments for the 1979 crops of corn, grain sorghum, and if designated by the Secretary, oats and barley. The 1979 established (target) price for corn shall be the 1978 target price ($2.10 per bushel) adjusted by the change in the 2-year moving average of variable, machinery, and general farm overhead costs. The payment rate for grain sorghum and, if designated by the Secretary, oats and barley, shall be such rate as the Secretary determines fair and reasonable in relation to the rate at which payments are made available for corn.

The Emergency Agricultural Act of 1978 provides that the Secretary may increase the established (target) price for feed grains over the level provided by the Food and Agriculture Act of 1977 to compensate producers for participation in a set-aside program.

i. *Other related provisions.* The Agricultural Act of 1949, as amended, also requires a number of other determinations in order to carry out the feed grain and soybean loan and purchase program such as (1) CCC minimum resale price, (2) commodity eligibility, (3) storage requirements, (4) premiums and discounts for grades, classes, and other qualities, and (5) such other provisions as may be necessary to carry out the programs.

Prior to determining the provisions of the 1979 feed grain program, consideration will be given to any data, views, and recommendations that may be received relating to the above items.

Comments will be made available for public inspection at the Office of the Acting Director during regular business hours (8:15 a.m. to 4:45 p.m.).

Executive Order 12044 (43 FR 12661, March 24, 1978) requires at least a 60-day public comment period on any proposed significant regulations except where the Agency determines this is not possible or in the best interests of the producers. Feed grain producers have expressed an interest in receiving 1979 feed program provisions before the mandatory date of November 15, 1978. Therefore, it is hereby found and determined that compliance with provisions of Executive Order 12044 is impossible and contrary to the public interest. Accordingly, comments must be received by October 6, 1978, in order to be assured of consideration.

NOTE.—The Agricultural Stabilization and Conservation Service (ASCS) has determined that this document does contain a major proposal requiring preparation of a Draft Impact Anaylsis Statement. The Draft Impact Analysis will be available September 1, 1978 from Orville I. Overboe (ASCS), 202-447-7987, or Paul Meyers (ASCS), 202-447-8373.

Dated: August 18, 1978.

RAY FITZGERALD,
Administrator, Agricultural Stabilization and Conservation Service and Executive Vice President, Commodity Credit Corporation.

[FR Doc. 78-23730 Filed 8-22-78; 8:45 am]

[3410-15]

Rural Electrification Administration

[7 CFR Part 1701]

SPECIFICATION FOR POLE TOP PINS

Revised REA Specification D-3

AGENCY: Rural Electrification Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Rural Electrification Administration (REA) proposes to issue the revised REA Specification D-3 "REA Specification for Pole Top Pins with 25.4 mm (1") Diameter Lead Threads." REA Specification D-3 outlines the REA requirements to which the pole top pins must be manufactured in order to be acceptable as a conductor support on systems of REA electrification borrowers. changes in REA's construction specification, metric conversion, and changes in the material composition of the pins' lead

threads have resulted in the need for updating the requirements of REA acceptable pole top pins. The action is expected to assure the quality and availability of the 25.4 mm pole top pins supplied to the REA electrification borrowers.

DATE: Public comments must be received by REA no later than September 25, 1978.

ADDRESS: Persons interested in the proposed revision of Specification D-3 may submit written data, views, or comments to the Director, Power Supply and Engineering Standards Division, Room 3304, South Building, U.S. Department of Agriculture, Washington, D.C. 20250. All written submissions made pursuant to this notice will be made available for public inspection at the Office of the Director, Power Supply and Engineering Standards Division during regular business hours.

FOR FURTHER INFORMATION CONTACT:

Mr. Rowland C. Hand, Sr., Director, Power Supply and Engineering Standards Division, Rural Electrification Administration, Room 3304, South Building, U.S. Department of Agriculture, Washington, D.C. 20250, telephone number 202-447-4413.

SUPPLEMENTARY INFORMATION: Notice is hereby given that pursuant to the Rural Electrication Act, as amended (7 U.S.C. 901 et seq.), REA proposes to revise REA Specification D-3. A summary of the proposed changes is as follows:

1. Specifying that the pin shall be made of either iron or steel, and be of a grade and quality suitable to meet the requirements of this specification.
2. Incorporating a lead thread torsion and tensile strength test.
3. Eliminating the required antimony content in the lead threads and specifying that the lead threads shall be made of a suitable alloy to meet the strength requirement of the Lead Thread Test.
4. Eliminating the 18" and 15" pins in the specification and incorporating the 20" pin.
5. Dual dimensioned units specified.
6. Specifying that the inspection procedure shall be in accordance with EEI Specification TD-16, "Line Hardware Materials Procedure," 1966.

A copy of the proposed revised REA Specification D-3 may be secured in person or by written request from the Director, Power Supply and Engineering Standards Division.

Dated: August 16, 1978.

RICHARD F. RICHTER,
Assistant Administrator, Electric.

[FR Doc. 70-23644 Filed 8-24-78; 8:45 am]

[3410-15]

[7 CFR Part 1701]

SPECIFICATION FOR INSULATOR SUPPORT BRACKETS FOR NARROW PROFILE CONSTRUCTION

Proposed REA Specification D-19

AGENCY: Rural Electrification Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Rural Electrification Administration (REA) proposes to issue REA Specification D-19, "REA Specification for Insulator Support Brackets (Metal) for Narrow Profile Construction." REA Specification D-19 outlines the REA requirements to which the insulator support brackets for narrow profile must be manufactured in order to meet material, strength, and testing requirements. Increased use of narrow profile construction on REA-financed distribution systems has brought about a large demand for narrow profile brackets (metal). Because of the concern for using only brackets with acceptable strength ratings and of acceptable design, REA considers it desirable to have references which clearly define the requirements of narrow profile brackets. No such guidelines presently exist. The action is expected to assure availability and the quality of the narrow profile brackets supplied to the REA electrification borrowers.

DATE: Public comments must be received by REA no later than September 25, 1978.

ADDRESS: Persons interested in the proposed Specification D-19 may submit written data, views, or comments to the Director, Power Supply and Engineering Standards Division, Room 3304, South Building, U.S. Department of Agriculture, Washington, D.C. 20250. All written submissions made pursuant to this notice will be made available for public inspection at the Office of the Director, Power Supply and Engineering Standards Division during regular business hours.

FOR FURTHER INFORMATION CONTACT:

Mr. Rowland C. Hand, Sr., Director, Power Supply and Engineering Standards Division, Rural Electrification Administration, Room 3304, South Building, telephone 202-447-4413.

A copy of the proposed REA Specification D-19 may be secured in person or by written request from the Director, Power Supply and Engineering Standards Division.

Dated: August 16, 1978.

RICHARD F. RICHTER,
Assistant Administrator, Electric.

[FR Doc. 78-23645 Filed 8-24-78; 8:45 am]

[3410-37]

Food Safety and Quality Service

[7 CFR Part 2852]

CANNED FREESTONE PEACHES [1]

U.S. Standards For Grades

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would change the grading standards for canned freestone peaches. This action is being taken at the request of the Canners League of California. The effect of this proposal would be to improve the standards.

DATE: Comments must be received on or before December 31, 1978.

ADDRESS: Comments should be sent to: Executive Secretariat, FSQS Room 3167-S, U.S. Department of Agriculture, Washington, D.C. 20250, Attention: Ann Langlois. Comments will be available of public inspection at the same address during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT:

Howard W. Schutz, Processed Products Branch, Fruit and Vegetable Quality Division, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250, 202-447-4693.

SUPPLEMENTARY INFORMATION: A proposed revision of the U.S. Standards for Grades of Canned Freestone Peaches, which would convert the current score points variables-type standard to an attributes-type standard based on statistical principles, was suggested by the Standards Committee of the Canners League of California. This request was based on results of previous studies conducted by the Department in conjunction with the Canners League of California on canned clingstone peaches. Because these two products are very similar in nature, the results of the canned clingstone peach studies may be applied to canned freestone peaches with only slight modifications.

At the request of the Standards Committee of the Canners League of

[1] Compliance with the provisions of these standards shall not excuse failure to comply with the provisions of the Federal Food, Drug, and Cosmetic Act, or with applicable State laws and regulations.

California, the Department is proposing a revision of the U.S. Standards for Grades of Canned Freestone Peaches which would:

(1) Convert the current score points variables-type standard to an attributes-type standard based on statistical principles;

(2) Eliminate the score points since the attributes approach is a go/no-go approach;

(3) Eliminate the separate grade criteria for "solid-pack" peaches, the U.S. Grade D classification, and the alternate grade nomenclature of fancy, choice, and standard from the various grade classifications, retaining only the letter grades U.S. Grade A, B, C, and substandard;

(4) Function in combination with the two statistical sampling plans recently added to the "Regulations Governing Inspection and Certification of Processed Fruits and Vegetables, Processed Products Thereof, and Certain Other Processed Food Products" §§ 2852.38a, 2852.38bn and 2852.38c (43 FR 10539).

(5) Provide for separate acceptance criteria for unofficially submitted samples. These are single sample units that do not represent a lot;

(6) Provide for various defect classifications according to severity or frequency of occurrence. These classifications are minor, major, severe, and critical, with descending allowances starting with the most liberal allowances for minor defects to the most restrictive allowances for the critical defects;

(7) Change size variation requirements for the styles of whole, halves, and quarters from a weight basis to a diameter basis since peaches are sized according to diameters rather than weight; and

(8) Eliminate minimum size requirements for individual units of halves and quarters.

The rule proposed is:

Sec.
2852.2601 Product description.
2852.2602 Styles.
2852.2603 Definitions of terms.
2852.2604 Recommended sample unit sizes.
2852.2605 Liquid media and Brix measurements.
2852.2606 Fill of container.
2852.2607 Fill of container for canned "solid-pack" freestone peaches.
2852.2608 Minimum drained weights.
2852.2609 Minimum fill weights.
2852.2610 Grades.
2852.2611 Factors of quality.
2852.2612 Classification of defects.
2852.2613 Tolerances for defects.
2852.2614 Sample size.
2852.2615 Compliance with quality requirements.

AUTHORITY: Agricultural Marketing Act of 1946, secs. 203, 205, 60 Stat. 1087, as amended 1090, as amended; (7 U.S.C. 1622, 1624).

§ 2852.2601 Product description.

Canned freestone peaches is the product represented as defined in the standards of identity for canned peaches (21 CFR 145.170 and 145.171) issued under the Federal Food, Drug, and Cosmetic Act. For the purposes of the standards in this subpart, and unless the text indicates otherwise, the terms "canned peaches" or "canned freestone peaches" include "canned yellow freestone peaches," "canned spiced yellow freestone peaches," "canned 'solid-pack' yellow freestone peaches" and "canned artificially sweetened yellow freestone peaches" as defined in the standards of identity.

§ 2852.2602 Styles.

(a) *"Whole"* consist of peeled, unpitted whole peaches with or without stems removed.

(b) *"Halved" or "Halves"* consist of peeled and pitted peaches cut approximately in half along the suture from stem to apex.

(c) *"Quartered" or "Quarters"* consist of halved peaches cut into two approximately equal parts.

(d) *"Sliced" or "Slices"* consist of peeled and pitted peaches cut into wedge-shaped sectors.

(e) *"Diced" or "Dice"* consist of peeled and pitted peaches cut into cube-like parts.

(f) *"Halves and pieces"* consist of peeled and pitted peaches in which more than 50 percent, by weight, of the peaches are havles.

(g) *"Pieces," "Irregular pieces," or "Mixed pieces of irregular sizes and shapes,"* consist of peeled, pitted peaches of irregular sizes and shapes or peaches that do not conform to any of the foregoing styles.

§ 2852.2603 Definitions of terms.

(a) *Acceptable Quality Level (AQL).* The maximum percent of defective units or the maximum number of defects per hundred units of product that, for purposes of acceptance sampling, can be considered satisfactory as a process average.

(b) *Blemished* means any unit which is affected by scab, hail injury, or discoloration to the extent that the appearance or eating quality is affected:

(1) not more than slightly;

(2) materially; or

(3) seriously.

(c) *Brightness* means the extent that the overall appearance of the sample unit as a mass is dulled by oxidation, pigmentation, or other causes.

(1) Grades A and B—not more than slightly affected.

(2) Grade C—materially affected.

(3) Substandard—fails Grade C.

(d) *Character* refers to the texture and tenderness of the product as follows:

(1) *Good character.*—(i) *Whole.* The units have a texture typical of properly prepared and processed peaches; the units are at least reasonably tender or the tenderness may be variable within the unit; the units may be slightly hard or slightly soft.

(ii) *Halves; halves and pieces; quarters; slices; pieces or irregular pieces.* The units have at least a reasonably tender texture typical of properly prepared and processed freestone peaches and may be soft and materially frayed. The peach halves may have a tendency to flatten.

(iii) *Diced.* The product generally has at least a reasonably tender texture typical of properly prepared and processed peaches; the units are intact and not excessively frayed.

(2) *Fairly good character.*—(i) *Whole.* The units have a fairly tender texture typical of properly prepared and processed peaches; the units may be lacking in uniformity of tenderness and may be substantially firm or very soft.

(ii) *Halves; halves and pieces; quarters; slices; pieces or irregular pieces.* The units have at least a fairly tender texture typical of properly prepared and processed freestone peaches and may lack uniformity of tenderness. The units may be very soft but not frayed to the extent that their normal shape is destroyed; the units may also be substantially firm.

(iii) *Diced.* The product generally has a fairly tender texture typical of properly prepared and processed peaches. The units are intact and may be frayed.

(3) *Poor character.—All styles.* The units are excessively soft or mushy or are hard.

(e) *Color.*—(1) *General.* The color of canned yellow freestone peaches, other than canned "spiced" peaches, refers to the predominant and characteristic color on the surface of whole units, and the outside surfaces of other units. The cut surfaces of such units are also considered when affected by discoloration.

(2) *Individual unit color classifications.*— (i) *Good color* means peach units that are equal to or better than light orangish-yellow.

(ii) *Fairly good color* means peach units that may fail to meet minimum color requirements for "good color" but are equal to or better than a dull greenish-yellow.

(iii) *Poor color* means peach units that may fail to meet minimum color requirements for "fairly good color."

(f) *Crushed or broken* in the styles of whole, halves, and quarters means:

(1) A unit is "crushed" if it has definitely lost its normal shape and is crushed not due to ripeness; and

(2) A unit is "broken" if severed into definite parts. Any unit in halves style

that is split from the edge to the pit cavity is not considered broken.

(g) *Defect.* Any nonconformance of a unit(s) of product from a specified requirement of a single quality characteristic.

(h) *Extraneous vegetable material.*—(1) *Small pieces* means long stems, pieces of twigs not more than 51 mm (2.0 inch) in length, or leaf material or portions thereof.

(2) *Short stem* means the woody stem which attaches the peach to the twig of the tree and is 3 mm (0.12 inch) to 10 mm (0.39 inch) in length. Dark brown stems less than 3 mm (0.12 inch) in length are also considered as short stems.

(i) *Mechanical damage.*—(1) *Partial slice,* in the style of slices, is a unit that has had a semblance of a slice with respect to thickness and shape but is less than three-fourths of an apparent full slice and that does not bear marks of crushing. Pieces are reassembled to equal an average full size slice and counted as one unit.

(2) *Detached piece,* in the style of halves and quarters, is a piece which has the appearance of a slice resulting from an off-suture cut or other improper cutting.

(3) *Gouges* mean holes or gouges that do not destroy the normal configuration of the unit but affect the appearance of the unit:

(i) Not more than slightly;

(ii) Materially; or

(iii) Seriously.

(4) *Off-suture cut,* in the style of halves and quarters, is a unit which has been cut at a distance from the suture greater than 10 mm (0.39 inch) at the widest measurement and the appearance is affected:

(i) Not more than slightly;

(ii) Materially; or

(iii) Seriously.

(5) *Partially detached piece,* in the style of halves and quarters, is a piece which has the appearance of a slice resulting from an off-suture cut or other improper cutting. The defect is attached to the half or quarter from which cut, but must be detached more than one-third of the length of the half or quarter along the suture approximately parallel with the suture.

(6) *Other mechanical damage* means a unit, in the styles of whole, halves and quarters, which is damaged to the extent that the shape of the unit is affected:

(i) Not more than slightly;

(ii) Materially; or

(iii) Seriously.

(j) *Peel* means all of the outer layer of the peach that is normally removed during processing.

(k) *Sample unit size.* The amount of product specified to be used for inspection. It may be:

(1) The entire contents of a container; or

(2) A portion of the contents of a container; or

(3) A combination of the contents of 2 or more containers; or

(4) a portion of unpacked product.

(l) *Shelly,* in the styles of halves, quarters, and slices, means a unit in which the pit cavity has been trimmed to such an extent as to leave the unit only fairly fleshy.

(m) *Slab,* in the style of slices, means an irregularly shaped unit resulting from the slicing operation that materially deviates from the normal shape of a wedge-shaped sector.

(n) *Sliver,* in the style of slices means any unit that weighs 3 g (0.12 ounce) or less and has the symmetry of a full slice.

(o) *Unit,* means one whole, half, quarter, slice, dice, or piece of peach as applicable for the style.

§ 2852.2604 Recommended sample unit sizes.

(a) *Factors of quality.* Compliance with requirements for factors of quality is based on the following sample unit sizes for the respective style.

(1) Halves; Quarters—25 units.

(2) Whole—25 units.

(3) Slices—50 units or 100 units.

(4) Diced—200 g (7 ounces).

(5) Halves and pieces; Pieces or irregular pieces—1000 g (35.3 ounces).

§ 2852. 2605 Liquid media and Brix measurements.

"Cut-out" requirements for liquid media in canned freestone peaches are not incorporated in the grades of the finished product since sirup or any other liquid medium, as such, is not a factor of quality for the purposes of these grades. The "cut-out" Brix measurements, as applicable, for the respective designations are as follows:

Designations	Brix measurements
"Extra heavy sirup;" or "Extra heavily sweetened fruit juice(s) and water;" or "Extra heavily sweetened fruit juice(s)".	22° or more but not more than 35°.
"Heavy sirup;" or "Heavily sweetened fruit juice(s) and water;" or "Heavily sweetened fruit juice(s)".	18° or more but less than 22°.
"Light sirup;" or "Lightly sweetened fruit juice(s) and water;" or "Lightly sweetened fruit juice(s)".	14° or more but less than 18°.
"Slightly sweetened water;" or "Extra light sirup;" or "Slightly sweetened fruit juice(s) and water;" or "Slightly sweetened fruit juice(s)".	10° or more but less than 14°.
"In water"	Not applicable.
"In fruit juice(s) and water"	Do.
"In fruit juice(s)"	Do.
"Artificially sweetened"	Do.

§ 2852.2606 Fill of container.

The standard of fill of container for canned freestone peaches is the maximum quantity of peach units that can be sealed in a container and processed by heat to prevent spoilage, without crushing or breaking such units. Canned freestone peaches that do not meet this requirement are "Below Standard in Fill."

§ 2852.2607 Fill of container for canned "solid-pack" freestone peaches.

The fill of container for canned solid-pack freestone peaches is not incorporated in the grades of the finished product since fill of container, as such, is not a factor of quality for the purposes of these grades. Each container of solid-pack freestone peaches shall be as full of peaches as practicable without impairment of quality and the product shall occupy not less than 90 percent of the volume of the container.

§ 2852.2608 Minimum drained weights.

(a) *General.* (1) The minimum drained weight for the various styles in Table I of this subpart are not incorporated in the grades of the finished product since drained weight, as such, is not a factor of quality for the purposes of these grades.

(2) The minimum drained weights are based on equalization of the product 30 days or more after the product has been canned.

(b) *Method for determining drained weight.* The drained weight of canned freestone peaches and canned "solid-pack" freestone peaches is determined by emptying the contents of the container, turning the pit cavities down in halves, upon a U.S. Standard No. 8 circular sieve of proper diameter containing 8 meshes to the inch (0.0937-inch ± 3 percent, square openings) so as to distribute the product evenly, inclining the sieve to an angle of 17 to 20 degrees to facilitate drainage, and allowing to drain for 2 minutes. The drained weight is the weight of the sieve and peaches less the weight of the dry sieve. A sieve 8 inches in diameter is used for the equivalent of No. 3 size cans (404 x 414) and smaller, and a sieve 12 inches in diameter is used for containers larger than the equivalent of the No. 3 size can.

(c) *Definitions of symbols.* (1) X_d. The average drained weight of all the sample units in the sample.

(2) LL. Lower limit for drained weights of individual sample units.

(d) *Compliance with drained weights.* A lot of canned freestone peaches is considered as meeting the minimum drained weight if the following criteria are met:

TABLE I. MINIMUM DRAINED WEIGHTS FOR CANNED FREESTONE PEACHES

Container designations (metal, unless otherwise stated)	Container size (overall dimensions)		Overflow capacity (fluid ounces)	Halves			
	Diameter (inches)	Height (inches)		In extra heavy sirup (ounces)		In any other liquid medium (ounces)	
				$\bar{X}_d$	LL	$\bar{X}_d$	LL
8Z tall	211	304	- - -	4.8	4.1	5.0	4.3
No. 300	300	407	- - -	8.6	7.8	8.8	8.0
No. 303	303	406	- - -	9.5	8.6	9.8	8.9
No. 303 glass			17.0	9.5	8.6	9.8	8.9
No. 2	307	409	- - -	11.5	10.4	11.9	10.8
No. 2½ glass			28.35	16.1	14.7	16.6	15.2
No. 2½, 7 count or more	401	411	- - -	16.6	15.2	17.1	15.7
No. 2½, 6 count or less	401	411	- - -	16.2	14.8	16.7	15.3
No. 10, 24 count or more	603	700	- - -	61.0	58.5	62.5	60.0
No. 10, 23 count or less	603	700	- - -	60.0	57.5	61.5	59.0

TABLE I. (Continued)

Container size (metal, unless otherwise stated)	Quarters, halves and pieces pieces or irregular pieces				Sliced			
	In extra heavy sirup (ounces)		In any other liquid medium (ounces)		In extra heavy sirup (ounces)		In any other liquid medium (ounces)	
	$\bar{X}_d$	LL	$\bar{X}_d$	LL	$\bar{X}_d$	LL	$\bar{X}_d$	LL
8z tall	4.9	4.2	5.1	4.4	4.7	4.1	4.9	4.3
No. 300	8.8	8.0	9.0	8.2	8.5	7.8	8.7	8.0
No. 303 glass	9.7	8.8	10.0	9.1	9.4	8.6	9.7	8.9
No. 303	9.7	8.8	10.0	9.1	9.4	8.6	9.7	8.9
No. 2	11.7	10.6	12.1	11.0	11.3	10.4	11.7	10.8
No. 2½ glass	16.4	15.0	16.9	15.5	15.8	14.7	16.3	15.2
No. 2½	16.9	15.5	17.4	16.0	16.3	15.2	16.8	15.7
No. 10	63.0	60.5	64.5	62.0	60.0	58.0	61.0	59.0

TABLE I. (Continued)

Container size (metal, unless otherwise stated)	Heavy pack (all styles) (ounces)		Solid-pack unsweetened (all styles) (ounces)	
	$\bar{X}_d$	LL	$\bar{X}_d$	LL
No. 2½			24.0	22.6
No. 10	70.0	67.5	90.0	87.5

(1) The average of the drained weights from all the sample units in the sample meet the minimum average drained weight (designated as "X_d" in Table I); and

(2) The number of sample units which fail to meet the drained weight lower limit for individuals (designated as "LL" in Table I) does not exceed the applicable acceptance number specified in the single sampling plan of Table II.

TABLE II—*Single sampling plan for drained weight*

Sample size (number of sample units)	3	6	13	21	29
Acceptance No.	0	1	2	3	4

§ 2852.2609 Minimum fill weights.

(a) *General.* The minimum fill weights specified in Table III are not incorporated in the grades of the finished product since fill weight, as such, is not a factor of quality for the purposes of these grades.

(b) *Method for determing fill weight.* Fill weight is determined in accordance with the U.S. Standards for Inspection by Variables and the U.S. Standards for Determination of Fill Weights.

(c) *Definitions of terms and symbols.* "Subgroup" means a group of sample units representing a portion of a sample.

$\bar{X}'_{min}$ means the minimum lot average fill weight.

$LWL_{\bar{x}}$ means the lower warning limit for subgroup averages.

$LRL_{\bar{x}}$ means the lower reject limit for subgroup averages.

LWL means the lower warning limit for individual fill weight measurements.

LRL means the lower reject limit for individual fill weight measurements.

R′ means a specified average range value.

R_{max} means a specified maximum range for a subgroup.

"Sampling allowance code" means a code letter on the Sampling Allowance Chart of the U.S. Standards for Inspection by Variables. This letter identifies the line which gives the amount of sampling allowance to be applied to the specification average for fill weights in order to determine compliance with requirements for fill weight averages for a sample.

(d) *Compliance with fill weights.* Compliance with the fill weights shall be in accordance with the acceptance criteria specified in the U.S. Standards for Inspection by Variables and the U.S. Standards for Determination of Fill Weights.

TABLE III. FILL WEIGHT VALUES FOR CANNED FREESTONE PEACHES

Container size (metal unless otherwise stated)	Halves							
	Fill weight values (ounces)							Sampling allowance code
	$\bar{X}'_{min}$	$LWL_{\bar{x}}$	$LRL_{\bar{x}}$	LWL	LRL	$\bar{R}'$	R_{max}	
8Z tall	5.6	5.1	4.9	4.6	4.1	1.2	2.5	I
No. 300	9.9	9.3	8.9	8.5	7.8	1.6	3.4	M
No. 303	11.0	10.3	10.0	9.5	8.7	1.7	3.7	N
No. 303 glass	11.0	10.3	10.0	9.5	8.7	1.7	3.7	N
No. 2	13.3	12.5	12.1	11.5	10.6	2.1	4.4	Q
No. 2½ glass	18.9	17.9	17.4	16.7	15.6	2.6	5.4	T
No. 2½, 7 count or more	19.4	18.4	17.9	17.2	16.1	2.6	5.4	T
No. 2½, 6 count or less	19.0	18.0	17.5	16.8	15.7	2.6	5.4	T
No. 10, 24 count or more	73.0	71.0	70.4	69.2	67.3	4.4	9.3	B1
No. 10, 23 count or less	72.0	70.3	69.4	68.2	66.3	4.4	9.3	B1

TABLE III. Continued

Container size (metal, unless otherwise stated)	Sliced							
	Fill weight values (ounces)							Sampling allowance code
	$\bar{X}'_{min}$	$LWL_{\bar{x}}$	$LRL_{\bar{x}}$	LWL	LRL	$\bar{R}'$	R_{max}	
8Z tall	5.6	5.2	5.0	4.7	4.2	1.1	2.2	H
No. 300	10.0	9.4	9.1	8.7	8.0	1.5	3.2	L
No. 303	11.1	10.5	10.1	9.7	9.0	1.6	3.4	M
No. 303 glass	11.1	10.5	10.1	9.7	9.0	1.6	3.4	M
No. 2	13.4	12.6	12.2	11.7	10.8	2.0	4.2	P
No. 2½	19.6	18.7	18.2	17.6	16.6	2.3	4.9	S
No. 2½ glass	19.1	18.2	17.7	17.1	16.1	2.3	4.9	S
No. 10	74.0	72.5	71.7	70.6	68.9	4.0	8.4	Z
	Quarters; -- Halves and pieces			Pieces or -- irregular pieces			fill weight values	
8Z tall	5.7	5.3	5.1	4.8	4.3	1.1	2.2	H
No. 303	11.3	10.7	10.3	9.9	9.2	1.6	3.4	M
No. 2	13.6	12.8	12.4	11.9	11.0	2.0	4.2	P
No. 2½	19.9	19.0	18.5	17.9	16.9	2.3	4.9	S
No. 10	76.0	74.5	73.7	72.6	70.9	4.0	8.4	Z

§ 2852.2610 Grades.

(a) *"U.S. Grade A"* is the quality of canned freestone peaches that:

(1) Meets the following prerequisites in which the peaches:

(i) Have similar varietal characteristics;

(ii) Have a normal flavor and odor;

(iii) Have overall brightness of the sample unit as a mass and are not affected by dullness;

(iv) Have units that are practically uniform in size and shape in sliced style;

(v) Are practically free from pit material, except for whole style;

(vi) Are practically free from crushed and broken units in the styles of whole, halves, and quarters;

(vii) Do not exceed the aggregate area of peel specified for the style as follows:

(A) Whole—5.5 cm^2 (0.85 in^2 or 1 × .85);

(B) Halves—4.5 cm^2 (0.7 in^2 or 1 × .7);

(C) Quarters—2.25 cm^2 (0.34 in^2 or 1 × .34);

(D) Slices—50 count—1.8 cm^2 (0.28 in^2 or 1 × .28); 100 count—3.5 cm^2 (0.54 in^2 or 1 × .54);

(E) Dice—0.5 cm^2 (0.08 in^2 or 1 × .08);

(F) Halves and pieces; Pieces or irregular pieces—3.25 cm^2 (0.5 in^2 or 1 × .5);

(viii) Have a good character such that the number of units that have fairly good character does not exceed the following:

(A) Whole; Halves; and Quarters—1 unit;

(B) Slices—50 count—3 units; 100 count—5 units;

(C) Halves and pieces; and Pieces or irregular pieces—50 g;

(D) Dice—10 g;

(2) Are within the limits for defects as classified in Table IV and specified in Tables V, VI, VII, VIII, or IX.

(b) *"U.S. Grade B"* is the quality of canned freestone peaches that:

(1) Meets the following prerequisites in which the peaches:

(i) Have similar varietal characteristics;

(ii) Have normal flavor and odor;

(iii) Have overall brightness of the sample unit as a mass and are not affected by dullness;

(iv) Have units that are practically uniform in size and shape in sliced style;

(v) Are practically free from pit material, except for whole style;

(vi) Are practically free from crushed and broken units in the styles of whole, halves, and quarters;

(vii) Do not exceed the aggregate area of peel specified for the style as follows:

(A) Whole—22.5 cm^2 (3.5 in^2 or 1 × 3.5);

(B) Halves—19 cm^2 (3 in^2 or 1 × 3);

(C) Quarters—9.5 cm^2 (1.5 in^2 or 1 × 1.5);

(D) Slices—50 count—7 cm^2 (1.1 in^2 or 1 × 1.1); 100 count—14 cm^2 (2.2 in^2 or 1 × 2.2);

(E) Dice—1.5 cm^2 (0.23 in^2 or 1 × 0.23);

(F) Halves and pieces; Pieces or irregular pieces—12 cm^2 (1.9 in^2 or 1 × 1.9);

(viii) Have a reasonably good character such that the number of units that have fairly good character does not exceed the following:

(A) Whole; Halves; and Quarters—3 units;

(B) Slices—50 count—5 units; 100 count—10 units;

(C) Halves and pieces; Pieces or irregular pieces—100 g;

(D) Dice—20 g;

(2) Are within the limits for defects as classified in Table IV and specified in Tables V, VI, VII, VIII, or IX.

(c) *"U.S. Grade C"* is the quality of canned freestone peaches that:

(1) Meets the following prerequisites in which the peaches:

(i) Have similar varietal characteristics;

(ii) Have a normal flavor and odor;

(iii) Have overall brightness of the sample unit as a mass which is not more than materially affected by dullness;

(iv) Have units that may be variable in size and shape and sliced style;

(v) Are practically free from pit material, except for whole style;

(vi) Are practically free from crushed and broken units in the styles of whole, halves, and quarters;

(vii) Do not exceed the aggregate area of peel specified for the style as follows:

(A) Whole—45 cm^2 (7 in^2 or 1 x 7);

(B) Halves—38 cm^2 (5.9 in^2 or 1 x 5.9);

(C) Quarters—19 cm^2 (3 in^2 or 1 x 3);

(D) Slices—50 count—15 cm^2 (2.3 in^2 or 1 x 2.3); 100 count—30 cm^2 (4.6 in^2 or 1 x 4.6);

(E) Dice—3 cm^2 (0.5 in^2 or 1 x .5);

(F) Halves and pieces; Pieces or irregular pieces—27 cm^2 (4.2 in^2 or 1 x 4.2);

(viii) Have a fairly good character such that the number of units that have poor character does not exceed the following:

(A) Whole; Halves; and Quarters—3 units;

(B) Slices—50 count—5 units; 100 count—10 units;

(C) Halves and pieces; Pieces or irregular pieces—100 g;

(D) Dice—20 g;

(2) Are within the limits for defects as classified in Table IV and specified in Tables V, VI, VII, VIII, or IX.

(d) *"Substandard"* is the quality of canned freestone peaches that fails to meet the requirements for U.S. Grade C.

§ 2852.2611 Factors of quality.

The grade of canned freestone peaches is based on compliance with the requirements for the following quality factors:

(a) Prerequisite quality factors:

(1) Similar varietal characteristics;

(2) Flavor and odor;

(3) Brightness;

(4) Uniformity of size of slices;

(5) Pit material;

(6) Crushed and broken units;

(7) Peel; and

(8) Character.

(b) Classified quality factors:

(1) Individual unit color;

(2) Workmanship;

(3) Blemishes;

(4) Uniformity of size of whole, halves and quarters;

(5) Mechanical damage; and

(6) Extraneous vegetable material.

§ 2852.2612 Classification of defects.

Defects are classified as minor, major, severe, or critical. Each "X" in Table IV represents "one (1) defect."

TABLE IV

CLASSIFICATION OF DEFECTS

Quality Factor	Defect	Classification			
		Min	Maj	Sev	Crit
	WHOLE				
Individual Unit Color	Fairly good (in grade A & B only		X		
	Poor (in grade A, B &C)			X	
Blemishes	Not more than slightly	X			
	Materially		X		
	Seriously			X	
Uniformity of size	Excessive variation (each unit)	X			
Mechanical Damage	Gouge:				
	Not more than slightly	X			
	Materially		X		
	Seriously			X	
	Other mechanical damage:				
	Not more than slightly	X			
	Materially		X		
	Seriously			X	
Extraneous Vegetable Material	Small piece (each piece)				X
	HALVES AND QUARTERS				
Individual Unit Color	Fairly good (in grade A & B only)		X		
	Poor (in grade A, B & C)			X	
Blemishes	Not more than slightly	X			
	Materially		X		
	Seriously			X	
Uniformity of size	Excessive variation (each unit)	X			
Mechanical Damage	Off-suture:				
	Not more than slightly	X			
	Materially		X		
	Seriously			X	
	Partially detached piece	X			
	Detached piece		X		
	Shelly unit (in grade A & B only)		X		
	Gouge:				
	Not more than slightly	X			
	Materially		X		
	Seriously			X	
	Other mechanical damage:				
	Not more than slightly	X			
	Materially		X		
	Seriously			X	
Extraneous Vegetable Material	Short stem (each stem)			X	
	Small piece (each piece)				X

TABLE IV Continued

Quality Factor	Defect	Classification			
		Min	Maj	Sev	Crit
	SLICED				
Individual Unit Color	Fairly good (in grade A & B only)		X		
	Poor (in grade A, B & C only)			X	
Workmanship	Sliver		X		
	Slab			X	
Blemishes	Not more than slightly		X		
	Materially			X	
	Seriously				X
Mechanical Damage	Shelly unit (in grade A & B only)		X		
	Gouge:				
	Not more than slightly		X		
	Materially			X	
	Seriously				X
	Partial slice		X		
Extraneous Vegetable Material	Short stem (each stem)			X	
	Small piece (each piece)				X
	DICED				
Individual Unit Color	Fairly good (in grade A & B only - each 8 g)		X		
	Poor (in grade A, B & C - each 8 g)			X	
Workmanship	More than 20 mm (0.79 inch) or less than 8 mm (0.31 inch) - each 8 g		X		
Blemishes	Materially (each 8 g)		X		
	Seriously (each 8 g)			X	
Extraneous Vegetable Material	Short stem & small piece (each piece)				X
	HALVES AND PIECES: PIECES OR IRREGULAR PIECES				
Individual Unit Color	Fairly good (in grade A & B only) (each 40 g)		X		
	Poor (in grade A, B & C) (each 40 g)			X	
Blemishes	Not more than slightly (each 40 g)		X		
	Materially (each 40 g)			X	
	Seriously (each 40 g)				X
Extraneous Vegetable Material	Short stem and Small piece (each piece)				X

§ 2852.2613 Tolerances for defects.

TABLE V

WHOLE

	GRADE A				GRADE B				GRADE C			
	Total 2/	Maj	Sev	Crit	Total 2/	Maj	Sev	Crit	Total 2/	Maj	Sev	Crit
AQL 1/	10.0	2.5	1.0	0.4	15.0	10.0	2.5	1.0	25.0	15.0	10.0	2.5

TABLE VI

HALVES: QUARTERS

	GRADE A				GRADE B				GRADE C			
	Total 2/	Maj	Sev	Crit	Total 2/	Maj	Sev	Crit	Total 2/	Maj	Sev	Crit
AQL 1/	15.0	8.5	2.5	0.4	25.0	15.0	5.0	1.0	40.0	25.0	15.0	2.5

1/ AQL expressed as defects per hundred units.

2/ Total = Minor + Major + Severe + Critical.

TABLE VII

SLICES

	GRADE A				GRADE B				GRADE C			
	Total 2/	Maj	Sev	Crit	Total 2/	Maj	Sev	Crit	Total 2/	Maj	Sev	Crit
AQL 1/	12.5	5.0	1.5	0.65	25.0	12.5	5.0	1.5	40.0	20.0	12.5	2.5

TABLE VIII

DICED

	GRADE A				GRADE B				GRADE C			
	Total 2/	Maj	Sev	Crit	Total 2/	Maj	Sev	Crit	Total 2/	Maj	Sev	Crit
AQL 1/	12.5	6.5	2.5	0.4	15.0	8.5	4.0	0.65	20.0	10.0	8.5	1.0

TABLE IX

HALVES AND PIECES: PIECES OR IRREGULAR PIECES

	GRADE A				GRADE B				GRADE C			
	Total 2/	Maj	Sev	Crit	Total 2/	Maj	Sev	Crit	Total 2/	Maj	Sev	Crit
AQL 1/	10.0	2.5	1.0	0.4	15.0	6.5	2.5	1.0	25.0	15.0	6.5	2.5

1/ AQL expressed as defects per hundred units.

2/ Total = Minor + Major + Severe + Critical.

§ 2852.2614 Sample size.

The sample size to determine compliance with requirements of these standards shall be as specified in the sampling plans and procedures in the "Regulations Governing Inspection and Certification of Processed Fruits and Vegetables, Processed Products Thereof, and Certain Other Processed Food Products" (7 CFR 2852.1-2852.83) for lot inspection and on-line inspection, as applicable.

§ 2852.2615 Compliance with quality requirements.

(a) *Lot inspection.* A lot of canned freestone peaches is considered as meeting the requirements for quality if:

(1) The prerequisite requirements specified in § 2852.2610 are met; and

(2) The Acceptable Quality Levels (AQL) in Table V, VI, VII, VIII and IX, as applicable for the style, are not exceeded.

(b) *On-line inspection.* A portion of production is considered as meeting requirements for quality if:

(1) The prerequisite requirements specified in § 2852.2610 are met; and

(2) The Acceptable Quality Levels (AQL) in Table V, VI, VII, VIII and IX, as applicable for the style, are not exceeded.

(c) *Single sample unit.* Each unofficial sample unit submitted for quality evaluation will be treated individually and is considered as meeting the requirements for quality if:

(1) The prerequisite requirements specified in § 2852.2610 are met; and

(2) The Acceptable Quality Levels (AQL) in Table V, VI, VII, VIII and IX, as applicable for the style, are not exceeded.

NOTE.—The Food Safety and Quality Service has determined that this document does not contain a major proposal requiring preparation of an inflation impact statement under Executive Order 11821 and OMB Circular A-107.

Done at Washington, D.C. on August 18, 1978.

SYDNEY J. BUTLER,
Acting Administrator,
Food Safety and Quality Service.

[FR Doc. 78-23672 Filed 8-24-78; 8:45 am]

[7590-01]

NUCLEAR REGULATORY COMMISSION

[10 CFR Parts 30, 40, 50, and 70]

DECOMMISSIONING CRITERIA FOR NUCLEAR FACILITIES

Public Meeting

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Public meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission has underway a reevaluation of policy on decommissioning (see the advanced notice of proposed rulemaking, 43 FR 10370, March 13, 1978). In this connection the Commission is planning to hold a public meeting to review the current status of the subject reevaluation.

DATES: Public meeting will be held between 10 a.m. and 5 p.m, October 18, 1978.

ADDRESSES: Interested persons are invited to attend the public meeting to be held at the General Services Administration Auditorium, 18th and F Streets NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT:

Dr. Carl Feldman, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, phone 301-443-5910.

SUPPLEMENTARY INFORMATION: The NRC is considering development of a more explicit overall policy for nuclear facility decommissioning and considering amending its regulations in 10 CFR Parts 30, 40, 50, and 70 to include more specific guidance on decommissioning criteria for production and utilization facility licensees and byproduct, source, and special nuclear material licensees. An advance notice of proposed rulemaking was published in the FEDERAL REGISTER on March 13, 1978 (43 FR 10370-10371, FR Doc. 78-6461). Shortly thereafter the NRC staff set forth in detail its proposed plan for the development of an overall NRC policy on decommissioning of nuclear facilities in NUREG-0436, "Plan for Reevaluation of NRC Policy on Decommissioning of Nuclear Facilities," March 1978.

To obtain the views of the States on its policy, NRC staff is holding three regional workshops in September 1978 (announced in the FEDERAL REGISTER on August 4, 1978, 43 FR 34564, FR Doc. 78-21506) to discuss the specifics of the NRC plan, NUREG-0436, as well as its first two decommissioning reports, NUREG-0278, "Technology, Safety, and costs of Decommissioning a Reference Nuclear Fuel Reprocessing Plant" and NUREG/CR-0130, "Technology, Safety, and Costs of Decommissioning a Reference Pressurized Water Reactor."

These workshops will be open to public attendance and observation on a space-available basis. However, to ensure that adequate channels for public participation are available at an early time in the NRC decisionmaking process regarding decommissioning policy, a public meeting will be held. The meeting will consist of an informative portion summarizing NRC policy issues, the technical decommissioning information base being developed through Battelle Pacific Northwest Laboratory (PNL), and the status of comment on the FEDERAL REGISTER notice of proposed rulemaking published on March 13, 1978 (FR 10370-10371, FR Doc. 78-6461). Following the informative session, the meeting will be opened for public discussion.

The agenda for the meeting will be as follows:

MORNING

Welcome—Overview (approximately 15 minutes).

Policy issue presentation (approximately 1.5 hours), Robert M. Bernero, Assistant Director for Material Safety Standards, Office of Standards Development U.S. NRC.

Recess: 12-1:30 p.m.

AFTERNOON

Technical presentation (approximately 1.5 hours), R. I. Smith, PNL.

Status of comment on FEDERAL REGISTER notice (approximately a half hour), D. F. Harmon, U.S. NRC.

Question-and-answer session.

A transcript of the meeting will be prepared and made available in the NRC Public Document Room, 1717 H Streets NW., Washington, D.C. 20555.

Copies of the NRC proposed plan for the reevaluation of NRC policy on decommissioning of nuclear facilities, NUREG-0436, will be available at the meeting. Copies of the first two decommissioning reports, NUREG-0278 for the reference nuclear fuel reprocessing plant and NUREG/CR-0130 for the reference pressurized water reactor, may be obtained by writing National Technical Information Service, Springfield, Va. 22161, at nominal cost.

Persons who wish further information about this meeting should write to Dr. Carl Feldman, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, or call 301-443-5910.

Dated at Rockville, Md. this 16th day of August 1978.

For the Nuclear Regulatory Commission.

ROBERT B. MINOGUE,
Director, Office of
Standards Development.

[FR Doc. 78-23451 Filed 8-24-78; 8:45 am]

[6320-01]

CIVIL AERONAUTICS BOARD

[14 CFR Part 312]

[Docket 32602; PDR-56; Dated: August 17, 1978]

IMPLEMENTATION OF THE NATIONAL ENVIRONMENTAL POLICY ACT, INCLUDING THE PREPARATION OF ENVIRONMENTAL IMPACT STATEMENTS

AGENCY: Civil Aeronautics Board.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This notice announces the Board's intention to revise its environmental regulation to adjust for its recent policy initiatives and to conform with the Council on Environmental Quality's new regulations. Issuance of a proposed rule is being postponed to allow the Board to analyze its experience in dealing with environmental problems in cases now before it and to await CEQ's adoption of its new regulations.

FOR FURTHER INFORMATION CONTACT:

Steven Rothenberg, Office of the General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue NW., Washington, D.C. 20428, 202-673-5423.

SUPPLEMENTARY INFORMATION: In a petition for rulemaking filed with the Board on May 3, 1978, National Airlines, Inc., requested that Part 312 of the Board's regulations, 14 CFR Part 312, be amended to allow more realistic initial environmental determinations in cases where multiple certificate awards are reasonably probable.

We agree that innovative environmental analysis is called for where multiple route awards, or other novel actions, are proposed. Increased fare flexibility and multiple route awards both make a forecast of the environmental impact of Board actions more difficult. However, contrary to the assertion in National's petition, the Board's information base is not limited to the information supplied by carriers. We have therefore endeavored to formulate new methods for forecasting the cumulative impact of a proposed action when multiple entry is being considered. While our forecasts might be improved by having available carrier environmental evaluations based on the possibility of multiple awards, we have not been unduly hampered in making our determinations by the fact that each carrier's evaluation is based on the assumption that only its application will be granted.

We believe that since we have been able to do adequate environmental analyses using the present regulation, we should postpone amending it until we develop a better idea of what information carriers might provide to help us in our forecasting. The present rule is sufficiently flexible to allow us to adjust our forecasts to our policy initiatives; thus the delay will not prevent us from complying with NEPA. In the meantime, carriers should feel free to include forecasts based on the possibility of multiple permissive awards, along with their traditional forecasts, in any environmental evaluations submitted to the Board.

Postponing action on National's petition will also allow us to combine the amendments called for by the Board's new policies with those necessary to conform Part 312 with the Council on Environmental Quality's new regulations. Those regulations should be adopted in the relatively near future, so that the amendments related to the Board's new policies should not be delayed by combining them with the changes necessary to conform Part 312 with CEQ's regulations.[1] By revising Part 312 in one step instead of two, we will be better able to insure that the regulation remains internally consistent and that the objectives of each set of amendments are fulfilled.

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-24007 Filed 8-24-78; 8:45 am]

[8010-01]

SECURITIES AND EXCHANGE COMMISSION

[17 CFR Part 249]

[Rel. No. 34-15074; File No. S7-751]

SECO BROKERS AND DEALERS REPORTS AND ANNUAL ASSESSMENTS

Proposed Form

AGENCY: Securities and Exchange Commission.

ACTION: Proposed form.

SUMMARY: The Securities Exchange Act (the "Act") authorizes the Commission to collect such reasonable fees and assessments as may be necessary to defray the costs of additional regulatory duties required to be performed with respect to registered broker-dealers who are not members of the National Association of Securities Dealers, Inc. ("nonmember" or "SECO" broker dealers). Pursuant to these sections of the Act, the Commission has adopted rule 15b9-2 to provide for annual assessments payable by those firms. This proposal deals with the adoption of form SECO-4-78 which would establish the levels for nonmember broker-dealer assessments for the current fiscal year.

DATES: Comments must be received on or before September 8, 1978.

ADDRESSES: All submissions should refer to file S7-751 and be delivered in triplicate to George A. Fitzsimmons, Secretary, Room 892, at 500 North Capitol Street, Washington, D.C. 20549. Copies of the proposed form are available on request from the Commission. Copies of all written submissions will be made available at the Commission's Public Reference Room, 1100 L Street NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT:

Daniel Bateman, Division of Market Regulation, room 501, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549, 202-755-1300.

SUPPLEMENTARY INFORMATION: The Securities and Exchange Commission has announced a proposal to adopt form SECO-4-78 (17 CFR 249.504*l*) establishing the annual assessments payable to the Commission by nonmember broker-dealers for the current fiscal year. The forms which set forth initial fees for a SECO broker-dealer and its associated persons, form SECO-5 (17 CFR 249.505) and form U-4 (17 CFR 249.502), respectively, would not be changed.[1] Under rule 15b9-2 annual assessments are generally due on or before September 1 of the calendar yer in which the assessments are established, 1978 in this instance. The Commission will not require the filing of form SECO-4 or the payment of fees pursuant to rule 15b9-2 until the new form SECO-4-78 becomes effective.

Proposed form SECO-4-78 reflects a reduction in the gross income assessment from 0.2 percent to 0.17 percent for municipal securities transactions and from 0.25 percent to 0.21 percent for other OTC transactions, and retains the basic annual SECO firm and personnel assessments of $250 and $5, respectively.

The assessments are being reduced to adjust the anticipated revenues to more closely approximate the expected regulatory costs of the SECO program and to continue the commission's policy over the years of maintaining general comparability with the NASD's fees and assessments.

The Securities and Exchange Commission, pursuant to its authority under the Securities Exchange Act of 1934 (15 U.S.C. 78a et seq., as amended by Pub. L. No. 94-29 (June 4, 1975)) and particularly sections 15(b)(7), 15(b)(8), and 23(a) thereof, hereby proposes to amend Part 249 of Title 17 of the Code of Federal Regulations by adopting § 249.504*l* as follows:

§ 249.504*l* Form SECO-4-78, 1978 assessment and information form for registered brokers and dealers not members of a registered national securities association.

This form shall be filed on or before October 31, 1978, pursuant to § 240.15b9-2 of this chapter, accompanied by the annual assessment fee required thereunder, for the fiscal year ended September 30, 1978, by every registered broker and dealer not a

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[1] Comments on the proposed regulations were due by August 11.

[1] The initial fee required to be paid by SECO broker-dealers is $500 and the fee to be paid on behalf of each associated person is $35. Additional fees are levied for the taking of qualifications examinations, when required.

member of a registered national securities association.

Copies of the proposed form have been filed with the Office of the Federal Register, and additional copies are available on request from the Commission.

By the Commission.

SHIRLEY E. HOLLIS,
Assistant Secretary.

AUGUST 18, 1978.

[FR Doc. 78-23915 Filed 8-24-78; 8:45 am]

[4830-01]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[26 CFR Part 1]

[EE-102-78]

INCOME TAX

Minimum Funding Standards—Asset Valuation

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations which define the term "reasonable actuarial method of valuation" for purposes of computing the minimum funding standard for pension plans. Changes in the applicable tax law were made by the Employee Retirement Income Security Act of 1974. The proposals would provide the public with guidance needed to comply with that Act and apply to all plans that are subject to the minimum funding standards.

DATE: Written comments and requests for public hearing must be delivered or mailed by October 24, 1978. Generally the proposed regulations apply to certain plan years beginning after December 31, 1975.

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

FOR FURTHER INFORMATION CONTACT:

Thomas F. Rogan of the Employee Plans and Exempt Organizations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, D.C. 20224 (Attention: CC:LR:T) (202-566-3589) (not a toll-free number).

SUPPLEMENTARY INFORMATION:

BACKGROUND

This document contains proposed amendments to the Income Tax Regulations (26 CFR Part 1) under section 412(c)(2) of the Internal Revenue Code of 1954, as added by section 1013(a) of the Employee Retirement Income Security Act of 1974 (88 Stat. 916) ("ERISA"). The regulations contained in this document are to be issued under the authority of sections 412(c)(2) and 7805 of the Internal Revenue Code of 1954 (88 Stat. 916 and 68A Stat. 917; 26 U.S.C. 412(c)(2) and 7805). These regulations will also apply for purposes of section 302 of ERISA.

EXPLANATION OF PROVISIONS

Section 412 provides minimum funding requirements with respect to certain pension plans, including the maintaining of a funding standard account. The charges and credits to the funding standard account are generally based upon the assumption that the plan will be continued by the employer. Based upon that assumption, the general purpose of these regulations is to allow defined benefit plans to use reasonable asset valuation methods designed to mitigate the effect on the funding standard account caused by shortrun changes in the fair market value of plan assets.

This purpose is in accord with H. Rep. No. 93-807, 93d Cong., 2d sess. 96 (1974). The rules contained in these proposed regulations provide standards for acceptable asset valuation methods, and provide rules for determining the fair market value of plan assets including certain contracts with insurance companies.

The principal limitation on using these methods is that the result must be no less than 80 nor more than 120 percent of the fair market value of the assets on the valuation date. This "corridor" of 20 percent is intended to cover cyclical or periodical variations as well as unusual fluctuations in value on the test date.

The proposed rules provide procedures for adopting and changing an actuarial asset valuation method. Transition rules are also provided for.

RELIANCE ON PROPOSALS

Pending the adoption of final regulations, taxpayers may rely on these proposed rules in making computations affected by these rules. If any provisions of the final regulations are less favorable to taxpayers than these proposed rules, those provisions will be effective only for periods after the date of adoption.

COMMENTS AND REQUESTS FOR A PUBLIC HEARING

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted (preferably eight copies) to the Commissioner of Internal Revenue. All comments are available for public inspection and copying. A public hearing will be held upon written request to the Commissioner by any person who has submitted written comments. If a public hearing is held, notice of the time and place will be published in the FEDERAL REGISTER.

DRAFTING INFORMATION

The principal author of these proposed regulations was J. Douglas Sorensen 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 regulation, both on matters of substance and style.

PROPOSED AMENDMENTS TO THE REGULATIONS

It is proposed to amend 26 CFR Part 1 by adding the following new section in the appropriate place:

§ 1.412(c)(2)-1 Valuation of plan assets; reasonable actuarial valuation methods.

(a) *Introduction*—(1) *In general.* This section prescribes rules for valuing plan assets under an actuarial valuation method which satisfies the requirements of section 412(c)(2)(A).

(2) *Exception for certain bonds, etc.* The rules of this section do not apply to bonds or other evidences of indebtedness for which the election described in section 412(c)(2)(B) has been made, nor are such assets counted in applying paragraphs (b) or (c) of this section.

(3) *Defined benefit plan.* See paragraph (b) of this section.

(4) *Defined contribution plan.* To satisfy the requirements of section 412(c)(2)(A), a defined contribution plan must value assets solely on the basis of their fair market value (under paragraph (c) of this section).

(b) *Defined benefit plans*—(1) *In general.* To satisfy the requirements of section 412(c)(2)(A), an actuarial method of valuing assets of a defined benefit plan must meet the requirements of this paragraph (b).

(2) *Purpose.* (i) In general, the purpose of this paragraph (b) is to permit use of reasonable actuarial valuation methods designed to mitigate shortrun changes in the fair market value of plan assets.

(ii) The funding of plan benefits and the charges and credits to the funding standard account required by section 412 are generally based upon the assumption that the defined benefit plan will be continued by the employer. Thus, shortrun changes in the value of plan assets presumably will offset one another in the long term. Accordingly, in the determination of the amount required to be contributed

under section 412 it is generally not necessary to recognize fully each change in fair market value of the assets in the period in which it occurs.

(iii) The asset valuation rules contained in this paragraph (b) permit a "smoothing" effect. Thus, investment performance, including appreciation or depreciation in the market value of the assets occurring in each plan year may be recognized gradually over several plan years. This "smoothing" effect is in addition to the "smoothing" effect which results from amortizing experience losses and gains over 15 or 20 years under section 412(b)(2)(B)(iv) and (3)(B)(ii).

(3) *Consistent basis.* (i) The actuarial asset valuation method must be applied on a consistent basis. Any change in meeting the requirements of this paragraph (b) is a change in funding method subject to section 412(c)(5).

(ii) A method may satisfy the consistency requirement even though computations are based only on the period elapsed since the adoption of the method or on asset values occurring during that period.

(4) *Statement of plan's method.* (i) The method of determining the actuarial value (but not fair market value) of the assets must be specified in the plan's actuarial report (required under section 6059) both for the first plan year such method is employed and for any subsequent plan year for which the method is modified. The method must be described in sufficient detail so that another actuary employing the method described would arrive at a reasonably similar result.

(ii) Any deviation from the described method is a change in funding method subject to section 412(c)(5), even if the deviation is made with respect to a new type or class of plan assets not previously held by the plan or is made because of an erroneous or incomplete description of the method.

(5) *Consistent valuation dates.* The same day (such as the first or the last day of a plan year) must be used for all purposes to value the plan's assets for each plan year for which a valuation is made. A change in the date used is a change in funding method.

(6) *Reflect fair market value.* The valuation method must make use of the fair market value (determined under paragraph (c) of this section) of the plan's assets as of the applicable asset valuation date, either in the direct computation of their actuarial value or in the computation of both maximum and minimum limits of such value. A method will not satisfy the requirement of the preceding sentence if it is designed to produce a result which will be significantly and consistently above or below fair market value.

(7) *80-120 corridor.* The method must result in an actuarial value of the plan's assets which is not less than 80 percent nor more than 120 percent of their current fair market value as of the applicable asset valuation date.

(8) *Examples.* This paragraph (b) may be illustrated by the following examples. In each example, assume that the pension plan uses a consistent actuarial method of valuing its assets.

Example 1. Plan A considers the value of its assets to be initial cost, increased by an assumed rate of growth of 4 percent annually. However, the method requires that the actuarial value be within an 80-120 percent corridor, i.e., that the result not be more than 120 percent nor less than 80 percent of the current fair market value as of the valuation date. Assuming that the 4 percent factor used by the plan is a reasonable assumption, this method is not designed to produce results consistently above or below fair market value. Since the method properly reflects fair market value and is within the required 80-120 corridor, it is permitted.

Example 2. Plan B considers the actuarial value of its assets to be their fair market value. However, if necessary an adjustment is made to make the actuarial value fall within a "5 percent" corridor. This corridor is plus or minus 5 percent of the following amount: the fair market value of the assets at the beginning of the valuation period plus an assumed annual growth of 4 percent and adjusted for contributions and benefit payments during the period. Assuming that the 4 percent factor used by the plan is a reasonable assumption, this method is not designed to produce results consistently above or below fair market value. However, this method is unacceptable because in some instances it may result in values outside the 80-120 corridor. This method would be permitted if a second corridor were imposed which would prevent the value of the total plan assets from falling outside of the 80-120 percent corridor.

Example 3. Plan C values it assets by multiplying their fair market value by an index number. The use of the index results in the hypothetical average value that plan assets present on the valuation date would have had it they had been held during the current and four preceding years, and had appreciated or depreciated at the actual yield rates including appreciation and depreciation experienced by the plan during that period. However, the method requires an adjustment, if necessary, to bring the resulting actuarial value of the assets inside the 80-120 corridor. This method is permitted.

Example 4. Plan D values its assets by multiplying their fair market value by 90 percent. Although the results of this method will always be within the required corridor, it is not acceptable because it will consistently and significantly result in a value less than fair market value.

(c) *Fair market value of assets*—(1) *In general.* Except as otherwise provided in this paragraph (c), the fair market value of a plan's assets for purposes of this section is the price at which the property would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy or sell and both having reasonable knowledge or relevant facts. The valuation principles in the regulations under section 2031 apply.

(2) *Insurance agreements.* (i) Agreements with an insurer (including agreements between the employer or plan trustee and an insurer) involving the payment of benefits under the plan shall be valued in accordance with paragraph (c)(3) or (c)(4) of this section, whichever is applicable.

(ii) For purposes of this paragraph (c), the term "insurer" means a company or association authorized to do business under a State law regulating insurance companies.

(3) *Insurance agreements; allocated portion of agreement.* (i) If an insurer has a legally enforceable obligation to provide plan benefits to specific plan participants or their beneficiaries, the plan must on a consistent basis apply one of the methods described in this paragraph (c)(3) to value the obligation. An insurer has a legally inforceable obligation to pay benefits if the insurer is obligated to provide such benefits without further obligation by the plan to pay any consideration for the benefits.

(ii) The plan may exclude the obligation's fair market value from the fair market value of plan assets. If this method is used, the plan must also exclude the value of such benefits from the computation of the plan's liability to pay benefits.

(iii) The plan may include in the fair market value of its assets the present value of the plan benefits which as of the valuation date are a legally enforceable obligation of the insurer and which are included in the computation of the plan's liability to pay benefits.

(iv) The plan may include in the fair market value of its assets the obligation's cancellation value. For purposes of this paragraph (c), the term "cancellation value" means the sum of funds which would be received by the plan if the agreement were terminated on the valuation date. Any payment to be made to the plan more than one year after the termination of the agreement must be taken into account at its present value. Cancellation value includes the present value of benefits which will continue to be guaranteed by the insurer, unless they are excluded from the computation of the plan's liability to pay benefits. To the extent that the plan, on termination of the agreement, may receive either funds or benefits continued to be guaranteed by the insurer, the cancellation value shall include the greater of the two amounts.

(4) *Insurance agreements; unallocated portion of agreement.* (i) If an insurer maintains a fund on behalf of the plan, and provides plan benefits from the fund either by direct payment from the fund or by the pur-

chase of annuity contracts, then the plan must apply the method described in paragraph (c)(4)(ii) of this section in valuing the fund. The plan must apply this method on a consistent basis whether or not the assets of the plan contributed to the fund are commingled with other assets held by the insurer.

(ii) The plan must include in the fair market value of its assets the fund's account balance computed pursuant to the agreement providing for the fund, whether or not the insurer maintains its own separate records based upon experience. However, this account balance shall not include any amount that the insurer is entitled to withdraw from the fund as consideration for an obligation to pay plan benefits. The amount which may be withdrawn is to be determined at the valuation date. See paragraph (c)(3) of this section for a description of an insurer's obligation to pay benefits.

(5) *Plan termination insurance.* For purposes of this section, plan termination insurance for which premiums are paid from plan funds pursuant to section 4006 of the Employee Retirement Income Security Act of 1974 is not a plan asset.

(d) *Effective date and transition rules*—(1) *Effective date.* This section applies to plan years to which section 412, or section 302 of the Employee Retirement Income Security Act of 1974, applies.

(2) *Special rule for certain plan years.* For plan years beginning prior to [the date this regulation is published in the FEDERAL REGISTER as a final regulation], the amounts required to be determined under section 412 may be computed on the basis of any reasonable actuarial method of asset valuation which takes into account the fair market value of the plans assets, even if the method does not meet the requirements of paragraphs (a) through (c) of this section.

(3) *Plan years beginning on or after [the date described in paragraph (d)(2) of this section].* Paragraphs (a) through (c) of this section apply beginning with the first valuation of plan assets made for a plan year to which section 412 applies that begins on or after [the date described in paragraph (d)(2) of this section]. The statement of the plan's actuarial asset valuation method required by paragraph (b)(4) of this section must be included with the plan's actuarial report for that year, in addition to any subsequent years specified in that paragraph.

(4) *Effect of change of asset valuation method.* A plan which is required to change its asset valuation method to comply with paragraphs (a) through (c) of this section must make the change when those rules first become applicable to the plan. A method of adjustment must be used to take account of any difference in the actuarial value of the plan's assets based on the old and new valuation methods. The plan may use either:

(i) A method of adjustment described in paragraph (d)(5) or (d)(6) of this section without prior approval by the Commissioner, or

(ii) Any other method of adjustment if the Commissioner gives prior approval under section 412(c)(5).

(5) *Retroactive recomputation method.* (i) Under this method of adjustment, the plan recomputes the balance of the funding standard account as of the beginning of the first plan year for which it must use its new asset valuation method. This recomputation is made as if the plan's new method applied as of the first day of the first plan year to which section 412 applies.

(ii) Beginning with the first plan year for which its new method must apply, the normal cost and amortization charges and credits to the funding standard account are computed as if its new method applied as of the first day of the first plan year to which section 412 applies.

(iii) If the recomputed aggregate charges exceed the recomputed aggregate credits to the funding standard account as of the end of the first plan year to which its new method applies, an additional contribution to the plan may be necessary to avoid an accumulated funding deficiency in that year.

(6) *Prospective gain or loss adjustment method.* (i) Under this method of adjustment the plan values its assets under its new method on the first valuation date following [the date described in paragraph (d) (2) of this section].

(ii) If the plan uses a spread gain type funding method, the difference in the value of the assets under the two asset valuation methods is not seperately amortized. Under a spread gain type of funding method, gains and losses are spread over future periods as a part of normal cost. Examples of this type of funding method are the aggregate cost method, frozen initial liability cost method, and the attained age normal cost method.

(iii) If the plan uses an immediate gain type of funding method the plan determines the difference in the value of the plan's assets based upon the old and new asset valuation methods. This difference is determined as of the first valuation date following [the date described in paragraph (d) (2) of this section]. Under an immediate gain type of funding method, gains and losses are seperately recognized and amortized over a fixed number of years. Examples of this type of funding method are the unit credit method, the entry age normal cost method, and the individual level premimum cost method.

(iv) The difference determined under paragraph (d) (6) (iii) of this section may be treated as arising from an experience loss or gain, and this amortized under section 412 (b) (2) (B) (iv) or (3) (B) (ii); or alternatively it may be treated as arising from a change in actuarial assumptions, and this amortized under section 412 (b) (2) (B) (v) or (3) (B) (iii).

JEROME KURTZ,
Commissioner of Internal Revenue.

[FR Doc. 78-23667 Filed 8-24-78; 8:45 am]

[4510-27]

DEPARTMENT OF LABOR

Wage and Hour Division

[29 CFR Part 800]

EQUAL PAY ACT—EMPLOYEE BENEFITS

Amendment to Interpretative Bulletin

AGENCY: Wage and Hour Division, Department of Labor.

ACTION: Proposed amendment to interpretative bulletin.

SUMMARY: The interpretative bulletin on the Equal Pay Act presently provides, with respect to insurance and other employee benefit plans, that the act is not violated where either the plan provides equal benefits to both men and women or the employer makes equal contributions to the plan on behalf of all employees. See 29 CFR 800.116(d) (1977). The Wage and Hour Administrator has proposed that this interpretation be withdrawn and that it be replaced with an interpretation which makes clear that employee benefits are "wages" within the meaning of the Equal Pay Act, that any differential in such benefits based on sex based actuarial distinctions violates the act, and that any sex-based differential in required employee contributions toward equal benefits similarly violates that act. This change in the interpretative bulletin is based on a thorough review of the legislative history and purposes of the Equal Pay Act, as well as on decisions of the Supreme Court and other courts.

DATES: Comments should be submitted by October 23, 1978.

ADDRESS: Written comments should be submitted in quadruplicate to the Director, Division of Equal Pay and Employment Standards, Wage and Hour Division, Room S-3028, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210. A copy of all public comments may be examined during normal business hours at the office of Xavier M. Vela, Administrator, Wage and Hour Division, Room S-35202, U.S. Department

of Labor, 200 Constitution Avenue NW., Washington D.C. 20210. The entire record or any part thereof may be purchased at the actual cost of duplication as computed pursuant to the fee schedule in 29 CFR Sec. 70.62(b).

FOR FURTHER INFORMATION CONTACT:

Richard A. McMullen, Chief, Branch of Equal Pay, Wage and Hour Division, Room S-3028 U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210, telephone 202-523-7605.

SUPPLEMENTARY INFORMATION:

HISTORY

In 1965, shortly after the Equal Pay Act became effective, the Wage-Hour Administrator issued the present section 116(d) of the interpretative bulletin on equal pay for equal work:

Contributions ot employee benefit plans. If employer contributions to a plan providing insurance or similar benefits to employees are equal for both men and women, no wage differential prohibited by the equal pay provisions will result from such payments, even though the benefits which accrue to the employees in question are greater for one sex than for the other. The mere fact that the employer may make unequal contributions for employees of opposite sexes in such a situation will not, however, be considered to indicate that the employer's payments are in violation of section 6(d), if the resulting benefits are equal for such employees. [29 CFR Sec. 800.116(d) (1977)]

This section was based on the understanding that employers could sometimes purchase more benefits for men than for women at a given price. In 1970, the section was interpreted to apply to retirement plans, which were often priced on the basis of sex-based actuarial tables reflecting the greater average longevity of women. Opinion Letter WH-70, August 25, 1970. CCH Wage-Hour Admin. Rulings para. 30,681; BNA WHM 95:621. Under this interpretation, The Equal Pay Act was not violated if either the plan provided equal benefits to both sexes or the employer made equal contributions to the plan on behalf of all employees even though, because of the use of sex-based actuarial tables, the resulting benefits were larger for men than for similarly situated women. (This will hereinafter be referred to as the "either-or rule.")

Since at least 1972, this either-or rule has been at variance with an Equal Employment Opportunity Commission interpretation of the broad sex discrimination prohibition of title VII of the Civil Rights Act of 1964. 42 U.S.C. sec. 2000e. EEOC guidelines specifically prohibit an employer from maintaining a pension or other benefit plan "which differentiates in benefits on the basis of sex." 29 CFR 1604.9(f). The EEOC guidelines further provide that it is no defense under title VII that the cost of benefits is greater for one sex. 29 CFR 1604.9(e).

After the EEOC issued these guidelines, the Department of Labor began to reconsider its either-or rule. Hearings were held in September 1974, and from these hearings the following facts appeared:

(1) Women as a group lived longer than men as a group.

(2) The overwhelming majority of retirement plans nonetheless provided equal periodic benefits in single-life annuities for men and women.

(3) Life insurance plans most commonly provided equal benefits for men and women.

(4) The minority of retirement plans which provided unequal benefits for men and women provided equal benefits to other groups with differing life expectancies, such as smokers and nonsmokers, drinkers and nondrinkers and different racial groups.

It thus appeared that in group insurance practice unequal life expectancies did not necessarily dictate unequal benefits.

Before the Department took any action, however, the question of unequal pension benefits was referred to the Equal Employment Opportunity Coordinating Council in an attempt to bring about uniform government-wide action. The Council determined as a matter of sound public policy that periodic payments to retired employees should not be differentiated on the basis of sex, but it did not take a position on whether such a differentiation was prohibited by existing statutes. In its official recommendation to the President on April 15, 1976, the Council proposed clarifying legislation to require equal benefits, but such legislation was never presented to the Congress. BNA 1976 DLR No. 122, E-1.

The continuing variance in interpretation of equal employment statutes has created confusion in the courts and impeded the EEOC's efforts to enforce title VII. See, e.g., *EEOC* v. *Colby College*, 439 F. Supp. 631 (D. Me. 1977), appeal pending. However, the Supreme Court's recent decision in *Los Angeles Dept. of Water & Power* v. *Manhart*, 46 U.S.L.W. 4347 (April 25, 1978) provides helpful guidance. On the basis of that decision, as well as its own legal analysis, the Department of Labor has now determined that its "either-or rule" is an incorrect interpretation of the Equal Pay Act and must therefore be revised.

THE MANHART DECISION

In the *Manhart* case the Supreme Court held that title VII was violated by a pension plan which required female employees to contribute a greater portion of their wages than male employees in order to fund equal periodic retirement benefits. The plan was defended on the ground that women as a class live longer (and therefore receive periodic retirement benefits longer) than men as a class. The Supreme Court held, however, that the plan violated title VII's basic policy of treating employees as individuals, and not as members of a sexual class. "Fairness to individuals" (who may or may not live as long as other members of their sex), not fairness to the class, was required. Further, the "cost justification" asserted by the defendant was not recognized as a defense.

The Supreme Court specifically rejected a defense based on the so-called Bennett Amendment to title VII, which provides that

"It shall not be an unlawful employment practice under this title for any employer to differentiate upon the basis of sex in determining the amount of wages or compensation paid or to be paid to employees of such employer if such differentiation is authorized by the [Equal Pay Act]." [42 U.S.C. Sec 2000e-2(h)]

The defendant argued that the pay differential was authorized as based on a "factor other than sex" under the Equal Pay Act (as interpreted by the either-or rule) and that consequently there was no violation of title VII. However, the Supreme Court rejected the argument, agreeing with the Ninth Circuit Court of Appeals that one cannot say that "an actuarial distinction based entirely on sex is 'based on any other factor other than sex.' Sex is exactly what it is based on." 46 U.S.L.W. at 4350.

The Court went onto make the following comments:

The administrative constructions of the provision look in two directions. The Wage and Hour Administrator, who is charged with enforcing the Equal Pay Act, has never expressly approved different employee contribution rates, but he has said that either equal employer contributions or equal benefits will satisfy the Act. 29 CFR Sec. 800.116(d) (1976). At the same time, he has stated that a wage differential based on differences in the average costs of employing men and women is not based on a "factor other than sex." 29 CFR Sec. 800.151 (1976). The Administrator's reasons for the second ruling are illuminating:

"To group employees solely on the basis of sex for purposes of comparison of costs necessarily rests on the assumption that the sex factor alone may justify the wage differential—an assumption plainly contrary to the terms and purposes of the Equal Pay Act. Wage differentials so based would serve only to perpetuate and promote the very discrimination at which the Act is directed, because in any grouping by sex of the employees to which the cost data relates, the group cost experience is necessarily assessed against an individual of one sex without regard to whether it costs an employer more or less to employ such individual than a particular individual of the opposite sex under similar working conditions in jobs requiring equal skill, effort, and responsibility." *Ibid.*

To the extent that they conflict, we find that the reasoning of Sec. 800.151 has more

"power to persuade" than the *ipse dixit* of Sec. 800.116. Cf. *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140. [46 U.S.L.W. at 4350 n. 26]

The Department of Labor agrees with the Supreme Court's comments. Section 800.151 is firmly grounded in the legislative history, language and policy of the Equal Pay Act, as summarized by the Supreme Court in the *Manhart* decision:

A broad cost differential defense was proposed and rejected when the Equal Pay Act became law. Representative Findley offered an amendment to the Equal Pay Act that would have expressly authorized a wage differential tied to the "ascertainable and specific added cost resulting from employment of the opposite sex." 109 Cong. Rec. 9217. He pointed out that the employment of women might be more costly because of such matters as higher turnover and state laws restricting women's hours. *Id.*, at 9205. The Equal Pay Act's supporters responded that any cost differences could be handled by focusing on the factor other than sex which actually caused the differences, such as absenteeism or number of hours worked. The amendment was rejected as largely redundant for that reason. *Id.*, at 9217.

The Senate Report, on the other hand, does seem to assume that the statute may recognize a very limited cost defense, based on "all of the elements of the employment costs of both men and women." S. Rep. No. 176, 88th Cong., 1st Sess., 4. It is difficult to find language in the statute supporting even this limited defense; in any event, no defense based on the *total* cost of employing men and women was attempted in this case. [46 U.S.L.W. at 4351 n. 32]

The either-or rule, on the other hand, appears not to have been based on any statutory language, legislative history, judicial interpretation, or administrative investigation of total employment costs.

REASONS FOR REVISION

The Equal Pay Act requires that workers receive equal "wages" for equal work, unless the differential is based on a factor other than sex. Thus, if employer contributions are "wages," they should be equal; if employee benefits are "wages," they should be equal; and if both are "wages," both should be equal. The either-or rule, however, ignores this basic command of the act. It appears to treat both contributions and benefits as "wages" within the meaning of the act, but it fails to require that both be equal.

In order to eliminate the basic incongruity of the either-or rule, the Department of Labor intends to withdraw it entirely. The Department further intends to take the following position with regard to employee benefits under the Equal Pay Act:

(1) Such benefits are "wages" within the meaning of the Act.

(2) A sex-based actuarial distinction is not a "factor other than sex" which may justify a wage differential under the Act.

EMPLOYEE BENEFITS ARE "WAGES" WITHIN THE MEANING OF THE EQUAL PAY ACT

The language of the Equal Pay Act and the Fair Labor Standards Act neither explicitly includes nor excludes employee benefits as "wages." However, consideration of the nature of employee benefits and of the purposes of the Equal Pay Act leads to the conclusion that such benefits are "wages" within the meaning of that act. The Department has long held that "[w]ages paid to an employee generally include all payments made to or on behalf of the employee as remuneration for employment." 29 CFR 800.100. (Other language in § 800.110 which might have been read as suggesting that "wages" within the meaning of the Equal Pay Act are limited to payments which may be counted toward the minimum wage is being revised. Further, reference in the last sentence of § 800.110 to "payments related to maternity" is being deleted, because some maternity-related payments may constitute remuneration for employment.) It is obvious that emloyee benefits are now a normal and important part of such remuneration. In 1976, for example, private employee benefit plan costs amounted to 17 percent of the expenditures for employee compensation of private non-farm employers with twenty or more employees. These benefits therefore must be regarded as "wages" if the Equal Pay Act is to have its intended effect. For example, if retirement benefits were not considered as "wages" under the Equal Pay Act, then the act would require equal payments to similarly situated workers performing equal work as long as they were employed but would permit unequal payments deriving from that employment relationship for any reason (including simple discrimination) once the workers retired. There is no reason to believe that Congress intended so anomalous a result.

In subchapter II of the Consumer Credit Protection Act (enforced by the Secretary of Labor) Congress has specifically stated that "earnings" (defined to mean "compensation paid or payable for personal services, whether denominated as wages, salary, commission, bonus, or otherwise") includes "periodic payments" pursuant to a pension or retirement program. 15 U.S.C. § 1672. Retirement benefits have long been recognized as "wages * * * or other conditions of employment" within the meaning of the National Labor Relations Act, 29 U.S.C. Sec. 151 et seq. *Inland Steel Co.* v. *National Labor Relations Board*, 170 F.2d 247 (7th Cir. 1948), cert. denied on this issue, 336 U.S. 960 (1949). While it does not necessarily follow that such benefits are "wages" within the meaning of the Equal Pay Act, it is significant that two of the purposes of the Equal Pay Act are also purposes of the National Labor Relations Act: To alleviate the depression of wages and to prevent labor disputes. 29 U.S.C. 151. If coverage of retirement benefits is necessary for the purposes of the National Labor Relations Act, it is equally necessary for the same purposes of the Equal Pay Act. Coverage of retirement benefits is also necessary for a third purpose of the Equal Pay Act: To promote the maximum utilization of labor resources. Women cannot be attracted into the labor force equally with men it they cannot hope to earn retirement benefits equally with men.

In a recent case concerning the reemployment rights of veterans, *Alabama Power Co.* v. *Davis*, 431 U.S. 581, 592 (1977), the Supreme Court specifically stated that "it is obvious that pension payments have some resemblance to compensation for work performed." The Court examined "the function of pension plans in the employment system" and stated, "a pension plan assures employees that by devoting a large portion of their working years to a single employer, they will achieve some financial security in their years of retirement." *Id.* at 594. Through retirement plans, then, employees trade off current compensation for future economic security. Employers should not be allowed to use this trade-off to create inequality where the Equal Pay Act otherwise clearly requires equality.

A SEX-BASED ACTUARIAL DISTINCTION IS NOT A "FACTOR OTHER THAN SEX"

The decision of the Supreme Court in the *Manhart* case squarely rejects the proposition that a sex-based actuarial distinction is a "factor other than sex" which may justify a wage differential under the Equal Pay Act. The Department adopts the Court's analysis of the act's language and legislative history in also rejecting the proposition. The general principles of section 800.151 of the interpretative bulletin apply to employee benefits just as they apply to other wages.

This document was prepared under the direction and control of Xavier M. Vela, Administrator, Wage and Hour Division.

In consideration of the foregoing, it is proposed to amend 29 CFR § 800.116(d) as follows:

§ 800.116(d) Equality and inequality of pay in particular situations

* * * * *

(d) *Employee benefits.* Employee benefits are "wages" within the meaning of the act. A differential in benefits based upon differences between the cost to the employer of providing

benefits to women as a group and the cost of providing benefits to men as a group does not qualify as a differential based on a "factor other than sex" within the meaning of section 6(d)(1)(iv) of the act. Such a differential therefore violates the equal pay requirements of the act. Similarly, the act is violated if employees of one sex are required to make greater contributions from their wages than are employees of the opposite sex in order to receive equal benefits. *Los Angeles Dept. of Water & Power* v. *Manhart*, 46 U.S.L.W. 4347 (April 25, 1978). See also sec. 800.151 of this chapter.

* * * * *

It is further proposed to amend 29 CFR § 800.110 as follows:

§ 800.110 Meaning of "wages"

Wages paid to an employee generally includes all payments made to or on behalf of the employee as remuneration for employment. The term "wages" used in section 6(d)(1) of the act (the purpose of which is to assure men and women equal remuneration for equal work) will therefore include payments which may not be counted under section 3(m) of the act toward the minimum wage (the purpose of which is to assure employees a minimum amount of remuneration unconditionally available in cash or in board, lodging or similar facilities). Similarly, the provisions of section 7(e) of the act under which some such payments may be excluded in computing an employee's "regular rate" of pay for purposes of section 7 do not authorize the exclusion of any such remuneration from the "wages" of an employee in applying section 6(d) of the act. Thus, vacation and holiday pay, and premium payments for work on Saturdays, Sundays, holidays, regular days of rest, or other days or hours in excess or outside of the employee's regular days or hours of work are remuneration for employment and therefore wage payments that must be considered in applying the equal pay provisions of the act, even though not a part of the employee's "regular rate." On the other hand, payments made by an employer to an employee which do not constitute remuneration for employment are not "wages" to be compared for equal pay purposes under section 6(d) of the act. Examples are such reasonable payments for reimbursable expenses of traveling on the employer's business as are discussed in section 778.217 of this chapter.

Signed at Washington, D.C. on this 18th day of August, 1978.

XAVIER M. VELA,
Administrator,
Wage and Hour Division.

[FR Doc. 78-23733 Filed 8-24-78; 8:45 am]

[4510-29]

Pension and Welfare Benefit Programs

[29 CFR Part 2520]

RULES AND REGULATIONS FOR REPORTING AND DISCLOSURE

Summary Annual Report

AGENCY: Department of Labor.

ACTION: Proposed rulemaking.

SUMMARY: This document sets forth a proposed regulation which, if adopted, would replace existing temporary regulations concerning the content, style, and format of the summary annual report (SAR) required to be furnished to participants and beneficiaries of employee benefit plans under the Employee Retirement Income Security Act of 1974 (ERISA). The proposed regulation is designed to make the SAR more useful to plan participants and beneficiaries, and easier to prepare, by prescribing a form which plan administrators would complete by inserting information in the appropriate blank spaces. The proposed regulation, if adopted, would affect participants and beneficiaries of employee benefit plans, and plan administrators and other persons involved in the preparation of SAR's.

DATE: Comments concerning the proposed regulation are due on or before October 10, 1978.

ADDRESSES: Interested persons are invited to submit written data, views, or arguments concerning any part or all of the proposal contained in this document to "Summary Annual Report Regulations," Room C-4526, Office of Regulatory Standards and Exceptions, Pension and Welfare Benefit Programs, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20216, on or before the date indicated above. All such submissions will be open to public inspection at the Public Documents Room, Pension and Welfare Benefit Programs, Department of Labor, Room N-4677, 200 Constitution Avenue NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT:

Peter A. Straub or John Christensen, Office of Regulatory Standards and Exceptions, Pension and Welfare Benefit Programs, U.S. Department of Labor, Washington, D.C. 20216, 202-523-8515. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Section 104(b)(3) of ERISA provides in part that, each year, administrators must furnish summaries of the plan's annual report to participants and beneficiaries. Section 109(c) of ERISA authorizes the Department of Labor (the Department) to adopt, and on July 29, 1976, the Department adopted regulations 29 CFR 2520.104b-10 and 2520.104b-11, specifying the content, style, and format of the SAR which must be furnished under that section.[1] Those regulations were adopted on a temporary basis, and at the same time public comment was requested as to whether they should be made permanent. Based on the comments and the reasons discussed below, the Department has now determined to withdraw the proposal that they be made permanent, and instead to propose new regulation § 2520.104b-10 which would replace both regulations §§ 2520.104b-10 and 2520.104b-11. The proposed regulation, if adopted, would apply with respect to plan years beginning in 1978 and thereafter. Thus, under the proposed regulation SAR's for the 1977 plan year will be prepared pursuant to the existing regulations. However, the Department invites comments as to whether the method of compliance prescribed in the proposed regulation should be made available as an optional method of complying with the SAR requirement for the 1977 plan year for those plans which, at the time the regulation becomes final, were not yet required to have distributed the SAR.

Numerous comments on termporary and proposed §§ 2520.104b-10 and 2520.104b-11 suggested that those regulations require an SAR which is unduly burdensome to prepare and cannot be readily understood by many participants and beneficiaries. The regulation now being proposed is designed to simplify and make less burdensome the summary annual reporting requirements, and to result in a less complicated SAR which would apprise plan participants and beneficiaries of the most significant aspects of the plan's financial status. This would be accomplished by prescribing a form which plan administrators would complete by inserting information in the appropriate blank spaces. It is anticipated that all information necessary to complete the form will be contained in the full annual report. The form, when completed in an accurate manner, would constitute the SAR for purposes of section 104(b)(3) of ERISA, and would be distributed to participants and beneficiaries in accordance with 29 CFR 2520.104b-1.[2]

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[1] 41 FR 32522, Aug. 3, 1976.

[2] Regulation 29 CFR 2520.104b-1 describes, among other things, types of deliv-

Footnotes continued on next page

Paragraph (c)(1) of the proposed regulation sets forth the form which would be followed by administrators of pension plans, and paragraph (c)(2) sets forth the form which would be followed by administrators of welfare plans. In each case, plan administrators could omit any part of the prescribed form which is not applicable to the plan, or which would require information which is not required to be reported on the annual report of that plan.[2a] However, they are not to include information not prescribed in the form.

In addition to prescribing a form for the SAR, the proposed regulation differs from the existing regulations in that, by requiring the inclusion of considerably less detailed information, it highlights the more important aspects of the annual report. Thus, for example, while the forms require disclosure of specified financial information of the plan,[3] they do not, unlike the SAR required under the existing temporary regulations, require attachment of complete copies of the statements of assets and liabilities and of income and expenses, and accompanying notes. Comments received on temporary and proposed §§ 2520.104b-10 and 2520.104b-11 suggested that such statements and accompanying notes were often lengthy and, therefore, costly to the plan to reproduce. Commentators also argued that, in many cases, participants and beneficiaries were not able to evaluate effectively the full statements and notes, and that many participants and beneficiaries made no serious attempt to do so.

Under the proposed new regulation, plan administrators would be required to furnish such statements and notes only when requested to do so by a participant or beneficiary. These documents, when requested, would have to be supplied free of charge, and the forms contain a notice advising participants and beneficiaries of that fact.[4] The forms also include a notice indicating that participants and beneficiaries may obtain a copy of the full annual report, or any part thereof, and indicating the types of disclosures to be found therein. The annual report is not required to be furnished free of charge.[5] The Department believes that the approach described above would provide plan participants and beneficiaries with financial information sufficient to form the basis for an initial appraisal of the plan's condition, while informing such persons of their right to obtain more detailed information about the plan's financial status if they desire.

The proposed regulation also omits the existing requirement that certain names and addresses, in addition to that of the plan administrator, be set forth in the SAR. This is because the summary plan description which must be furnished to plan participants and beneficiaries under section 104(b)(1) of ERISA includes substantially identical information.[6]

The proposed regulation, like the existing temporary regulations §§ 2520.104b-10 and -11, provides that the administrators of certain plans which have substantial numbers of participants who are not literate in English must offer assistance to such participants in understanding the SAR.

With regard to the date by which the plan administrator must furnish the SAR, the proposed regulation, like the existing temporary ones, would require that the SAR be furnished to plan participants and beneficiaries within 9 months after the close of the plan year or, in the case of certain welfare plans which use group insurance arrangements, within 9 months of the close of the fiscal year of the trust or other entity which files the annual report under 29 CFR 2520.104a-6. This is 2 months after the date by which the full annual report must be filed with the Department, and it is also 2 months after the date by which the SAR would otherwise have to be furnished under section 104(b)(3) of ERISA. If an extension of time in which to file an annual report has been approved by the Internal Revenue Service, the SAR is required to be furnished within 2 months after the close of the period for which the extension was granted. The proposed filing date would enable plan administrators to supply current information in the SAR without having specially to compile the necessary data, since such data will have been recently compiled in order to prepare the full annual report.[7] Plan administrators could, of course, furnish the SAR at whatever earlier time they choose. For example, a plan administrator required to supply participants and beneficiaries with a summary of a material modification under 29 CFR 2520.104b-3 might find it convenient to furnish the SAR together with that information.

Exemptions

The proposed regulation would preserve the exemptions from the requirement to furnish an SAR contained in existing regulations for certain welfare, pension, day care, and apprenticeship plans.

In consideration of the matters discussed above, it is proposed to amend part 2520 of chapter XXV of title 29 of the Code of Federal Regulations by rescinding § 2520.104b-11, and amending § 2520.104b-10 to provide as set forth below.

(Secs. 104, 109, 110, 505 Pub. L. 93-406, 88 Stat. 847, 851, 894 (29 U.S.C. 1024, 1029, 1030, 1135).)

Subpart F—Disclosure Requirements

§ 2520.104b-10 Summary annual report.

(a) *Obligation to furnish.* Except as otherwise provided in paragraph (f) of this section, the administrator of any employee benefit plan shall furnish annually to each participant and beneficiary of such plan a summary annual report conforming to the requirements of this section. Such furnishing of the summary annual report shall take place in accordance with the requirements of § 2520.104b-1 of this part.

(b) *When to furnish.* Except as otherwise provided in this paragraph (b), the summary annual report required

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ery or mailing procedures which are acceptable where a plan administrator is required to furnish materials to participants and beneficiaries.

[2a] Specifically, annual report form 5500K, which is filed by certain small pension plans, requires less detailed information in some respects than forms 5500 or 5500C. Persons filing form 5500K may omit from the prescribed SAR form those items which would require information not required by form 5500K. For example, the prescribed SAR form requires disclosure of administrative expenses, but there is no corresponding entry on the form 5500K. Accordingly, persons filing form 5500K may omit reference to administrative expenses in their SAR.

[3] The figures disclosed in the form would be the same as those reported in the latest annual report.

[4] Under sec. 110 of ERISA, the Department may prescribe alternative methods of compliance with the reporting and disclosure requirements with respect to pension plans if, among other things, the alternative method will provide adequate disclosure to participants and beneficiaries, and application of the statutory requirement would cause the plan to incur increased costs or administrative burdens, and would be adverse to the interests of plan participants in the aggregate. Similarly, sec. 104(a)(3) of ERISA gives the Department authority to exempt welfare plans from all or part of the statute's reporting and disclosure requirements where such requirements are inappropriate as applied to welfare plans. For the reasons indicated above, the Department is of the view that the procedure being proposed herein would be consistent with these standards, notwithstanding that sec. 104(b)(3) of ERISA states in effect that statements of assets and liabilities and statements of income and expenses must be furnished to each participant and beneficiary as part of the SAR.

[5] Persons requesting the full annual report may, but need not, be charged for the copying of that document or any part thereof. Charges, if any, may not exceed those determined by reference to regulation 29 CFR 2520.104b-30.

[6] See 29 CFR 2520.102-3 (42 FR 37178, July 19, 1977).

[7] The Department's authority for delaying the date by which SAR's must be furnished is set forth in section 104(a)(3) of ERISA with respect to welfare plans, and section 110 of ERISA with respect to pension plans. See note 4, supra.

by this section shall be furnished to participants and beneficiaries within nine months after the close of the plan year.

(1) In the case of a welfare plan described in § 2520.104-43, such furnishing shall take place within 9 months after the close of the fiscal year of the trust or other entity which files the annual report under § 2520.104a-6.

(2) When an extension of time in which to file an annual report has been approved by the Internal Revenue Service, such furnishing shall take place within 2 months after the close of the period for which the extension was granted.

(c) *Contents, style, and format.* The summary annual report furnished to participants and beneficiaries of an employee pension benefit plan pursuant to this section shall consist of a completed copy of the form prescribed in subparagraph (1) of this paragraph (c), and the summary annual report furnished to participants and beneficiaries of an employee welfare benefit plan pursuant to this section shall consist of a completed copy of the form prescribed in subparagraph (2) of this paragraph (c): *Provided however,* That any portion of the forms set forth in this paragraph (c) which is not applicable to the plan to which the summary annual report relates, or which would require information which is not required to be reported on the annual report of that plan, may be omitted. The information used to complete the form shall be based upon information contained in the most recent annual report of the plan which is required to be filed in accordance with section 104(a)(1) of the act.

(1) *Form for summary annual report relating to pension plans.*

This is a summary of the annual report for (name of plan and EIN) for (period covered by this report). The annual report was filed on (date) with the Internal Revenue Service, as required under the Employee Retirement Income Security Act of 1974 (ERISA).

Benefits under the plan are provided by (indicate funding arrangements). Plan expenses were ($). These expenses included ($) in administrative expenses and ($) in benefits paid to participants and beneficiaries, and ($) in other expenses. A total of ( ) persons were participants in or beneficiaries of the plan at the end of the plan year, although not all of these persons had yet earned the right to receive benefits.

[*If the plan is funded other than solely by allocated insurance contracts:*]

The value of plan assets held in trust, after subtracting liabilities of the plan, was ($) as of (the end of the plan year), compared to ($) as of (the beginning of the plan year).

During the plan year the plan experienced an (increase) (decrease) in its net assets of ($). This (increase) (decrease) included unrealized appreciation and depreciation in the value of plan assets. It had total income of ($), including employer contributions of ($), employee contributions of ($), (gains) (losses) of ($) from the sale of assets, and earnings from investments of ( ). [For plans filing form 5500K, omit separate entries for employer contributions and employee contributions and insert instead "contributions by employer and employees of ( )"].

[*If any funds are used to purchase allocated insurance contracts:*]

The plan has (a) contract(s) with (name of insurance carrier(s)) which allocate(s) funds toward (state whether individual policies, group deferred annuities or other). The total premiums paid for the plan year ending (date) was ($).

[*If the plan is a defined benefit plan:*]

An actuary's statement shows that contributions to the plan (met the minimum funding standards of ERISA) (failed to meet the minimum funding standards of ERISA in the amount of $).

[*If the plan is a defined contribution plan covered by funding requirements:*]

Contributions to the plan (met the minimum funding standards of ERISA) (failed to meet the minimum funding standards of ERISA in the amount of $).

You have the right to receive a copy of the full annual report, or any part thereof, on request. The items listed below are included in that report:

1. An accountant's report;
2. Assets held for investment;
3. Transactions between the plan and parties in interest (that is, persons who have certain relationships with the plan);
4. Loans or other obligations in default;
5. Leases in default;
6. Transactions in excess of 3 percent of plan assets;
7. Insurance information including sales commissions paid to insurance carriers; and
8. Actuarial information regarding the funding of the plan.

To obtain a copy of the full annual report, or any part thereof, write or call the office of (name), who is (state title; e.g.; the plan administrator), (business address and telephone number). The charge to cover copying costs will be ($) for the full annual report, or ($) per page for any part thereof.

You also have the right to receive from the plan administrator, on request and at no charge, a statement of the assets and liabilities of the plan and accompanying notes, or a statement of income and expenses of the plan and accompanying notes, or both. If you request a copy of the full annual report from the plan administrator, these two statements and accompanying notes will be included as part of that report. The charge to cover copying costs given above does not include a charge for the copying of these portions of the report because these portions are furnished without charge.

You also have the legally protected right to examine the annual report at the main office of the plan (address) and at the U.S. Department of Labor in Washington, D.C., or to obtain a copy from the U.S. Department of Labor upon payment of copying costs. Requests to the Department should be addressed to: Public Disclosure Room, N4677, Pension and Welfare Benefit Programs, Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20216.

(2) *Form for Summary Annual Report Relating to Welfare Plans.* This is a summary of the annual report of the (name of plan, EIN and type of welfare plan) for (period covered by this report). The annual report was filed on (date) with the Internal Revenue Service, as required under the Employee Retirement Income Security Act of 1974 (ERISA).

[*If any of the funds are used to purchase insurance contracts:*]

The plan has (a) contract(s) with (name of insurance carrier(s)) to pay (all, certain) (state type of) claims incurred under the terms of the plan. The total premiums paid for the plan year ending (date) was ($).

[*If applicable add:*]

Because it is a so-called "experience-rated" contract, the premium costs are affected by, among other things the number and size of claims under the policy. The total of all benefit claims paid under the policy during the plan year was ($).

[*If any funds of the plan are held in trust:*]

The value of plan assets held in trust, after subtracting liabilities of the plan, was ($) as of (the end of plan year), compared to ($) as of (the beginning of the plan year). During the plan year the trust experienced an (increase) (decrease) in its net assets of ($). This (increase) (decrease) included unrealized appreciation and depreciation in the value of plan assets.

During the plan year, the trust had total income of ($) including employer contributions of ($), employee contributions of ($), realized (gains) (losses) of ($) from the sale of assets, and earnings from investments of ($).

Plan expenses were ($). These expenses included ($) in administrative expenses, ($) in benefits paid to participants and beneficiaries, and ($) in other expenses.

You have the right to receive a copy of the full annual report, or any part thereof, on request. The items listed below are included in that report:

1. An accountant's report;
2. Assets held for investment;
3. Transactions between the plan and parties in interest (that is, persons who have certain relationships with the plan);
4. Loans or other obligations in default;
5. Leases in default;
6. Transactions in excess of 3 percent of plan assets; and
7. Insurance information including sales commissions paid to insurance carriers.

To obtain a copy of the full annual report, or any part thereof, write or call the office of (name), the plan administrator, (business address and telephone number). The charge to cover copying costs will be ($) for the full annual report, or ($) per page for any part thereof.

You also have the right to receive from the plan administrator, on request and at no charge, a statement of the assets and liabilities of the plan and accompanying notes, or a statement of income and expenses of the plan and accompanying notes, or both. If you request a copy of the full annual report from the plan administrator, these two statements and accompanying notes will be included as part of that report. The charge to cover copying costs given above does not include a charge for the copying of these portions of the report because these portions are furnished without charge.

You also have the legally protected right to examine the annual report at the main office of the plan (address) and at the U.S. Department of Labor in Washington, D.C. or to obtain a copy from the U.S. Depart-

ment of Labor upon payment of copying costs. Requests to the Department should be addressed to Public Disclosure Room, N4677, Pension and Welfare Benefit Programs, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20216.

(d) *Foreign languages.* In the case of either—

(1) A plan which covers fewer than 100 participants at the beginning of a plan year in which 25 percent or more of all plan participants are literate only in the same non-English language, or

(2) A plan which covers 100 or more participants in which 500 or more participants or 10 percent or more of all plan participants, whichever is less, are literate only in the same non-English language, the plan administrator for such plan shall provide these participants with an English-language summary annual report which prominently displays a notice, in the non-English language common to these participants, offering them assistance. The assistance provided need not involve written materials, but shall be given in the non-English language common to these participants. The notice offering assistance shall clearly set forth any procedures participants must follow to obtain such assistance.

(e) *Furnishing of additional documents to participants and beneficiaries.* A plan administrator shall promptly comply with any request by a participant or beneficiary for additional documents to the extent that the forms set forth in paragraph (c) of this section indicate that such requests will be honored. Communications from plan participants or beneficiaries which might reasonably be construed as requests for information which is required to be supplied without charge shall be so construed. Any charges assessed to cover the cost of furnishing copies of the full annual report, or any part thereof, shall be determined in accordance with 29 CFR 2520.104b-30. Such charges shall not include the cost of furnishing, either separately or as part of the full annual report, copies of statements of assets and liabilities and of income and expenses, and accompanying notes.

(f) *Exemptions.* Notwithstanding the provisions of this section, a summary annual report is not required to be furnished with respect to the following: (1) A totally unfunded welfare plan described in 29 CFR 2520.104-44(b)(1)(i); (2) a welfare plan which meets the requirements of 29 CFR 2520.104-20(b); (3) an apprenticeship plan which meets the requirements of 29 CFR 2520.104-22; (4) a pension plan for selected employees which meets the requirements of 29 CFR 2520.104-23; (5) a welfare plan for selected employees which meets the requirements of 29 CFR 2520.104-24; (6) a day care center referred to in 29 CFR 2520.104-25; (7) a dues financed welfare plan which meets the requirments of 29 CFR 2520.104-26; and (8) a dues financed pension plan which meets the requirements of 29 CFR 2520.104-27.

Signed at Washington, D.C., this 16th day of August 1978.

IAN D. LANOFF,
Administrator, Pension and Welfare Benefit Programs, Labor-Management Services Administration.

[FR Doc. 78-23674 Filed 8-21-78; 9:48 am]

[4310-05]

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[30 CFR PART 715]

SURFACE COAL MINING AND RECLAMATION OPERATIONS

Appendix—Alluvial Valley Floors Technical Guidelines

Notice of Public Hearing

AGENCY: Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior.

ACTION: Proposed policy and interpretation; notice of public hearing.

SUMMARY: The Surface Mining Control and Reclamation Act of 1977 (Public Law 95-87) establishes a comprehensive regulatory scheme for the preservation and protection of alluvial valley floors in the arid and semiarid areas of the United States west of the 100th meridian west longitude from the adverse effects of surface coal mining operations. The Office of Surface Mining Reclamation and Enforcement (OSM) is today publishing proposed guidance to assist both State regulatory authorities and OSM in the interpretation and application of section 515(b)(10) and 510(b)(5) of the act and 30 CFR 715.17(j) (42 FR 62687, December 13, 1977) to pending permit applications and mining and reclamation plans for surface coal mining operations which may be subject to those sections of the act and regulations. This guidance is proposed in order to promote uniformity of interpretation and application of the act and regulations relating to alluvial valley floors among regulatory authorities who share responsibility under the act, and to give fair notice to operators of the information which may be requested by regulatory authorities when a surface coal mining operation will or may affect the essential hydrologic functions, uses, or productivity or alluvial valley floors.

DATES: Comments or suggestions regarding the proposed policy and interpretation should be submitted on or before October 23, 1978. A public hearing regarding the proposal will be conducted on October 13, 1978, at 10 a.m. in the Auditorium (Room 269), Old Post Office Building, 1823 Stout Street, Denver, Colo.

ADDRESSES: Comments should be sent to the Regional Director, Office of Surface Mining Reclamation and Enforcement, Region V, 1823 Stout Street, Denver, Colo. 80202.

FOR FURTHER INFORMATION CONTACT:

John Hardaway, Office of Surface Mining Reclamation and Enforcement, Region V, 1823 Stout Street, Denver, Colo., 80202, 303-837-5511. Additional copies may be obtained from Mr. Hardaway.

SUPPLEMENTARY INFORMATION: While the inherent complexity of alluvial valley floor systems—the interrelationships of geologic, hydrologic, pedologic, and botanical characteristics—as well as regional and site specific diversity, make it difficult to develop absolute standards for identification and study, this paper does provide definitive interpretations of some of the issues that have arisen during implementation of the act. The proposed guidance is not a rule or a set of absolute requirements. It is the result of numerous requests for assistance in detailing criteria for alluvial valley floor identification and requirements for baseline study which would reveal the nature of essential hydrologic functions and their supporting characteristics. This guidance, though not regulatory in nature, represents OSM's interpretation of scientific and technical requirements which permit alluvial valley floor identification and study.

The primary author of this document is Jack Schmidt, Consultant to the Office of Surface Mining Reclamation and Enforcement, 1012 Billings Avenue, Helena, Mont., 59601, 404-442-0448. The proposed document was prepared under the guidance of a task force including representatives from the U.S. Geological Survey Water Resource, Geologic and Conservation Divisions; the Bureau of Land Management; the EPA; the Office of Surface Mining; and, the Office of the Solicitor. The proposed document was developed with the cooperation and assistance of representatives of the coal mining regulatory authorities in Colorado, Montana, New Mexico, North Dakota, Utah, and Wyoming, but represents only the proposed policy and interpretation of the Office of Surface

Mining Reclamation and Enforcement.

TONEY HEAD, Jr.,
Assistant Director
for Management and Budget.

DRAFT

TECHNICAL IDENTIFICATION AND STUDY OF ALLUVIAL VALLEY FLOORS

GUIDELINES

Office of Surface Mining

Department of the Interior

August 1, 1978

Revised August 15, 1978

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INTRODUCTION

Consideration by the Congress of the effect of surface coal mining on alluvial valley floors in western valleys was prompted by a statement in a report issued in 1974 by the National Acedemy of Sciences:

"In the planning of any proposed mining and rehabilitation it is essential to stipulate that alluvial valley floors and stream channels be preserved. The unconsolidated alluvial deposits are highly susceptible to erosion as evidenced by the erosional history of many western valleys which record several periods of trenching in the past several thousand years * * * Removal of alluvium from the thalweg of the valley not only lowers the water table but also destroys the protective vegetation cover by draining soil moisture. Rehabilitation of trenched valley floors would be a long and expensive process and in the interim these highly productive granting areas would be removed from use." (National Academy of Sciences, 1974, 44-45)

In considering alluvial valley floors, the Congress recognized the special role of such areas in maintaining agricultural activities and it ultimately defined alluvial valley floors and provided specifically for their protection. The role of alluvial valley floors in western agriculture was expressed as follows:

"Of special importance in the arid and semiarid coal mining areas are alluvial valley floors which are the productive lands that form the backbone of the agricultural and cattle ranching economy in these areas. For instance, in the Powder River Basin of eastern Montana and Wyoming, agricultural and ranching operations which form the basis of the existing economic system of the region, could not survive without hay production from the naturally subirrigated and flood irrigated meadows located on the alluvial valley floors." (House Rept. No. 95-218, p. 116; 1977)

Alluvial valley floors are of special concern under the United States Surface Mining Control and Reclamation Act of 1977 (Pub. L. 95-87). Under this law and adopted regulations (Department of the Interior, 1977), it is necessary to evaluate an area for the presence of alluvial valley floors, to study the alluvial valley floors identified, and then to evaluate a proposed mining and reclamation plan and its relation so the identified alluvial valley floors. (OSM Regulations, 30 CFR 715.17(j)).

This technical guidance paper includes guidelines for preliminary identification of alluvial valley floors (part I), guidelines for study of those areas preliminarily identified as alluvial valley floors in order that a final determination of alluvial valley floor status may be made (part II), and guidelines for detailed study of alluvial valley floors resulting in identification of "essential hydrologic functions" (§ 510(b)(10)(F) and associated supporting characterisitics (part III).

The identification, study, and evaluation procedures (covered in this technical guidance paper) and a possible subsequent procedure for application of Pub. L. 95-87 provisions is indicated in figure 1. Figure 1 shows that at least at the time following detailed study and identification of essential hydrologic functions, determinations must be made by the regulatory authority of (1) what constitutes preservation of the essential hydrologic functions, (2) what level of change constitutes "material damage" (Pub. L. 95-87, § 510(b)(5)(B)) to the water system supplying an alluvial valley floor, and (3) in what areas mining would "interrupt, discontinue, or preclude farming" on an alluvial valley floor (Pub. L. 95-87, § 510(b)(5)(A)).

Relevant sections of the law include:

(1) The statutory definition of alluvial valley floors—"alluvial valley floors" means the unconsolidated stream laid deposits holding streams where water availability is 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 by unconcentrated runoff or flope wash, together with tallus, other mass movement accumulation and windblown deposits. (Pub. L. 95.87, § 701(1)).

(2) Statutory provisions which apply to all alluvial valley floors which include—

General performance standards shall be applicable to all surface coal mining and reclamation operations and shall require the operation as a minimum to * * * minimize the disturbances to the prevailing hydrologic balance at the mine-site and in associated offsite areas and to the quality and quantity of water in surface and ground water systems both during and after surface coal mining operations and during reclamation by * * * preserving throughout the mining and reclamation process the essential hydrologic functions of alluvial valley floors in the arid and semiarid areas of the country. (Pub. L. 95-87, § 515(b)(10)(F)); and

No permit or revision application shall be approved unless the application affirmatively demonstrates and the regulatory authority finds in writing on the basis of the information set forth in the application or from information otherwise available which will be documented in the approval, and made availble to the applicant, that * * * the proposed surface coal mining operation, if located west of the one hundredth meridian west longitude, would * * * not materially damage the quantity or quality of water in surface or underground water systems that supply these valley floors in (A) of subsection (b)(5). (Pub. L. 95-87, § 510(b)(5)(B)).

(3) Statutory provisions applying to some alluvial valley floors—

No permit or revision application affirmatively demonstrates and the regulatory authority finds in writing on the basis of the information set forth in the application or from information otherwise available to the applicant that * * * the proposed surface coal mining operation, if located west of the one hundredth meridian west longitude, would not interrupt, discontinue, or preclude farming on alluvial valley floors that are irrigated or naturally subirrigated, but excluding undeveloped range lands which are not significant to farming on said alluvial valley floors and those lands as to which the regulatory authority finds that if the farming that will be interrupted, discontinued, or precluded is of such small acreage as to be of negligible impact on the farm's agricultural production. (Pub. L. 95-87, § 510(b)(5)(A)).

FIGURE 1

Diagram of a possible procedure for identifying and investigating the important characteristics of alluvial valley floors ("AVF's")

Reconnaissance evaluation of area for potential AVF

areas not AVF

Areas may be AVF

) PART I OF (THIS GUIDELINE)

Further study of probable AVF

Final determination of status of an area as an AVF

areas not AVF

Area is an AVF

) PART II OF (THIS GUIDELINE)

Detailed study of AVF and surrounding area resulting in identification of essential hydrologic functions and important supporting characteristics

) PART III OF (THIS GUIDELINE)

Determination of what constitutes preservation of the "essential hydrologic functions" of the AVF

If essential hydrologic functions cannot be preserved, mining plan not approved

Review and revision of mining plan to ensure preservation of "essential hydrologic functions"

Determination of what constitutes "material damage" to the AVF: determination of whether mining plan will result in "material damage" during or after mining.

If material damage unavoidable from entire mining plan, plan not approved

If "material damage" unavoidable from part of mining plan, plan revised; regulatory authority finds no "material damage" from mine plan

Determination of in what areas mining would "interrupt, discontinue, or preclude farming," excluding undeveloped rangeland not significant to farming and areas so small as to be of "negligible impact on the farm's agricultural production; applicable areas deleted from mining plan

Plan approved in reference to AVF issue; criteria established for monitoring effects of mining the AVF or mining near AVF during or after mining

Note: Determinations of "material damage" and whether mining would "interrupt, discontinue, or preclude farming" may be appropriate prior to completion of efforts required to identify the important supporting characteristics in certain site specific cases.

Section 515(b)(10)(F) applies to all areas of the arid and semiarid West meeting the criteria of the § 701(1) definition. Section 510(b)(5) applies to those alluvial valley floors west of the one hundredth meridian west longitude which not only meet criteria of water availability, but are or may be "farmed." Specifically excluded from the definition of farming are "undeveloped range lands which are not significant to farming on said alluvial valley floors and those lands * * * that if the farming that will be interrupted, discontinued, or precluded is of such small acreage as to be of negligible impact on the farm's agricultural production." (Pub. L. 95-87, § 510(b)(5)(A)).

Although the definition of alluvial valley floors establishes that the existence of a water supply sufficient for agricultural activities is a necessary characteristic of an alluvial valley floor, the Congress did not give a quantitative criteria by which the adequacy of this supply for agricultural activities should be evaluated. These guidelines, in part, are designed to overcome the lack of specificity in evaluating water availability. The guidelines are also designed to provide uniform criteria for identification of alluvial valley floors in all geographic areas. This guideline provides guidance which is not a mandatory requirement, and is intended for use by State regulatory authorities and operators to achieve uniform application of alluvial valley floor provisions contained in the statute (Pub. L. 95-87) and regulations. This paper will be used by OSM as a guideline in its own evaluation of alluvial valley floor questions. In every case, the applicant for a permit to mine should consult with the appropriate regulatory authority prior to initiating a study of potential or designated alluvial valley floors.

Regional and site specific diversity does not permit development of quantitative criteria for every important characteristic of alluvial valley floors. In many cases, it is likely that determinations and evaluations of alluvial valley floors will involve site-specific judgments by experienced personnel.

These guidelines involve examinatibn of areas which in many cases will be beyond the limits of the area proposed to be directly affected by mining and reclamation, i.e., "off site" areas. This analysis of off site areas is necessary to meet the requirements of § 510(b)(5) of the act which states that proposed surface coal mining operations cannot adversely affect most alluvial valley floors either directly (§ 510(b)(5)(A)) or indirectly (§ 510(b)(5)(B)). Thus alluvial valley floors within the area that may be affected by the proposed operations should be investigated. Some of this land may not be owned by the operator. The operator should endeavor to obtain access to these lands in order to complete specified studies. If access is not allowed by the landowner, the regulatory authority may try to assist the operator in obtaining access through discussions with landowners. If access is rejected after a good faith effort by the operator and regulatory authority, studies should be continued elsewhere within the designated study area, and estimates made of baseline conditions, and the effects on the restricted area should be predicted through the use and extrapolation of data collected nearby.

Each of the following parts includes specifications for data collection. Presentations of data collected by proposed operators are best when accompanied by interpretative sections which synthesize collected data. These reports should include discussions of the interrelationships among hydrologic, geologic, pedologic, vegetative, and land use data.

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PART I—GUIDELINE FOR PRELIMINARY IDENTIFICATION OF ALLUVIAL VALLEY FLOORS

Preliminary identification of alluvial valley floors is necessary

(1) In regional evaluations which identify potential coal mining areas and possible mining constraints, such as the development of regional coal leasing programs;

(2) In evaluation of specific potential coal lease tracts by either lessees or lessors;

(3) In evaluation of a proposed mining tract by a proposed operator or regulatory authority; and

(4) In development of premining environmental baseline studies.

These guidelines of part I are intended to permit preliminary identification in each of these cases. Identification can be made by qualified professionals in the earth and botanical sciences. Land use data, interpretation of infrared aerial photography, and reconnaissance field work are the basis of the preliminary identification procedure. Mapping of the proposed area of operation is generally adequate if completed at a scale no smaller than 1:6000 but larger scales (such as 1:4800) may be necessary to show sufficient detail of complex areas. Mapping of areas beyond the proposed permit area should provide sufficient detail and have sufficient accuracy to permit identification of important topographic features. Normally, maps at a scale of 1:25000 or larger (such as a standard USGS 1:24000 topographic quadrangle) will be necessary to be sufficiently accurate or detailed.

These guidelines for preliminary identification are structured in a step-by-step fashion (figure 2). Geomorphic features are first identified (part I.A). These features typically exist in and describe any potential alluvial valley floor area and they focus attention on stream-channel areas and their nearby environments. Following identification of geomorphic features, water availability factors are evaluated (part I.B). The presence of any one of these factors is used in determining which geomorphic valley floors should be identified for further study under provisions of Pub. L. 95-87.

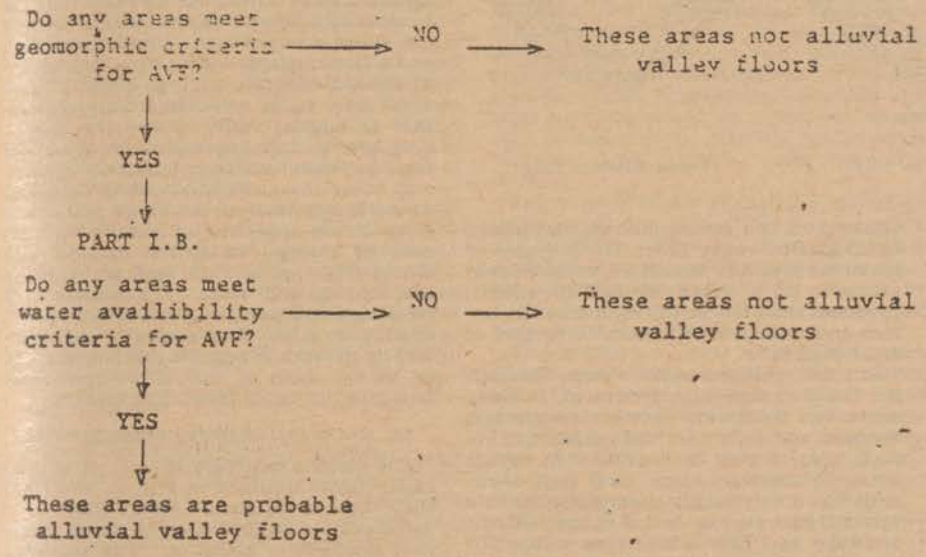
An underlying philosophy of these guidelines is that identification of alluvial valley floors first requires identification of hydrologic systems. Alluvial valley floors are portions of a drainage system which at some downstream location become sufficiently broad, contain suitable and sufficient soils, and begin to contain enough water in stream channels and unconsolidated valley fill material to provide sufficient water supplies for flood irrigation or subirrigation agricultural activities. The combination of these characteristics result in the special agricultural importance of alluvial valley floors. These guidelines are designed to identify an integrated geologic-hydrologic-biologic system which supplies water for observed agricultural uses or where water is available for such uses.

These guidelines describe acceptable procedures to be used by an applicant to examine the drainage basin within which the proposed operation will be located. Although an applicant's focus of concern is obviously on the proposed mine site, an understanding of the entire drainage basin in which the mine and possible alluvial valley floors are located is necessary to identify the extent to which the geologic-hydrologic-biologic system supports or may support agricultural use of valley floors. As a general rule, part I of these guidelines describes a reconnaissance examination of all lands within 2 miles of the proposed permit boundaries. A 2-mile area is justified by the occurrence of observable groundwater drawdown impacts 2 miles from an operating western strip coal mine subject to intensive studies (VanVoast, W. R., and R. Hedges, 1975). This guideline

recognizes that in specific cases the limits of actual impacts may occur closer or farther away than 2 miles. More precise estimates may be developed at any stage of these guidelines but usually require detailed aquifer testing and modeling which is not included until part III of this guidance. Site conditions and the nature of cumulative effects of many mines in one area may also affect the size of the area of concern, and in each case, the study area should be reviewed with the responsible regulatory authority prior to application of this guideline.

FIGURE 2

Diagram of procedure for preliminary identification of alluvial valley floors



I.A. GEOMORPHIC CHARACTERISTICS

Guideline Procedure: Map all active flood plains and terraces underlain by unconsolidated material found in the lower parts of topographic valleys, in which are found identifiable stream channels. In a plan view, these terraces, together with the active flood plain and channel, would normally form one contiguous unit, separated only by minor amounts of non-alluvial materials, such as bedrock outcrops or thin layers of eolian sand or silt. Identifiable stream channels are considered here as all drainage courses shown on a USGS 1:24000 topographic quadrangle, as well as any other perennial stream channels and other drainageways at least three feet in bankfull width and/or 0.5 feet in depth at bankfull stage.

This procedure should identify all stream laid deposits associated with an identified stream channel and exclude isolated higher terraces which cannot be construed to be a part of a "valley floor." Terrace deposits along major upland drainage divides should not be included in this identification process. The total areal extent of each deposit should be mapped, with the upslope contact drawn where the essentially flatlying stream laid deposits encounter the sloping deposits of the surrounding hillsides.

Discussion: The Act describes the geomorphic and stratigraphic features of alluvial valley floors as being "unconsolidated stream laid deposits holding streams • • • [and not including] upland areas which are generally overlain by a thin veneer of colluvial deposits composed chiefly of debris from sheet erosion, deposits by unconcentrated runoff or slope wash, together with talus, other mass movement accumulation and windblown deposits" (Pub. L. 95-87, section 701(1)). Alluvial valley floors thus are considered in this guidance to be nearstream environments whose general character is due primarily to the action of a stream and to the associated ground water regime.

Physiographic components. The physiographic components of an alluvial valley floor are the channel, active flood plain, and, in most cases, terraces. A *channel* is a defined water-course which carries streamflow at some times of a year. The channel bottom is usually unvegetated, unless streamflow is infrequent. Portions of some western valleys do not have channels in them, such as headwater areas, where runoff has been insufficient to cut a channel, and in valleys cut by former glacial outwash streams. Valleys without stream channels are not considered in this paper to be alluvial valley floors, since they are not "unconsolidated stream laid deposits *holding streams*" (emphasis added). The applicant may consider channels to be those drainage courses shown on a standard USGS 1:24000 topographic quadrangle or map of similar scale, as well as all other perennial stream channels and those ephemeral or intermittent drainageways at least three feet in width (at bankfull stage) and/or 0.5 foot in bankfull depth, unless equivalent or more detailed specifications are appropriate for the area. Bankfull width of braided streams is measured from the edge of each bank within which flow occurs.

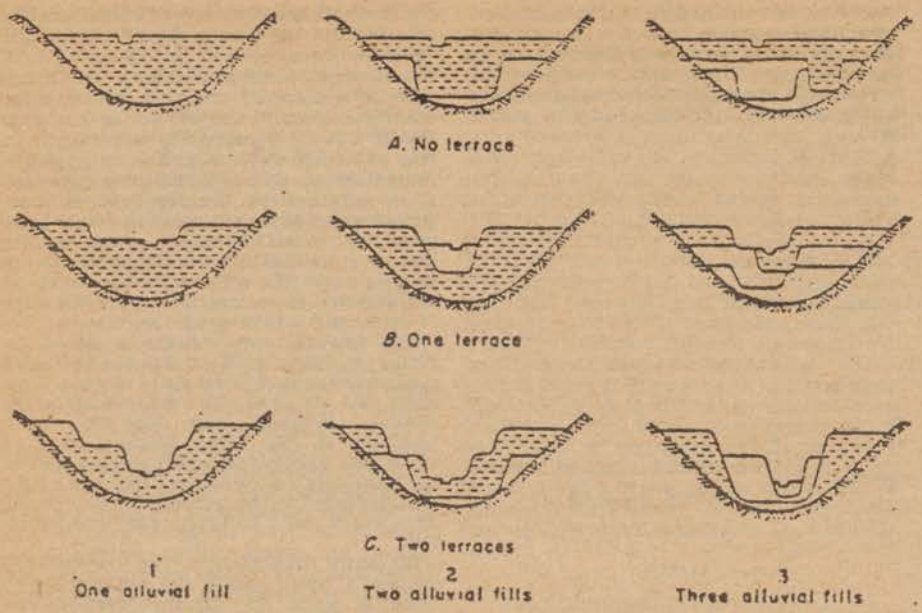
The channel size criteria is based on review of Apley (1976), a channel geometry study of ephemeral streams of eastern Wyoming, and review of other channel geometry studies (Hedman and Kastner, 1977; Lowham, H. W., 1976). Channel sizes of three feet in bankfull width and 0.5 foot in bankfull depth are smaller than any channels discussed in this guideline which might have water yields sufficient for flood irrigation.

An *active flood plain* is "the lowland that borders a river, usually dry but subject to flooding when the stream overflows its banks. It is that flat area constructed by the present river in the present climate" (Leopold, 1974). This definition specifically refers to the flatlying area inundated by frequent floods and does not refer to areas inundated by floods of long recurrence intervals, such as 100-year floods (Leopold, Wolman, Miller, 1964). For example, mapping by the USGS in Campbell County, Wyoming, estimates that flood plains are inundated at least once every 2-3 years (Fullerton and Kirkham, 1977). Flood plains are found along most channels, except in upland headwater areas.

A *terrace* is "a former flood plain no longer being actively constructed by the river in the present climate" (Leopold, 1974). Terraces may be found at many heights above the present channel, including hundreds of feet above large streams with a history of active erosion. Although at one time a terrace may have extended throughout the length of a stream, subsequent erosion may have eliminated much of a terrace level. This is typically the case where stream gradients steepen and where valleys narrow.

Since part I is intended to permit identification of areas clearly not alluvial valley floors and those areas which may be alluvial valley floors, it is prudent to examine all areas where detailed study might identify an alluvial valley floor. Since agricultural activities supplied by ditch system flood irrigation and subirrigation may occur on terraces higher than the lowest terrace, it is therefore necessary to investigate all terraces having potential for irrigation or subirrigation as potential alluvial valley floors during this part of the preliminary identification. Also, since rooting depth of a crop such as alfalfa has been known to reach extreme depths in excess of 50 feet (Robinson, 1958), it is prudent to include higher terraces where crops like alfalfa may be subirrigated by the alluvial ground water system.

The complex structure of terraces and valley fill is illustrated in idealized diagrams in figure 3. All terraces shown in these examples would meet the geomorphic characteristics criteria of this part.



(Leopold, L.B. and Miller, J.P., 1954 in Schumm, S.A., 1977, fig. 6-22)

Where terraces are not adjacent to other terraces, are separated by substantial bedrock outcrops, colluvial deposits, or residual material, and cannot be construed to lie in a valley floor, these areas generally are not to be included as alluvial valley floors, even if they are subirrigated or have the ability to be flood irrigated.

Relationship of surface landform (terrace) to underlying material (valley fill). To the geologist, the term terrace refers only to a surface landform. Terraces may be underlain by unconsolidated material or bedrock. Alluvial valley floors are areas where terraces are underlain by unconsolidated material. Collectively, this unconsolidated material is called a valley fill, and is mostly composed of unconsolidated or partly consolidated stream laid material, while along the margins of these areas deposits from surrounding hillslopes may be found. The distinction between alluvium (material deposited by streams either in the channel or on the floor plain) and colluvium (material deposited by hillslope processes such as slides, falls, soil creep, or sheetwash) is difficult to make in many western valleys. This guidance does not necessitate that a distinction between colluvium and alluvium in valley fills be made. Many detailed geomorphic studies conducted throughout the arid west have noted the gradational inter-fingering of alluvium and colluvium (Leopold, Emmett, Myrick, 1966). Most of the alluvial fills of the arid west are composed predominately of silt, often fine sandy silt, sometimes silty fine sand, and their alluvial origin is best determined by observing the surface landform which the material underlies (Leopold, Emmett, Myrick, 1966). Other characteristics of these deposits such as presence of gravel lenses and roundness and shape of these gravels, may be useful in identifying alluvial deposits but are more difficult to apply. Since terrace landforms are themselves indicative of a stream process origin, their occurrence is considered diagnostic of the geomorphic characteristics of an alluvial valley floor. The presence of materials typically associated with colluvial processes on a terrace created by alluvial processes shall not justify excluding the terrace and underlying fill from being part of an alluvial floor.

In some upstream areas, stream channels are found in flatlying of terraces. In these areas, the distinction between stream laid deposits and colluvium and sheetwash deposits may be even more difficult in terrace areas. In upstream areas, each type of deposit has a very gently sloping surface (0-4 percent) and may be found in the bottoms of swales and hills. These type valley fills should be included within the alluvial valley floor area if the areas adjacent to the stream course are essentially flat lying, and there is a discernible break-in-slope where flatlying areas contact hillslope deposits. If, however, valley fill deposits grade continuously upslope to surrounding hills, the stream side area alluvial valley floor.

Alluvial fans. An alluvial fan is "a low, outspread, relatively flat to gently sloping mass of loose rock material, shaped like an open fan or a segment of a cone, deposited by a stream at the place where it issues from a narrow mountain valley upon a plain or broad valley, or where a tributary stream is near or at its junction with the main stream, or wherever a constriction in a valley abruptly ceases or the gradient of the stream suddenly decreases" (Gary, et al, 1972). Review of various Congressional reports, as well as previous mapping efforts, indicates that the entire depositional surface of alluvial fans should not necessarily be designated as an alluvial valley floor (House Report 95-218; Congressional Record, May 20, 1977, pp. S8083-8096). Although alluvial fans clearly include unconsolidated debris deposited by streams, the deposits usually do not form valley landforms. Portions of a fan surface may be of various ages and usually do not relate to the existing stream which cuts through the fan. For purposes of alluvial valley floor determination, flood plains and terraces associated with an existing stream course should be identified as an alluvial valley floor, and these usually do not include the entire fan surface. Similarly, where streams cut across fans in a transverse direction, those areas with terrace landforms related to the existing stream are alluvial valley floors, but the former fan surfaces are not.

Upland areas. Statutory language specifically excludes "upland areas" from consideration as alluvial valley floors (§ 701(1)). Upland areas, although not specifically defined, are characterized as being "generally overlain by a thin veneer of colluvial deposits composed chiefly of debris from sheet erosion, deposits by unconcentrated runoff or slope wash, together with tales, other mass movement accumulation and windblown deposits."

Discussion in the Senate (Congressional Record, May 20, 1977) indicates that the upland area exclusion was intended to apply in situations where "alluvial plains" occupy the entire area between "a mountain range and a flood plain of a stream" (Congressional Record, May 20, 1977, p. S5085). These areas were to be excluded from consideration as alluvial valley floors. Specifically, they may include upper portions of alluvial fans, pediment surfaces, landslide deposits, and other unconsolidated debris deposited by such processes as mudflows and debris flows. Areas underlain by bedrock and covered by residual weathered material and debris deposited by sheetwash and rillwash are also upland areas. The existence of small, isolated patches of colluvium or bedrock in a valley floor generally characterized by streamlaid deposits was not intended to be the basis of excluding those areas from alluvial valley floor consideration.

I.B. WATER AVAILABILITY CHARACTERISTICS

The water availability criteria of alluvial valley floors outlined in Pub. L. 95-87 are that those areas should have "water * * * sufficient for subirrigation or flood irrigation agricultural activities." The following steps outline a procedure for establishing water availability based on the evidence of agriculutral land use, vegetative growth, and on water yield estimates and data. During the period of detailed study outlined in part II, areas identified in part I would be examined in greater detail in order to provide a basis for a final determination as to the presence of an alluvial valley floor.

The following steps would be applied to all areas which meet the geomorphic criteria of part I.A. Areas which do not meet the part I.A. criteria are excluded from further alluvial valley floor consideration, regardless of other characteristics of the area. Areas which meet the part I.A. criteria but do not meet the part I.B. criteria are similarly excluded from further alluvial valley floor consideration. However, for an area to meet part I.B. criteria, it need only meet the criteria of one subpart. Thus, an area meets part I criteria if it falls under part I.A. and either subpart I.B.1, I.B.2, I.B.3, or I.B.4.

Guideline procedure:

I.B.1. *Flood irrigation or special management activities. Map the perimeter of all areas identified in part I.A. which are flood irrigated, where old flood irrigation structures, no longer in use, once supplied water to the valley floor, and all areas that were historically flood irrigated. Also map all valley floor areas where agricultural activities involve special management of the valley floor area, including all cropped or harvested lands.*

Discussion: Alluvial valley floors include those valley floors where "water availability is sufficient for * * * flood irrigation agricultural activities" (Pub. L. 95-87, section 701(1)). Flood irrigation is "irrigation through natural overflow or temporary diversion of high flows in which the entire surface of the soil is covered by a sheet of water" (Office of Surface Mining regs., 30 CFR 710.5). Characteristically, these systems involve diversion ditches, water spreading systems such as contour dikes, contour ditches, or graded borders, and may include pipe drains. On small streams, particularly in the northern Great Plains, channels are dammed and floodflows thereby diverted to a water spreading system. Flood irrigation may also include diversion from small reservoirs constructed to retain floodflows of ephemeral or intermittent streams. Pumping from streams, reservoirs, or ground water should not be considered to meet this criteria, except in the special case where pumping simulates direct diversion and water is pumped immediately into an irrigation canal. Irrigation water must be supplied by water diverted from the stream channel associated with the irrigable land in question, and not from another stream in another drainage basin.

Areas where agricultural activites involve special management of the valley floor area include valley floor pastureland specifically fenced to manage grazing of those areas, valley floor areas with water supply systems specifically designed to encourage use of valley floor vegetation, and areas cultivated or harvested for alfalfa, native or introduced grasses, or other crops which probably use water from the valley floor hydrologic system.

Guideline procedure:

I.B.2. *Extrapolation of irrigable land using surficial geologic characteristics. Extending downstream to the confluence with the next largest stream and upstream one-half mile from each area identified in subpart I.B.1, map any area identified in part I.A. which is a similar height above the channel as those areas identified in subpart I.B.1.*

Discussion: The definition of alluvial valley floors in section 701(1) of Pub. L. 95-87 concerns areas where water availability is sufficient for floor irrigation or subirrigation agricultural activities, and does not refer only to those areas where agricultural activities currently occur, or have in the past occurred. Current or past land use, in conjunction with surficial geologic characteristics, is one basis by which to establish what other areas have water availability sufficient for agricultural activities. Since surface water flows usually increase in the downstream direction, identification of terraces of similar heights above the channel as those already irrigated or otherwise used is a reasonable process to identify additional irrigable lands. Since floodflows generally are similar through small reaches of streams, it is also reasonable to extend the identification process one-half mile upstream from the areas of agricultural activity.

Guideline procedure:

I.B.3. *Flood irrigation capability. Map all areas that have the capability of being flood irrigated.*

Areas that have the capability of being flood irrigated are those areas where:

(1) A diversion ditch can be constructed at some point along a channel which will lead water from the same drainage basin onto the areas in question, by gravity flow through structures such as ditches, canals, or pipes; and

(2) There are 2 acre-feet of water available per acre of land which can feasibly be flood- or ditch-irrigated sometime during the period May 1 to September 15 for more than one-third of most years. The 2 acre-feet quantity may be adjusted to reflect regional differences in evapotranspiration rates and specific crop needs of the area in question. Feasibility shall not be construed to include the legal right to use the water.

Discussion: The assessment of water availability is tied both to the quantity of water available and the point of its diversion. Obviously, the further upstream water is diverted, the higher are terraces which can be irrigated. However, less water is generally available from upstream sites. In performing this analysis, it should be reasonably expected that water from a ditch would be diverted to the first available sites for flood irrigation. Thus, hypothetical diversion systems must be shown to supply water not only to the area in question, but to other upstream areas irrigable from the same ditch.

Estimates of water availability should be based on gaging station data, if available, and regional studies based on streamflow analyses, drainage basin, or channel geometry characteristics. Estimates should be made of annual and monthly streamflow for purposes of this analysis.

The question of legal right to use water should not be considered in this analysis since the intent is to identify those areas where flood irrigationwater is hydrologically feasible. Water rights may be transferred over time and water that is presently unavailable for irrigation of specific plots of land may become available in the future.

This analysis is intended to hypothetically evaluate all water available in a stream at its point of diversion. It may be appropriate that a given amount of water remain in the stream for other uses. These other uses should especially be considered on major streams where fish and wildlife resources would be lost if excessive diversions occurred.

Guideline procedure:

I.B.4. *Vegetation characteristics which may indicate subirrigation or flood inundation. Based on a reconnaissance vegetation survey and use of aerial photography, map all other areas where agriculturally useful vegetation is dependent on moisture supplied by ground water or frequent floodflows.*

Discussion: This step attempts to identify all other areas where agriculturally useful valley floor vegetation is dependent on subirrigation or flood inundation. An experienced botanist or range scientist should use the best available aerial photography and reconnaissance fieldwork to identify those valley floor areas which differ significantly from the surrounding uplands. Criteria to be used in differentiating range communities should include:

(a) Significant differences in the species or species groups that are ecological dominants in the plant community;

(b) Significant differences in the proportion of species or species groups that are the ecological dominants of the plant community;

(c) Significant differences in the total potential (ungrazed) annual production of the plant community.

In addition, indicator species which may reflect subirrigation or excess moisture from frequent flooding should exist in the valley floor vegetation community. Valley floor areas, however, that have been heavily grazed may not have identifiable indicator species, and in these cases, SCS range site criteria should be used along with observations of vegetation in similar physiographic areas in better range condition. In order to warrant further study under part II, there should be an agricultural use (grazing or cropping) for the species and communities identified in this step. For example, bog and marsh areas in the glaciated portion of the northern Great Plains, which serve no useful agricultural function, would not be identified as possible alluvial valley floors since their dominant vegetation is sedges and reeds, which are not useful for grazing or cropping. In each State of the arid and semiarid West, reference should be made to the SCS lists of potential vegetation community for flood inundated and subirrigated range sites in the process of identifying indicator species of flood inundation and subirrigation.

Where adequate aerial photography is unavailable to permit mapping, color infrared photos should be taken toward the end of the growing season, especially at the time when upland growth has gone dormant, but not after the first killing frost on the valley floor. Photos should permit accurate mapping at a scale of 1:25,000 or larger.

Part II—Guidelines for Further Study and Final Determination of the Presence of an Alluvial Valley Floor

Following preliminary identification of alluvial valley floors (part I), further study by an applicant is necessary in order to facilitate final decisions concerning the presence of alluvial valley floors. This part of the guilelines outlines a procedure for further study of potential alluvial valley floor areas and suggests some criteria that may be useful to indicate the presence or absence of alluvial valley floors.

Areas to be studied for final determination are those areas identified as probable alluvial valley floors under the guidelines for preliminary identification (part I). Areas containing alluvial valley floors should be mapped upstream at least to the point where the total width of the valley floor (including the areas on either side of the channel) is less than 30 feet in width. Isolated areas upstream of this point should generally be larger than 10 acres in order to be identified as alluvial valley floors. These size limitations are considered the lower limit of useful agricultural advantage of alluvial valley floors and reflect the interpretation that alluvial valley floors are not discontinuous and small patches of irrigated or subirrigated lands. However, additional studies and possible designation of smaller tracts of land is possible if the smaller tracts may be agriculturally important. As a general rule, part II guidelines would best be applied to any probable alluvial valley floors within 2 miles of the boundaries of a proposed area of operations, unless obvious hydrologic or geologic features dictate otherwise.

Under the procedures of this guideline, alluvial valley floors should contain the geomorphic features of part II.A. and some

part of the water availability features of part II.B. All water availability characteristics would be examined at some stage of the investigation. For example, if an area meets part II.B.1. criteria, the alluvial valley floor area should also be examined for the presence of the other water availability characteristics described in parts II.B.2. and II.B.3. It may be possible to defer these other investigations until part III of the guidance.

II.A. GEOMORPHIC CRITERIA

Guideline procedure: The area should be within the topographic confines of a valley and be underlain by unconsolidated deposits whose surface landform is characteristic of fluvial deposition (i.e., channels, flood plains, and terraces). Terraces overlain by colluvial material, as identified by lithologic logs, pits, or wells, should be included as alluvial valley floors if they meet any water availability criteria of part II.B.

Discussion: This information would have already been collected of part I.A. of the guidelines were followed. At this later stage, lithologic logs, developed from coring or geophysical logging should be compiled, if available to the applicant. Lithologic logs of all observation wells and backhoe pits described in section II.B.2 should also be compiled.

II.B. WATER AVAILABILITY CRITERIA

Guideline procedure:

II.B.1 *Flood irrigation. The area is presently or has during 5 of the preceding 20 years been flood irrigated for production of harvestable crops or grazing forage.*

Discussion: The existence of present or past flood irrigation is direct evidence that the area is an alluvial valley floor, unless flood irrigation was attempted and later discontinued because of unacceptable water quantity, quality, and/or soil conditions. If the latter case exists, it must be documented. Data for identification of these areas may be obtained from:

(a) Land use mapping based on present air photos, and conversations with landowners (work will have been completed during the preliminary identification phase, part I.B.1).

(b) Conversations with resource managers and field personnel familiar with past management problems.

Guideline procedure:

II.B.2 *Subirrigation. The area is naturally subirrigated and constitutes an agriculturally useful natural vegetation community different from those of surrounding uplands; or the area is naturally subirrigated and is cropped, otherwise mechanically harvested, or subject to special management as described in part I.B.1.*

Discussion: On the basis of water level and soil moisture measurements, one or more of the following characteristics of subirrigation should be observable in a subirrigated area:

(1) Diurnal fluctuation of the water table, due to the difference in night and daytime evaporanspiration rates;

(2) Increasing soil moisture from a portion of the rooting zone down to the water table, due to capillary action;

(3) Mottling of the soils in the root zones;

(4) Observation of an important part of the root zone within the capillary fringe or water table of an alluvial aquifer;

(5) Stream flow and ground water monitoring indicating an increase in flow immediately after the first killing frost on the valley floor.

Water level measurements should document levels during the growing season.

Guideline Procedure: Subirrigation means irrigation of plants where water is delivered to the root systems from below, through semisaturated or saturated zones of unconsolidated deposits. The vegetation is thus able to continue growth despite extended periods of low precipitation. Subirrigation should be related to the ground water system of the valley floor in question and not be artificially maintained by reservoirs or irrigation ditches.

Subirrigation could be substantiated by demonstrating any of the characteristics listed above. Robinson (1958) has demonstrated how diurnal fluctuations of water table level result from different evapotranspiration rates of phreatophytic plants using alluvial ground waters. Water level measurements from observation wells and continuous monitoring would substantiate such fluctuations. An increase in soil moisture with increasing depth down to a saturated zone is direct evidence that capillary action is capable of carrying water upward from a water table. Soil moisture measurements, such as with a neutron probe access tube, taken in conjunction with regular measurement of water table levels would indicate these gradients. Mottling of soils in the root zone is indicative of ground water fluctuations if water levels have existed in the root zone. Direct observation of rooting depths in backhoe pits and their relation to the water table and/or capillary fringe could document subirrigation at the time of observation. Increases in stream flow and ground water levels after a killing frost may indicate that water had been used by the vegetation prior to the frost and thus be an indicator of subirrigation. If investigation showed no subsurface water present, the area would be assumed to have no subirrigated areas and the detailed studies would likely not be necessary.

In order to document the exitence of subirrigation, the measurements of water levels, soil moisture conditions, stream flow and rooting depths should be completed for those areas whose vegetation or land use has indicated possible subirrigation. Identification of these areas was addressed in parts I.B.1 or I.B.4 of this paper.

Depending on site specific conditions and requirements, the applicant should establish observation wells along transects crossing the potential alluvial valley floor area in order to monitor the height of the water table of the alluvial aquifer and fluctuations during various time periods. Generally at least three well sites should be established along each transect. Wells should be completed to the base of the alluvial aquifer, and the casing should be slotted to insure reception of water from the entire saturated thickness. If more than one aquifer is found in the valley fill, it would be appropriate to complete separate wells to separate aquifers, since each well should receive water from only one aquifer. Transect locations should be located so as to describe the longitudinal stream and valley profile, as well as in representative portions of the valley. Detailed lithologic logs should be obtained from well cores or backhoe pits.

Water level in those wells identified by the regulatory authority should be continuously recorded. Water levels in all other wells should be measured monthly and all measurements should be to an accuracy ± 0.01 foot. The accuracy is necessary to establish subirrigation relationships. Water level measurements should be taken throughout the growing season in order to establish the relationship between vegetative growth and groundwater availability.

Measurements of soil moisture within the rooting zone of different soils in different topographic locations and vegetative communities should be made in order to assess water changes with depth. Measurements should be made near observation wells in order to correlate soil moisture with ground water levels. Stream flow measurements should be taken at a point so as to record flow increases after vegetation on the valley floor has ceased growing

Guidance Procedure:

II.B. 3. *Flood irrigation capability.*

The area is capable of being flood irrigated.

Discussion: The area is capable of being flood irrigated if:

(1) A diversion ditch can be constructed at some point along a channel which will lead water from the same drainage basin onto areas identified in I.A., by gravity flow through structures such as ditches, canals, or pipes; and

(2) There are two acre-feet (unless otherwise required) of water available per acre of land to be irrigated sometime during the period May 1 to September 15 for more than one-third of all years; and

(3) The quality of surface waters, and the characteristics of the soil to be irrigated are such that the water delivered to the soil will not degrade the quality of the soil such that long-term irrigated or dryland agricultural use would be threatened.

Discussion: The evaluation of water quantity will have been completed under part I.B. 3, guidelines for preliminary identification of alluvial valley floors.

Analysis of stream flow quality and soil characteristics is necessary to place limits on the irrigability of the lands in question. For example, SAR (sodium absorption ratio) values or salinity for either soils or water might prohibit successful irrigation. Also, evaluation should be made of any historical land use data concerning poor irrigation success. This paper assumes, based on discussions with State regulatory authorities, that if significant soil degradation would take palce after twenty years of hypothetical irrigation, then flood irrigation would not be considered possible.

Stream flow at at least one site in the area of the potential alluvial valley floor, and stream flow at other locations as appropriate to identify changes should be analyzed for water quality characteristics. Sampling should be conducted in accordance with accepted standards and for one full year. Sampling of stream flow should be conducted for one full year. In the case of ephemeral streams, however, where flow is of short duration, samples collected from snowmelt runoff and during runoff resulting from major rainstorm events may be considered sufficient for characterization of each stream's water quality. Analyses of samples should be conducted consistent with the guidelines for water quality analyses used in the state where the mine is proposed. Analyses should focus on constituents which might affect irrigability.

A soil survey of adequate detail is needed to establish the effect of irrigation on soils and to assess capabilities of the soils as plant growth mediums. The soil survey should be conducted in accordance with

standards of the National Cooperative Soil Survey (U.S.D.A. Handbooks 436 and 18). The survey should cover the alluvial valley for under consideration. The soils should be described and mapped to the phases of series or series variants. Common soil series names or numbers should be correlated to the described soils. Soil mapping units may consist of more than one component where delineation to individual phases of series or series variants is impractical or unnecessary to meet the objectives of the survey. Phases of series or series variants that are greater than 2.0 acres should be delineated when such distinction is necessary. When soil mapping units consist of more than one component, the relative percentage of each component should be adjusted to represent the affected lands. The soil inventory map submitted in the application should be on a single contour map or aerial photograph (scale 1:6,000 or larger).

Map unit descriptions which are consistent with the National Cooperative Soil Survey should be included in the application. For each series phase or series variant of a soil unit occurring on affected lands, a profile typical of the soil within the permit area should be described. The location of the described profile should be marked in the field and shown on the soil inventory map. Percent of coarse fragments by volume, amount and depth of roots, relative amount of carbonates, and evidence of a water table, should be noted in the description of each series phase or series variant. The range in characteristics of a soil over the affected area should be described if significantly different from the described typical profile.

Soils should be described for their dryland and irrigated capability. Detailed chemical and physical analyses or soils, based on the guidelines for the state in which mining is proposed, should be conducted for all soil types. Water holding properties of soils should be documented through bulk density, texture, and percent organic matter tests conducted on selected representative soil horizons within the root zones.

Part III—Guideline for Detailed Study of Designated Alluvial Valley Floors to Determine Important Characteristics

Following final determination of alluvial valley floor status, detailed study is necessary to identify those important characteristics which support the essential hydrologic functions of a particular alluvial valley floor with a sufficient degree of certainty. Part III identifies more detailed studies that may be necessary to develop a reclamation plan that adequately addresses the performance standards of section 510(b)(10(G) of the Act. Detailed investigations might focus on leaky aquifer conditions, prezometric surfaces, perched water tables and zones of high moisture content, discharge and recharge of alluvial and bedrock aquifers, natural changes in surface flows, and vegetation surveys. Detailed study is generally necessary for alluvial valley floors lying within the proposed permit area and for alluvial valley floors which receive water from the mined and reclaimed areas.

The area for detailed study should be determined as part of a multiphase program designed to project any surface and subsurface effects of mining. Sufficient aquifer pump tests to permit estimation of drawdown effects in all affected aquifers should be performed to establish the area of potential influence on ground waters, and the area for further ground water study. It is recommended that two or more pump tests be performed in each hydrologically distinct area to be mined and in any adjacent alluvial valley floor.

The initial hydrologic and geomorphic study described in part II will generally identify the area of surface water influence. These investigations, may, in specific cases, be insufficient to determine the effects of proposed mining on alluvial valley floors in proximity to the proposed area of operations and more study of flow and quality, often of longer duration, may be necessary, in order for the regulatory authority to make a scientifically reliable decision.

As a general rule, the following criteria will be considered to determine the boundaries of the area of detailed study:

Case A. Where part of an alluvial valley floor is within the proposed area of operations, the study area may consist of:

(1) That part of the alluvial valley floor within the proposed area of operations;

(2) Any lands within an area two miles in radius about the boundaries of the area described in (A)(1); and

(3) Any other lands within the proposed area of operations.

Case B. Where part of an alluvial valley floor is within two miles of the boundary of the proposed area of operations, the study area may consist of:

(1) That part of the alluvial valley floor within two miles of the boundary of the proposed area of operations;

(2) Any lands within an area two miles in radius about the boundaries of the area described in (B)(1); and

(3) Any other lands within the proposed area of operations designated by the regulatory authority.

These guidelines should be altered to the degree justified by analysis of the hydrologic, hydrogeologic, topographic and land use data collected during all parts of the study. Discussions should be held with the regulatory authority prior to initiating and prior to completing these studies.

Study requirements differ in scope depending on whether an area is designated an alluvial valley floor because of flood irrigation characteristics (subparts II.B.1. and II.B.3), subirrigation characteristics (subpart II.B.2.), or both. Table 1 outlines study requirements as a function of the characteristics which lead to an alluvial valley floor designation. In making submittals of these data, accompanying interpretative tests are of great assistance.

Table 1—*Detailed study guideline outline*

	Study prior to final determination (parts I, II)	Study after final determination based on flood irrigation characteristics (no subirrigation)	Study after final determination based on subirrigation characteristics (no flood irrigation)	Study after final determination based on subirrigation and local irrigation characteristics
III.A. *Surface Hydrologic Data Specifications:*				
III.A.1 Streamflow records	X	X	.....	X
III.A.2 Streamflow analyses	X	X	.....	X
III.A.3 Estimates of runoff, tributary flow, and sediment yield from proposed area of operations	.....	X	.....	X
III.A.4 Surface water quality analyses	X	X	.....	X
III.B. *Geohydrologic Data Specifications:*				
III.B.1 Observation well establishment (bedrock) and water level measurements	.....	.....	X	X
III.B.2 Groundwater contour maps	.....	.....	X	X
III.B.3 Aquifer testing	.....	.....	X	X
III.B.4 Well and spring inventory	.....	.....	X	X
III.B.5 Groundwater quality analyses	.....	.....	X	X
III.B.6. Observation well establishment (alluvium), water level measurement	X	.....	X	X
III.C. *Geologic Data Specifications:*				
III.C.1 Geologic, geologic structure, surficial geological maps	X	X	X	X
III.C.2 Geologic cross-sections	.....	X	X	X
III.C.3 Overburden analyses	.....	.....	X	X
III.C.4 Field geomorphic surveys and geomorphic study	.....	X	.....	X
III.C.5 Lithologic logs of any previous drilling activity in alluvial valley floor	X	.....	.....	
III.D. *Soils Data Specifications:*				
A Soil Survey (scale 1:6000)	X	X	X	X
B Chemical and physical analyses	X	X	X	X
C Soil moisture	X	.....	.....	
III.E. *Vegetation Data Specifications:*				
III.A Vegetation inventory	X	X	X	X
III.F. *Land Use Data Specifications:*	.....	X	X	X
III.F.1 Crop yields	.....	X	X	X
III.F.2 Current uses of land map	X	X	X	X

III.A. Surface Hydrologic Data Specifications

III.A.1. *Stream flow gaging and records.* At least one continuous discharge measurement site should be established in the channel of each affected alluvial valley floor. Other gaging station sites may be required to ascertain recharge areas, discharge areas,

runoff and changes in water quality. Where flumes are used for gaging purposes, crest stage gages should be located upstream of the flumes so that major flows, which might wash out the flume, can be estimated. In northern areas where low temperatures would necessitate heat sources during winter for proper function of gaging stations, it may be permissible to allow stations on intermittent or ephemeral streams to be non-operational for the coldest period of the winter months. In some cases, data from adjacent stream reaches where stations already exist may be substituted for this data. Stream flow records for a one-year period, as well as rating curves used to relate stage to discharge, should be prepared.

III.A.2. *Stream flow analyses.* Where nearby gaging station records are sufficiently long and are applicable to the initially designated alluvial valley floor, flood frequency and low flow analyses should be undertaken. Where records are not available or adequate, flood flow estimates should be made for the reach of alluvial valley floor in question. Using this data, the area inundated by selected recurrence floods (up to 100-year) should be identified. Estimates of average annual and average monthly stream flow will have been completed under part I.B.3 in the evaluation of water availability for flood irrigation.

III.A.3. *Estimates of runoff and tributary flow contribution.* Estimates should be made of the runoff contribution and sediment yield from the proposed area of operations to the alluvial valley floor. Estimates should be made for runoff and sediment yield from hillsides and flow and sediment transport in tributary channels to the alluvial valley floor. In the case of estimates of overland flow and sediment yield, a soil survey and soil characteristics such as infiltration rate; vegetation characteristics, such as plant cover; and topographic characteristics, such as slope steepness, should be evaluated in relationship to expected precipitation events of various recurrence intervals. Wherever possible, actual erosion rates and sediment delivery ratios should be measured. The use of rainfall simulators and ring infiltrometers may be helpful in this effort. In the case of estimates of flow from tributary channels, channel and drainage basis characteristics and regional flow estimation techniques based on similar basin and climate characteristics should be used to estimate average annual and peak flow contributions to the alluvial valley floor.

Determination of runoff characteristics may require establishment of gaging stations, or crest stage gages on any major tributaries in order to describe the surface hydrology. Estimates of sediment transport in tributary channels may be accomplished by suspended and bedload sediment sampling, and establishment of scour chains and channel surveys.

III.A.4. *Other data specifications.* Surface water quality data collected during parts I and II of this paper may have to be increased during the more detailed study (part III) to include water quality sampling for a longer period and to include other sampling sites if extreme variability on longer term trends are suspected.

III.B. GEOHYDROLOGIC DATA SPECIFICATIONS

III.B.1. *Observation well establishment (bedrock) and water level measurement.* Observation wells should be established in the various bedrock aquifers which likely discharge to or are recharged from the alluvial valley floor. Individual observation wells should be completed into separate aquifers. Specific location of observation wells will be a function of site geology, and should be located in concert with a regional hydrologic program in order to facilitate the necessary analysis of accumulative hydrologic impacts. The location of wells should permit identification of flow patterns, direction of vertical movement, extent of interaquifer leakage, and relationship of bedrock and alluvial aquifer systems. Detailed lithologic logs of each well site should be obtained by either coring or geophysical logging. Water level should be measured continuously on one well in each aquifer and monthly in other wells. Measurements should be to an accuracy of 0.01 foot in order to identify any influence of vegetation, barometric pressure or recharge on the depth to water within the root zone or in areas supplying alluvial valley floors.

III.B.2. *Groundwater contour maps.* Contour maps (scale 1:6000 or larger for proposed area of operation and scale 1:25,000 or larger for the entire affected area) of water table and/or potentiometric surface water in each bedrock aquifer which subcrops or underlies the valley fill and which will be disturbed by mining should be prepared. Topographic base maps should be used and their accuracy must be to within 1.5 feet horizontally and 3 feet vertically.

III.B.3. *Aquifer testing.* Tests should be conducted on observation wells completed into each aquifer to determine hydraulic conductivity, transmissivity, storage coefficients and other relevant aquifer characteristics. Aquifer test methods and the number of tests should be based on sound hydrologic principles.

III.B.4. *Well and spring inventory.* Inventory all wells and springs in the alluvial valley floor for a distance five miles downstream of the boundary of the proposed area of operations. Areas outside of alluvial valleys need not be inventoried. Data should be presented in tabular form and locations shown on a topographic map (scale 1:25,000 or larger). The following information should be collected if obtainable: location, indicated condition of well, land surface elevation, well depth, aquifer source(s), pumping water level, discharge and drawdown during pumping, length of pumping test, discharge from springs, and any available water quality data. Investigation should include monitoring of spring discharges on a weekly basis for a period of not less than one month.

III.B.5. *Ground water quality analyses.* Water quality analyses should be completed for each existing well or spring whose source of water is an aquifer of an alluvial valley floor identified within the area of the well and spring inventory. Water quality analyses should also be completed for each aquifer for which observation wells have been completed. Samples should be repeated six months after the first samples are collected. As with all ground water tests, sampling should be immediately preceded, if reasonably possible, by continuous pumping of not less than three times the volume of water present in the well. Costituents to be sampled should conform to sampling guidelines and analytical quality controls connected with State and Federal requirements.

III.B.6. *Other data specifications.* Observation wells and backhoe pits will have been developed into the alluvial aquifer. Water level measurements will have been taken on these wells and should be continued during the detailed study period.

III.C. GEOLOGIC DATA SPECIFICATIONS

III.C.1. *Geologic, geologic structure, surficial geologic maps.* Geologic, geologic structure, and surficial geologic maps (scale 1:25,000 and 1:6000) for the study area should be prepared. Data for these maps should be based on field mapping, drill hole data, and other geologic data. The geologic map should show each distinguishable and mappable lithologic unit, faults, and prominent fracture zone. The geologic structure map should show structure contours on each coal bed proposed for mining. The surficial geologic map should distinguish, for example, between flood plain alluvium, terrace alluvium, alluvial fan deposits, lake and pond sediments, landslide deposits, and residual deposits.

III.C.2. *Geologic cross-sections.* Detailed geologic cross-sections (scale 1:6000) of alluvial valley floors within the study area, based on detailed lithologic logs, showing significant changes in subsurface lithology within the alluvial fill as well as in underlying bedrock units. Cross-sections should be developed along each transect and longitudinally along the valley axis. Transect cross-sections should extend horizontally one mile into the surrounding bedrock areas and to a depth showing all bedrock units proposed for mining.

III.C.3. *Overburden sampling and analyses.* Detailed chemical and physical analyses characterizing all overburden material scheduled to be disturbed within the proposed permit area should be completed. These data are necessary to project the effect of mining and reclamation on ground water quality. These data should be correlated to the geologic maps and cross-sections and lithologic logs. Subsurface sampling intervals should not be greater than ten feet and need not be less than two feet. Sampling intensity should be determined by the degree of variability of the stratigraphy and lithology at the site should be compatible with any requirements developed by the State within which mining is proposed.

III.C.4. *Field geomogrphic surveys and geomorphic study.* Field surveys should be made of the longitudinal profile of the thalweg, flood plain, and one terrace surface of the alluvial valley floor, for the entire length of valley within the proposed area of operations. For each longitudinal survey, indicate depth of bedrock along the profile, and variations in depth. Survey ground surface elevation at several cross-sections across the alluvial valley floor, with cross-sections extending entirely across terrace surfaces, to upland slopes on each side of the valley, and determine depth to bedrock along the cross-section. Cross-sections should be located with sufficient frequency to give the representative geologic (and hydrologic) information and should include areas near observation well transects. Representative bed and bank material samples should be collected at each cross-section site, and mechanically analyzed. All geomorphic data should be reported in a format consistent with that used for Vigial Network sites (Emmett, W. W. and R. F. Hadley, 1968), and should be located so that cross-sections can be resurveyed at later times. These data are of use in channel restoration and in monitoring channel changes. Cross-

section and longitudinal profile data should be reported at scales sufficient to show valley physiographic details.

Based on the best available geomorphic, geologic, soils, and other relevant information, a description of the geomorphic history of the valley floor in question should be prepared. Particular attention should be paid to erosional or depositional trends identified in the valley system.

III.C.5. *Other data specifications.* Lithologic logs of any drilling activity of relevance to these studies will have been submitted under part II.

III.D. SOILS DATA SPECIFICATIONS

Soil survey, chemical, and physical analysis of soil types, and soil moisture data will have been collected during part II studies. Soil moisture studies should be expanded to quantitatively assess soil moisture characteristics of the alluvial valley floor.

III.E. VEGETATION DATA SPECIFICTIONS

A vegetation map (scale 1:6000) of areas designated as alluvial valley floors, showing vegetation types and plant communities, should be submitted. A narrative description should be provided of each vegetation type, describing and defining it so that similar mapping could be repeated by an independent worker. The narrative description should also list all species found in the vegetation type and rank each species in the vegetation type as to relative dominance. Quantitative data should be collected for each vegetative type separately. Specific items to be measured are: (1) Percent cover by species, (2) percent litter, and (3) percent bare ground. Annual above ground production should be measured by species at the end of the growing season. Care should be taken in controlling the effects of grazing by large animals prior to measurement. Generally, measured areas should be excluded from grazing for a one-year period prior to study. Rooting depths for predominant species on each terrace level for each vegetative type should be recorded in the field and the type of root (tap, fibrous) should be note. The actual and potential animal unit months per acre should be calculated for each vegetative type and the condition class and trend should be evaluated. Possible reasons for trends should be given.

III.F. LAND USE DATA SPECIFICATIONS

III.F.1. *Crop yields.* For any cultivated or harvested crop areas on alluvial valley floors within the study area, crop yield measurements representing different precipitation and temperature conditions should be analyzed.

III.F.2. *Land use mapping.* Current uses of land within alluvial valley floors should be presented on a map (scale 1:6000), with categories to include managed grazing land, wild hay lands, seeded hay lands, alfalfa and other crop lands, irrigated lands. Fence lines should be shown.

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[FR Doc. 78-23668 Filed 8-18-78; 4:55 pm]

[4810-25]

DEPARTMENT OF THE TREASURY

Office of the Secretary

[31 CFR Part 10]

PRACTICE BEFORE THE INTERNAL REVENUE SERVICE

Proposed Revision of the Provisions Governing Solicitation by Practitioners Before the Internal Revenue Service

AGENCY: Department of the Treasury.

ACTION: Hearing on proposed rule.

SUMMARY: A notice of proposed rulemaking to amend the regulations governing advertising and solicitation by practitioners before the Internal Revenue Service was published in the FEDERAL REGISTER on Wednesday, June 14, 1978 (43 FR 25695). While no hearing on the proposed amendment was contemplated, the notice stated that if an interested person desired an opportunity to comment orally and raised a genuine issue, one may be held. Since requests to comment orally have been received, a hearing has been scheduled.

DATE: The hearing on the proposed rule is scheduled for Tuesday, September 26, 1978, beginning at 10 a.m. in the Cash Room, Main Treasury Building, 15th Street and Pennsylvania Avenue NW., Washington, D.C. It is anticipated that the hearing will not exceed 3 hours.

ADDRESS: All requests and statements should be sent to the Office of Director of Practice, U.S. Department of the Treasury, Washington, D.C. 20220.

FOR FURTHER INFORMATION CONTACT:

Mr. Leslie S. Shapiro, Director of Practice, 202-376-0767.

SUPPLEMENTARY INFORMATION: The hearing will be open to the public as space is available. Persons wishing to make oral statements should advise the Director of Practice in writing by September 20, 1978, and should submit the written text or, at a minimum, an outline of comments they propose to make. Comments will be restricted to 10 minutes in length.

Dated: August 22, 1978.

HENRY C. STOCKELL, Jr.,
Acting General Counsel.

[FR Doc. 78-23972 Filed 8-24-78, 8:45 am]

[8320-01]

VETERANS ADMINISTRATION

[38 CFR Part 17]

MEDICAL BENEFITS

Former Members of the Armed Forces of Poland and Czechoslovakia

AGENCY: Veterans Administration.

ACTION: Proposed regulation.

SUMMARY: This proposed regulation provides authority for furnishing hospital care, domiciliary care, and medical services to those former members of the Armed Forces of Poland and Czechoslovakia who: (1) Served during World War I or World War II in armed conflict against an enemy of the United States, and (2) served during the same period in or with the Armed Forces of France or Great Britain, and (3) have been citizens of the United States for 10 years, and (4) are not entitled to payment for equivalent care and services under a program established by the foreign government concerned for persons who served in its Armed Forces in World War I or World War II. This proposed regulation implements legislation.

DATE: Comments must be received on or before September 25, 1978. It is proposed to make this new section effective October 14, 1976, the effective date of Pub. L. 94-491 (90 Stat. 2363).

ADDRESSES: Send written comments to Administrator of Veterans Affairs (271A), Veterans Administration, 810 Vermont Avenue NW., Washington, D.C. 20420. Comments will be available for inspection at the address shown above during normal business hours until October 4, 1978.

FOR FURTHER INFORMATION CONTACT:

Joseph L. Erwin, Chief, Policies and Procedures, Medical Administration Service, Department of Medicine and Surgery, Veterans Administration, Washington, D.C. 20420, 202-389-3785.

SUPPLEMENTARY INFORMATION: This proposed regulation implements section 109(c), title 38, United States Code, as added by Pub. L. 94-491. It permits the furnishing of hospital care, domiciliary care, and medical services by the Veterans Administration within the United States to specified former members of the Armed Forces of Poland and Czechoslovakia.

ADDITIONAL COMMENT INFORMATION

Interested persons are invited to submit written comments, suggestions, or objections regarding the proposal to the Administrator of Veterans Affairs (271A), Veterans Administration, 810 Vermont Avenue NW., Washington, D.C. 20420. 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 October 4, 1978. 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. Such visitors to any VA field facility will be informed that the records are available for inspection only in central office and furnished the address and the above room number.

Approved: August 18, 1978.

By direction of the Administrator.

RUFUS H. WILSON,
Deputy Administrator.

A new center title and § 17.55 are added to read as follows:

MEDICAL CARE FOR CZECHOSLOVAKIAN AND POLISH VETERANS

§ 17.55 Medical care for certain former members of Czechoslovakian and Polish Armed Forces.

Hospital, domiciliary care, and medical services may be furnished to former members of the Armed Forces of Poland or Czechoslovakia if they:

(a) Served during World War I or World War II in armed conflict against an enemy of the United States, and

(b) Served during the same period in or with the Armed Forces of France or Great Britain, and

(c) Have been citizens of the United States for 10 years, and

(d) Are not entitled to payment for equivalent care and services under a program established by the foreign government concerned for persons who served in its Armed Forces in World War I or World War II. Such care or services may be furnished those individuals to the same extent as if they had served in the U.S. Armed Forces. Qualifying service may be established through an authenticated certification from the French Ministry of Defense or the British War Office which clearly indicates such military service, or otherwise through satisfactory evidence, under guidelines prescribed by the Chief Medical Director, of having served in the Czechoslovakian or Polish Armed Forces and in or with the Armed Forces of France or Great Britain while in armed conflict against an enemy of the United States during World War I or World War II.

[FR Doc. 78-23951 Filed 8-24-78; 8:45 am]

[8320-01]

[38 CFR Part 21]

VETERANS EDUCATION

Policies and Procedures

AGENCY: Veterans' Administration.

ACTION: Request for public comment.

SUMMARY: The Veterans' Administration is publishing for public comment new and revised statements of policy and procedures which have been adopted by the Agency to administer its education loan program. These policy and procedural statements will better acquaint veterans, eligible persons, educational institutions and the public at large with the way in which the program will be administered.

DATE: Comments must be received on or before September 25, 1978.

ADDRESS: Send written comments to: Administrator of Veterans Affairs (271A), Veterans' Administration, 810 Vermont Avenue NW., Washington, D.C. 20420.

Comments will be available for inspection at the address shown above during normal business hours until October 3, 1978.

FOR FURTHER INFORMATION CONTACT:

June C. Schaeffer, Assistant Director of Policy and Program Administration, Education and Rehabilitation Service, Department of Veterans Benefits, Veterans' Administration, 810 Vermont Avenue NW., Washington, D.C. 20420, 202-389-2092.

SUPPLEMENTARY INFORMATION: This publication contains DVB Circular 20-78-28. This circular deals with the policy and procedures necessary to administer the Veterans' Administration education loan program. This circular has been implemented and has been or will be distributed through normal channels to interested persons.

ADDITIONAL COMMENT INFORMATION

Interested persons are invited to submit written comments, suggestions, or objections regarding this document to the Administrator of Veterans Affairs (271A), Veterans' Administration, 810 Vermont Avenue NW., Washington, D.C. 20420. 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 October 3, 1978. 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. Such visitors to a VA field station will be informed that the records are available for inspection only in Central Office and furnished the address and the above room number.

Approved: August 17, 1978.

By direction of the Administrator:

RUFUS H. WILSON,
Deputy Administrator.

[DVB Circular 20-78-28]
DEPARTMENT OF VETERANS BENEFITS,
VETERANS' ADMINISTRATION,
Washington, D.C., May 12, 1978.

VETERANS' ADMINISTRATION EDUCATION LOAN PROCESSING

1. *Purpose.* The original intent of the VA education loan program was to provide an additional source of financial aid for students attending high-cost institutions who would not otherwise be financially able to enter or continue pursuing a program of education. An analysis of earlier loans granted under the VA education loan program indicates that loans have been used to meet expenses other than education-related costs. In addition, early default trends on loans that have become due and payable clearly indicate a need for additional controls. This circular provides guidelines to insure the continuing integrity of the VA education loan program and to insure the utilization of the program in accordance with its original intent.

2. *General.* The following specific areas are covered in separate paragraphs:

a. Loan period limited to one semester, two quarters, or 6 months for schools not operating on semester or quarter system (par. 3).

b. Separate application and approval required for each enrollment period (par. 3).

c. For purposes of the VA education loan program, summer session is now defined as a designated summer term of at least 8 weeks duration (par. 3).

d. Income and expenses to be considered during the loan approval process will be the student's income and educational expenses only (par. 4).

e. Expenses specifically excluded from consideration under the education loan program (par. 4).

f. Loan approvals will require two signatures, and the second signature authorizing the approved loan must be that of a senior adjudicator or higher level employee (par. 5).

g. Processing education loan applications from students with education overpayments (par. 6).

h. Additional controls are set out to assist the student in establishing a repayment plan and initiating payment of the loan under the repayment plan (par. 7).

i. The responsibilities of the school financial aid officer are clarified and restated (par. 8).

j. Effective dates of these new guidelines (par. 10).

3. *Enrollment Period to Which Loans May Apply.* To insure that VA education loans are approved only for students who are satisfactorily pursuing their educational programs and who need additional financial assistance to remain in school, maximum enrollment periods to which loans may apply have been established.

a. The maximum enrollment period to which a loan may apply is a semester, two quarters, a summer session (8 or more weeks), or 6 months for a course not operating on a term basis.

b. A separate loan application will be required for each semester. A separate application will also be required for a summer session. Because of the relative brevity of quarters, applications will be accepted for enrollment periods of two consecutive quarters of a school year. Loans to students attending courses not operating on a term system will require a separate application for each 6-month portion of the enrollment period.

c. Although the cumulative total of loans that a student may receive during an academic year is $2,500 (not to exceed $311 multiplied by the months of remaining entitlement at the beginning of the enrollment period to which the loan applies), each individual loan is limited to the following maximum enrollment periods and the corresponding maximum loan amounts:

(1) Courses organized on a term basis:

Period	Maximum
Semester	$1,250
Quarter	830
Two quarters	1,660
Summer session [1]	830

[1] For purposes of the VA education loan program, summer session is now defined as a designated summer term of at least 8 weeks duration.

(2) Courses not organized on a term basis:

Length of Course	Maximum
3 through 5 months (per month)	$270
6 months	1,660

4. *Income and School-Related Expenses.* Loans may be granted in an amount equal to the amount by which school-related expenses exceed available resources, but not to exceed a rate of $2,500 for an ordinary school year. Under previous guidelines, expenses not related to education have been considered, while not all available resources have been included. These revised guidelines require the counting of all available resources and allow as expenses only the student's *school-related expenses.*

a. Available resources:

(1) *Non-VA financial assistance* must be listed under Part II, Resources, on VA Form 22-8725, Application for Education Loan. Such financial assistance includes, but is not limited to, Guaranteed Student Loans (item 10A), National Direct Student Loans (item 10B), Basic Education Opportunity Grants (item 10C), Supplemental Education Opportunity Grants (item 10D), College Work-Study (non-VA) (item 10E), and any other grants, fellowships, scholarships and loans (item 10F). The amounts of these resources applied for will be considered available to the student and will be included in the student's resources unless the student's application for a specific resource has been disapproved.

(2) *Family contributions* toward education and living expenses (item 10G) will include *all* cash contributions made by the student's family and/or spouse toward the student's educational and living expenses.

(3) *Cash assets* (item 11) will include, but are not limited to, cash on hand (item 11A), amounts held in checking (item 11B) and savings accounts (item 11C), certificates of deposit, negotiable stocks and bonds, and any other liquid asset available to the student (item 11D).

(4) *VA educational assistance* to be received during period to which the loan will apply (item 12A) will be listed, but only that portion that applies solely to the student will be considered. For example, only the single veteran rate of chapter 34 benefits would be counted.

(5) *VA work-study benefits* to be received during the period to which the loan applies (item 12B) will also be listed.

(6) *Estimated current year net available income* will be listed for the student only.

(a) *Item 13A* will include *adjusted gross income* (wages, salary, dividends, interest, rental, business, etc.) for the student only, less:

1. Authorized deductions for exemptions (currently $750 per exemption);

2. Itemized or standard deduction, whichever is greater (however, the standard deduction which may be deducted for this purpose shall be $2,200 for a single veteran, $3,200 for a married veteran filing a joint return if the spouse has no income, $1,600 for a married veteran filing a joint return if the spouse has income, $3,200 for a surviving spouse with a dependent child, or $1,600 for a married person filing a separate return);

3. Mandatory withholdings such as Federal and State income taxes, social security, and other mandatory deductions.

(b) *Item 13B* will include current year nontaxable income for the student only. This includes income from sources such as VA compensation and pension, disability retirement, unemployment compensation, welfare payments, social security benefits, etc.

b. *Allowable expenses.* Only those school-related expenses that are attributable to the student will be included under Part III, Costs and Enrollment Data, VA Form 22-8725. Expenses for dependents will *not* be included (see subpar. (2), below).

(1) *Books and supplies* (items 14 A and B) are an allowable expense. Such items must, however, be *required* by the school for all similarly enrolled students. Books and supplies in excess of $200 per semester, $133 per quarter, or $266 per other enrollment period (6 months in length) will require specific development for verification.

(2) *Noninstitutional room and board* (item 14C) may be included if the student is a commuting student. The allowable expense may not exceed room and board charges at the school.

(a) If the school does not provide room and board, the noninstitutional room and board charges may not exceed the room and board charges at the nearest State university or State college providing room and board. The school financial aid officer will provide this information (item 15E), if known. If an application is received without room and board information, the Liaison activity will be requested to furnish it from the current school catalog. The room and board will be entered (and initialed) by the adjudicator or education claims clerk in item 15G of the application along with the name of the school selected.

(b) A student living off campus may list: Rent, utilities, and food. Utilities may include water and sewage, trash collection, gas

or fuel oil, and electricity. When living arrangements are shared with others (including spouse or other dependents), only the student's prorated share will be included. These expenses or the school charges (or the charges at the nearest State university or State college) for room and board, whichever is less, will be allowed.

(3) *Commuting expenses* (item 14D) are the actual costs of commuting from the student's residence to the school, not to exceed 12 cents per mile. In no event may the daily commuting expense exceed the expense that would result from a 110 mile round trip (55 miles one way). Although the maximum allowable commuting expense is $13.20 (110 miles × 12¢ = $13.20) for each day of classes, care must be taken to allow only the actual cost of commuting, not to exceed the 12 cents per mile limitation. For example, if a student lives 5 miles from school, the maximum allowable commuting expense for each day of classes is $1.20 (10 miles × 12¢ = $1.20). If the same student takes the subway at 80 cents per round trip, the maximum allowable commuting expenses would be 80 cents for each day of classes.

(4) Other expenses (item 14E) that may be considered are the student's health insurance and miscellaneous school-related expenses such as typing of research papers. Expenses paid to the school, such as tuition and fees and institutional room and board, are listed by the school on VA form 22-8725 (see par. 8).

c. *Excluded expenses.* The following are examples of expenses specifically excluded from consideration as allowable expenses:

(1) Living expenses of dependents. (Deductions for dependents have been made from available resources.)

(2) Debts, both legal and personal. (Includes installment sales contracts, as well as revolving charge accounts and bank credit cards.)

(3) Car payments, car insurance, car repairs, and other car related expenses. (These items have been provided for in the 12 cents per mile.)

(4) Life insurance premiums.

(5) Home improvements.

(6) Recreation and entertainment.

(7) Charitable donations.

(8) Legal fees.

(9) Court fines and costs.

(10) Dependent's tuition.

(11) Gifts.

5. *Two-Signature Loan Approvals.* To insure the accuracy and validity of loan processing, loan approvals will require two signatures. All actions granting education loans will be authorized by a senior adjudicator or higher level employee.

6. *Loan Applications Where Overpayments Exist.* An education loan payment will not be made to an eligible student if there is an outstanding overpayment in his/her education account.

a. The adjudicator or education claims clerk will initially process the loan application to determine if the student is eligible for a loan.

(1) If the student *is not eligible* for a loan, the application will be disapproved.

(2) If the student *is eligible* for a loan, the folder will be reviewed to determine if an education overpayment exists.

(a) If an overpayment *does not exist*, the adjudicator or education claims clerk will continue processing the loan application.

(b) If an overpayment *exists* but it also appears that it will be cleared prior to final processing of the loan application, the adjudicator or education claims clerk will continue processing the loan application.

(c) If an overpayment *exists* and it does not appear that it will be cleared prior to final processing of the loan application, the application will be given conditional approval. The 230 end product will be taken and the student will be notified of all the following conditions by dictated letter:

1. His/her loan application has received conditional approval;

2. The loan payment cannot be made until the overpayment has been cleared;

3. The loan payment cannot be made unless the overpayment is cleared prior to the end of the enrollment period to which the loan applies; and

4. He/she must notify the VA when the overpayment is cleared if he/she wants the application processed for payment.

If the student states, and Finance verifies, that the overpayment has been cleared during the enrollment period, the adjudicator or education claims clerk will complete processing of the application.

b. In addition to education overpayments, VAR 14501(B)(2) specifically precludes education loans to students who have defaulted on a previous education loan and there is a remaining payment due the VA.

7. *Repayment Notification and Followup Actions.* Additional controls in the Finance activity will be implemented to encourage students to establish a timely repayment plan prior to the repayment due date (matured) of VA education loans.

a. Every effort will be taken to insure that students who have received education loans are apprised of their responsibility to repay the loan. This will be accomplished by maintaining contact with the student during the grace period of the loan. (The grace period is the 9-month period from date of termination of training to loan repayment due date.)

b. New VA form letters are being developed to be used by the Finance activity when advising students of the repayment due date of their loans. These letters will also request a current address which will enable the VA to maintain contact with the student. The letters will be forwarded to the student on:

(1) The date training is terminated (this includes completion of training, withdrawal, and reduction to less than one-half time); and

(2) 3½ months after the date of termination.

c. The present FL 4-322 (repayment agreement) will continue to be issued 7½ months after the date of termination. An additional FL 4-322, marked "Second Request," will be forwarded 9 months after the date of termination if a reply has not been received to the first FL 4-322.

d. Strict controls will be established in the Finance activity to obtain a repayment plan and to assure prompt and aggressive followup when a payment is delinquent.

8. *School Financial Aid Officer's Responsibilities:*

a. The financial aid officer (or other school official acting in that capacity) is generally in the best position to help those students in financial need. He/she knows the current status of various financial assistance programs, the availability of other types of financial aid, and the current costs of school attendance that the average student must meet. It is therefore extremely important for the success of the VA education loan program that appropriate VA field station personnel develop and maintain a close working relationship with school financial aid officers.

b. The following subparagraphs list those items that are to be listed by the school on the education loan application:

(1) Educational or vocational objective (item 15A).

(2) Expected date of graduation (item 15B).

(3) Beginning and ending dates of enrollment period (item 15C).

(4) Credit hour load or clock hour load (item 15D).

(5) Tuition and fees for enrollment period (item 15E).

(6) Room and board charges (item 15E). (The actual charges for the student must be listed unless the student is living off campus, in which case the average charges for a student receiving institutional room and board must be listed. If the school does not offer room and board, list the room and board charges at the nearest State university or State college providing room and board, if known.)

(7) The school must indicate if they will receive the education loan payment check and deliver it to the student (item 15F).

(8) *Item 15G, "Remarks":*

(a) The school must also review the student's financial resources (Part II, VA Form 22-8725) and related educational expenses (Part III, VA Form 22-8725). It is extremely important that the school carefully review these items and determine if they appear to be accurate and reasonable based upon the school's current experience with other similarly situated and similarly enrolled students. If the school feels that certain items are not accurate or reasonable, the certifying official must list the item numbers as exceptions in item 15G, "Remarks," on VA Form 22-8725.

(b) For example, if a student lists $200 for books and the school feels that $75 would be reasonable, the school would indicate, "Exception to item 14A—$75" in item 15G.

(c) If the school lists a lesser amount, the school's figure will be used in computing the loan amount. If a loan is in order, the student will be advised of the adjustment and that evidence may be submitted to justify the higher amount.

9. *Liaison With School Financial Aid Officers.* Additional liaison should be undertaken with schools to assist school financial aid officers in understanding their responsibilities under the VA education loan program. Such liaison should be positive in nature and should provide school financial aid officers with sufficient information to enable them to not only meet their responsibilities under the loan program, but also to assist those veterans and eligible persons who, without additional financial assistance, might not be able to enter or continue pursuing a program of education.

10. *Effective Dates.* These new guidelines are for application for those enrollment periods which begin on or after August 1, 1978. The application form, VA Form 22-8725, Application for Education Loan, and the worksheet, VA Form 22-8727, Education Loan Worksheet, are being revised to reflect the above changes. If any applications are received on old application forms for enrollment periods which begin on or after August 1, 1978, the claim will be carefully reviewed to determine if sufficient informa-

tion is present which would allow action to be taken on the claim under the procedures outlined in this circular. If sufficient information is not present, specific development must be undertaken.

11. *Prior Publications.* Pending modification of existing regulations and manuals, the provisions of this circular will be followed in conjunction with appropriate portions of: DVB [1] Manual M22-2, part IV, chapter 14: DVB [1] Circular 20-76-84, Appendix E; DVB Circular 20-77-61; and DVB Circular 20-77-97, Appendix C.

DOROTHY L. STARBUCK,
Chief Benefits Director.

[FR Doc. 78-24091 Filed 8-24-78; 8:45 am]

[1505-01]

POSTAL SERVICE

[39 CFR Part 111]

OFFICIAL MAIL

Mandatory Use of Reply Mail by Federal Agencies

Correction

In FR Doc. 78-22611 appearing at page 35951 in the issue for Monday, August 14, 1978, in the second column on page 35952, the second line was inadvertently omitted. That line should read: "agency headquarters is located if mail."

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 52]

[FRL 953-7]

APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Revisions to the Pima County Air Quality Control District's Rules and Regulations in the State of Arizona

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed rulemaking.

SUMMARY: Revisions to the Pima County Air Quality Control District's (AQCD) rules and regulations have been submitted to the Environmental Protection Agency (EPA) by the Governor for the purpose of revising the Arizona State Implementation Plan (SIP). The intended effect of these revisions is to incorporate into the SIP a "Manual of Procedures" for the Pima County Air Pollution Hearing Board outlining the general requirements for the conduct of business. The EPA invites public comments on this manual, especially as to its consistency with the Clean Air Act.

DATES: Comments may be submitted up to September 25, 1978.

ADDRESSES: Comments may be sent to: Regional Administrator, Attention: Air and Hazardous Materials Division, Air Programs Branch, AZ-NV-PI Plans section (A-4), Environmental Protection Agency, Region IX, 215 Fremont Street, San Francisco, Calif. 94105. Copies of the proposed revisions are available for public inspection during normal business hours at the EPA Region IX office at the above address and at the following locations:

Pima County Air Quality Control District, 151 West Congress Street, Tucson, Ariz. 85701.

Arizona Department of Health Services, State Health Building, 1740 West Adams Street, Phoenix, Ariz. 85007.

Public Information Reference Unit, Room 2922 (EPA Library), 401 M Street SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:

Judith C. Steenhoven, AZ-NV-PI Plans Section, EPA, Region IX, 415-556-7720.

SUPPLEMENTARY INFORMATION: The State of Arizona submitted the following new rules on March 21, 1978:

Rule 1. Scope of Rules and Legal Authority.
Rule 2. Definitions.
Rule 3. Organization.
Rule 4. Officers and Staff.
Rule 5. Meetings.
Rule 6. Notices of Appeal and Petitions.
Rule 7. Contest Cases; Notice; Hearings; Records.
Rule 8. Notice and Time of Hearing; Appearance and Practice Before the Board.
Rule 9. Hearings for the Purpose of Taking Evidence; Procedure.
Rule 10. Evidence.
Rule 11. Extension of Time.
Rule 12. Intervention.
Rule 13. Conferences.
Rule 14. Consolidation.
Rule 15. Decisions.
Rule 16. Rehearings.
Rule 17. Filing and Service of Papers.
Rule 18. Computation of Time.

Under section 110 of the Clean Air Act as amended, and 40 CFR Part 51, the Administrator is required to approve or disapprove the regulations submitted as revisions to the SIP. In addition to this action, the Administrator is required to provide opportunity for a public hearing where the State has not done so. The Regional Administrator hereby issues this notice setting forth these revisions as proposed rulemaking. Interested persons may participate by submitting written comments on the approval or disapproval of these regulations and may request the opportunity for a public hearing. Comments should be submitted to the Region IX Office. Those comments received on or before September 25, 1978 will be considered. Comments received will be available for public inspection at the EPA Region IX Office and the EPA Public Information Reference Unit.

AUTHORITY: Sections 110 and 301(a) of the Clean Air Act as amended (42 U.S.C. 7410 and 7601(a)).

Dated: August 17, 1978.

SHEILA M. PRINDIVILLE,
Acting Regional Administrator.

[FR Doc. 78-24015 Filed 8-24-78; 8:45 am]

[6560-01]

[40 CFR Part 52]

[FRL 955-2]

APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Revisions to the Great Basin Unified Air Pollution Control District's Rules and Regulations in the State of California

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed rulemaking.

SUMMARY: Revisions to the Great Basin Unified Air Pollution Control District's (APCD) rules and regulations have been submitted to the Environmental Protection Agency (EPA) by the California Air Resources Board for the purpose of revising the California State Implementation Plan (SIP). The intended effect of these revisions is to update the rules and regulations and to correct deficiencies in the SIP. The EPA invites public comments on these rules, especially as to their consistency with the Clean Air Act.

DATES: Comments may be submitted up to September 25, 1978.

ADDRESSES: Comments may be sent to: Regional Administrator, Attention: Air and Hazardous Materials Division, Air Programs Branch, California SIP section (A-4), Environmental Protection Agency, Region IX, 215 Fremont Street, San Francisco, Calif. 94105. Copies of the proposed revisions are available for public inspection during normal business hours at the EPA Region IX office at the above address and at the following locations:

Great Basin Unified Air Pollution Control District, 873 North Main Street, Suite 213, Bishop, Calif. 93514.

California Air Resources Board, 1102 Q Street, P.O. Box 2815, Sacramento, Calif. 95814.

Public Information Reference Unit, Room 2922 (EPA Library), 401 M Street SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:

Wally Woo, Chief, California SIP Section, EPA, Region IX, 415-556-7288.

[1] Not distributed to DVBE.

SUPPLEMENTARY INFORMATION: The California Air Resources Board submitted the following rules and regulations on June 22, 1978:

Rule 419. Gasoline Loading into Stationary Tanks.
Rule 601. Filing Petitions.

Under section 110 of the Clean Air Act as amended, and 40 CFR Part 51, the Administrator is required to approve or disapprove the regulations submitted as revisions to the SIP. The Regional Administrator hereby issues this notice setting forth these revisions, including rule deletions caused thereby, as proposed rulemaking and advises the public that interested persons may participate by submitting written comments to the Region IX Office. Comments received on or before September 25, 1978. Comments received will be available for public inspection at the EPA Region IX Office and the EPA Public Information Reference Unit.

AUTHORITY: Sections 110 and 301(a) of the Clean Air Act as amended (42 U.S.C. §§ 7410 and 7601(a)).

Dated: July 28, 1978.

SHEILA M. PRINDIVILLE,
Acting Regional Administrator.

[FR Doc. 78-24016 Filed 8-24-78; 8:45 am]

[6560-01]

[40CFR Part 65]

[FRL 952-8]

STATE AND FEDERAL ADMINISTRATIVE ORDERS PERMITTING A DELAY IN COMPLIANCE WITH STATE IMPLEMENTATION PLAN REQUIREMENTS

Proposed Approval of Three Administrative Orders Issued by the Ohio Environmental Protection Agency to Lima State Hospital, Miami University, and Dayton Mental Health Center

AGENCY: U.S. Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (USEPA) proposes to approve three administrative orders issued by the Ohio Environmental Protection Agency to Lima State Hospital, Miami University, and Dayton Mental Health Center. The first order requires Lima State Hospital to bring air emissions from its coal-fired boiler house in Lima, Ohio, into compliance with certain regulations contained in the federally approved Ohio State implementation plan (SIP) by June 1, 1978. The second order requires Miami University to bring emissions from its power plant in Oxford, Ohio, into compliance with the Ohio plan by May 15, 1979. The last order requires Dayton Mental Health Center to bring its power plant into compliance with the Ohio plan by June 1, 1979. Because the orders have been issued to major sources and permit a delay in compliance with provisions of the SIP, they must be approved by EPA before they become effective as delayed compliance orders under the Clean Air Act (the Act). If approved by EPA, the orders will constitute additions to the SIP. In addition, a source in compliance with an approved order may not be sued under the Federal enforcement or citizen suit provisions of the act for violations of the SIP regulations covered by the order. The purpose of this notice is to invite public comment on EPA's proposed approval of the orders as delayed compliance orders.

DATES: Written comments must be received on or before September 25, 1978.

ADDRESSES: Comments should be submitted to Mr. James O. McDonald, Director, Enforcement Division, USEPA, Region V, 230 South Dearborn Street, Chicago, Ill. 60604. The State orders, supporting material, and public comments received in response to this notice may be inspected and copied (for appropriate charges) at this address during normal business hours.

FOR FURTHER INFORMATION CONTACT:

Mr. Michael G. Smith, Enforcement Attorney, at the above address or telephone 312-353-2082.

SUPPLEMENTARY INFORMATION: Lima State Hospital operates a boiler house at Lima, Ohio. The order under consideration addresses emissions from three coal-fired boilers at the facility, which are subject to regulations AP-3-07 and AP-3-11, which have been renumbered as OAC 3745-17-07 and OAC 3745-17-10, respectively. The regulations limit the emissions of opacity and particulate matter, and are part of the federally approved Ohio State implementation plan. The order requires final compliance with the regulations by June 1, 1978, through the installation of particulate matter control equipment. The source has consented to the terms of the order.

Miami University is currently in the process of replacing its existing facility with three new boilers and appropriate control equipment which shall consist of baghouses or electrostatic precipitators. The order requires compliance with Ohio implementation plan regulations AP-3-07 (OAC 3745-17-07) and AP-3-11 (OAC 3745-17-10) by May 15, 1979.

Dayton Mental Health Center operates a boiler house in Dayton, Ohio. The order, which is proposed to be approved, requires the center to achieve compliance with Ohio implementation plan regulations AP-3-07 (OAC 3745-17-07) and AP-3-11 (OAC 3745-17-10) by the installation of mechanical control devices by June 1, 1979.

Because these orders have been issued to major sources of particulate emissions and permit a delay in compliance with the applicable regulations, they must be approved by EPA before they become effective as delayed compliance orders under section 113(d) of the Clean Air Act (the Act). EPA may approve the orders only if they satisfy the appropriate requirements of this subsection.

If the orders are approved by EPA, source compliance with their terms would preclude Federal enforcement action under section 113 of the act against the sources for violations of the regulations covered by the orders during the period the orders are in effect. Enforcement against the sources under the citizen suit provision of the act (section 304) would be similarly precluded. If approved, the orders would also constitute additions to the Ohio SIP.

All interested persons are invited to submit written comments on the proposed orders. Written comments received by the date specified above will be considered in determining whether EPA may approve the orders. After the public comment period, the Administrator of EPA will publish in the FEDERAL REGISTER the Agency's final action on the orders in 40 CFR Part 65.

The Provisions of 40 CFR Part 65 will be promulgated by EPA soon, and will contain the procedure for EPA's issuance, approval, and disapproval of orders under section 113(d) of the act. In addition, part 65 will contain sections summarizing orders issued, approved, and disapproved by EPA. A prior notice proposing regulations for part 65, published at 40 FR 14876 (April 2, 1975), will be withdrawn, and replaced by a notice promulgating these new regulations.

(42 U.S.C. 7413, 7601.)

Dated: July 28, 1978.

VALDAS V. ADAMKUS,
Acting Regional Administrator, U.S. Environmental Protection Agency, Region V.

In consideration of the foregoing, it is proposed to amend 40 CFR Chapter I, as follows:

PART 65—DELAYED COMPLIANCE ORDERS

1. By adding § 65.401 to read as follows:

§ 65.401 State delayed compliance orders issued and approved under section 113(d) (1), (2), and (4) of the Act.

OHIO ENVIRONMENTAL PROTECTION AGENCY

LIMA STATE HOSPITAL

ORDER

The Director of Environmental Protection (hereinafter "Director") hereby makes the following findings of fact and, pursuant to sections 3704.03 (S) and (I) of the Ohio Revised Code and section 113(d) of the Clean Air Act, as amended, 42 U.S.C. 7401 et seq., issues the following orders, which will not take effect until the Administrator of the U.S. Environmental Protection Agency has approved their issuance under the Clean Air Act.

FINDINGS OF FACT

1. Lima State Hospital (hereinafter "LSH") is a mental health facility located in Lima, Allen County, Ohio, and operated by the State of Ohio through the Department of Mental Health and Mental Retardation.

2. LSH owns and operates three (3) coal-fired boilers at its facility. These boilers are identified as follows:

Boiler No. 1, application No. 0302020256 B001—Babcock and Wilcox, 33.3 MMBtu (25,000 pounds of steam per hour) spreader stoker (in the process of being converted to underfeed).

Boiler No. 2, application No. 0302020256 B002—Union Iron Works, 34.6 MMBtu (26,000 pounds of steam per hour) underfeed stoker.

Boiler No. 3, application No. 0302020256 B003—Bigalow, 34.6 MMBtu (26,000 pounds of steam per hour) underfeed stoker.

3. On November 10, 1976, LSH submitted applications for permits to operate the three coal-fired boilers.

4. In the course of operation of said boilers, air contaminants are emitted in violation of OAC 3745-17-10 and OAC 3745-17-07.

5. LSH is unable to comply with OAC 3745-17-10 and OAC 3745-17-07.

6. On February 4, 1977, the Director proposed to deny the applications for permits to operate.

7. LSH is using and will continue to use coal of sufficiently low sulfur content to maintain their existing status of compliance with federally promulgated sulfur oxide standards (U.S. Environmental Protection Agency sulfur oxide plan for Ohio, 41 FR 36324 (August 27, 1976)).

8. Implementation by LSH of interim control measures contained in the Orders below will fulfill the requirements of section 113(d)(7) of the Clean Air Act, as amended.

9. The compliance schedule set forth in the orders below requires compliance with applicable emission regulations as expeditiously as practicable.

10. The Director's determination to issue the orders set forth below is based on his consideration of reliable, probative, and substantial evidence relating to the technical feasibility and economic reasonableness of compliance with such orders, and their relation to benefits to the people of the State to be derived from such compliance.

ORDERS

Whereupon, after due consideration of the above findings of fact, the Director hereby issues the following orders pursuant to sections 3704.03 (S) and (I) of the Ohio Revised Code and section 113(d) of the Clean Air Act, as amended, 42 U.S.C. 7401 et seq., which will not take effect until the Administrator of the United States Environmental Protection Agency has approved their issuance under the Clean Air Act.

1. Compliance with OAC 3745-17-10 shall be achieved by the installation of an appropriate mechanical fly ash collector in common ducting for all boilers to control emissions of particulate matter from LSH to a rate of 0.20 pounds per million Btu input. This emission restriction shall be based upon a maximum heat input of 102.5 million Btu (77,000 pounds of steam per hour).

2. Compliance with OAC 3745-17-10 shall be achieved no later than June 1, 1978 in accordance with the following schedule.

Submission of final control plans for source: Complete.
Award bids: Complete.
Begin construction: Complete.
Complete construction: March 1, 1978.
Testing of equipment: May 1, 1978.
Achievement of compliance with State and Federal statutes and regulations: June 1, 1978.

3. The maximum steam load for the boilers shall be 35,000 pounds of steam per hour.

4. The mechanical fly ash collector shall maintain compliance from the minimum load through the range of the maximum load specified in order (3) above.

5. If LSH desires to operate the boilers at a steam load of greater than 35,000 pounds of steam per hour, LSH shall apply for and obtain a permit to install from the Ohio Environmental Protection Agency (hereinafter "OEPA") in accordance with OAC 3745-31-02. Included in such application shall be the results of a stack test, conducted in accordance with procedures approved by the Director, which show that the boilers operated at the increased steam load are in compliance with OAC 3745-17-07 and OAC 3745-17-10 (a particulate emission rate of 0.20 pounds per million Btu input). Written notification of intent to test shall be provided to the Northwest District Office of the OEPA thirty (30) days prior to the testing date.

6. LSH shall operate no more than two of the boilers at any one time. Any two boilers may be operated concurrently.

7. The boilers shall be operated in compliance with OAC 3745-17-07. This shall be accomplished by operation at turn down ratios compatible with boiler design limits and sulfur dioxide dew points.

8. The boilers shall each be provided with opacity instrumentation and recorders. Oxygen analyzers and recorders shall also be provided for each of the boilers for the control of excess air for the coal-fired units.

9. On a quarterly basis, LSH shall report to the Northwest District Office of the OEPA any excursions above the 20 percent opacity limitation set out in OAC 3745-17-07. LSH shall keep on file all stack monitoring data for a minimum of 2 years.

10. Coal analysis for boiler fuel shall be as follows: less than or equal to seven (7) percent ash; less than or equal to three (3) percent sulfur; greater than or equal to 12,800 Btu per pound of coal, as specified by the Ohio Department of Mental Health and Mental Retardation. LSH and the Ohio Department of Mental Health and Mental Retardation shall note this fuel quality requirement in any bidding document for the purchase of fuel.

11. Pending achievement of compliance with order (1) above, LSH shall use the best practicable systems of emission reduction for the period during which this order is in effect in accordance with section 113(d) (7) of the Clean Air Act, as amended. Such interim measures shall include:

a. The use of coal with an analysis of: less than or equal to seven (7) percent ash; less than or equal to three (3) percent sulfur; greater than or equal to 12,800 Btu per pound of coal.

b. Conversion of the boilers to underfeed stokers.

c. Equipping each boiler with opacity instrumentation and recorders and oxygen analyzers and recorders.

d. Regular maintenance of the boilers.

12. Within five (5) days after the scheduled achievement date of each of the increments of progress specified in the compliance schedule in order (2) above, LSH shall submit a progress report to the Northwest District Office of the OEPA. The person submitting these reports shall certify whether each increment of progress has been achieved.

13. LSH shall submit to the Northwest District Office of the OEPA an analysis of each shipment of coal burned at LSH on an as received basis.

14. LSH shall comply with any other emission monitoring and reporting required by chapter 3704 of the Ohio Revised Code and the regulations promulgated thereunder.

15. Emission tests at the normal rate of operation and at the maximum rate of operation shall be conducted upon the boilers to verify compliance with order (1) above. Such tests shall be conducted no later than the date specified in the compliance schedule in order (2) above in accordance with procedures approved by the Director. Written notification of intent to test shall be provided to the Northwest District Office of the OEPA thirty (30) days prior to the testing date.

16. LSH shall apply for and obtain permits to operate the boilers in accordance with OAC 3745-35-02.

17. LSH is hereby notified that unless it is exempted under section 120(a)(2) (B) or (C) of the Clean Air Act, as amended, failure to achieve final compliance with order (1) above by July 1, 1979, will result in a requirement to pay a noncompliance penalty under section 120 of the Clean Air Act, as amended.

NED. E WILLIAMS, P.E.,
Director of Environmental Protection.

WAIVER

The Ohio Department of Mental Health and Mental Retardation agrees that the attached findings and orders are lawful and reasonable and agrees to comply with the attached orders. The Ohio Department of Mental Health and Mental Retardation hereby waives the right to appeal the issuance or terms of the attached findings and orders to the Environmental Board of Review, and it hereby waives any and all rights it might have to seek judicial review of said findings and orders either in law or equity. The Ohio Department of Mental Health and Mental Retardation also waives

any and all rights it might have to seek such judicial review of any approval by U.S. EPA of the attached findings and orders or to seek a stay of enforcement of said findings and orders in connection with any judicial review of Ohio's air implementation plan (or portion thereof).

JAMES F. MCAVOY,
Authorized Representative of Ohio Department of Mental Health and Mental Retardation.

OHIO ENVIRONMENTAL PROTECTION AGENCY

MIAMI UNIVERSITY

ORDER

Pursuant to section 3704.03(S) of the Ohio Revised Code and in accordance with section 113(d) of the Clean Air Act, as amended, 42 U.S.C. 7401 et seq., the Director of Environmental Protection (hereinafter "Director") hereby makes the following findings of fact and issues the following orders, which will not take effect until the Administrator of the U.S. Environmental Protection Agency has approved their issuance under the Clean Air Act.

FINDINGS OF FACT

1. Miami University (hereinafter "Miami") is a state owned institution of higher education located in Oxford, Ohio.

2. Miami owns and operates four coal-fired boilers (hereinafter "the boilers") which provide the steam and heating requirements for most of Miami's buildings and facilities. These boilers are identified in the original variance application of August 15, 1972 as follows:

Application No. 1809090081 B001—Babcock and Wilcox 77.545 MMBtu chain grate stoker.
Application No. 1809090081 B002—Henry Vogt VL 59.650 MMBtu underfeed stoker.
Application No. 1809090081 B003—Two Wickes 57.264 MMBtu underfeed stokers.

3. On January 17, 1974 and February 1, 1974, Miami submitted to the Ohio Environmental Protection Agency (hereinafter "OEPA") an application for an extension of a previously issued variance to operate the boilers.

4. On September 29, 1976, Miami submitted to the OEPA an application for a permit to install new boilers with control equipment as the compliance strategy for the boilers identified in finding of fact (2) above.

5. On December 3, 1976, the Director proposed to deny the variance extension application. Miami thereafter filed a timely request for adjudication hearing upon such proposal.

6. On June 16, 1977, the Director proposed to deny the permit to install application. Miami thereafter filed a timely request for adjudication hearing upon such proposal.

7. In the course of operation of the boilers identified in finding of fact (2) above, air contaminants are emitted in violation of OAC 3745-17-10 and OAC 3745-17-07.

8. Miami is unable to comply with OAC 3745-17-10 and OAC 3745-17-07.

9. Potential emissions of air pollutants from the boilers are equal to or more than one hundred tons per year, and therefore these sources constitute a major stationary source as defined in section 302(j) of the Clean Air Act, as amended.

10. Miami is using and will continue to use coal of sufficiently low sulfur content to maintain its existing status of compliance with federally promulgated sulfur oxide standards (U.S. Environmental Protection Agency sulfur oxide plan for Ohio, 41 FR 36324 (August 27, 1976)).

11. Implementation by Miami of interim control measures contained in the orders below will fulfill the requirements of section 113(D)(7) of the Clean Air Act, as amended.

12. The compliance schedule set forth in the orders below requires compliance with applicable emission regulations as expeditiously as practicable.

13. The Director's determination to issue the orders set forth below is based on his consideration of reliable, probative and substantial evidence relating to the technical feasibility and economic reasonableness of compliance with such orders, and their relation to benefits to the people of the State to be derived from such compliance.

ORDERS

Whereupon, after due consideration of the above findings of fact, the Director hereby issues the following orders pursuant to section 3704.03(S) of the Ohio Revised Code and in accordance with section 113(d) of the Clean Air Act, as amended, 42 U.S.C. 7401 et seq., which will not take effect until the Administrator of the U.S. Environmental Protection Agency has approved their issuance under the Clean Air Act.

1. Compliance with OAC 3745-17-10 and 3745-17-07 shall be achieved no later than May 15, 1979, by the installation of new boilers with a baghouse(s) or electrostatic precipitator(s) sufficient to control emissions of particulate matter from the Miami boiler facility to the applicable emission rate of 0.146 pounds per million Btu input. This emission restriction is based upon a maximum total heat input of 285 million Btu per hour (three boilers each at 95 million Btu and 80,000 pounds of steam per hour).

2. Compliance with order (1) above, shall be achieved in accordance with the following schedule:

Submission of descriptive plan: Complete.
Submission of final control plans: Complete.
Awarding of contracts: Complete.
Commence on site construction: Complete.
Submit amended final particulate emission control plans: February 15, 1978.
Advertise for bids for augmented control equipment: March 1, 1978.
Award contracts for augmented control equipment: May 1, 1978.
Complete construction of facility. Achieve compliance with all applicable state and federal statutes and regulations: May 15, 1979.

3. The boilers identified in finding of fact (2) and those identified in order (1) above shall be operated in compliance with OAC 3745-17-07. This shall be accomplished by operation at turn down ratios compatible with boiler design limits and sulfur dioxide dew points.

4. The boilers identified in order (1) above shall be provided with an opacity monitor and recorder in the common breeching. Oxygen analyzers and recorders shall be provided for each of the boilers for the control of excess air for the coal-fired units. Miami shall keep on file all stack monitoring opacity data for these boilers for a minimum of 2 years and shall report any excursions above the 20 percent opacity limitation set out in OAC 3745-17-07 on a quarterly basis to the Southwestern Ohio Air Pollution Control Division.

5. Upon the effective date of the order and pending achievement of compliance with order (1) above, Miami shall operate the boilers described in finding of fact (2) above by using the best practicable systems of emission reduction for the period during which this order is in effect in accordance with section 113(d)(7) of the Clean Air Act, as amended. Such interim measures shall include:

a. The use of coal with an analysis of: less than or equal to six (6) percent ash (as received basis); less than or equal to one (1) percent sulfur (dry basis); greater than or equal to 13,500 Btu per pound of coal (as received basis).

b. Utilization of opactiy instrumentation and alarm.

c. Use of the reworked boiler control system in the main boiler house to enhance fuel and air mixture control.

d. Regular maintenance of the boilers.

6. Within five (5) days after the scheduled achievement date of each of the increments of progress specified in the compliance schedule in order (2) above, Miami shall submit a progress report to the Southwestern Ohio Air Pollution Control Division. The person submitting these reports shall certify whether each increment of progress has been achieved. Between May 1, 1978 and May 15, 1979, Miami shall submit progress reports every three (3) months.

7. Miami shall continue to submit every six months to the Southwestern Ohio Air Pollution Control Division an analysis of the coal burned at Miami University on an as received basis.

8. Miami shall comply with any other emission monitoring and reporting ordered by the Director as required by chapter 3704 of the Ohio revised Code and the regulations promulgated thereunder.

9. Miami shall apply for and obtain permits to operate the boilers described in order (1) above in accordance with OAC 3745-35-02.

10. Miami is hereby notified that failure to achieve final compliance with order (1) above by July 1, 1979 will result in a requirment to pay a noncompliance penalty under section 120 of the Clean Air Act, as amended, unless it is exempted under section 120(a)(2) (B) or (C) of the Clean Air Act, as amended.

NED E. WILLIAMS, P.E.,
Director of Environmental Protection.

WAIVER

Miami University agrees that the attached findings and orders are lawful and reasonable and agrees to comply with the attached orders. Miami University hereby waives the right to appeal the issuance or terms of the attached findings and orders to the Environmental Board of Review, and it hereby waives any and all rights it might have to seek judicial review of said findings and orders before any court of competent jurisdiction either in law or equity. Miami University also waives any and all rights it might have to seek such judicial review of any approval by U.S. EPA of the attached findings and orders or to seek a stay of enforcement of said findings and orders in connection with an judicial review of Ohio's

air implementation plan (or portion thereof).

FLOYD GOGGIN,
Authorized Representative of Miami University.

OHIO ENVIRONMENTAL PROTECTION AGENCY

DAYTON MENTAL HEALTH CENTER

ORDER

The Director of Environmental Protection (hereinafter "Director") hereby makes the following findings of fact and, pursuant to §§ 3704.03 (S) and (I) of the Ohio Revised Code and in accordance with section 113(d) of the Clean Air Act, as amended, 42 U.S.C. 7401 et seq., issues the following orders, which will not take effect until the Administrator of the U.S. Environmental Protection Agency has approved their issuance under the Clean Air Act.

FINDINGS OF FACT

1. Dayton Mental Health Center (hereinafter "DMHC") is a mental health facility located in Dayton, Montgomery County, Ohio.

2. DMHC owns and operates three (3) coal-fired boilers at its facility. These boilers are identified as follows:

Boiler No. 1, application No. 0857041060 B001—Wickes Model 59990, 35 MMBtu per hour.
Boiler No. 2, application No. 0857041060 B004—Union Iron Works, 35 MMBtu per hour underfeed.
Boiler No. 4, application No. 0857041060 B003—Vogt Model WT, 80 MMBtu (60,000 pounds of steam per hour).

3. On April 1, 1977, DMHC submitted applications for variances to operate the coal-fired boilers. The compliance strategy for the boilers was to be the installation of new boilers with control equipment.

4. In the course of operation of said boilers, air contaminants are emitted in violation of OAC 3745-17-10 and OAC 3745-17-07.

5. DMHC is unable to comply with OAC 3745-17-10 and OAC 3745-17-07.

6. On August 4, 1977, the Director proposed to deny the applications for variations for variances to operate.

7. Potential emissions of air pollutants from the boilers described in finding of fact (2) above are equal to or more than 100 tons per year, and therefore these sources constitute a major stationary source as defined in section 302(j) of the Clean Air Act, as amended.

8. DMHC is using and will continue to use coal of sufficiently low sulfur content to maintain its existing status of compliance with federally promulgated sulfur oxide standards (U.S. Environmental Protection Agency sulfur oxide plan for Ohio, 41 FR 36324 (Aug. 27, 1976)).

9. Implementation by DMHC of interim control measures contained in the orders below will fulfill the requirements of section 113(d)(7) of the Clean Air Act, as amended.

10. The compliance schedule set forth in the orders below requires compliance with applicable emission regulations as expeditiously as practicable.

11. The Director's determination to issue the orders set forth below is based on his consideration of reliable, probative, and substantial evidence relating to the technical feasibility and economic reasonableness of compliance with such orders, and their relation to benefits to the people of the State to be derived for such compliance.

ORDERS

Whereupon, after due consideration of the above findings of fact, the Director hereby issues the following orders pursuant to §§ 3704.03 (S) and (I) of the Ohio Revised Code and in accordance with section 113(d) of the Clean Air Act, as amended, 42 U.S.C. 7401 et seq., which will not take effect until the Administrator of the U.S. Environmental Protection Agency has approved their issuance under the Clean Air Act.

1. Compliance with OAC 3745-17-10 and OAC 3745-17-07 shall be achieved by the installation of two new boilers with appropriate mechanical fly ash collectors sufficient to control emissions of particulate matter from DMHC to a rate of 0.22 pounds per million Btu input. This emission restriction is based upon a maximum heat input of 77.8 million Btu per hour (two boilers each at 38.9 million Btu and 27,500 pounds of steam per hour).

2. Compliance with OAC 3745-17-10 and OAC 3745-17-07 shall be achieved no later than June 1, 1979, in accordance with the following schedule:

Submission of final control plans for source: March 1, 1978.
Take bids: April 15, 1978.
Award bids: June 1, 1978.
Begin construction of boilers and installation of control equipment: July 1, 1978.
Complete installation of No. 2 boiler with control equipment: September 1, 1978.
Complete installation of No. 1 boiler with control equipment: March 1, 1979.
Testing of equipment: April 1, 1979.
Achievement of compliance with State and Federal statutes and regulations: June 1, 1979.

4. The boilers identified in order (1) above shall be operated in compliance with OAC 3745-17-07. This shall be accomplished by operation at turn down ratios compatible with boiler design limits and sulfur dioxide dew points.

5. The boilers identified in order (1) above shall each be provided with approved instrumentation installed to measure and record opacity and oxygen in the boiler outlet gas stream. DMHC shall keep on file all stack monitoring data for a minimum of 2 years and shall report any excursions above the 20-percent opacity limitation set out in OAC 3745-17-07 to the regional air pollution control agency on a quarterly basis.

6. Coal analysis for boiler fuel shall be as follows: Less than or equal to ten (10) percent ash; less than or equal to one (1) percent sulfur; greater than or equal to 13,500 Btu per pound of coal, as specified by the Ohio Department of Mental Health and Mental Retardation. DMHC and the Ohio Department of Mental Health and Mental Retardation shall note this fuel quality requirement in any bidding document for the purchase of fuel.

7. Pending achievement of compliance with order (1) above, DMHC shall use the best practicable systems of emission reduction for the period during which this order is in effect in accordance with section 113(d)(7) of the Clean Air Act, as amended. Such interim measures shall include:

a. The use of coal with an analysis of: Less than or equal to ten (10) percent ash; less than or equal to one (1) percent sulfur; greater than or equal to 13,500 Btu per pound of coal.

b. Use of new No. 2 boiler as soon as its installation is complete instead of the boilers described in finding of fact (2) above.

c. Regular maintenance of the boilers.

8. Within five (5) days after the scheduled achievement date of each of the increments of progress specified in the compliance schedule in order (3) above, DMHC shall submit a progress report to the regional air pollution control agency. The person submitting these reports shall certify whether each increment of progress has been achieved. If it has not been achieved, the report shall contain a detailed explanation of the reasons for the failure to achieve that increment of progress.

9. DMHC shall submit monthly to the regional air pollution control agency, an analysis of a representative sample of each shipment of coal burned at DMHC on an as received basis, except that each shipment of coal need not be analyzed more than once. This analysis shall specify the average Btu content, percent sulfur, percent ash, percent moisture, and total tonnage of the coal burned the previous month.

10. DMHC shall comply with any other emission monitoring and reporting required by chapter 3704 of the Ohio Revised Code and the regulations promulgated thereunder.

11. Emission tests shall be conducted upon the new boilers described in order (1) above to verify compliance with order (1). Such tests shall be conducted no later than the date specified in the compliance schedule in order (3) above in accordance with procedures approved by the Director. Written notification of intent to test shall be provided to the regional air pollution control agency thirty (30) days prior to the testing date.

12. DMHC shall apply for and obtain permits to operate the boilers in accordance with OAC 3745-35-02.

13. DMHC is hereby notified that unless it is exempted under section 120(a)(2) (B) or (C) of the Clean Air Act, as amended, failure to achieve final compliance with order (1) above by July 1, 1979, will result in a requirement to pay a noncompliance penalty under section 120 of the Clean Air Act, as amended.

NED E. WILLIAMS, P.E.,
Director of Environmental Protection.

WAIVER

The Ohio Department of Mental Health and Mental Retardation agrees that the attached findings and orders are lawful and reasonable and agrees to comply with the attached orders. The Ohio Department of Mental Health and Mental Retardation hereby waives the right to appeal the issuance or terms of the attached findings and orders to the environmental board of review, and it hereby waives any and all rights it might have to seek judicial review of said findings and orders either in law or equity. The Ohio Department of Mental Health and Mental Retardation also waives any and all rights it might have to seek such judicial review of any approval by U.S. EPA of the attached findings and orders or to seek a stay of enforcement of said findings and orders in connection with any judicial

review of Ohio's air implementation plan (or portion thereof).

JAMES F. MCAVOY,
Authorized Representative of Ohio Department of Mental Health and Mental Retardation.

[FR Doc. 78-23832 Filed 8-24-78; 8:45 am]

[6560-01]

[40 CFR Part 65]

[FRL 952-7]

STATE AND FEDERAL ADMINISTRATIVE ORDERS PERMITTING A DELAY IN COMPLIANCE WITH STATE IMPLEMENTATION PLAN REQUIREMENTS

Notice of Proposed Approval of an Administrative Order Issued by Hammond Air Pollution Control Department to Industrial Fuel & Asphalt Co. of Indiana, Inc.

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve an administrative order issued by the Hammond Air Pollution Control Department to Industrial Fuel & Asphalt Co. of Indiana, Inc. The order requires the company to bring air emissions from its crude oil and gasoline storage vessels in Hammond, Ind., into compliance with certain regulations contained in the federally approved Indiana State implementation plan (SIP) by May 15, 1979. Because the order has been issued to a major source and permits a delay in compliance with provisions of the SIP, it must be approved by EPA before it becomes effective as a delayed compliance order under the Clean Air Act (the Act). If approved by EPA, the order will constitute an addition to the SIP. In addition, a source in compliance with an approved order may not be sued under the Federal enforcement or citizen suit provisions of the act for violations of the SIP regulations covered by the order. The purpose of this notice is to invite public comment on EPA's proposed approval of the order as a delayed compliance order.

DATE: Written comments must be received on or before September 25, 1978.

ADDRESS: Comments should be submitted to Director, Enforcement Division, EPA, Region V, 230 South Dearborn Street, Chicago, Ill. 60604. The State order, supporting material, and public comments received in response to this notice may be inspected and copied (for appropriate charges) at this address during normal business hours.

FOR FURTHER INFORMATION CONTACT:

Anne Swofford, Attorney, Enforcement Division, U.S. EPA, Region V, 230 South Dearborn Street, Chicago, Ill. 60604, 312-353-2082.

SUPPLEMENTARY INFORMATION: Industrial Fuel & Asphalt Co. of Indiana, Inc., operates a refinery at Hammond, Ind. The order under consideration addresses emissions from two crude oil storate vessels and one gasoline storage vessel at the facility, which are subject to Indiana Regulation APC-15. The regulation limits the emissions of hydrocarbons, and is part of the federally approved Indiana SIP. The order requires final compliance with the regulation by May 15, 1979, through the installation of floating roofs on its crude oil and gasoline storage vessels. During the period in which the order is in effect, the company will operate its crude topping unit at a production maximum of 6,000 barrels per day and an interim emission limit of 1.2 tons of hydrocarbon matter per day. The source has consented to the terms of the order and has waived its right to a notice of violation under section 113(a)(1) of the Clean Air Act. The source has waived any and all rights under any provision of law to challenge the order.

Because this order has been issued to a major source of hydrocarbon emissions and permits a delay in compliance with the applicable regulation, it must be approved by EPA before it becomes effective as a delayed compliance order under section 113(d) of the Clean Air Act (the Act). EPA may approve the order only if it satisfies the appropriate requirements of this subsection.

If the order is approved by EPA, source compliance with its terms would preclude Federal enforcement action under section 113 of the act against the source for violations of the regulation covered by the order during the period the order is in effect. Enforcement against the source under the citizen suit provision of the act (section 304) would be similarly precluded. If approved, the order would also constitute an addition to the Indiana SIP.

All interested persons are invited to submit written comments on the proposed order. Written comments received by the date specified above will be considered in determining whether EPA may approve the order. After the public comment period, the Administrator of EPA will publish in the FEDERAL REGISTER the Agency's final action on the order in 40 CFR Part 65.

The provisions of 40 CFR Part 65 will be promulgated by EPA soon, and will contain the procedure for EPA's issuance, approval, and disapproval of orders under section 113(d) of the act. In addition, part 65 will contain sections summarizing orders, approved, and disapproved by EPA. A prior notice proposing regulations for part 65, published at 40 FR 14876 (April 2, 1975), will be withdrawn, and replaced by a notice promulgating these new regulations.

(42 U.S.C. 7413, 7601.)

Dated: August 7, 1978.

VALDAS V. ADAMKUS,
Acting Regional Administrator, Region V.

HAMMOND AIR POLLUTION CONTROL DEPARTMENT

[Order No. HAPC 3-78-B]

In the matter of: Industrial Fuel & Asphalt Co. of Indiana, Inc., proceeding under section 113(d) of the Clean Air Act, as amended.

ORDER

The following order is issued this date pursuant to section 113(d) of the Clean Air Act, as amended 42 U.S.C. 7401 et seq. (hereinafter referred to as "the Act"). Public notice, opportunity for public hearing and 30 days notice to the State of Indiana and the USEPA have been provided pursuant to section 113(d)(1) of the Act. This order contains a schedule for compliance, for interim control requirements, and reporting requirements. Final compliance is required as expeditiously as practicable, but not later than May 15, 1979.

On December 22, 1977, the Hammond Air Pollution Control Department received a draft of a compliance program from the Industrial Fuel & Asphalt Co. of Indiana, Inc. (hereinafter referred to as ("the Company") for storage tanks Nos. 55, 56, and 52 at the Company's Hammond facility. Such tanks are in violation of Indiana regulation APC-15 and Hammond air quality control ordinance No. 3522 (as amended), article VI, section 6.5. Such tanks must operate with floating roofs in order to comply with the above-mentioned regulations. Presently, the emission limit is two (2) tons per year of hydrocarbon emission losses (based on acceptable techniques) for both crude storage vessels having true vapor pressure not in excess of 3.4 psia (at bulk liquid temperature) and a gasoline storage vessel having true vapor pressure not in excess of 5.8 psia (at bulk liquid temperature). Actual hydrocarbon emissions from these fixed-cone roof storage vessels (Nos. 55, 56, and 52) are 438 tons per year while at a production capacity of 6,000 barrels per day.

On February 1, 1978, at the USEPA region V office, a meeting was held at the Company's request to discuss its operations and difficulties with a compliance program. Present were representative of the Company, the Hammond Air Pollution Control Department, and the U.S. Environmental Protection Agency. At that time, the Company agreed to commit itself to a compliance schedule through an order issued under section 113(d) of the Act.

The Company has waived its right to a notice of violation under section 113(a)(1) of the Act, and any notice requirements of the State of Indiana and city of Hammond Air Pollution Control Ordinance.

After thorough investigation of all relevant facts, including public comment, it is determined that the schedule for compliance set forth in this order is as expeditious as practicable, and that the terms of this order comply with section 113(d) of the Act.

Therefore, *It is hereby ordered*, That:

I. The Company shall complete the following acts with respect to its storage tanks Nos. 55, 56, and 52.

A. Submit drawings and specifications prior to April 15, 1978.

B. Submit installation permits prior to May 1, 1978.

C. Appropriate funds prior to October 15, 1978.

D. Commence construction and installation of necessary equipment—tank No. 55, prior to March 15, 1979; tank No. 56, prior to April 10, 1979; tank No. 52, prior to May 1, 1979.

E. Date of final compliance for tanks Nos. 55, 56, and 52 prior to May 15, 1979.

II. The Company shall achieve final compliance with all the above-mentioned regulations by May 15, 1979.

III. Pursuant to section 113(d)(7) of the Act, during the period in which this order is in effect, the Company shall use the best practicable system(s) of emission reduction so as to avoid an imminent and substantial endangerment to the health of persons and shall further comply with the requirements of the applicable implementation plan insofar as it is able to.

IV. During the period in which this order is in effect, the Company shall operate its crude topping unit at a production maximum 6,000 barrels per day and an iterim emission limit of 1.2 tons of hydrocarbon matter per day. The Company shall maintain records throughout the period in which this order is in effect which demonstrate that the provisions of this paragraph are being followed. Such records shall be available for inspection by the USEPA, State of Indiana, and the Hammond Air Pollution Control Department.

V. The Company shall submit reports to the Hammond Air Pollution Control Department detailing progress made with respect to each requirement of this order. To enable verification that this order will be achieved as expeditiously and as practicable, the Company shall submit its quarterly financial statement to the Hammond Air Pollution Control Department within five (5) days of its receipt. Such quarterly financial statement shall be considered confidential information by this agency. Such quarterly financial statement shall begin with the last quarter of 1977 and shall terminate with the completion of this order. In addition, no later than June 15, 1979, the Company shall certify to the Hammond Air Pollution Control Department that the facility is in final compliance with all applicable regulations.

VI. In the event that the Company has not achieved final compliance as required by this order by May 15, 1979, it shall thereafter be subject to any applicable form of enforcement action for each day of violation beyond May 15, 1979. A failure to meet any incremental date of this order shall be considered a violation of this order. This order does not preclude the USEPA or the State of Indiana to bring an enforcement action under section 113(b) of the Act for each day of violation beyond May 15, 1979.

VII. All submissions and notifications to the Hammond Air Pollution Control Department pursuant to this order shall be made to the Chief, Hammond Air Pollution Control Department, 5925 Calumet Avenue, Hammond, Ind. 46320.

VIII. Nothing in this order shall be construed so as to affect the Company's responsibility to comply with any other Federal, State, or local regulations.

IX. Nothing in this order shall be construed as a waiver by the USEPA, State of Indiana or Hammond Air Pollution Control Department of any rights or remedies under the Clean Air Act, 42 U.S.C. section 7603, and any State statutes, regulations, or local ordinances.

X. The Company is hereby notified that its failure to achieve final compliance by July 1, 1979, will result in a requirement to pay a noncompliance penalty under section 120 of the Act. In the event of such failure, the Company will be formally notified, pursuant to section 120(b)(3) and any regulations promulgated thereunder, of its noncompliance.

XI. The Department has found that the Company is presently unable to comply with the State of Indiana implementation plan thereby necessitating the promulgation of this order.

XII. This order shall be terminated in accordance with section 113(d)(8) of the Act if the Chief of the Hammond Air Pollution Control Department determines on the record, after the notice and hearing, that the Company has brought the storage tanks Nos. 55, 56, and 52 prior to the final compliance date of this order.

XIII. This order is effective upon receipt of formal approval from the USEPA Regional Administrator. Such approval will be addendum to this order.

Dated: April 28, 1978.

RONALD L. NOVAK,
Chief, Hammond
Air Pollution Control Department.

The Industrial Fuel & Asphalt Co. of Indiana, Inc., has reviewed this order and believes it to be a reasonable means by which it can achieve compliance with State of Indiana regulation APC-15, Hammond Air Pollution Control Ordinance No. 3522 as amended, article VI, section 6.5. The Company stipulates to the correctness of all facts stated above and consents to the requirements and terms of this order. The Company waives its right to a notice of violation under section 113(a)(1) of the Clean Air Act and any notice requirement of the State of Indiana and city of Hammond Air Pollution Control Ordinance. The Company further waives any and all rights under any provision of law to challenge this order.

Dated: April 26, 1978.

JOHN F. SWAIN,
President, Industrial Fuel &
Asphalt Co. of Indiana, Inc.

[FR Doc. 78-23833 Filed 8-24-78; 8:45 am]

[6560-01]

[40 CFR Part 65]

[Docket No. DCO-78-7; FRL 953-5]

STATE AND FEDERAL ADMINISTRATIVE ORDERS PERMITTING A DELAY IN COMPLIANCE WITH STATE IMPLEMENTATION PLAN REQUIREMENTS

Proposed Approval of an Administrative Order Issued by the Commonwealth of Kentucky, Department for Natural Resources and Environmental Protection to Berea College

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve an administrative order issued by the Commonwealth of Kentucky of Berea College. The order requires Berea College to bring air emissions from its heating plant in Berea, Ky., into compliance with certain regulations contained in the federally approved Kentucky State implementation plan (SIP) by March 1, 1979. Because the order has been issued to a major source and permits a delay in compliance with provisions of the SIP, it must be approved by EPA before it becomes effective as a delayed compliance order under the Clean Air Act (the Act). If approved by EPA, the order will constitute an addition to the SIP. In addition, a source in compliance with an approved order may not be sued under the federal enforcement or citizen suit provisions of the Act for violations of the SIP regulations covered by the order. The purpose of this notice is to invite public comment on EPA's proposed approval of the order as a delayed compliance order.

DATE: Written comments musts be received on or before September 25, 1978.

ADDRESSES: Comments should be submitted to and copies of the order available from: Director, Enforcement Division, EPA, Region IV, 345 Courtland Street NE., Atlanta, Ga. 30308. The State order, supporting material, and public comments received in response to this notice may be inspected and copied (for appropriate charges) at this address during normal business hours.

FOR FURTHER INFORMATION CONTACT:

Richard S. DuBose, Air Enforcement Branch, U.S. Environmental Protection Agency, Region IV, 345 Courtland Street NE., Atlanta, Ga. 30308, telephone 404-881-4298.

SUPPLEMENTARY INFORMATION: Berea College operates a heating plant at its facility in Berea, Ky. The order under consideration addresses emissions from a 60,000 pound per hour indirect heat exchanger at the facility, which is subject to Kentucky Air Pollution Control regulation KAR 401 3:060, section 3(3)(b) and section 3(3)(d). The regulation limits the emissions of particulate matter, and is part of the federally approved Kentucky State implementation plan. The order requires final compliance with the regulation by March 1, 1979, through the implementation of the following schedule for the construction or installation of control equipment:

(1) Submit final control plan for achieving compliance with applicable regulation by April 3, 1978.

(2) Award contract for required control equipment by June 9, 1978.
(3) Commence on-site construction or installation of control equipment by June 19, 1978.
(4) Complete construction or installation of control equipment by January 31, 1979.
(5) Submit proof of final compliance by March 1, 1979.

The source has consented to the terms of the order and has agreed to meet the order's increments during the period of this informal rulemaking. The source is required to submit monthly coal analysis data in order to monitor emissions prior to the demonstration of final compliance. As an interim control the visible emissions from the noncomplying indirect heat exchanger shall not exceed 65 percent capacity at any time prior to the installation of controls.

Because this order has been issued to a major source of particulate matter emissions and permits a delay in compliance with the applicable regulation, it must be approved by EPA before it becomes effective as a delayed compliance order under section 113(d) of the Clean Air Act (the Act). EPA may approve the order only if it satisfies the appropriate requirements of this subsection. EPA has tentatively determined that the above referenced order satisfies these requirements.

If the order is approved by EPA, source compliance with its terms would preclude federal enforcement action under section 113 of the Act against the source for violations of the regulation covered by the order during the period the order is in effect. Enforcement against the source under the citizen suit provision of the Act (section 304) would be similarly precluded. If approved, the order would also constitute an addition to the Kentucky SIP. Compliance with the proposed order will not exempt the company from the requirements contained in any subsequent revisions to the SIP which are approved by EPA.

All interested persons are invited to submit written comments on the proposed order. Written comments received by the date specified above will be considered in determining whether EPA may approve the order.

After the public comment period, the Administrator of EPA will publish in the FEDERAL REGISTER the Agency's final action on the order in 40 CFR Part 65.

The provisions of 40 CFR Part 65 will be promulgated by EPA soon, and will contain the procedure for EPA's issuance, approval, and disapproval of orders under section 113(d) of the Act. In addition, part 654 will contain sections summarizing orders issued, approved, and disapproved by EPA. A prior notice proposing regulations for part 65, published at 40 FR 14876 (April 2, 1975), will be withdrawn, and replaced by a notice promulgating these new regulations.

Authority: 42 U.S.C. 7413, 7601.

Dated: July 28, 1978.

PAUL TRAINA,
Acting Regional Administrator, Region IV.

[FR Doc. 78-23872 Filed 8-24-78; 8:45 am]

[6560-01]

[40 CFR Part 65]

[FRL 953-6]

STATE AND FEDERAL ADMINISTRATIVE ORDERS PERMITTING A DELAY IN COMPLIANCE WITH STATE IMPLEMENTATION PLAN REQUIREMENTS

Proposed Approval of an Administrative Order Issued By Ohio Environmental Protection Agency To City of Akron

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve an administrative order issued by the Ohio Environmental Protection Agency to the city of Akron. The order requires the company to bring air emissions from its sludge incinerators in Akron, Ohio, into compliance with certain regulations contained in the federally approved Ohio State implementation plan (SIP) by July 1, 1979. Because the order has been issued to a major source and permits a delay in compliance with provisions of the SIP, it must be approved by EPA before it becomes effective as a delayed compliance order under the Clean Air Act (the Act). If approved by EPA, the order will constitute an addition to the SIP. In addition, a source in compliance with an approved order may not be sued under the Federal enforcement or citizen suit provisions of the Act for violations of the SIP regulations covered by the order. The purpose of this notice is to invite public comment on EPA's proposed approval of the order as a delayed compliance order.

DATE: Written comments must be received on or before September 25, 1978.

ADDRESSEES: Comments should be submitted to and copies of the Order available from: Director, Enforcement Division, EPA, Region V, 230 South Dearborn Street, Chicago, Ill. 60604. The State order, supporting material, and public comments received in response to this notice may be inspected and copied (for appropriate charges) at this address during normal business hours.

FOR FURTHER INFORMATION CONTACT:

Roger M. Grimes, U.S. Environmental Protection Agency, Enforcement Division, 230 South Dearborn Street, Chicago, Ill. 60604 312-353-2082.

SUPPLEMENTARY INFORMATION: The city of Akron operates four sludge incinerators at Akron, Ohio. The order under consideration addresses emissions from the stacks of each incinerator at the facility, which are subject to Ohio Administrative Code (OAC) 3745-17-09 and OAC 3745-17-07. The regulation limits the emissions of particulate matter, and is part of the federally approved Ohio State implementation plan. The order requires final compliance with the regulation July 1, 1979, through rebuilding of incinerators and installation of pollution control equipment.

Because this order has been issued to a major source of particulate matter emissions and permits a delay in compliance with the applicable regulation, it must be approved by EPA before it becomes effective as a delayed compliance order under section 113(d) of the Clean Air Act (the Act). EPA may approve the order only if it satisfies the appropriate requirements of this subsection.

If the order is approved by EPA, source compliance with its terms would preclude Federal enforcement action under section 113 of the Act against the source for violations of the regulation covered by the order during the period the order is in effect. Enforcement against the source under the citizen suit provision of the Act (section 304) would be similarly precluded. If approved, the order would also constitute an addition to the Ohio SIP.

All interested persons are invited to submit written comments on the proposed order. Written comments received by the date specified above will be considered in determining whether EPA may approve the order. After the public comment period, the Administrator of EPA will publish in the FEDERAL REGISTER the Agency's final action on the order in 40 CFR Part 65.

The provisions of 40 CFR Part 65 will be promulgated by EPA soon, and will contain the procedure for EPA's issuance, approval, and disapproval of orders under section 113(d) of the Act. In addition, part 65 will contain sections summarizing orders issued, approved, and disapproved by EPA. A prior notice proposing regulations for part 65, published at 40 FR 14876 (April 2, 1975), will be withdrawn, and replaced by a notice promulgating these new regulations.

(Authority: 42 U.S.C. 7413, 7601.)

Dated: August 10, 1978.

VALDAS V. ADAMKUS,
Acting Regional Administrator, Region V.

[FR Doc. 78-23873 Filed 8-24-78; 8:45 am]

[6560-01]

[40 CFR Part 761]

[FRL 955-1]

POLYCHLORINATED BIPHENYLS (PCB's)

Manufacturing, Processing, Distribution in Commerce, and Use Bans; Clarification

AGENCY: Environmental Protection Agency.

ACTION: Clarification of contents of Official Record of Proposed Rulemaking.

SUMMARY: This notice clarifies that the official record of rulemaking for the proposed PCB ban regulation includes the official record for the Administrator's promulgation of toxic pollutant effluent standards for PCB's under section 307(a) of the Clean Water Act.

FOR FURTHER IFORMATION CONTACT:

Peter P. Principe, Office of Toxic Substances (TS-794), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, telephone 202-755-0920.

SUPPLEMENTARY INFORMATION: On June 7, 1978, the Environmental Protection Agency published a proposed regulation concerning PCB manufacturing, processing, distribution in commerce, and use bans (43 FR 24802). On page 24813, second column of the proposal, EPA stated: "In addition, all reports and articles referenced in the USEPA OTS Support Document Voluntary EIS are included in the Official Record. The record for the section 307 Water Effluent Standards for PCB's may be examined by the public at the Office of Hearing Clerk, Room 3708A, Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460."

EPA wishes to clarify that the official record of rulemaking for the proposed PCB ban regulation includes the Official Record for the Administrator's promulgation of toxic pollutant effluent standards for PCB's under section 307(a) of the Clean Water Act (42 FR 6532-6555, February 2, 1977). The record for the PCB effluent standards may be examined by the public as indicated above and may be cited as "In the Matter of: Proposed Toxic Pollutant Effluent Standards for Polychlorinated Biphenyls (PCB's), FWPCA (307), Docket No. 4."

Dated: August 21, 1978.

STEVEN D. JELLINEK,
Assistant Administrator for Toxic Substances.

[FR Doc. 78-24024 Filed 8-24-78; 8:45 am]

[4510-27]

DEPARTMENT OF LABOR

Office of Federal Contract Compliance Programs

[41 CFR Part 60-20]

EXECUTIVE ORDER 11246—EMPLOYEE BENEFITS

Amendment to Regulations

AGENCY: Office of Federal Contract Compliance Programs, Department of Labor.

ACTION: Proposed amendment to regulations.

SUMMARY: The Office of Federal Contract Compliance Programs' sex discrimination guidelines presently provide, with respect to insurance, pensions, welfare programs, and other similar "fringe benefits," that the guidelines are not violated where employer contributions for such programs are equal for men and women or where the resulting benefits are equal. See 41 CFR 60-20.3(c). The Secretary of Labor proposes to amend these regulations to make clear that Executive Order 11246, as amended by Executive Order 11375, and the regulations at 41 CFR 60-20.3(c) are violated if (1) a differential in benefits is based on differences between the cost to the employer of providing benefits to women as a group and the cost of providing benefits to men as a group, or (2) employees of one sex are required to make greater contributions from their wages than are employees of the opposite sex in order to receive equal benefits.

DATE: Comments on this proposal will be received until October 23, 1978.

ADDRESS: Send comments to the Director, Office of Federal Contract Compliance Programs, Room C-3324, New Department of Labor Building, 200 Constitution Avenue NW., Washington, D.C. 20210. Comments received will be available for inspection during regular working hours at the above address.

FOR FURTHER INFORMATION CONTACT:

Doris P. Wooten, Acting Associate Director, Office of Federal Contract Compliance Programs, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210.

SUPPLEMENTARY INFORMATION: The Department of Labor recognizes the need for meaningful enforcement of those Federal equal employment opportunity laws which it administers and the importance of achieving a reasonable degree of consistency among the several Federal equal employment opportunity agencies in interpreting the requirements of Executive Order 11246, as amended, and title VII of the Civil Rights Act of 1964, as amended. Achieving the desired level of interagency consistency among agency requirements concerning sex discrimination in the administration of insurance, pension, and retirement benefit programs has been particularly troublesome. The Administrator of the Department of Labor's Wage and Hour Division originally ruled that the requirements of the Equal Pay Act would be met if an employer made equal contributions for male and female employees or if the resulting benefits were equal. This interpretation was originally followed by the Office of Federal Contract Compliance Programs (OFCCP) in administering Executive Order 11246, as amended. In 1972, the EEOC amended its guidelines to state explicitly that it was unlawful for an employer to have an insurance, pension, or retirement plan which differentiates in benefits paid on the basis of sex.

Similarly, the Administrator of the Department of Labor's Wage and Hour Division today has proposed an amendment to the interpretive bulletin on the Equal Pay Act which makes clear that employee benefits are "wages" within the Equal Pay Act, that any differential in such benefits based on sex-based actuarial distinctions violates the act, and that any sex-based differential in required employee contributions toward equal benefits violates the act.

In consideration of the foregoing and in consideration of the reasons expressed in support of Wage and Hour Division's proposed amendment, it is proposed to amend 41 CFR 60-20.3(c) as set forth below.

This document was prepared under the direction and control of Weldon J. Rougeau, Director, OFCCP.

Dated: August 18, 1978.

RAY MARSHALL,
Secretary of Labor.

DONALD ELISBURG,
Assistant Secretary Employment Standards Administration.

RICHARD J. DEVINE,
Acting Director, Office of Federal Contract Compliance Programs.

§ 60-20.3 Job policies and practices.

* * * * *

(c) The employer must not make any distinction based upon sex in employment opportunitites, wages, hours, or other conditions of employment. In the area of employer contributions for insurance, pensions, welfare programs, and other similar "fringe benefits," a differential in benefits based upon differences between the cost to the employer of providing benefits to women as a group and the cost of providing benefits to men as a group violates Executive Order 11246, as amended by Executive Order 11375, and these regulations. Similarly, Executive Order 11246, as amended by Executive Order 11375, and these regulations are violated if employees of one sex are required to make greater contributions from their wages than are employees of the opposite sex in order to receive equal benefits.

[FR Doc. 78-23732 Filed 8-24-78; 8:45 am]

[4110-35]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Health Care Financing Administration

[42 CFR Part 405]

FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Review of Provider Reimbursement Review Board Decision

AGENCY: Health Care Financing Administration (HCFA), HEW.

ACTION: Notice of Decision to Issue Regulations.

SUMMARY: This proposal would specify the criteria and procedures for review of Provider Reimbursement Review Board Decisions by the Administrator, HCFA. The amendment is necessary to resolve current confustion concerning the procedures and to comply with the Administrative Procedure Act. The intent is to assure uniform, expeditious handling of all cases and a single Departmental position on similar matters.

FOR FURTHER INFORMATION CONTACT:

Erica L. Gosnell, Office of Attorney-Advisor, Room G-50, Altmeyer Building, Baltimore, Md. 21235, phone 301-594-5132.

Dated: August 17, 1978.

WILLIAM D. FULLERTON,
Acting Administrator, Health Care Financing Administrator.

[FR Doc. 78-24000 Filed 8-24-78; 8:45 am]

[4110-35]

[42 CFR Part 405]

FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Hospital Insurance: Entitlement, Deductible, and Coinsurance Requirements

AGENCY: Health Care Financing Administration (HCFA), HEW.

ACTION: Notice of decision to revise regulations.

SUMMARY: The proposed regulations would reorganize, simplify, and clarify certain portions of the Medicare, Part A regulations so that beneficiaries and potential beneficiaries can more easily understand the conditions that would make them eligible for Medicare and how much money they would have to contribute toward the cost of their hospital care. This revision will be part of "Operation Common Sense," the Department's commitment to revise and recodify its regulations to promote public understanding.

FOR FUTHER INFORMATION CONTACT:

John B. Russell, Medicare Bureau, room 1-H-5 East Building, 6401 Security Boulevard, Baltimore, Md. 21235, telephone 301-594-8260.

Dated: August 17, 1978.

WILLIAM D. FULLERTON,
Acting Administrator, Health Care Financing Administrator.

[FR Doc. 78-24012 Filed 8-24-78; 8:45 am]

[4110-35]

[42 CFR Part 405]

FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Conditions of Participation: Hospitals

AGENCY: Health Care Financing Administration (HCFA), HEW.

ACTION: Notice of decision to revise regulations.

SUMMARY: Current regulations specify in detail the health and safety requirements that hospitals must meet to participate in the Medicare-Medicaid programs. They have been in effect over 10 years. We are proposing to revise the regulations because of changes in methods of health care delivery, the need to control the increasing cost of hospital care, and our commitment to simplify HEW regulations. The intent of the revision is to retain the basic principles of the existing requirements but allow hospitals greater flexibility in their use of staff and other resources.

FOR FURTHER INFORMATION CONTACT:

Janet M. Harryman, room 301, East High Rise, 6401 Security Boulevard, Baltimore, Md. 20235, telephone 301-594-712.

Dated: August 17, 1978.

WILLIAM D. FULLERTON,
Acting Administrator, Health Care Financing Administrator.

[FR Doc. 78-24013 Filed 8-24-78; 8:45 am]

[4110-35]

[42 CFR Parts 405 and 449]

FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED; SERVICES AND PAYMENT IN MEDICAL ASSISTANCE PROGRAMS

Conditions of Participation: Skilled Nursing Facilities and Intermediate Care Facilities

AGENCY: Health Care Financing Administration (HCFA), HEW.

ACTION: Notice of decision to revise regulations.

SUMMARY: The Department is recodifying, revising, and consolidating the present regulations governing participation of Skilled Nursing Facilities (SNF's) and Intermediate Care Facilities (ICF's) in the Medicare and Medicaid programs.

In keeping with our commitment to simplify regulations, we plan to retain the basic principles of current requirements while allowing the providers greater flexibility in their use of resources. We believe this will permit cost control, without jeopardizing the health or safety of patients, employees, or the public.

FOR FURTHER INFORMATION CONTACT:

Constance A. Conrad, Health Care Financing Administration, East Building, High Rise, Room 300, 6401 Security Boulevard, Baltimore, Md. 21235, 301-594-9722.

Dated: August 17, 1978.

WILLIAM D. FULLERTON,
Acting Administrator, Health Care Financing Administration.

[FR Doc. 78-24014 Filed 8-24-78; 8:45 am]

[6712-01]

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Part 73]

[BC Docket No. 78-264; RM-3121]

FM BROADCAST STATIONS IN WHITEHOUSE AND TYLER, TEX.

Proposed Changes in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: Action taken herein proposes the assignment of a fourth FM channel to Tyler, Tex. Petitioner had proposed the channel for Whitehouse, Tex., but the Commission believed the proposed assignment to Tyler could better respond to area needs while still being available for use at Whitehouse.

DATES: Comments must be received on or before October 16, 1978, and Reply comments must be received on or before November 6, 1978.

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

FOR FURTHER INFORMATION CONTACT:

Mildred B. Nesterak, Broadcast Bureau, 202-632-7792.

SUPPLEMENTARY INFORMATION:

Adopted: August 14, 1978.

Released: August 21, 1978.

In the matter of amendment of § 73.202(b), *Table of Assignments*, FM Broadcast Stations, Whitehouse and Tyler, Tex., BC Docket No. 78-264, RM-3121.

1. The Commission has before it a petition[1] filed by Smith County Broadcasters ("petitioner") licensee of AM Station WTBB, Tyler, Tex., proposing the assignment of Channel 257A to Whitehouse, Tex. The channel could be assigned in conformity with the minimum distance separation requirements. Oppositions were filed, KDOK Broadcasting Co. ("KDOK"), licensee of AM Station KDOK and FM Station KNUE, and Tyler Broadcasting Co., licensee of AM Station KZEY and FM Station KROZ, Tyler, Tex.

2. Whitehouse (pop. 1,245), in Smith County (pop. 97,096)[2], is located approximately 92 kilometers (57 miles) northwest of Lufkin, Tex., and 14 kilometers (9 miles) south of Tyler, Tex. There is no local aural broadcast service in Whitehouse.

3. The preclusion study shows that the proposal would preclude future assignments only on Channel 257A. The Texas communities without local aural broadcast service, which are located in the precluded area, are Big Sandy (pop. 1,022), Overton (pop. 2,084), and Troup (pop. 1,668). A future FM assignment at Gladewater, Tex. (pop. 5,574), which has a daytime-only AM station, would also be precluded.

4. Petitioner states that Whitehouse is a growing community which has increased its city limits three times during the past 2 years with the addition of six residential areas and asserts that there is also a sizable growth outside the city limits. We are told that Whitehouse has an abundance of recreational areas located just 3 miles from it at Lake Tyler East and Lake Tyler West which offer fishing and camping facilities. Petitioner adds that Whitehouse, with a mayor-council form of government, has its own fire department, police department, outpatient clinic, churches, schools, and civic organizations. It notes that Whitehouse is served by a local weekly newspaper.

5. In opposition, KDOK alleges that Whitehouse is a tiny bedroom community, located within the Tyler urbanized area and is served by all mass media located in Tyler; namely, seven AM and FM stations, television stations, CATV system, and several newspapers, and that industry in Whitehouse is negligible and the recreational areas are owned by the city of Tyler. KDOK argues that, in considering market size and media sources, it is reasonable to anticipate that the addition of another media outlet may fractionalize advertising revenues to the extent that existing facilities will be forced to reduce or curtail services and programing. KDOK asserts that Whitehouse, as a tiny community, poses the question of whether a channel assignment there would result in an efficient utilization of spectrum space since it already receives a plethora of aural services from nearby and adjacent communities, and the Channel 257A station at Whitehouse would not serve an unserved or underserved area. It notes that the proposed channel could be assigned to Gladewater, Tex. (pop. 5, 574), which is about 40 kilometers (25 miles) northeast of Tyler and which, it alleges, has no local aural service. It points out that, if the channel is assigned to Whitehouse, it would preclude its use in Gladewater. KDOK concludes that, since Whitehouse is located within the Tyler urbanized area, receives primary service from a number of existing aural facilities nearby and has a very small population and economic base, petitioner has not presented reliable evidence that a local station is or will be supported by its residents.

6. In support of the KDOK opposition, Tyler Broadcasting asserts that Smith has failed to support its proposal properly. Tyler asserts that Whitehouse is not an independent, self-sufficient community. It contends that the proximity of the two communities requires consideration of a suburban community issue and it urges denial of the petition.

7. The petitioner is requesting assignment of a Class A FM channel to a community of 1,245 inhabitants, which is located some 14.5 kilometers (9 miles) from the city of Tyler which has a population of 57,770 persons (1970 U.S. Census). For several reasons we do not think it appropriate to propose making the assignment at Whitehouse. It is a very small community close to Tyler, a much larger one. Whitehouse's need for the assignment is not clear, but another assignment in the area nevertheless might be warranted. Tyler is presently assigned two Class C and one Class A FM channels. According to the population guidelines, it qualifies for another FM assignment. With that in mind, we are proposing to assign Channel 257A to Tyler. Assigned in this manner, the channel would still be available under the "10-mile" rule for use at Whitehouse. Before the channel can be assigned, we need to be provided with a showing that a transmitter site meeting the spacing requirements is available from which a Class A FM station would be able to provide the requisite city-grade signal over the entire community of Tyler. The above showing should be supported by terrain profiles to indicate whether or not there would be an obstacle to signal propagation over the community. The proponent should also indicate whether there are any other channels available for assignment to the communities located in the precluded area referred to in paragraph 3 above.

8. Opponents have questioned the feasibility of permitting another FM station to be established in the Tyler market. Since this question involves the economics of station operation, resolution of the issue is not appropriate at this stage, rather it is our practice to defer such issues for consideration in connection with any application for construction permit when there will be greater opportunity to investigate and weigh the merits of various allegations.

9. In light of the foregoing, the Commission proposes to amend the FM Table of Assignments, § 73.202(b) of the Commission's rules, as follows:

City and Channel No.

Tyler, Tex.; Present: 221A, 226, 268; Proposed: 221A, 226, 257A, 268.

10. The Commission's authority to institute rulemaking proceedings; showings required; cut-off procedures; and filing requirements are contained in the attached appendix below and are incorporated herein.

NOTE.—A showing of continuing interest is required by paragraph 2 of the appendix before a channel will be assigned.

11. Interested parties may file comments on or before October 16, 1978, and reply comments on or before November 6, 1978.

FEDERAL COMMUNICATIONS COMMISSION,
NEAL K. MCNAUGHTEN,
Acting Chief, Broadcast Bureau.

[1] Public Notice of the petition was given on June 7, 1978, Report No. 1125.

[2] Population figures are taken from the 1970 U.S. Census.

APPENDIX

1. Pursuant to authority found in sections 4(i), 5(d)(1), 303 (g) and (r), and 307(b) of the Communication Act of 1934, as amended, and § 0.281(b)(6) of the Commission's rules, it is proposed to amend the FM table of assignments, § 73.202(b) of the Commission's rules and regulations, as set forth in the notice of proposed rulemaking to which this appendix is attached.

2. *Showings required.* Comments are invited on the proposal(s) discussed in the notice of proposed rulemaking to which this appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build the station promptly. Failure to file may lead to denial of the request.

3. *Cut-off procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of Commission rules.)

(b) With respect to petitions for rulemaking which conflict with the proposal(s) in this notice, they will be considered as comments in the proceeding, and public notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

4. *Comments and reply comments; service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's rules and regulations, interested parties may file comments and reply comments on or before the dates set forth in the notice of proposed rulemaking to which this appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420 (a), (b), and (c) of the Commission rules.)

5. *Number of copies.* In accordance with the provisions of § 1.420 of the Commission's rules and regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public inspection of filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street NW., Washington, D.C.

[FR Doc. 78-23964 Filed 8-24-78; 8:45 am]

[6712-01]

[47 CFR Part 73]

[Docket No. 20954; RM-2684; RM-2772; RM-2982]

FM BROADCAST STATION IN STAUNTON, VA.

Proposed Changes in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Second further notice of proposed rulemaking.

SUMMARY: This further notice proposes examination of the requested assignment of class B FM channel 259 to Waynesboro, Va., by the alternative of assigning it to Staunton, Va. This would also permit licensing of the channel (if assigned to Staunton) to Waynesboro under the Commission's 15-mile rule. This proposed amendment to the table of assignments, rule section 73.202, arises from comments filed in an earlier proceeding which initially involved Crozet and Amherst, Va.

DATES: Comments on the proposed amendment to the table of assignments must be filed by October 16, 1978, and reply comments by November 6, 1978.

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

FOR FURTHER INFORMATION CONTACT:

Stanley Wiggins, Broadcast Bureau, 202-632-7792.

SUPPLEMENTARY INFORMATION: The proposed assignments in Crozet and Amherst, which led to the instant further notice were resolved in a report and order found at 43 FR 36942, published August 21, 1978.

In the matter of amendments of § 73.202(b), Table of Assignments FM Broadcast Stations (Staunton, Va.). Second further notice of proposed rulemaking. (See also 42 FR 58417, November 9, 1977.).

Adopted: August 17, 1978.

Released: August 24, 1978.

By the Acting Chief, Broadcast Bureau:

1. This further notice proposes examination of the requested assignment of class B FM channel 259 to Waynesboro, Va., and related expressions of interest in assigning the same frequency to nearby Staunton, Va., instead. It arises initially from a counterproposal made by WANV, Inc., in a separate proceeding,[1] which has since been resolved without foreclosing consideration of the counterproposal in this proceeding.

2. By way of background, the Commission acted in 1967 to provide protection from interference to the National Radio Astronomy Observatory ("NRAO") at Green Bank, W. Va., and the Naval Radio Research Station ("NRRS") at Sugar Grove, W. Va. A "radio quiet zone" was established and several assignments in the affected area were deleted, including one each to Waynesboro, Staunton, and Harrisonburg, Va. *Amendment of Section 73.202, Table of Assignments for FM Broadcast Stations,* docket 16991, 6 FCC 2d 793 (1967). Showings that the NRAO and NRRS had been consulted and tentatively approved proposals for broadcast service were and are expected as part of petitions for assignment which propose restoration of deleted FM channels assigned to communities in the quiet zone. See, for example, *Amendment of Section 73.202, Table of Assignments for FM Broadcast Stations (Harrisonburg, Va.),* 14 FCC 2d 814 (1968). After assignment of a frequency in or near this protected area, applicants for construction permits are required by 47 CFR 73.215 to notify NRAO and NRRS as part of the application procedure. Both the proposals before us in this proceeding must comply with the quiet zone procedures at the assignment and application stage, but neither party has yet established clearance for its assignment request by NRAO and NRRS.

3. WANV, Inc., the licensee of WANV(AM) in Waynesboro, first suggested assignment of channel 259 to Waynesboro in commenting on a proposal for that channel's assignment to Crozet, Va. (docket 20954). In its comments WANV asserted that a class A facility would be inadequate to serve Waynesboro because it would necessarily be located on the floor of the Shenandoah Valley, where unacceptable interference to quiet zone activities is more likely, and if directionalized to avoid such interference would not reach the western portions of the Staunton-Waynesboro "market"—which WANV considers necessary to the economic viability of such a station. In reply comments submitted in the Crozet proceeding, Augusta County Broadcasting Corp., licensee of WTON-AM and WSGM-FM, Staunton, asserted that WANV's counterproposal did not meet Commission standards for assignment of channels within the quiet zone, and would impermissibly intermix the classes of FM channels in the Staunton-Waynesboro "market." Augusta also stated it would likely apply for a class B assignment in Waynesboro if its objections to such

[1] The first report and order in docket 20954 (Crozet, Va.), assigns class A channel to Crozet rather than the originally requested class B FM channel 259 which, if assigned, would have precluded use of that frequency in Waynesboro or Staunton. The same report an order assigned class B FM channel 300 to Amherst, Va.

an assignment were not heeded. As the resolution of the Crozet proceeding leaves the requested channel open for use in the communities of Staunton or Waynesboro, we are soliciting comments on such an assignment in either of those communities—or in any other community which would be precluded by an assignment to Staunton or Waynesboro.

4. Staunton (1970 population 24,504) is located immediately east of the Allegheny Mountains which encompass the quiet zone observatories, some 196 kilometers (122 miles) southwest of Washington, D.C. It is presently served by two AM stations, one of them full time, and a single class A FM facility owned by the operator of the daytime AM facility (WTON), Augusta County Broadcasting Corp.

5. *Waynesboro.* Waynesboro (1970 population 16,707) is some 19 kilometers (12 miles) east-southeast of Staunton, on the eastern portion of the Shenandoah Valley, and is presently served by two full time AM stations, including WANV. Both communities are incorporated, and are of sufficient size to warrant assignment of a class B channel under our population guidelines without requiring a showing of the special circumstances requisite to such an assignment where smaller communities such as Crozet are involved. The Augusta County population outside Waynesboro and Staunton is 44,220 (1970).

6. As noted, WANV, Inc., has proposed assignment of channel 259B to Waynesboro, which presently has no FM facilities. Augusta County Broadcasting Corp., in its reply comments filed in the Crozet proceeding, suggest that if any assignment to Waynesboro is to be made in the face of numerous existing broadcast services in Augusta County, a class A facility would adequately serve Waynesboro as Augusta's own WSGM-FM now serves Staunton. Augusta further states that if a class B frequency is assigned to Waynesboro, it would seriously consider applying for it. The record to this point indicates only one class B frequency available for assignment in this area (after assigning class B channel 300 Amherst), and no interest in class B channel 259 has yet been evidenced by the significant precluded communities of Harrisonburg and Bridgewater. Entirely apart from such a prospect, the incomplete submissions of WANV and Augusta indicate a need for substantial further information before determining whether to assign a class B facility to either of those communities and, if so, to which one. Because of the context in which interest in this assignment of channel 259 was first raised, we consider it appropriate to invite comments from any interested parties in the precluded communities as well.

7. The inclusion of both Staunton and Waynesboro in the radio quiet zone requires that petitions for assignment involving those communities both recognize and resolve any potential interference problems which might be created for the NRAO and NRRS. The general requirement that a petition for assignment specify a community, and state the petitioner's intent to construct if authorized, was brought to WANV's attention by the further notice, but the counterproposal does not include a satisfactory showing that it has taken the necessary steps to deal with the potential quiet zone problems involving any Waynesboro assignment to the satisfaction of the protected installations. The earlier deletion of assignments at Waynesboro, inter alia, found at 6 FCC 2d 793 (1967), as well as prior practice in protecting the quiet zone from television interference,[2] make clear that such a demonstration is expected as part of a petition for assignment of a frequency to a quiet zone community. WANV accurately asserts that the 1967 deletions of class A frequencies assigned to Waynesboro explicitly left open the prospect of their replacement if the observatories were accommodated,[3] but this does not relieve petitioners from the requirement of making a detailed initial showing that quiet zone installations are in fact protected by the petition's proposal, and are recognized as protected by NRAO and NRRS.[4] See generally the assignment of channel 282 to Harrisonburg, found at 14 FCC 2d 814 (1968). Such a showing must be submitted with any comments in support of the assignment set out for comment by this notice.

8. If the channel were assigned to Staunton, the larger community would have the only two channels and it would create intermixture. On the other hand, assigning it to Waynesboro would mean that a class B channel was assigned to the smaller community and a class A channel to the larger one. Finally, if channel 259 were assigned to Staunton, its use could be proposed for Waynesboro as well since it is within 15 miles of the assigned community of Staunton. It is also true that the existing Staunton class A licensee could seek to obtain use of the class B channel there.

9. After consideration of the pleadings in this matter, it seems reasonable to suggest as an initial matter that if the single class B facility feasible in this area must be constructed near the larger of the two communities for technical reasons, it should be assigned to Staunton consistent with general principles of assignment. It will also be open to application as a Waynesboro-licensed facility under the 15-mile rule. As the two communities presently have similar levels of local aural service, such an approach recognizes the possible difficulties in assigning a higher power facility with less natural shielding to the Waynesboro area, as well as the broader public interest in assigning higher power facilities to larger communities. The latter interest is particularly important where the net effect is to permit applications by parties from both communities which have expressed interest—a prospect not technically possible if channel 259 is assigned to Waynesboro. Accordingly, this notice proposes such an assignment to Staunton.

10. This notice should not be construed as indicating that the overall desirability of creating future intermixture situations has been resolved, and we expect commenting parties to address this problem in light of the effects of the area's only class B channel as well as the feasibility of alternative class A service to Waynesboro. We expect WANV in particular to directly address the issue of Waynesboro's need for a third aural service independently of its position on the technical feasibility of a directionalized class A facility.[5] Finally, while we have asserted our reasons for proposing a class B assignment to Staunton, any considerations favoring assignment to Waynesboro should be brought to the Commission's attention.

11. Further comments are invited, in accordance with the discussion supra, on proposals to further amend the FM table of assignments (§ 73.202(b) of the Commission's rules) for the following community:

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[2] *Educational Assignment (TV) in Staunton, Va.* (docket 16882), 5 FCC 2d 537 (1966), 8 RR 2d 1623.

[3] *Amendment of Section 73.202, FM Table of Assignments (Harrisonburg, Staunton, and Waynesboro, inter alia)*, 6 FCC 2d 793 (1967). Two applicants for channel 224A at Waynesboro were accorded an additional 120 days by the proposal for deletion of that channel in which to agree with NRAO and NRRS on a proposed facility, but elected to withdraw their petitions.

[4] This requirement would, of course, apply to any proposal for a class A assignment to Waynesboro just as it does to the instant petition for a higher power class B assignment.

[5] Commission staff analysis indicates, for instance, that channel 240A would be available for assignment to Waynesboro if located at least 10.5 kilometers (6.5 miles) northwest of the community, and we are soliciting comments on such an assignment, including WANV's interest in constructing such a facility if (i) the class B channel is assigned to Staunton and WANV fails to win authority to construct such a facility and, in the alternative, (ii) no class B channel is authorized.

City	Channel No.	
	Present	Proposed
Staunton, Va	228A*	228A, 259

12. The Commission's authority to institute rulemaking proceedings; showings required; cutoff precedures; and filing requirements are contained in the attached appendix and are incorporated herein.

NOTE.—A showing of continuing interest is required by paragraph 2 of the appendix before a channel will be assigned.

13. Interested parties may file comments on or before October 16, 1978, and reply comments on or before November 6, 1978.

FEDERAL COMMUNICATIONS COMMISSION,

NEAL K. MCNAUGHTEN,
Acting Chief, Broadcast Bureau.

APPENDIX

1. Pursuant to authority found in sections 4(i), 5(d)(1), 303 (g) and (r), and 307(b) of the Communications Act of 1934, as amended, and section 0.281(b)(6) of the Commission's rules, it is proposed to amend the FM table of assignments, section 73.202(b) of the Commission's rules and regulations, as set forth in the notice of proposed rulemaking to which this appendix is attached.

2. *Showings required.* Comments are invited on the proposal(s) discussed in the notice of proposed rulemaking to which this appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build the station promptly. Failure to file may lead to denial of the request.

3. *Cutoff procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of Commission rules.)

(b) With respect to petitions for rulemaking which conflict with the proposal(s) in this notice, they will be considered as comments in the proceeding, and public notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

4. *Comments and reply comments; service.* Pursuant to applicable procedures set out in sections 1.415 and 1.420 of the Commission's rules and regulations, interested parties may file comments and reply comments on or before the dates set forth in the notice of proposed rulemaking to which this appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420 (a), (b), and (c) of the Commission rules.)

5. *Number of copies.* In accordance with the provisions of section 1.420 of the Commission's rules and regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public inspection of filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street NW., Washington, D.C.

[FR Doc. 78-23963 Filed 8-24-78; 8:45 am]

notices

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

[3410-07]

DEPARTMENT OF AGRICULTURE

Farmers Home Administration

[Designation No. A646]

IOWA

Designation of Emergency Areas

The Secretary of Agriculture has determined that farming, ranching, or aquaculture operations have been substantially affected in the following Iowa counties as a result of intermittent hail, high winds, and rain (with flooding in some areas) during the period June 1 through July 7, 1978:

Calhoun	Humboldt
Cerro Gordo	Kossuth
Cherokee	Sac
Clay	Webster
Franklin	Woodbury
Hamilton	

Therefore, the Secretary has designated these areas as eligible for emergency loans pursuant to the provisions of the Consolidated Farm and Rural Development Act, as amended, and the provisions of 7 CFR 1904 subpart C, exhibit D, paragraph VB, including the recommendation of Gov. Robert D. Ray that such designation be made.

Applications for emergency loans must be received by this department no later than February 12, 1979, for physical losses and August 15, 1979, for production losses, except that qualified borrowers who receive initial loans pursuant to this designation may be eligible for subsequent loans. The urgency of the need for loans in the designated area makes it impracticable and contrary to the public interest to give advance notice of proposed rulemaking and invite public participation.

Done at Washington, D.C., this 18th day of August 1978.

GORDON CAVANAUGH,
Administrator,
Farmers Home Administration.

[FR Doc. 78-23895 Filed 8-24-78; 8:45 am]

[3410-07]

[Designation No. A645]

KANSAS

Designation of Emergency Areas

The Secretary of Agriculture has determined that farming, ranching, or aquaculture operations have been substantially affected in the following Kansas counties as a result of hail, wind, rain (with some flooding), and/or tornadoes during the incidence period April 30 through June 20, 1978:

Barton	Jackson
Butler	Jewell
Clark	Marion
Edwards	Meade
Ellsworth	Miami
Finney	Montgomery
Ford	McPherson
Gray	Reno
Greeley	Rice
Hamilton	Sherman
Hodgeman	Wichita

Therefore, the Secretary has designated these areas as eligible for emergency loans pursuant to the provisions of the Consolidated Farm and Rural Development Act, as amended, and the provisions of 7 CFR 1904 subpart C, exhibit D, paragraph VB, including the recommendation of Gov. Robert F. Bennett that such designation be made.

Applications for emergency loans must be received by this Department no later than February 7, 1979, for physical losses and August 13, 1979, for production losses, except that qualified borrowers who receive initial loans pursuant to this designation may be eligible for subsequent loans. The urgency of the need for loans in the designated area makes it impracticable and contrary to the public interest to give advance notice of proposed rulemaking and invite public participation.

Done at Washington, D.C., this 18th day of August, 1978.

GORDON CAVANAUGH,
Administrator,
Farmers Home Administration.

[FR Doc. 78-23896 Filed 8-24-78; 8:45 am]

[3410-07]

[Designation No. A644]

MASSACHUSETTS

Designation of Emergency Areas

The Secretary of Agriculture has determined that farming, ranching, or aquaculture operations have been substantially affected in Bristol County, Mass., as a result of excessive rainfall September 15 through October 15, 1977.

Therefore, the Secretary has designated this area as eligible for emergency loans pursuant to the provisions of the Consolidated Farm and Rural Development Act, as amended, and the provisions of 7 CFR 1904 subpart C, exhibit D, paragraph VB, including the recommendation of Gov. Michael S. Dukakis that such designation be made.

Applications for emergency loans must be received by this Department no later than February 5, 1979, for physical losses and August 9, 1979, for production losses, except that qualified borrowers who receive initial loans pursuant to this designation may be eligible for subsequent loans. The urgency of the need for loans in the designated area makes it impracticable and contrary to the public interest to give advance notice of proposed rulemaking and invite public participation.

Done at Washington, D.C., this 18th day of August 1978.

GORDON CAVANAUGH,
Administrator,
Farmers Home Administration.

[FR Doc. 78-23897 Filed 8-24-78; 8:45 am]

[3410-07]

[Designation No. A643]

NEBRASKA

Designation of Emergency Areas

The Secretary of Agriculture has determined that farming, ranching, or aquaculture operations have been substantially affected in the following Nebraska counties as a result of hail and high winds in Boyd County; June 21, 1978, Dakota, Dixon, Logan, and McPherson Counties; June 17, 1978, and York County; May 30, 1978; hail, rain and high winds in Gage County;

May 30, 1978; and hail, high winds, tornadoes, rain, and flooding in Brown, Keya Paha, and Rock Counties; June 21, 22, and 25, 1978. Brown, Keya Paha, Logan, McPherson, and Rock Counties also reported insect infestation (grasshoppers).

Therefore, the Secretary has designated these areas as eligible for emergency loans pursuant to the provisions of the Consolidated Farm and Rural Development Act, as amended, and the provisions of 7 CFR 1904 subpart C, exhibit D, paragraph VB, including the recommendation of Gov. J. James Exon that such designation be made.

Applications for emergency loans must be received by this Department no later than February 5, 1979, for physical losses and August 9, 1979, for production losses, except that qualified borrowers who receive initial loans pursuant to this designation may be eligible for subsequent loans. The urgency of the need for loans in the designated area makes it impracticable and contrary to the public interest to give advance notice of proposed rulemaking and invite public participation.

Done at Washington, D.C., this 18th day of August 1978.

GORDON CAVANAUGH,
Administrator,
Farmers Home Administration.

[FR Doc. 78-23898 Filed 8-24-78; 8:45 am]

[3410-07]

[Designation No. A647]

TEXAS

Designation of Emergency Areas

The Secretary of Agriculture has determined that farming, ranching, or aquaculture operations have been substantially affected in the following Texas counties as a result of drought July 1, 1977, through June 1, 1978, in Crockett County; January 1, 1978, through June 9, 1978, in Culberson, Hudspeth, and Jeff Davis Counties; September 1, 1977, through June 30, 1978, in Taylor County; March 1, 1977, through June 14, 1978, in Terrell County; and June 1, 1977, through May 31, 1978, in Val Verde County; and also hailstorms June 2, 1978, in Culberson County; June 2 and June 4, 1978, in Hudspeth County; and June 5 and June 6, 1978, in Terrell County.

Therefore, the Secretary has designated these areas as eligible for emergency loans pursuant to the provisions of the Consolidated Farm and Rural Development Act, as amended, and the provisions of 7 CFR 1904, subpart C, exhibit D, paragraph VB, including the recommendation of Gov. Dolph Briscoe that such designation be made.

Applications for emergency loans must be received by this Department no later than February 12, 1979, for physical losses and August 15, 1979, for production losses, except that qualified borrowers who receive initial loans pursuant to this designation may be eligible for subsequent loans. The urgency of the need for loans in the designated area makes it impracticable and contrary to the public interest to give advance notice of proposed rulemaking and invite public participation.

Done at Washington, D.C., this 18th day of August 1978.

GORDON CAVANAUGH,
Administrator,
Farmers Home Administration.

[FR Doc. 78-23899 Filed 8-24-78; 8:45 am]

[6320-01]

CIVIL AERONAUTICS BOARD

[Order 78-8-103; Docket 33237, et al.]

CALIFORNIA-ARIZONA LOW FARE ROUTE PROCEEDING, ET AL.

Order Instituting Proceeding

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 18th day of August 1978.

In the matter of California-Arizona low fare route proceeding, Docket 33237; applications of Hughes Air Corp., d.b.a. Hughes Airwest, Docket 32286; Pacific Southwest Airlines, Inc., Docket 32129; Trans World Airlines, Inc., Docket 32309; Western Air Lines, Inc., Docket 32303.

On February 15, 1978, Pacific Southwest Airlines (PSA) filed an application in Docket 32139 requesting nonstop authority between Los Angeles and San Diego, Calif., on the one hand, and Phoenix, Ariz., on the other. It also seeks authority to carry interstate Phoenix traffic on all of its California segments which have been authorized by the California Public Utilities Commission. On March 7, 1978, PSA filed a motion requesting a hearing on this application. In support of its motion, PSA states that it will bring the benefits of its systemwide low fare services to these two large California-Phoenix markets. PSA promises reductions of 29 percent in the standard coach fare in the Los Angeles-Phoenix market and 38 percent in San Diego-Phoenix. The carrier also suggests that by tacking this new authority to its existing intra-California route system, it will be able to provide first single-plane service in the Phoenix - Stockton/Fresno/Monterey/Sacramento markets.

Three carriers, Hughes Airwest, Trans World Airlines, and Western Air Lines, filed motions to consolidate related applications with any proceeding instituted to consider PSA's application in Docket 32129. Airwest has applied for identical authority in Docket 32286. TWA has applied in Docket 32309 for new authority in the Phoenix-San Diego and Phoenix-Palm Springs markets. Western's application in Docket 32303 requests the removal of restrictions in each of six Phoenix markets,[1] and new authority between Tucson and Phoenix and seven Tucson-California markets.[2] TWA promises a 32-percent reduction in the standard coach fare between Phoenix and Palm Springs. Western promises no specific fare reductions, but its motion to consolidate argues that the expansion requested by Western will "enable consideration of nonstop low fare services" between Phoenix and Tucson and many California points.[3]

Several persons have filed answers to the PSA motion for hearing and to the motions to consolidate. American Airlines opposes both the former and TWA's motion to consolidate. American argues that all of these markets are well served and that American's Super-Saver fares already provide passengers in these markets with substantial savings. Western filed a short answer asking the Board to defer consideration of the PSA motion until it could consider Western's own motion to consolidate. TWA answered the PSA motion in the following fashion: it supports the requests for hearing of the needs of the Phoenix-San Diego market; it would have the Board add consideration of the Phoenix-Palm Springs market; and it opposes consideration of the Phoenix-Los Angeles market. PSA filed an answer in opposition to Western's motion to consolidate, urging the Board to confine its investigation to the Phoenix-Los Angeles/San Diego markets in order that its application might be processed more quickly.

Hughes Airwest filed an answer to Western's motion to consolidate. Airwest opposes expanded consideration of any markets beyond the three suggested by PSA and TWA (Phoenix-Los Angeles/San Diego/Palm Springs). It characterizes the Western motion to consolidate as an attempt to delay Board consideration of the service needs of the larger markets where Western is an incumbent. Airwest also notes that many of the markets for which Western seeks consolidation are quite small (5 of the Tucson markets

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[1] Between Phoenix and: Los Angeles/Long Beach, Oakland, Ontario/San Bernardino, Palm Springs, Sacramento, and San Francisco/San Jose.

[2] Between Tucson and: Los Angeles/Long Beach, Oakland, Ontario/San Bernardino, Palm Springs, Sacramento, San Diego, and San Francisco/San Jose.

[3] Western motion to consolidate at pp. 2-3.

each had less than 30 daily local and connecting passengers in the year ended March 31, 1977).

United States Senator Dennis DeConcini and the Arizona parties [4] each filed answers in support of the PSA motion. The Tucson Airport Authority filed an answer in support of Western's motion to consolidate. Finally, the State of California and the California Public Utilities Commission filed a joint petition to intervene.

We have decided to grant PSA's motion for hearing and institute the California-Arizona Low Fare Route Proceeding, Docket 33237. We have also decided to conduct a broad investigation of the scope suggested by TWA and Western rather than confine the proceeding to the two markets advanced by PSA. The investigation shall consider the need for new nonstop authority in the following markets:

Phoenix-Tucson	Tucson-Los Angeles
Phoenix-Los Angeles	Oakland
Ontario	Ontario
Palm Springs	Palm Springs
San Francisco	Sacramento
San Jose	San Francisco
San Diego	San Jose

Phoenix-Oakland, Phoenix-Sacramento, and Tucson-San Diego will not be included since the needs of these three markets will be considered in other proceedings (Docket 30699, Docket 28981 and Docket 32709, respectively). We have set down San Jose as a separate point and eliminated San Bernardino and Long Beach on the assumption that Western included these cities only because of their appearance in its current certificate.

As we have made clear in recent decisions (see, e.g., *Service to Oakland Case*, Order 78-4-121), we believe that market forces are in most circumstances more likely then selections of carriers by the Board to result in optimum service at optimum fares since the market therefore consider the possible grant of permissive authority to all fit, willing and able applicants, and the extent to which such awards encourage the efficiency, innovation and competition deemed to be in the public interest by Section 102 of the Act. In view of this, we are less inclined than we were when we laid down the policy in our order instituting the *Chicago-Albany/Syracuse-Boston Competitive Service Investigation*, Order 77-12-50, to give heavy weight in carrier selection to the offer or failure to offer low prices, since open competition will ensure these offers more effectively than restrictive carrier selections based on their promise.

We are therefore concerned about the delay and costs of the evidentiary burdens which traditional carrier-selection cases entail for the parties, the Board and the Board's staff, and particularly with the burden of introducing and evaluating evidence that will be unnecessary if the case results in multiple permissive awards. We invite the parties and the administrative law judge to explore ways of reducing the quantity of required exhibit material, eliminating duplication and superfluous detail, standardizing methodology, and focusing on the significant facts and assumptions. Specifically, we are interested in reducing or eliminating the tremendous amount of detail on schedules, traffic, profitability and diversion typically required to adjudicate the issue of comparative carrier selection. The possibility of stipulating facts and eliminating comparative selection evidence should be carefully explored. In particular, carriers interested in being selected for a market only if multiple, permissive authority is awarded generally should be excused from submitting the full panoply of comparative selection evidence for that market.[5] Further, although low fares naturally will continue to be reflected in any revenue estimates submitted, we are not interested in any detailed comparative examination of the price/quality options arrived at by the various applicants. Ultimately, of course, we leave the resolution of all of these matters to the administrative law judge.

Accordingly, *it is ordered*, That:

1. The motion of Pacific Southwest Airlines for immediate hearing of its application in docket 32129 be granted;

2. An investigation to be known as the *California-Arizona Low Fare Route Proceeding*, Docket 33237, be instituted under section 204 of the act and be set for hearing before an administrative law judge of the Board, at a time and place to be designated later;

3. The investigation instituted in paragraph 2, above, shall consider whether the public convenience and necessity require that new nonstop authority be granted in the following markets:

Phoenix-Tucson	Tucson-Los Angeles
Phoenix-Los Angeles	Oakland
Ontario	Ontario
Palm Springs	Palm Springs
San Francisco	Sacramento
San Jose	San Francisco
San Diego	San Jose

4. If the answer to the issues in paragraph 3, above, is affirmative, the investigation shall consider which air carrier or carriers should be authorized to provide service in each market and whether any new or existing authority should be subject to any terms, conditions, or limitations;

5. If an interstate carrier applicant for the authority in paragraph 3 is selected, the investigation shall consider whether it should be permitted to carry these passengers on its operations conducted pursuant to authority issued by the California Public Utilities Commission, and also the appropriate form of such authority under the Federal Aviation Act of 1958, as amended;

6. The investigation shall consider whether the applicants are fit, willing, and able to perform properly the transportation proposed in their applications and to conform to the provisions of the Federal Aviation Act of 1958, as amended;

7. Any authority awarded in this investigation be category II subsidy ineligible;

8. The motions to consolidate of Hughes Airwest in docket 32286, Trans World Airlines in docket 32309 and Western Air Lines in docket 32303 be granted to the extent indicated above; to the extent not granted, they be denied;

9. The applications of Hughes Airwest in docket 32286, PSA in docket 32129, TWA in docket 32309, and Western in docket 32303 be consolidated to the extent that they conform to the scope of the investigation described in paragraph 3, above; to the extent that they do not conform to the scope of the investigation described in paragraph 3, as to the scope of the proceeding described in docket 32709,[6] they be dismissed;

10. The following be made parties to the investigation instituted by paragraph 2, above: American Airlines, Hughes Airwest, Pacific Southwest Airlines, Trans World Airlines, Western Air Lines, the Arizona parties, the State of California, and the California Public Utilities Commission, and the Tucson Airport Authority;

11. Applications, amendments to applications, motions to consolidate, and

[4] The Arizona Department of Transportation, the City of Phoenix, and the Phoenix Metropolitan Chamber of Commerce.

[5] Moreover, for those who wish to pursue a traditional carrier selection theory of the case, detailed cost accounting evidence, e.g., separate estimates for every segment or each type of fare, need not be required to justify the various price and quality proposals. For the Board's purposes, an analysis of profit of any applicant's proposal shall be adequate if the expense estimates are calculated in accordance with the methodology described for local service carrier route applicants in the Board's procedural regulations. 14 CFR 302.1101 et seq., Subpart K and PR-172, April 14, 1978. Applicants, including new entrants, whose data are not included in this costing system shall submit costings based on their internal company data, in Subpart K format to the extent feasible. While all applicants are of course free to include estimates of expense computed using a different methodology, we do not believe that it is a fruitful use of the applicants', the staff's or the Board's resources to require an analysis of the cost of an applicant's proposal by a second costing method.

[6] The Tucson-San Diego parties of Western's application in docket 32303 has been consolidated in docket 32709, order 78-7-163, July 31, 1978.

petitions for reconsideration of this order shall be filed within 20 days of the date of service of this order and answers shall be filed within 10 days after that;[7] and

12. All carriers filing applications or amendments to applications which they seek to have consolidated into this proceeding shall file environmental evaluations under section 312.12 of the Board's regulations within 30 days of the date of service of this order.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board.[8]

PHYLLIS T. KAYLOR,
Secretary.

O'MELIA, MEMBER, SEPARATE STATEMENT

I strongly favor the institution of a proceeding to ascertain whether the public convenience and necessity require new nonstop authority in selected California-Arizona markets. There are, however, two aspects of the Board's instituting order on which I would briefly comment.

First, in this case the Board once again asserts its predilection to have the market place determine what might constitute optimum service in a given market, and, accordingly, makes known its predisposition to grant permissive authority to all fit, willing, and able applicants. I have previously expressed in the *Oakland Service Case* (Order 78-4-121, April 19, 1978) and in the *Chicago-Midway Low Fare Route Proceeding* (Order 78-4-40, July 12, 1978; dissenting statement issued August 11, 1978) my reservations as to the legal validity of the multiple permissive award concept, despite its procompetitive benefits, and have indicated my preference that the Board not interject that concept routinely into every route proceeding (see concurring statement in *United States-Benelux Low-Fare Proceeding,* Order, 78-6-97, June 13, 1978.) I am particularly concerned that the Board should do this since there is some likelihood that the multiple permissive award policy might be challenged in court as soon as a multiple permissive award case reaches an appealable stage, and it is not inconceivable that a court might find such a policy in conflict with our present act.[9] However, I take note of the Board's determination to continue to press forward with this policy in its instituting orders, and will withhold further comment on that until such time as a definitive multiple permissive award is made.

Similarly, I would note that this order reasserts the Board's decision to give new direction in route cases to the parties and to the administrative law judges with respect to reducing evidentiary burdens which traditional carrier-selection cases entail, particularly in cases resulting in multiple permissive awards. I have previously expressed my disagreement with this so-called "boilerplate." [10] Again recognizing the Board's decision to insert this new orientaion into future route cases, I will, without prejudice to my position, refrain from commenting on this development in future instituting orders.

RICHARD J. O'MELIA.

[FR Doc. 78-23995 Filed 8-24-78; 8:45 am]

[6320-01]

CONTINENTAL AIRLINES, INC.

Proposed Approval

Application of Continental Air Lines, Inc., for exemption or approval under section 408 of the Federal Aviation Act of 1958, as amended, docket 33096.

Notice is hereby given, pursuant to the statutory requirements of section 408(b) of the Federal Aviation Act of 1958, as amended, that the undersigned intends to issue the attached order under delegated authority. Interested persons are hereby afforded until September 5, 1978, to file comments or request a hearing with respect to the action proposed in the order.

Dated at Washington, D.C., August 22, 1978.

MICHAEL E. LEVINE,
Director, Bureau of Pricing and Domestic Aviation.

[Docket 33096]

ORDER OF APPROVAL

Issued under delegated authority.

Application of Continental Air Lines, Inc., for approval or exemption under section 408 of the Act.

Continental Air Lines, Inc., requests the Board to approve or exempt its acquisition of the assets of the Aviation Services Division of PRC Computer Center, Inc., under section 408 of the Act.

The Aviation Services Division (ASD) of PRC provides computerized flight plans for commercial airlines. PRC is interested in selling ASD because of its persistent losses. Continental, a small trunk air carrier, wishes to buy ASD to supplement its present flight planning services. The air carrier believes that through consolidation it may realize a profit in providing flight planning services for commercial aircraft.

In support of its request, Continental states that the acquisition will have no anticompetitive effects since the market for flight planning services remains fluid, with numerous competitors and with short-term contracts that maintain the flexibility of the contracting air carriers; [1] that Continental's share of this market, even when added to ASD's share, is less than 8 percent of the domestic market and less than 20 percent of the foreign market; [2] that, in fact, the acquisition may enhance competition since ASD may be deemed a "failing company"; and that the acquisition of ASD will not jeopardize Continental's own financial stability for, even if ASD's losses continue, they represent a small fraction of Continental's operating revenues.

No one has filed comments on this application or requested a hearing.

We conclude that Continental is a certificated air carrier whose acquisition of ASD, a person engaged in a phase of aeronautics, is subject to section 408(a)(6) of the Act. However, the acquisition, we conclude, will not affect the control of an air carrier directly engaged in the operation of aircraft in air transportation, or tend to restrain trade unreasonably, substantially lessen competition, or create a monopoly. The transaction was the result of arm's length bargaining, and there appear to be no interlocking relationships between Continental and PRC. No person disclosing a substantial interest in the proceeding is currently requesting a hearing, and we conclude that the public interest does not require a hearing, since the transaction appears consistent with the public interest and meets the requirements of section 408. The acquistion will allow expansion of Continental's flight planning services, without curbing competition in the market for these services. The combined market share of Continental and ASD will continue to be small. Nor should the acquisition threaten Continental's ability to perform its certificate obligations as the potential losses are insignificant relative to Continental's resources.[3]

We find, under authority delegated by the Board in its regulations, 14 CFR 385.13, that it is in the public interest to approve without hearing the acquisition described above under the third proviso of section 408(b), and that all other requests in this application should be dismissed.

We have published in the FEDERAL REGISTER a notice of intent to dispose of this ap-

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[7] We delegate to the presiding administrative law judge the authority to consolidate by order any applications which conform to the scope of the proceeding.

[8] All Members concurred and Member O'Melia filed the attached separate statement.

[9] Although multiple permissive awards, as such, are not presently under court review, the validity of permissive awards is already being litigated. (See *Delta* v. *C.A.B.*, C.A.D.C. No. 78-1516, filed 6-8-78, and *Delta* v. *C.A.B.*, C.A.D.C. No. 78-1719, filed 7-28-78.) It is unlikely that the Board will have any indication of how those two cases which have now been consolidated, may be decided until sometime next spring. An adverse finding in that proceeding, could significantly disrupt a number of cases recently instituted by the Board, particularly where we have so limited the record as to require, on remand, a new hearing and not merely a review of an existing incomplete record.

[10] See concurring and dissenting statement in *Florida Service Case,* Order 78-7-128, July 25, 1978 and dissenting statement in Order 78-8-48, August 10, 1978, which introduced the "boilerplate" language into nine route cases previously instituted.

[1] ASD's and Continental's principal competitors are Lockheed, United, Eastern, Pan Am, and KLM.

[2] As defined by the number of aircraft for which flight plans are provided by all flight planning contractors.

[3] No interlocking relationships will be created by this acquisition, although Continental intends to offer continued employment to ASD's key employees.

plication without a hearing and have furnished a copy of such notice to the Attorney General not later than the day after such publication, both in accordance with the requirements of section 408(b) of the Act.

Accordingly, *It is ordered*, That: 1. The acquisition of ASD by Continental be approved under section 408(b) of the Act; and

2. Except to the extent specifically granted here, the application be dismissed.

Persons entitled to petition the Board for review of this order under the Board's regulations, 14 CFR 385.50, may file such petitions within 10 days of the date of service of this order.

This order shall be effective and become the action of the Civil Aeronautics Board upon expiration of the above period unless within such period a petition for review is filed, or the Board gives notice that it will review this order on its own motion.

MICHAEL E. LEVINE,
Director, Bureau of Pricing and Domestic Aviation.

———— ————,
Secretary.

[FR Doc. 78-23994 Filed 8-24-78; 8:45 am]

[6320-01]

[Order 78-8-94; Docket 33216, et al.]

LOUISVILLE-KANSAS CITY NONSTOP ROUTE INVESTIGATION, ET AL.

Order Instituting Investigation

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 17th day of August 1978.

In the matter of Louisville-Kansas City nonstop route investigation, Docket 33216; applications of Frontier Airlines, Inc., Docket 28183; Ozark Air Lines, Inc., Docket 31678.

By Order 77-10-94, October 20, 1977, we stated that the question of additional service in the Louisville-Kansas City/St. Louis markets should be set down for hearing and that any such hearing should include the question of the possible deletion of Eastern's Louisville-St. Louis and TWA's Louisville-Kansas City authority. We called for comments on the procedural avenue to use. By Order 77-12-113, December 22, 1977, we expanded the issues in the *St. Louis-San Francisco / Oakland / San Jose Nonstop Route Proceeding*, Docket 31491, to include the issue of new nonstop Louisville-St. Louis authority. We stated that we would handle Louisville-Kansas City service matters in a separate order, and we will do so now.

We have decided to institute the *Louisville-Kansas City Nonstop Route Investigation*, Docket 33216, to consider the need for new nonstop authority in the Louisville-Kansas City market.

As we have made clear in recent decisions (see, *e.g., Service to Oakland Case*, Order 78-4-121), we believe that market forces are more likely to result in optimum service at optimum fares since the market selection process operates continuously and efficiently. We will therefore consider the possible grant of permissive authority to all fit, willing and able applicants, and the extent to which such awards encourage the efficiency, innovation, and competition deemed to be in the public interest by section 102 of the act. In view of this, we are less inclined than we were when we laid down the policy in our order instituting the *Chicago-Albany/Syracuse-Boston Competitive Service Investigation*, Order 77-12-50, to give heavy weight in carrier selection to the offer or failure to offer low prices, since open competition will insure these offers more effectively than restrictive carrier selections based on their promise.

We are therefore concerned about the delay and costs of the evidentiary burdens which traditional carrier-selection cases entail for the parties, the Board and the Board's staff, and particularly with the burden of introducing and evaluating evidence that will be unnecessary if the case results in multiple permissive awards. We invite the parties and the administrative law judge to explore ways of reducing the quantity of required exhibit material, eliminating duplication and superfluous detail, standardizing methodology, and focusing on the significant facts and assumptions. Specifically, we are interested in reducing or eliminating the tremendous amount of detail on schedules, traffic, profitability and diversion typically required to adjudicate the issue of comparative carrier selection. The possibility of stipulating facts and eliminating comparative selection evidence should be carefully explored. In particular, carriers interested in being selected for a market only if multiple, permissive authority is awarded generally should be excused from submitting the full panoply of comparative selection evidence for that market.[1] Further, although low fares naturally will continue to be reflected in any revenue estimates submitted, we are not interested in any detailed comparative examination of the price/quality options arrived at by the various applicants. Ultimately, of course, we leave the resolution of all of these matters to the administrative law judge.

All applications, amendments to applications, motions to consolidate, and petitions for reconsideration of this order shall be filed within 30 days of the date of servie of this order and answers shall be filed within 10 days thereafter. Environmental evaluations under § 312.12 of the Board's Regulations shall be filed within 30 days of the date of service of this order.

Accordingly, *it is ordered*, That:

(1) An investigation designated the *Louisville-Kansas City Nonstop Route Investigation*, Docket 33216, be instituted under section 204 of the Federal Aviation Act and set for hearing before an administrative law judge of the Board at a time and place to be determined later;

(2) This case shall consider whether the public convenience and necessity require that new nonstop authority be granted in the Louisville-Kansas City market; if so, which air carrier(s) should be authorized; whether the new or existing authority should be subject to any terms, limitations, or conditions; and whether TWA's authority in the Louisville-Kansas City market should be deleted;

(3) The application of Frontier Airlines, in Docket 28183, and Ozark Air Lines, Inc. in Docket 31678, be consolidated into the proceeding instituted by (1) above;

(4) Any authority awarded in this investigation shall be Category II subsidy ineligible;

(5) The following are made parties to the proceeding instituted in (1) above: Louisville and Jefferson County Air Board and Louisville Area Chamber of Commerce, Braniff Airways, Frontier Airlines, Ozark Air Lines, and Trans World Airlines;

(6) Applications, amendments to applications, motions to consolidate, and petitions for reconsideration of this order shall be filed no later than September 21, 1978, and answers shall be filed no later than October 2, 1978; [2] and

(7) Frontier, Ozark, Braniff, and any other applicants shall file environmental evaluations under § 312.12 of the Board's Regulations no later than September 21, 1978.

This order will be published in the FEDERAL REGISTER.

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[1] Moreover, for those who wish to pursue a traditional carrier selection theory of the case, detailed cost accounting evidence, e.g., separate estimates for every segment or each type of fare, need not be required to justify the various price and quality proposals. For the Board's purposes, and analysis of profit of any applicant's proposal shall be adequate if the expense estimates are calculated in accordance with the methodology described for local service carrier route applicants in the Board's procedural regulations. 14 CFR 302.1101 et seq., Subpart K and PR-172, Apr. 14, 1978. Applicants, including new entrants, whose data are not included in this costing system shall submit costings based on their internal company data, in Subpart K format to the extent feasible. While all applicants are of course free to include estimates of expense computed using a different methodology, we do not believe that it is a fruitful use of the applicants', the staff's or the Board's resources to require an analysis of the cost of an applicant's proposal by a second costing method.

[2] We delegate to the presiding administrative law judge the authority to consolidate by order any applications which conform to the scope of the proceeding.

By the Civil Aeronautics Board: [3]

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-23996 Filed 8-24-78; 8:45 am]

[6335-01]

COMMISSION ON CIVIL RIGHTS

ARKANSAS 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 press conference of the Arkansas Advisory Committee (SAC) of the Commission will convene at 9 a.m. and will end at 11 a.m. on August 30, 1978, Camelot Inn, Black Knight Room, Markham and Broadway, Little Rock, Arkansas 722201.

Persons wishing to attend this open meeting should contact the Committee Chairperson, or the Southwestern Regional Office of the Commission, 106 Broadway, Room 249, San Antonio, Tex. 78205.

The purpose of the meeting is to release the Arkansas School handbook.

This meeting will be conducted pursueant to the provisions of the rules and regulations of the Commission.

Dated at Washington, D.C., August 22, 1978.

JOHN I. BINKLEY,
Advisory Committee Management Officer.

[FR Doc. 78-24001 Filed 8-24-78; 8:45 am]

[6335-01]

KENTUCKY 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 conference (press conference) of the Kentucky Advisory Committee (SAC) of the Commission will convene at 2 p.m. and will end at 3 p.m. on September 15, 1978, at the Colt House, Fourth Street at River Road, General's Room, 2d Floor, Louisville, Ky. 48201.

Persons wishing to attend this open meeting should contact the Committee Chairperson, or the Southern Regional Office of the Commission, 75 Piedmont Avenue NE., Atlanta, Ga. 30303.

The purpose of this meeting is that the SAC will issue a statement regarding the followup activity to the study on employment in the Kentucky State Bureau of Police.

This meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

[3] All members concurred.

Dated at Washington, D.C., August 22, 1978.

JOHN I. BINKLEY,
Advisory Committee Management Officer.

[FR Doc. 78-24002 Filed 8-24-78; 8:45 am]

[6335-01]

MICHIGAN 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 planning meeting of the Michigan Advisory Committee (SAC) of the Commission will convene at 10 a.m. on September 14, 1978, City Hall, Room 609, Grand Rapids, Mich. 49503.

Persons wishing to attend this open meeting should contact the Committee Chairperson, or the Midwestern Regional Office of the Commission, 230 South Dearborn Street, 32d Floor, Chicago, Ill. 60604.

The purpose of this meeting is to review impact of the Bakke decision in Michigan, plan for fiscal year 1979.

This meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, D.C., August 22, 1978.

JOHN I. BINKLEY,
Advisory Committee Management Officer,

[FR Doc. 78-24003 Filed 8-24-78; 8:45 am]

[6335-01]

MINNESOTA 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 planning meeting of the Minnesota Advisory Committee (SAC) of the Commission will convene at 5 p.m. and will end at 9 p.m. on October 13, 1978, Neighborhood House, 179 East Robie, St. Paul, Minn. 55107.

Persons wishing to attend this open meeting should contact the Committee Chairperson, or the Midwestern Regional Office of the Commission, 230 South Dearborn Street, 32d Floor, Chicago, Ill. 60604.

The purpose of this meeting is to discuss phase I and II of Police Study, solicit input from community in westside St. Paul.

This meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, D.C., August 22, 1978.

JOHN I. BINKLEY,
Advisory Committee Management Officer.

[FR Doc. 78-24004 Filed 8-24-78; 8:45 am]

[6335-01]

TEXAS 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 factfinding meeting of the Texas Advisory Committee (SAC) of the Commission will convene at 9 a.m. and will end at 5 p.m. on September 12, 1978, thru September 14, 1978, at American Unity Council, 2300 West Commerce Street, San Antonio, Tex. 78207.

Persons wishing to attend this open meeting should contact the Committee Chairperson, or the Southwestern Regional Office of the Commission, 106 Broadway, Room 249, San Antonio, Tex. 78205.

A hearing on the immigration issues in the State of Texas.

This meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, D.C., August 22, 1978.

JOHN I. BINKLEY,
Advisory Committee Management officer.

[FR Doc. 78-24005 Filed 8-24-78; 8:45 am]

[6335-01]

VIRGINIA 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 planning meeting of the Virginia Advisory Committee (SAC) of the Commission will convene at 1 p.m. and will end at 5 p.m. on September 27, 1978, at John Marshall Hotel (the Jackson Room), 5th and Franklin Streets, Richmond, Va. 23919.

Persons wishing to attend this open meeting should contact the Committee Chairperson, or the Mid-Atlantic Regional Office of the Commission, 2120 L Street NW., Room 510, Washington, D.C. 20037.

The purpose of this meeting is to plan 1979 activities of the committee.

This meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, D.C., August 22, 1978.

JOHN I. BINKLEY,
Advisory Committee Management Office.

[FR Doc. 78-24006 Filed 8-24-78; 8:45 am]

[3510-25]

DEPARTMENT OF COMMERCE

Industry and Trade Administration

[Order No. 43-1 (Amdt. 1; Transmittal No. 233)]

BUREAU OF EXPORT DEVELOPMENT

Organization and Function Order

This order amends ITA Organization and Function Order 43-1 of December 4, 1977 (43 FR 9177), as follows:

Sections 7.02 and 7.05 are revised to read:

.02 The *Major Export Projects Division* shall serve as the focal point in the Department for providing government-wide assistance to U.S. firms on major international business transactions; identify foreign capital projects and equipment sales opportunities having major export potential which should be brought to the attention of U.S. industry or which are likely to require special U.S. Government assistance for successful participation by American firms; inform U.S. firms of specific large-scale projects and equipment procurements overseas with significant potential for exports of U.S. goods and services and assist these firms on a case-by-case basis in competing for the contracts involved. The Division communicates directly with other Washington agencies and with U.S. missions abroad as appropriate to obtain the quick reaction needed to assist U.S. firms in winning major foreign contract awards.

.05 The *Overseas Business Opportunities Division* shall be responsible for the dissemination of foreign investment and foreign trade opportunity data and for providing assistance to firms in obtaining overseas business. In this regard it shall be responsible for the collection of specific foreign trade opportunity leads and their dissemination to interested U.S. firms through the Trade Opportunity Program; identify and register TOP subscribers; develop appropriate trade opportunity dissemination formats and techniques; identify and distribute to other offices within ITA export opportunities requiring special handling; act on U.S. Foreign Service requests for information about specific U.S. companies, products or processes in connection with potential export opportunities; and provide information and counsel, consistent with U.S. balance of payments policies and objectives, to U.S. businesspersons concerning their existing and planned overseas investments; identify and disseminate for the benefit of the U.S. business community, foreign investment, licensing and joint venture proposals; and furnish information to U.S. foreign investors on private and public sources of investment capital, particularly foreign sources, guarantees and related types of investment and loan capital available for financing investment abroad, particularly developing countries.

Effective August 11, 1978.

FRANK A. WEIL,
Assistant Secretary for Industry and Trade.

RICHARD GARNITZ,
Acting Deputy Assistant Secretary for Export Development.

[FR Doc. 78-23939 Filed 8-24-78; 8:45 am]

[3510-22]

National Oceanic and Atmospheric Administration

MID-ATLANTIC FISHERY MANAGEMENT COUNCIL

Public Meeting

AGENCY: National Marine Fisheries Service, NOAA.

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council, established by section 302 of the Fishery Conservation and Management Act of 1976 (Pub. L. 94-265), will meet to discuss: (1) Surf clam management plan, (2) mackerel management plan, (3) squid management plan, (4) butterfish management plan, and (5) other administrative matters. For more information on the agenda contact the Executive Director.

DATES: The meeting will begin at 1 p.m., on September 12, 1978, and adjourn approximately 1 p.m., on September 14, 1978. The meeting is open to the public.

ADDRESS: The meeting will be held at the Airport Motel, Philadelphia International Airport, Route 291, Philadelphia, Pa. 19153, telephone 215-365-7000.

FOR FURTHER INFORMATION CONTACT:

Mr. John C. Bryson, Executive Director, Mid-Atlantic Fishery Management Council, North and New Streets, Room 2115, Federal Building, Dover, Del. 19901, telephone 302-674-2331.

Dated: August 21, 1978.

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

[FR Doc. 78-23876 Filed 8-24-78; 8:45 am]

[1505-01]

Office of the Secretary

[Department Organization No. 40-1; Amdt. 1; Transmittal 403]

INDUSTRY AND TRADE ADMINISTRATION

Organization Order Series

Correction

In FR Doc. 78-22317 appearing at page 35522 in the issue for Thursday, August 10, 1978, the transmittal number carried in the heading should have read "403" instead of "397".

[3910-01]

DEPARTMENT OF DEFENSE

Department of the Air Force

PROPOSED CLOSURE OF GOODFELLOW AFB, TEX.

Environmental Impact Analysis Process

AUGUST 22, 1978.

The Air Force has begun the formal environmental impact analysis process for the proposed closure of Goodfellow Air Force Base (AFB), Tex.

Preliminary review of Air Force training requirements indicates that the Air Force basing structure is supporting more capacity for training than required now or in the future. It thus appears that closure of a training installation would improve the facility utilization and achieve resources savings which would then be allocated to higher priority readiness requirements. Goodfellow AFB has been nominated as a candidate for possible closure during fiscal year 1980 because it is a small, single-mission base with a relatively high per capita operating cost. The Air Force cryptological training mission would move from Goodfellow AFB to Lowry AFB Colo., or as an alternate, to another ATC installation, e.g. Sheppard AFB Tex. Other alternative locations to receive the cryptological training mission may develop during the study process.

The environmental impact analysis process will consider the impact on the area surrounding Goodfellow AFB of the departure of approximately 1,120 assigned military personnel, plus an average student load of 1,075, and an estimated change in civilian jobs as follows:

Loss of approximately 315 Department of the Air Force civil service jobs.

Loss of other jobs (contract base exchange, concessionaire, nonappropriated fund), as follows:

Approximately 90 full time.

Approximately 160 part time.

The environmental impact analysis process will also consider the impact

on the areas surrounding Lowry AFB and Sheppard AFB of gaining approximately 570 military and 100 civilian positions and an average student load of approximately 1,075.

The environmental impact analysis process will lead to a formal environmental assessment which will be used to determine if a draft environmental impact statement (EIS) will be prepared or if a finding of no significant impact is appropriate.

If the formal environmental assessment indicates there may be signficant impact on the quality of the human environment, the Air Force will file a draft EIS with the Environmental Protection Agency and release it to the public.

If such impacts are not found, a finding of no significant impact will be prepared and released.

Any comments or questions should be directed to the Deputy of Environment and Safety, Office of the Secretary of the Air Force, Room 4C885, the Pentagon, Washington, D.C. 20330, telephone 202-697-9279.

FRANKIE S. ESTEP,
Air Force Federal Register Liaison Officer.

[FR Doc. 78-23962 Filed 8-24-78; 8:45 am]

[3710-08]

DEPARTMENT OF DEFENSE

Department of Army

PRIVACY ACT OF 1974

New System of Records

AGENCY: Department of the Army, DOD.

ACTION: Notification of a new system of records.

SUMMARY: The Department of the Army proposes a new system of records identified as AFAI-1, entitled: "Federal Acquisition Personnel Information System". The record system notice is published in its entirety below.

DATES: This system shall become effective as proposed without further notice in 30 calendar days from the date of this publication (September 24, 1978), unless comments are received on or before September 24, 1978, which would result in a contrary determination requiring republication for further comments.

ADDRESS: Send comments to the system manager identified in the record system notice.

FOR FURTHER INFORMATION CONTACT:

Mr. Jack Livingston, Special Assistant to the Director, Federal Acquisition Institute, Room 7N-08, AMC Building, 5001 Eisenhower Avenue, Alexandria, Va. 22333, telephone 202-274-8771.

SUPPLEMENTARY INFORMATION: The Federal Acquisition Institute (FAI) (formerly called Federal Procurement Institute) was established by the Office of Management and Budget, Office of Federal Procurement Policy Memorandum of July 14, 1976. Its functions derive from Title 41 U.S.C. §§ 404, 406 and 411; Title 5 U.S.C. §§ 4103 and 4105; and the Office of Federal Procurement Policy Memorandum of July 14, 1976. For the purpose of the Privacy Act of 1974 (5 U.S.C. § 552a), the FAI is considered a part of the Department of the Army whose policy and procedures are published in 32 CFR Part 505 and in Army Regulation 340-21 and shall apply with equal force to FAI. The proposed new system of records was submitted by the Department of the Army, which provides administrative support to the FAI.

The Department of the Army systems of records notices, as prescribed by the Privacy Act, have been published in the FEDERAL REGISTER as follows:

FR Doc. 77-28225 (42 FR 50396) September 28, 1977.
FR Doc. 77-32975 (42 FR 59099) November 15, 1977.
FR Doc. 78-1855 (43 FR 3151) January 23, 1978.
FR Doc. 78-9239 (43 FR 14713) April 7, 1978.
FR Doc. 78-9713 (43 FR 15383) April 12, 1978.
FR Doc. 78-17146 (43 FR 26606) June 21, 1978.
FR Doc. 78-17737 (43 FR 27882) June 27, 1978.
FR Doc. 78-18880 (43 FR 29600) July 10, 1978.
FR Doc. 78-19614 (43 FR 30594) July 17, 1978.
FR Doc. 78-21772 (43 FR 34520) August 4, 1978.

The Department of the Army has submitted a new system report on July 13, 1978, pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a(o)).

AUGUST 22, 1978.

MAURICE W. ROCHE,
Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.

AFAI-1

System name:

Federal Acquisition Personnel Information System

System location:

Federal Acquisition Institute (FAI), 5001 Eisenhower Avenue, Alexandria, Va. 22333.

Categories of individuals covered by the system:

Personnel of Federal agencies (civilian and military) involved in Federal acquisition and logistics management. Such individuals are generally employed in the Business and Industry (GS-1100); Equipment, Facilities and Services (GS-1600); Quality Assurance, Inspection and Grading (GS-1900); Supply (GS-2000); and Transportation (GS-2100) General Schedule occupational fields, or equivalent military fields.

Categories of records in the system:

Records contain biographical data on individuals such as name, social security number (SSN), birth date, past and present pay levels, position title, occupational series, training, and past personnel actions. Data also include employee's work such as description of tasks, types and number of contracts assigned.

Authority for maintenance of the system:

a. Title 41 U.S.C. § 404, 406, and 411, which established the Office of Federal Procurement Policy (OFPP), OMB, and requires executive agencies to furnish such Office access to all information and records determined to be necessary for the performance of its missions.

b. OFPP Policy Memorandum of July 14, 1976, which established the Federal Procurement Institute (now the Federal Acquisition Institute) and delegated responsibility to the Institute for the Government-wide planning, development, implementation and evaluation of programs in procurement research, education and training, and career development.

c. Memorandum of Understanding for the Sponsorship and Operation of the Federal Procurement Institute (May 11, 1976), which is an agreement between its signatories (at present: 24 Federal departments and agencies) for the interagency sponsorship and operation of the FAI and further provides that the FAI's policies and programs will be under the direction and guidance of a Policy Board comprised of representatives from the FAI's member departments and agencies.

d. Title 5 U.S.C. § 4103 and 4105, which authorize agencies to establish interagency training facilities such as the FAI, and to jointly operate training programs for Government personnel.

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

The primary purpose of this system of records is to enable the FAI to prepare statistical reports on characteristics of the acquisition and logistics occupations and to periodically contact

individual employees for personnel research projects that extend over a period of time (longitudinal studies). The FAI obtains data from employees and the management information systems of its member agencies, applying such data in the development of training, career development, education and research reports and programs.

Automated data processing services are provided FAI by the Bureau of Personnel Management Information Systems, U.S. Civil Service Commission; Defense Manpower Data Center (Alexandria, Va.); Air Force Human Resources Laboratory (Lackland Air Force Base, Tex.); and the U.S. Army Military Personnel Center (Alexandria, Va.).

Records at the FAI are used to prepare reports on the acquisition and logistics workforce, addressing: (a) The distribution of acquisition and logistics tasks among Federal occupations, agencies and pay levels, (b) employee perceptions of the relative learning difficulty of each acquisition and logistics task, and (c) the frequency of promotions in acquisition and logistics occupations as compared to other Federal professional and administrative occupations. These reports consist of summary descriptive statistics only. No individually identifiable information on employees is disclosed in the reports. Copies of the reports are therefore made available to Federal agencies, educational institutions, and any other individual who requests general statistical information on acquisition and logistics occupations.

The FAI may transmit lists of names, SSN's, birth dates, organizational mailing addresses and phone numbers of individual employees to the Federal agencies listed below. Purposes served thereby are to identify specific individuals who should be included in agency reports on members of the acquisition and logistics workforce and/or to locate specific individuals for personnel research. No individually identifiable data will be disclosed that would permit an individual's employing agency to make a decision about the individual.

Department of Energy.
National Aeronautics and Space Administration.
General Services Administration.
Department of Health, Education and Welfare.
Department of Justice.
Department of the Interior.
Environmental Protection Agency.
State Department.
Veterans Administration.
Department of Transportation.
Department of Treasury.
Department of Agriculture.
Department of Housing and Urban development.
Department of Commerce.
Small Business Administration.
United States Civil Service Commission.
Department of Defense.
Department of Labor.
National Science Foundation.
Office of Management and Budget.

The above agencies are signatories to the memorandum of understanding for the sponsorship and operation of the FAI. No individually identifiable information is furnished outside the agencies enumerated above.

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

Storage:

At FAI: Paper records and computer printouts.

At the U.S. Civil Service Commission; Defense Manpower Data Center; Air Force Human Resources Laboratory; and U.S. Army Military Personnel Center: Magnetic tapes and discs, and computer printouts.

The FAI may, on occasion, employ contractors to print questionnaires, transfer questionnaire responses to magnetic tapes and discs, and analyze responses. No such contractor shall be allowed to retain any data on individual employees for longer than 1 year, and any such contractor shall be obligated to observe the policies and practices of this notice and in Army regulation 340-21 for storing, retrieving, accessing, retaining, and disposing of records in this system.

Retrievability:

By name, SSN, and date of birth.

Safeguards:

Manual records are stored in buildings which employ security guards; records are accessible only to authorized personnel.

Automated records are under the control of a cardkey access system which requires positive identification and authorization, and are located in a designated controlled area to which access is limited to selected personnel only. Output products bear the annotation: "This document contains Privacy Act information and will not be released unless request meets the requirements of AR 340-21."

Retention and disposal:

Records are retained indefinitely by FAI for longitudinal studies of changes in the acquisition and logistics workforce. Reexamination of the same population will occur at 4-year intervals (approximate) to update records on work assigned employees. Biographical data are updated annually through the acquisition of data from the Central Personnel Data File of the U.S. Civil Service Commission and agency personnel management information systems.

System manager and address:

Director, FAI, 5001 Eisenhower Avenue, Alexandria, Va. 22333.

Notification procedure:

Information may be obtained from the System Manager.

Record access procedures:

Requests from individuals should be addressed to the System Manager. Written requests should contain the individual's full name, SSN, birth date, and current address.

Contesting record procedures:

The FAI is guided by the Army's rules for access to records, contesting contents, and appealing initial determinations. These are contained in 32 CFR part 505 (Army regulation 340-21).

Record source categories:

The Civil Service Commission's Central Personnel Data File is the primary source of biographical data on members in this system of records. The primary source of data on work performed by an employee is the employee to whom the record pertains. This information is collected through questionaires which are reissued to employees on a 4-year cycle to update their records. Additional information may be obtained from management information systems of individual's employing agency, from professional societies (which would report only the names and other identifiers of individual Federal employees they have certified as professional acquisition or logistics specialists), and from educational institutions (which would report only the names and other identifiers of individual Federal employees who have attended educational programs in the fields of acquisition and logistics management) on an annual basis.

Systems exempt from certain provisions of the act:

None.

[FR Doc. 78-23953 Filed 8-24-78; 8:45 am]

[3710-08]

TOOELE ARMY DEPOT, UTAH

Filing of Final Environmental Impact Statement

In compliance with the National Environmental Policy Act of 1969, the Army on August 18, 1978, provided the Environmental Protection Agency with the final environmental impact statement concerning disposal of hydrogen cyanide at Tooele Army Depot, Utah.

Copies of the statement have been forwarded to concerned Federal, State, and local agencies. Interested organizations or individuals may obtain

copies from Project Manager for Chemical Demilitarization and Installation Restoration, Building E-4585, Attn: DRCPM-DR-T (Mr. Edward A. Coale), Aberdeen Proving Ground, Md. 21010, phone 301-671-2054.

In the Washington area, inspection copies may be seen in the Environmental Office, Office of the Assistant Chief of Engineers, Room 1E676, Pentagon, Washington, D.C. 20310, phone 202-694-1163.

Dated: August 23, 1978.

BRUCE A. HILDEBRAND,
Deputy for Environmental Affairs, Office of the Assistant Secretary of the Army (Civil Works).

[FR Doc. 78-24048 Filed 8-24-78; 8:45 am]

[3128-01]

DEPARTMENT OF ENERGY

Economic Regulatory Administration

DOMESTIC CRUDE OIL ALLOCATION PROGRAM

Entitlement Notice for June 1978

In accordance with the provisions of 10 CFR 211.67 relating to the domestic crude oil allocation program of the Department of Energy (DOE), administered by the Economic Regulatory Administration (ERA), the monthly notice specified in § 211.67(i) is hereby published.

Based on reports for June 1978 submitted to the DOE by refiners and other firms as to crude oil receipts, crude oil runs to stills, eligible product imports and imported naphtha utilized as a petrochemical feedstock in Puerto Rico; application of the entitlement adjustment for residual fuel oil production for sale in the east coast market provided in § 211.67(d)(4); application of the entitlement adjustments for California lower tier and upper tier crude oil provided in § 211.67(a)(4); July 1978 deliveries of crude oil for storage in the Strategic Petroleum Reserve; and application of the entitlement adjustment for small refiners provided in § 211.67(e), the national domestic crude oil supply ratio for June 1978 is calculated to be .190912.

In accordance with § 211.67(b)(2), to calculate the number of barrels of deemed old oil included in a refiner's adjusted crude oil receipts for the month of June 1978, each barrel of old oil is equal to one barrel of deemed old oil and each barrel of upper tier crude oil is equal to .185587 of a barrel of deemed old oil.

The issuance of entitlements for the month June 1978 to refiners and other firms is set forth in the appendix to this notice. The appendix lists the name of each refiner or other firm to which entitlements have been issued, the number of barrels of deemed old oil included in each such refiner's adjusted crude oil receipts, the number of entitlements issued to each such refiner or other firm, and the number of entitlements required to be purchased or sold by each such refiner or other firm.

Pursuant to 10 CFR 211.67(i)(4), the price at which entitlements shall be sold and purchased for the month of June 1978 is hereby fixed at $8.19, which is the exact differential as reported for the month of June between the weighted average per barrel costs to refiners of old oil and of imported and exempt domestic crude oil, less the sum of 21 cents.

In accordance with 10 CFR 211.67(b), each refiner that has been issued fewer entitlements for the month of June 1978 than the number of barrels of deemed old oil included in its adjusted crude oil receipts is required to purchase a number of entitlements for the month of June 1978 equal to the difference between the number of barrels of deemed old oil included in those receipts and the number of entitlements issued to and retained by that refiner. Refiners which have been issued a number of entitlements for the month of June 1978 in excess of the number of barrels of deemed old oil included in their adjusted crude oil receipts for that month and other firms issued entitlements shall sell such entitlements to refiners required to purchase entitlements. In addition, certain refiners are required to purchase or sell entitlements to effect corrections for reporting errors for the months September 1975 through May 1978 pursuant to 10 CFR 211.67(j)(1).

The listing of refiners' old oil receipts contained in the appendix reflects any adjustments made by ERA pursuant to § 211.67(h).

The listing contained in the appendix identifies in a separate column labeled "Exceptions and Appeals" additional entitlements issued to refiners pursuant to relief granted by the Office of Hearings and Appeals (prior to March 30, 1978, the Office of Administrative Review of the Economic Regulatory Administration). Also set forth in this column are adjustments for relief granted by the Office of Hearings and Appeals for 1975 and 1976, which adjustments are reflected in monthly installments. The number of installments is dependent on the magnitude of the adjustment to be made. For a full discussion of the issues involved, *see Beacon Oil Company, et al.*, 4 FEA par. 87,024 (Nov. 5, 1976).

The listing contained in the appendix continues the "Consolidated Sales" entry initiated in the October 1977 entitlement notice. The "Consolidated Sales" entry is equal to the June 1978 entitlement purchase requirement of Arizona Fuels less a number of entitlements equal to the amount, in dollars, of entitlement purchases required pursuant to the Court's order signed July 20, 1978, in *United States of America* v. *Arizona Fuels Corp. and Eugene Dalton, President*, Civ. 77-689 PHX-CAM (D. Ariz. 1977). The purpose of providing for the "Consolidated Sales" entry is to insure that Arizona Fuels is not relieved of its June 1978 entitlement purchase requirement and that no one firm will be unable to sell its entitlements by reason of a default by Arizona Fuels. For a full discussion of the issues involved, *see* Entitlement Notice for October 1977 (42 FR 64401, Dec. 23, 1977).

For purposes of § 211.67(d) (6) and (7), which provide for entitlement issuances to refiners or other firms for sales of imported crude oil to the U.S. Government for storage in the Strategic Petroleum Reserve, the number of barrels sold to the Government totaled 5,067,361 barrels.

For purposes of the adjustments to refiners' crude run volumes under § 211.67(d)(4), total production of residual fuel oil for sale in the east coast market (in excess of the first 5,000 barrels per day thereof for each refiner reporting such production) was 10,934,739 barrels for June 1978. For that month, imports of residual fuel oil eligible for entitlement issuances totaled 24,541,987 barrels.

In accordance with § 211.67(a)(4), the number of entitlements issued to each refiner reporting receipts of California lower tier crude oil has been increased by a number of entitlements equal to the number of barrels of California lower tier crude oil included in a refiner's adjusted crude oil receipts multiplied by a fraction, the numerator of which is $2.38, plus or minus $0.09 for each degree (counting any remaining fractional degree as a whole degree) that the weighted average gravity of all California lower tier crude oil included in that refiner's adjusted crude oil receipts either falls below or exceeds, respectively, 18° API, and the denominator of which is the entitlement price for that month. In addition, the number of entitlements issued to each refiner reporting receipts of California upper tier crude oil has been increased by a number of entitlements equal to the number of barrels of California upper tier crude oil included in a refiner's adjusted

crude oil receipts multiplied by a fraction, the numerator of which is $1.45, plus or minus $0.09 for each degree (counting any remaining fractional degree as a whole degree) that the weighted average gravity of all California upper tier crude oil included in that refiner's adjusted crude oil receipts either falls below or exceeds, respectively, 18° API, and the denominator of which is the entitlement price for that month. The number of barrels of California lower tier and upper tier crude oil as reported by refiners to the DOE, and the weighted average gravity thereof are as follows:

	Volumes	Weighted average gravity
California lower tier crude oil	9,805,408	19°
California upper tier crude oil	7,277,554	20°

The total number of entitlements required to be purchased and sold under this notice is 19,323,216.

Based on reports submitted to the DOE by refiners as to their adjusted crude oil receipts for June 1978, the pricing composition and weighted average costs thereof are as follows:

Category	Volumes	Weighted average cost	Percent of total volumes*
Lower tier	90,274,922	$5.89	19.0
Upper tier	88,555,155	12.56	18.7
Exempt domestic:			
Alaskan	32,764,913	12.84	6.9
Stripper	35,338,498	14.52	7.5
Naval petroleum reserve	2,761,206	13.44	.6
Total domestic	249,694,694	10.47	52.7
Total imported	224,310,845	14.47	47.3
Total reported crude oil receipts	474,005,539	12.36	100.0

*Individual listings are rounded, and may not total 100 pct. when added.

Payment for entitlements required to be purchased under 10 CFR § 211.67(b) for June 1978 must be made by August 31, 1978.

On or prior to September 10, 1978, each firm which is required to purchase or sell entitlements for the month of June 1978 shall file with the DOE the monthly transaction report specified in 10 CFR § 211.66(i) certifying its purchases and sales of entitlements for the month of June. The monthly transaction report forms for the month of June have been mailed to reporting firms. Firms that have been unable to locate other firms for required entitlement transactions by August 31, 1978, are requested to contact the ERA at 202-254-3336 to expedite consummation of these transactions. For firms that have failed to consummate required entitlement transactions on or prior to August 31, 1978, the ERA may direct sales and purchases of entitlements pursuant to the provisions of 10 CFR § 211.67(k).

This notice is issued pursuant to subpart G, 10 CFR part 205. Any person aggrieved hereby may file an appeal with the Office of Hearings and Appeals in accordance with subpart H of 10 CFR part 205. Any such appeal shall be filed on or before September 25, 1978.

Issued in Washington, D.C., on August 21, 1978.

DAVID J. BARDIN,
Administrator, Economic Regulatory Administration.

ENTITLEMENTS FOR DOMESTIC CRUDE OIL
June 1978

REPORTING FIRM SHORT NAME	DEEMED OLD OIL ADJUSTED RECEIPTS	********** TOTAL ISSUED	EXCEPTIONS AND APPEALS	ENTITLEMENT POSITION ENTITLEMENTS PRODUCT	CALIFORNIA	REQUIRED TO BUY	********** REQUIRED TO SELL
*CONSOLID-SALES	*127,467	0	0	0	0	0	127,467*
A-JOHNSON	0	137,536	0	14,307	0	0	137,536
ALLIED	145,137	57,317	0	0	0	87,820	0
AMER-PETROFINA	793,927	788,804	0	0	0	5,123	0
AMER-ULTRAMAR	0	121,945**	0	0	0	0	121,945
AMERADA-HESS	1,209,372	2,931,054**	0	44,575	0	0	1,721,682
AMOCO	9,199,200	5,944,656	0	0	0	3,254,544	0
ANCHOR	109,800	154,016	0	0	22,532	0	44,216
APCO	54,292	76,092	0	0	0	0	21,800
ARCO	4,087,207	4,322,278	0	0	75,734	0	235,071
ARIZONA	274,190	92,004	6,122	0	10,731	182,186	0
ASAMERA	113,821	153,872	0	0	0	0	40,051
ASHLAND	1,266,092	2,041,956	0	0	0	0	775,864
ASIATIC	0	108,066	0	108,066	0	0	108,066
AUGSBURY	0	3,084	0	3,084	0	0	3,084
BASIN	208,152	193,520	0	0	65,954	14,632	0
BAYOU	31,563	47,708	0	0	0	0	16,145
BEACON	239,085	262,879	84,606	0	42,926	0	23,794
BELCHER	0	10,852	0	10,852	0	0	10,852
BI-PETRO	6,695	127,150	0	0	0	0	120,455
BP-TRADING	0	351,202	0	0	0	0	351,202
BRUIN	4,478	125,813	0	0	0	0	121,335
C&H	86	161	0	0	0	0	75
CALCASIEU	0	56,893	0	0	0	0	56,893
CALUMET	21,714	28,768	0	0	0	0	7,054
CANAL	54,261	72,986	0	0	0	0	18,725
CARIBOU	82,882	90,558	0	0	0	0	7,676
CASTLE	0	374	0	374	0	0	374
CHAMPLIN	1,557,571	1,345,444	0	0	235,550	212,127	0
CHANTER	942,787	894,854	454,971	0	0	47,933	0
CHEVRON	6,180,167	6,491,834	0	0	296,341	0	311,647
CIRILLO	0	21,017	0	21,017	0	0	21,017
CITGO	1,844,841	1,462,115	0	0	0	382,726	0
CLAIBORNE	89,086	51,183	0	0	0	37,903	0
CLARK	194,427	705,058	0	0	0	0	510,631
COASTAL	177,097	1,222,312	0	40,773	0	0	1,045,215
COLONIAL	0	29,418	0	29,418	0	0	29,418
CONOCO	2,197,869	2,282,915	0	26,774	166,929	0	85,046
CORCO	0	983,777	82,489***	220,408	0	0	983,777
CRA-FARMLAND	315,438	481,630	0	0	0	0	166,192
CROSS	51,636	94,412	0	0	0	0	42,776
CROWN	311,666	597,823	0	0	0	0	286,157
CRYSTAL-OIL	177,361	160,667	0	0	0	16,694	0
CRYSTAL-REF	7,291	26,564	0	0	0	0	19,273
DELTA	206,787	336,013	0	0	0	0	129,226
DEMENNO	5,290	72,293	0	0	5,290	0	67,003
DERBY	0	198,618**	0	0	0	0	198,618
DIAMOND	478,770	349,843	0	0	0	128,927	0
DILLMAN	0	2,028	0	0	0	0	2,028
DORCHESTER	*56,173	150,893	0	0	0	0	207,066
DOW	62,996	91,714	0	0	0	0	28,718
E-SEABOARD	0	36,946	0	36,946	0	0	36,946
ECO	97,569	90,671	0	0	31,449	6,898	0
EDDY	38,118	43,178	0	0	0	0	5,060
ENERGY-COOP	0	772,769	0	0	0	0	772,769
ERICKSON	229	181,247	0	0	0	0	181,018
EVANGELINE	31,628	41,960	0	0	0	0	10,332
EXXON	8,446,659	8,063,801	0	390,343	0	362,858	0
EZ-SERVE	9,684	37,803	0	0	0	0	28,119
FARMERS-UN	173,966	299,013	0	0	0	0	125,047
FLETCHER	12,076	184,594	0	0	2,179	0	172,518
FLINT	7,519	8,835	0	0	0	0	1,316
GARY	109,307	95,303	0	0	0	14,004	0
GETTY	896,602	941,572	0	0	0	0	44,970
GIANT	39,221	54,781	0	0	0	0	15,560
GLACIER-PARK	90,274	46,757	0	0	0	43,517	0
GLADIEUX	69,983	97,537	0	0	0	0	27,554
GLENROCK	842	4,607	0	0	0	0	3,765

REPORTING FIRM SHORT NAME	DEEMED OLD OIL ADJUSTED RECEIPTS	********** TOTAL ISSUED	EXCEPTIONS AND APPEALS	ENTITLEMENT POSITION ENTITLEMENTS PRODUCT	CALIFORNIA	REQUIRED TO BUY	********** REQUIRED TO SELL
GOLDEN-EAGLE	0	148,444	0	0	0	0	148,444
GOLDKING	59,390	101,886	0	0	0	0	42,496
GOOD-HOPE	55,040	260,926	0	0	0	0	205,886
GUAM	0	263,089	0	0	0	0	263,089
GULF	7,073,539	5,106,905	0	18,615	52,337	1,966,634	0
GULF-STS	31,374	126,130	0	0	0	0	94,756
HIRI	0	427,851	0	0	0	0	427,851
HOWARD	0	35,655	0	35,655	0	0	35,655
HOWELL	190,082	268,825	0	0	0	0	78,743
HUDSON-OIL	12,905	190,503	0	0	0	0	177,598
HUNT	194,712	217,302	0	0	0	0	22,590
HUSKY	409,006	409,006	139,566	0	0	0	0****
INDEPENDENT-REF	46,436	125,913	0	0	0	0	79,477
INDIANA-FARM	34,926	179,904	0	0	0	0	144,978
J&W	64,574	51,758	0	0	0	12,816	0
KENCO	22,793	33,358	0	0	0	0	10,565
KENTUCKY	15,765	15,123	0	0	0	642	0
KERN	330,219	389,247	167,627	0	72,103	0	59,028
KERR-MCGEE	1,207,910	869,495	0	0	0	338,415	0
KOCH	311,153	708,831	0	0	0	0	397,678
LAGLORIA	426,679	250,994	0	0	0	175,685	0
LAKESIDE	6,398	35,773	0	0	0	0	29,375
LAKETON	122,395	149,494	37,259	0	0	0	27,099
LITTLE-AMER	1,246,326	1,003,145	579,039	0	0	243,181	0
LOUISIANA-LAND	187,333	280,619	0	0	0	0	93,286
MACMILLAN	50,607	144,792	0	0	8,439	0	94,185
MARATHON	4,919,789	3,115,644	0	0	0	1,804,145	0
MARION	93,991	194,504	0	0	0	0	100,513
METROPOLITAN	0	31,048	0	31,048	0	0	31,048
MID-AMER	96,079	36,455	0	0	0	59,624	0
MID-TEX	16,523	23,528	0	0	0	0	7,005
MOBIL	6,083,461	5,163,775	0	25,482	450,992	919,686	0
MOBILE-BAY	0	135,680	0	0	0	0	135,680
MOHAWK	382,449	480,535	172,968	0	81,583	0	98,086
MONOCO	0	5,566	0	5,566	0	0	5,566
MONSANTO	228,204	267,942	0	0	0	0	39,738
MORRISON	14,550	12,388	0	0	0	2,162	0
MOUNTAINEER	8,973	8,542	0	0	0	431	0
MT-AIRY	30,529	126,264	0	0	0	0	95,735
MURPHY	775,670	691,378	0	0	0	84,292	0
N-AMER-PETRO	19,076	143,198	0	0	0	0	124,122
NATL-COOP	246,575	366,847	0	0	0	0	120,272
NAVAJO	335,339	329,033	63,234	0	0	6,306	0
NEVADA	15,046	34,196	0	0	0	0	19,150
NEW-EDGINGTON	546,602	587,937	179,278	0	167,742	0	41,335
NEW-ENGL-PETRO	0	232,930	0	232,930	0	0	232,930
NEWHALL	218,583	225,729	0	0	72,034	0	7,146
NORTHEAST-PETRO	0	2,870	0	2,870	0	0	2,870
NORTHLAND	23,179	16,411	0	0	0	6,768	0
NORTHVILLE	0	29,649	0	29,649	0	0	29,649
OKC	123,543	207,079	0	0	0	0	83,536
OXNARD	4,685	12,969	0	0	3,031	0	8,284
PEMEX	0	158,951 **	0	0	0	0	158,951
PENNZOIL	391,714	315,308	0	0	0	76,406	0
PESTER	102,676	204,799	0	0	0	0	102,123
PHILLIPS	2,633,847	1,581,511	0	0	0	1,052,336	0
PHILLIPS-PR	0	270,179	0	270,179	0	0	270,179
PIONEER	35,712	57,089	0	0	0	0	21,377
PLACID	225,917	282,176	0	0	0	0	56,259
PLATEAU	134,629	157,922	0	0	0	0	23,293
POWERINE	483,975	500,561	0	0	150,210	0	16,586
PR-OLEFINS	0	63,986	0	63,986	0	0	63,986
PRIDE	53,278	142,467	0	0	0	0	89,189
PRINCETON	-5,943	60,137	0	0	0	0	66,080
QUAKER-ST	38,558	228,904	0	0	0	0	190,346
RANCHO-REF	0	11,622	0	0	0	0	11,622
RAYMAL	519	12,635	0	0	0	0	12,116
RICHARDS	366	60,267	0	0	0	0	59,901

REPORTING FIRM SHORT NAME	DEEMED OLD OIL ADJUSTED RECEIPTS	********** TOTAL ISSUED	EXCEPTIONS AND APPEALS	ENTITLEMENT POSITION ENTITLEMENTS PRODUCT	CALIFORNIA	REQUIRED TO BUY	********** REQUIRED TO SELL
ROAD-OIL	0	2,120	0	0	0	0	2,120
ROCK-ISLAND	255,610	297,649	0	0	0	0	42,039
SABER-TEX	17,531	197,303	0	0	0	0	179,772
SABRE-CAL	3,818	80,695	0	0	4,248	0	76,877
SAGE-CREEK	2,420	4,294	0	0	0	0	1,874
SAN-JOAQUIN	503,104	324,530	*13,450	0	151,633	178,574	0
SEMINOLE	12,136	44,514	0	0	0	0	32,378
SENTRY	11,757	115,277	0	0	0	0	103,520
SHELL	9,668,572	6,369,170	0	0	490,770	3,299,402	0
SHEPHERD	48,563	71,462	0	0	0	0	22,899
SIGNOR	39,612	125,423	0	0	0	0	85,811
SO-HAMPTON	35,875	125,934	0	0	0	0	90,059
SOHIO	1,351,129	2,184,463	0	0	0	0	833,334
SOMERSET	14,530	48,881	0	0	0	0	34,351
SOUND	0	82,936	0	0	0	0	82,936
SOUTHERN-UNION	256,456	259,123	0	0	0	0	2,667
SOUTHLAND	424,893	320,259	129,372	0	0	104,634	0
SOUTHWESTERN	4,523	4,161	0	0	0	362	0
SPRAGUE	0	26,043	0	26,043	0	0	26,043
STEUART	0	17,797	0	17,797	0	0	17,797
SUN-TRADING	0	12,890 **	0	0	0	0	12,890
SUNLAND	3,729	123,996	0	0	1,530	0	120,267
SUNOCO	4,172,193	3,114,826	0	0	0	1,057,367	0
SWANN	0	24,612	0	24,612	0	0	24,612
T&S	22,180	64,022	0	0	0	0	41,842
TARRICONE	0	10,009	0	10,009	0	0	10,009
TENNECO	550,902	532,265	0	0	11,137	18,637	0
TESORO	127,279	421,832	0	0	12,185	0	294,553
TEXACO	8,540,970	6,198,609	0	178,232	287,362	2,342,361	0
TEXAS-AMERICAN	31,909	95,596	0	0	0	0	63,687
TEXAS-ASPH	5,582	26,060	0	0	0	0	20,478****
TEXAS-CITY	131,747	187,352	0	0	0	0	55,605
THAGARD	225,762	198,135	28,058	0	68,277	27,627	0
THRIFTWAY	33,288	40,047	0	0	0	0	6,759
THUNDERBIRD	111,668	129,555	0	0	0	0	17,887
TIPPERARY	03,873	80,511	0	0	0	3,362	0
TONKAWA	37,887	49,946	0	0	0	0	12,059
TUSCO	1,145,808	2,011,994	747,656	0	296,864	0	866,186
TOTAL-PETROLEUM	242,883	366,974	0	0	0	0	124,091
UCC-CARIBE	0	155,480	0	155,480	0	0	155,480
UNION-OIL	3,402,281	2,676,883	0	5,727	279,273	725,398	0
UNION-PETRO	0	9,890	0	9,890	0	0	9,890
UNTD-REF	105,660	308,478	0	0	0	0	202,818
US-OIL	16,257	193,790	0	0	4,775	0	177,533
USA-PETROCHEM	30,819	180,063	0	0	7,768	0	149,244
VAL-VERDE	223	1,625	0	0	0	0	1,402
VICKERS	190,175	400,258	0	0	0	0	210,083
VULCAN	5,568	271,045	0	0	0	0	265,477
WARRIOR	64,901	50,491	14,855	0	0	14,410	0
WEST-COAST	72,355	167,580	0	0	51,423	0	95,225
WESTERN	66,508	106,093	0	0	0	0	39,585
WINSTON	105,325	158,614	0	0	0	0	53,289
WIREBACK	0	793	0	0	0	0	793
WITCO	85,406	194,855	0	0	24,777	0	109,449
WYATT	0	24,951	0	24,951	0	0	24,951
WYOMING	58,978	173,381	0	0	0	0	134,403
YETTER	0	596	0	0	0	0	596
YOUNG	51,579	47,918	13,900	0	0	3,661	0
TOTAL	105,274,971	105,274,971	2,887,550	2,115,658	3,706,108	19,323,216	19,323,216

* See discussion in Notice.

** Includes entitlements issued for sales of imported crude oil to the United States Government for storage in the Strategic Petroleum Reserve.

*** Authorization to sell these entitlements is subject to conditions set forth in a DOE Decision and Order issued to Commonwealth Oil and Refining Company on March 20, 1978.

**** This is consistent with the court's order prohibiting any further entitlement purchase requirements by this firm pursuant to the terms of the court's Judgment in Husky Oil Co. v. DOE, et al., Civ. Action No. C77-190-B (D.Wyo., filed March 14, 1978).

***** This does not include the purchase obligation stayed by court order in Texas Asphalt & Refinery Co. v. FEA Civ. Action No. 4-75-268 (N.D. Tex., filed October 31, 1975).

[FR Doc. 78-23999 Filed 8-24-78; 8:45 am]

[6740-02]

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. G-4904 et al.]

AMOCO PRODUCTION CO. ET AL.

Applications for Certificates, Abandonment of Service and Petitions To Amend Certificates [1]

AUGUST 16, 1978.

Take notice that each of the applicants listed herein has filed an application or petition pursuant to section 7 of the Natural Gas Act for authorization to sell natural gas in interstate commerce or to abandon service as described herein, all as more fully described in the respective applications and amendments which are on file with the Commission and open to public inspection.

Any person desiring to be heard or to make any protest with reference to said applications should on or before September 14, 1978, 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 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Persons wishing to become parties to a proceeding or to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure a hearing will be held without further notice before the Commission on all applications in which no petition to intervene is filed within the time required herein if the Commission on its own review of the matter believes that a grant of the certificates or the authorization for the proposed abandonment is required by the public convenience and necessity. Where a petition for leave to intervene is timely filed, or where 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 applicants to appear or to be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[1] This notice does not provide for consolidation for hearing of the several matters covered herein.

Docket No. and date filed	Applicant	Purchaser and location	Price per 1,000 ft³	Pressure base
G-4904, C, July 31, 1978	Amoco Production Co., Security Life Bldg., Denver, Colo. 80202.	Cities Service Gas Co., Julian 1-10 well, sec. 10-29S-40W, Hugoton Field, Stanton County, Kans.	(1)	14.65
G-5004, D, July 28, 1978	Shell Oil Co., 2 Shell Plaza, P.O. Box 2099, Houston, Tex. 77001.	Texas Eastern Transmission Corp., Nada field, Colorado County, Tex.	Wells plugged and abandoned and lease expired.	
G-5005, D, July 18, 1978	Shell Oil Co	United Gas Pipe Line Co., Red Fish Bay field, Nueces County, Tex.	Nonproduction since April 1977 and contains no more developable reserves.	
G-5073, D, July 28, 1978	do	Colorado Interstate Gas Co., Keyes Dome field, Cimarron County, Okla.	Ceased production and lease surrendered to mineral interest owners.	
G-8837, D, July 31, 1978	do	Tennessee Gas Pipeline Co., Halter Island et al., fields, Plaquemines Parish, La.	Certain acreage surrendered.	
G-10143, D, July 17, 1978	Atlantic Richfield Co., P.O. Box 2819, Dallas, Tex. 75221.	Tennessee Gas Pipeline Co., certain acreage in the West Delta area, offshore, Louisiana.	Nonproductive and Applicant had no plans to develop this acreage in the future.	
G-10164, D, July 20, 1978	Gulf Oil Corp., P.O. Box 2100, Houston, Tex. 77001.	Tennessee Gas Pipeline Co., Timbalier Bay field, Lafourche Parish and offshore, Louisiana.	Leases expired and wells plugged and abandoned.	
G-12761, D, July 27, 1978	The Superior Oil Co., P.O. Box 1521, Houston, Tex. 77001.	Northern Natural Gas Co., Perryton West field, Ochiltree County, Tex.	Leases expired of their own terms or ceased to produce.	
G-13416, D, Aug. 4, 1978	Getty Oil Co., P.O. Box 1404, Houston, Tex. 77001.	Northern Natural Gas Co., McKinney field, Clark and Meade Counties, Kans.	Nonproductive since 1961, and Applicant's interest has expired.	
G-14366, D, July 24, 1978	Coastal States Gas Producing Co., 5 Greenway Plaza East, Houston, Tex. 77046.	Natural Gas Pipeline Co. of America, various fields, Duval, Webb, and LaSalle Counties, Tex.	Nonproduction since November 1976. Wells plugged and abandoned and leases dropped.	
G-16091, D, Aug. 4, 1978	Gulf Oil Corp	Transwestern Pipeline Co., certain acreage in the Mendota, Northwest field, Hemphill County, Tex.	Lease has been canceled or assigned to other parties.	
G-20224, D, July 28, 1978	Shell Oil Co	Natural Gas Pipeline Co. of America, Harrington field, Texas County, Okla.	Ceased production and lease surrendered to mineral interest owners.	
CI64-555, D, Aug. 3, 1978	Sun Oil Co., P.O. Box 20, Dallas, Tex. 75221.	Northern Natural Gas Co., Southeast Como field, Beaver County, Okla.	Lease released and surrendered unto the landowners on Jan. 31, 1977 and plugged and abandoned.	
CI65-453, C, Aug. 3, 1978	Atlantic Richfield Co., P.O. Box 2819, Dallas, Tex. 75221.	Northern Natural Gas Co., Ozona field, Crockett County, Tex.	(2)	14.65
CI71-281, D, July 12, 1978	Anadarko Production Co., P.O. Box 1330, Houston, Tex. 77001.	Panhandle Eastern Pipe Line Co., Reust "A" No. 1 well, all of sec. 32-4N-14ECM, Texas County, Okla.	Ceased production, plugged and abandoned and there are no known potential gas reserves underlying the acreage.	
CI72-440, C, July 27, 1978	Amoco Production Co., Security Life Bldg., Denver, Colo. 80202.	Panhandle Eastern Pipe Line Co., certain acreage in the Warlock and Chieftan fields, Adams County, Colo.	(1)	15.025
CI73-25, D, Aug. 1, 1978	Exchange Oil & Gas Corp., 16th Floor, 1010 Common St., New Orleans, La. 70112.	Transcontinental Gas Pipe Line Corp., block 6, Vermilion block 16 field, Vermilion Parish, La.	Depletion of reserves and release of lease.	
CI77-133, C, July 19, 1978	CIG Exploration, Inc., 5 Greenway Plaza East, Houston, Tex. 77046.	Colorado Interstate Gas Co., Brown No. 1-6 well, Lott field, Wheeler County, Tex.	(1)	14.65
CI78-29, C, July 12, 1978	Anadarko Production Co	Panhandle Eastern Pipe Line Co., Cities Service "F" No. 1 well, South Hough field, Texas County, Okla., limited to the Cherokee Formation only.	(1)	14.65
CI78-33, C, Aug. 7, 1978	Amoco Production Co., P.O. Box 3092, Houston, Tex. 77001.	El Paso Natural Gas Co., Empire South deep Unit No. 18 well, N/2 sec. 30-T17S-R29E, Eddy County, N. Mex., limited to Morrow Formation.	(3)	14.73
CI78-146, C, July 24, 1978	Belco Petroleum Corp., 1 Dag Hammarskjold Plaza, New York, N.Y. 10017.	El Paso Natural Gas Co., Edwards No. 2 well (Fusselman Formation), Glasscock County, Tex.	(1)	14.73

Docket No. and date filed	Applicant	Purchaser and location	Price per 1,000 ft³	Pressure base
CI78-520, C, July 17, 1978.....	Southland Royalty Co., 1000 Fort Worth Club Tower, Fort Worth, Tex. 76102.	El Paso Natural Gas Co., Eddy "GM" State Com No. 1 well, SE/4 of sec. 36-T19S-R27E, Eddy County, N. Mex., limited to the Morrow Formation.	(1)	14.65
CI78-758, C, July 28, 1978.....	Exxon Corp., P.O. Box 2180, Houston, Tex. 77001.	Columbia Gas Transmission Corp., West Cameron block 608, offshore, Louisiana.	(1)	14.73
CI78-759, C, July 28, 1978.....	.....do.....	Northern Natural Gas Co., West Cameron block 608, offshore, Louisiana.	(1)	14.73
CI78-882, C, July 28, 1978.....	Exxon Corp.....	Trunkline Gas Co., West Cameron block 608, offshore, Louisiana.	(1)	14.73
CI78-902, C, July 24, 1978.....	MRT Exploration Co., 9900 Clayton Rd., St. Louis, Mo. 63124.	Mississippi River Transmission Corp., Feitel No. 1, Sherrill No. 7, and Faulk No. 1 wells, all located in Leatherman Creek field, Claiborne Parish, La.	(1)	15.025
CI-78-977, A, July 10, 1978....	Harper Oil Co., 904 Hightower Bldg., 105 North Hudson, Oklahoma City, Okla. 73102.	Arkansas Louisiana Gas Co., No. 1 Hightower unit, sec. 30-8N-22E, Haskell County, Okla.	(1)	14.65
CI78-978, A, July 10, 1978.....	Columbia Gas Development Corp., P.O. Box 1350, Houston, Tex. 77001.	Southwest Gas Corp., certain acreage in Eddy County, N. Mex.	(5)	14.73
CI78-981, C, July 28, 1978.....	Exxon Corp.....	Natural Gas Pipeline Co. of America, West Cameron block 608, offshore, Louisiana.	(1)	14.73
CI78-985, A, July 10, 1978.....	.....do.....	Columbia Gas Transmission Corp., Lirette field, Terrebonne Parish, La.	(1)	15.025
CI78-986, A, July 10, 1978.....	.....do.....	Northern Natural Gas Co., Lineberry field, Loving County, Tex.	(1)	14.65
CI78-1001, A, July 17, 1978....	Cabot Corp., 1 Houston Center, Suite 1000, Houston, Tex. 77002.	Panhandle Eastern Pipe Line Co., certain acreage in Hutchinson County, Tex.	(1)	14.73
CI78-1002, A, July 18, 1978....	Southland Royalty Co. (Operator), 1000 Fort Worth Club Tower, Fort Worth, Tex. 76102.	Northern Natural Gas Co., Chester Formation from the Ehrhardt No. 1-27 well located in sec. 27-T5N-R18E, Texas County, Okla.	(1)	14.73
CI78-1004 (CI64-375), B, July 17, 1978.	Texaco Inc., P.O. Box 430, Bellaire, Tex. 77401.	Natural Gas Pipe Line Co. of America, Hostetter and Eubank fields, Duval and McMullen Counties, Tex.	Leases released, and there are no known physically recoverable gas reserves contained in the acreage.	
CI78-1005, A, July 17, 1978....	Phillips Petroleum Co., 5 C4 Phillips Bldg., Bartlesville, Okla. 74004.	United Gas Pipe Line Co., Waveland field, Hancock County, Miss.	(1)	15.025
CI78-1006, A, July 17, 1978....	Cotton Petroleum Corp., 4200 1 Williams Center, Tulsa, Okla. 74103.	Northern Natural Gas Co., Thomas Hill No. 1-7 well, sec. 7-14N-25W, Roger Mills County, Okla., limited to Granite Wash Formation only.	(1)	14.65
CI78-1007 (CI70-956), B, July 14, 1978.	Creslenn Oil Co. (Operator), et al., 1800 First National Bank Bldg., Dallas, Tex. 75202.	Michigan Wisconsin Pipe Line Co., Hugoton-Anadarko area, Woodward County, Okla.	Reserves depleted.	
CI78-1010, A, July 19, 1978....	Mesa Petroleum Co., P.O. Box 2009, Amarillo, Tex. 79189.	Natural Gas Pipeline Co. of America, Hansford Lower Morrow field, Hansford County, Tex.	(1)	14.65
CI78-1011, A, July 11, 1978....	Anadarko Production Co., P.O. Box 1330, Houston, Tex. 77001.	Panhandle Eastern Pipe Line Co., Davis Trust "A" No. 1 well, Greenough field, Beaver County, Okla.	(1)	14.65
CI78-1012 (CI68-150), B, July 12, 1978.	Anadarko Production Co.....	Northern Natural Gas Co., certain acreage in Ochiltree County, Tex.	All acreage assigned to third party (Graham-Michaelis Drilling Co.).	
CI78-1013 (CI65-599), B, July 12, 1978.	.....do.....	Kansas-Nebraska Natural Gas Co., Inc., certain acreage in the Bradshaw field, Hamilton County, Kans.	Depleted, leases terminated as result of cessation of production.	
CI78-1014, A, July 14, 1978....	Exxon Corp., P.O. Box 2180, Houston, Tex. 77001.	Columbia Gas Transmission Corp., Pecan Island field, Vermilion Parish, La.	(1)	15.025
CI78-1015, A, July 14, 1978....	Amoco Production Co., Security Life Bldg., Denver, Colo. 80202.	Montana-Dakota Utilities Co., Little Knife field, Stark, Dunn, McKenzie, and Billings Counties, N.D.	(1)	15.025
CI78-1016, A, July 20, 1978....	Florida Gas Exploration Co., P.O. Box 44, Winter Park, Fla. 32790.	Florida Gas Transmission Co., No. 1 Shirley L. Sherman well in the Oakvale field, Jefferson Davis County, Miss.	(1)	15.025
CI78-1017 (CI76-165), B, July 20, 1978.	Dorchester Exploration, Inc., 1100 Midland National Bank Tower, Midland, Tex. 79701.	El Paso Natural Gas Co., Wilson (Penn) field, Lea County, N. Mex.	Well depleted with respect to the Morrow Gas Formation.	
CI78-1018, A, July 21, 1978....	CNG Producing Co., 445 West Main St., Clarksburg, W. Va. 26301.	Consolidated Gas Supply Corp., "A" platform, block A-298, High Island area, offshore, Texas.	(1)	14.73
CI78-1021, (G-9308), B, July 21, 1978.	Amoco Production Co., P.O. Box 50879, New Orleans, La. 70150.	Hassie Hunt Exploration Co., Northeast Lisbon field, Clairborne, Parish, La.	Ceased gas deliveries July 1974 and leases released, and there are no physically recoverable reserves underlying dedicated acreage.	
CI78-1022, A, July 21, 1978....	Southland Royalty Co., 1000 Forth Worth Club Tower, Forth Worth, Tex. 76102.	Northwest Pipeline Corp., Mesaverde Formation from the San Juan 32-7 Com No. 24 well located in sec. 21-T32N-R7W, San Juan County, N. Mex.	(1)	14.73
CI78-1023, A, July 24, 1978....	Napeco, Inc., 122 South Michigan Ave., Chicago, Ill. 60603.	Natural Gas Pipeline Co. of America, C. L. Brent No. 1 well, Polk County, Tex.	(1)	14.65
CI78-1024, A, July 24, 1978....	Tenneco Oil Co., (Operator), et al., P.O. Box 2511, Houston, Tex. 77001.	Arkansas Louisiana Gas Co., Caspiana Plantation No. 1 well, sec. 22-T15N-R12W, Caddo and Bossier Parishes, La.	(1)	15.025
CI78-1025, A, July 24, 1978....	Enserch Exploration, Inc., 1817 Wood St., Dallas, Tex. 75201.	Panhandle Eastern Pipe Line Co., Dilts-Cooke Federal No. 1-1 well, sec. 1-T39N-R74W, Converse County, Wyo., from the First Frontier Formation.	(1)	15.025
CI78-1026, A, July 5, 1978.....	Sun Oil Co., P.O. Box 20, Dallas, Tex. 75221.	Arkansas Louisiana Gas Co., SW/4 of sec. 9-T1N-R8W, SE Stage Stand Field (Nellie area), Stephens County, Okla. limited to production from the surface to a depth of 5,200 ft.	(8)	14.65

Docket No. and date filed	Applicant	Purchaser and location	Price per 1,000 ft³	Pressure base
CI78-1028 (CI68-727), B, July 14, 1978.	Tenneco Oil Co., P.O. Box 2511, Houston, Tex. 77001.	Northwest Pipeline Corp., East LaBarge field, Sublette County, Wyo.	As of Apr. 1, 1977, Tenneco Oil Co. assigned all its rights, title, and interest of Belco Petroleum Corp.	
CI78-1029 (CI65-188), B, July 24, 1978.	Amoco Production Co., P.O. Box 50879, New Orleans, La. 70150.	United Gas Pipe Line Co., Greenwood-Waskom field, Caddo Parish, La.	(2)	
CI78-1030, A, July 24, 1978....	The Superior Oil Co., P.O. Box 1521, Houston, Tex. 77001.	Natural Gas Pipeline Co. of America, blocks 14 and 17, Sabine Pass area, offshore, Texas.	(1 18)	14.65
CI78-1031, A July 24, 1978.....	Chevron U.S.A., Inc., 575 Market St., San Francisco, Calif. 94105.	Natural Gas Pipeline Co. of America, High Island blocks A-337 and A-342, offshore, Texas.	(1)	14.65
CI78-1032, B, Aug. 3, 1978	Rex Oil & Gas Co., P.O. Box 486, Clending, W. Va. 25045.	Consolidated Gas Supply Corp., Big Sandy field, Kanawha County, W. Va.	(8)	
CI78-1033, A, July 24, 1978....	Marathon Oil Co., 539 South Main St., Findlay, Ohio 45840.	Colorado Interstate Gas Co., certain acreage located in the Wamsutter Arch area, Carbon and Sweetwater Counties, Wyo.	(1)	15.025
CI78-1034 (G-15221), B, July 24, 1978.	Cabot Corp. (successor to Godfrey L. Cabot, Inc.), P.O. Box 1473, Charleston, W. Va. 25325.	Consolidated Gas Supply Corp., (successor to New York State Natural Gas Corp.), W. M. Reiter Well No. 2, Clearfield field, Clearfield County, Pa.	(9)	
CI78-1035, A, July 25, 1978....	Panhandle Western Gas Co., P.O. Box 1348, Kansas City, Mo. 64141.	Panhandle Eastern Pipe Line Co., Hay Reservoir area, Sweetwater County, Wyo.	(1 10)	14.65
CI78-1036, A, July 25, 1978....	Panhandle Western Gas Co	do	(1 10)	14.65
CI78-1037, A, July 25, 1978....	do	do	(1 10)	14.65
CI78-1038 (CI75-698), B, July 26, 1978.	MRT Exploration Co., 9900 Clayton Rd., St. Louis, Mo. 63124.	Mississippi River Transmission Corp., Haughton field, Bossier Parish, La.	Hosston reservoir depleted. Further evaluation of the productive zones through workover attempts proved noncommercial.	
CI78-1039, A, July 26, 1978....	Atlantic Richfield Co., P.O. Box 2819, Dallas, Tex. 75221.	El Paso Natural Gas Co., certain acreage in Buckhorn field, Schleicher County, Tex.	(1)	14.65
CI78-1040, B, July 27, 1978....	Phillips Petroleum Co., 5 C4 Phillips Bldg., Bartlesville, Okla. 74004.	Reeves County Gas Co., Fort Stockton field, Pecos County, Tex.	Contract terminated Apr. 15, 1978. All gas being returned to lease for fuel and has been since 1975.	
CI78-1041, A July 27, 1978.....	Texaco Inc., P.O. Box 2100, Denver, Colo. 80201.	Montana-Dakota Utilities Co., Mondak field, Richland County, Mont.	(1)	15.025
CI78-1043, A, July 27, 1978....	Chevron U.S.A., Inc., 575 Market St., San Francisco, Calif. 94105.	Natural Gas Pipeline Co. of America, High Island blocks A-337 and A-342, offshore, Texas.	(1)	14.65
CI78-1044, A, July 25, 1978....	Panhandle Western Gas Co	Panhandle Eastern Pipe Line Co., certain acreage in Sweetwater County, Wyo.	(1 10)	14.65
CI78-1045, A, July 25, 1978....	Panhandle Western Gas Co., P.O. Box 1348, Kansas City, Mo. 64141.	Panhandle Eastern Pipe Line Co., certain acreage in the Hay Reservoir area, Sweetwater County, Wyo.	(1 10)	14.65
CI78-1046, A, July 27, 1978....	Mesa Petroleum Co., P.O. Box 2009, Amarillo, Tex. 79189.	Transco Gas Supply Co., South Pelto area, block 13, offshore, Louisiana.	(1)	14.73
CI78-1047 (CI71-377), B, July 27, 1978.	Getty Oil Co., P.O. Box 1404, Houston, Tex. 77001.	El Paso Natural Gas Co., Cogdell (Canyon Reef) unit and Fuller gasoline plant, Scurry and Kent Counties, Tex.	(11)	
CI78-1048, A, July 27, 1978....	Cities Service Co., P.O. Box 300, Tulsa, Okla. 74102.	Northern Natural Gas Co., No. 1 Selley "B" well, sec. 28-29N-20W and No. 1 Selley "C" well, sec. 33-29N-20W, Woods County, Okla., limited to the Mississippian Chester Formation.	(1)	14.65
CI78-1049, A, July 27, 1978....	Cabot Corp. (SW) et al., 1 Houston Center, Suite 1000, Houston, Tex. 77002.	Northern Natural Gas Co., a portion of High Island block A-532, south addition, Federal offshore, Texas.	(12)	14.73
CI78-1050, A, July 31, 1978....	Napeco, Inc., 122 South Michigan Ave., Chicago, Ill. 60603.	Natural Gas Pipeline Co. of America, R. L. Clamon No. 1 well, Polk County, Tex.	(1)	14.65
CI78-1051, A, July 27, 1978....	Continental Oil Co., P.O. Box 2197, Houston, Tex. 77001.	El Paso Natural Gas Co., West Lindreth field, Rio Arriba County, N. Mex.	(13)	14.65
CI78-1052, A, July 28, 1978....	Gulf Oil Corp., P.O. Box 2100, Houston, Tex. 77001.	Equitable Gas Co., certain acreage located in the Glenville North field in Gilmer County, W. Va.	(1)	14.73
CI78-1055, F, July 31, 1978....	Energy Reserves Group, Inc. (partial successor in interest to Prenalta Corp., et al.), P.O. Box 1201, Wichita, Kans. 67201.	Colorado Interstate Gas Co., Hay Reservoir field, Sweetwater County, Wyo.	(1 14)	14.65
CI78-1056, A, July 31, 1978....	Helmerich & Payne, Inc., 1579 East 21st St., Tulsa, Okla. 74114.	El Paso Natural Gas Co., East Reydon field, Roger Mills County, Okla.	(15)	14.73
CI78-1057, A, July 31, 1978....	HNG Fossil Fuels Co., P.O. Box 1188, Houston, Tex. 77001.	National Fuel Gas Supply Corp., block A-330 field, South High Island and West Cameron areas, offshore Texas and Louisiana.	(1)	14.65
CI78-1058, A, July 31, 1978....	HNG Oil Co., P.O. Box 1188, Houston, Tex. 77001.	Northern Natural Gas Co., Nordan Trust "45" No. 1 well, sec. 45, block 33, H & TC R.R. Co. survey, Barstow (Wolfcamp) field, Ward County, Tex.	(1)	14.73
CI78-1059, A, July 31, 1978....	HNG Oil Co	Natural Gas Pipeline Co. of America, Shoebar Ranch unit "3" No. 1 well, north ½ of sec. 3, TWP. 17S, RGE. 35E, Shoebar Ranch (Morrow) field, Lea County, N. Mex.	(1)	14.73
CI78-1060, A, July 31, 1978....	Transco Exploration Co., P.O. Box 1396, Houston, Tex. 77001.	Transcontinental Gas Pipe Line Corp., East Cameron area, block 263, offshore, Louisiana.	(1)	15.025
CI78-1061, A, July 31, 1978....	Aminoil U.S.A., Inc., Golden Center 1, 2800 North Loop West, Houston, Tex. 77018.	Florida Gas Transmission Co., certain acreage located in block 75 (block 76 field), Grand Isle area, offshore, Louisiana.	(1)	15.025
CI78-1062, A, July 31, 1978....	Atlantic Richfield Co., P.O. Box 2819, Dallas, Tex. 75221.	Transco Gas Supply Co., West Cameron area, block 222 field, offshore, Louisiana.	(1)	15.025
CI78-1063 (G-18880), B, Aug. 1, 1978.	Getty Oil Co., P.O. 1404, Houston, Tex. 77001.	Natural Gas Pipeline Co., Camrick Southeast field, Beaver County, Okla.	Plugged and abandoned.	

Docket No. and date filed	Applicant	Purchaser and location	Price per 1,000 ft³	Pressure base
CI78-1065, A, July 31, 1978....	Gas Producing Enterprises, Inc., 5 Greenway Plaza East, Houston, Tex. 77046.	Transcontinental Gas Pipe Line Corp., J. J. & J. field, Zapata County, Tex.	(1)	14.65
CI78-1067 (CI72-174), B, Aug. 3, 1978.	Morris Cannan, 1645 Milam Bldg., San Antonio, Tex. 78205.	Texas Eastern Transmission Corp., Burnell field, Bee County, Tex.	Prohibitive cost of gathering system to Texas Eastern pipeline system.	
CI78-1068 (CI73-593), B, July 31, 1978.	Getty Oil Co., P.O. Box 1404, Houston, Tex. 77001.	Cities Service Gas Co., R. V. Gill No. 1 well, in the Locke field, Roberts County, Tex.	Plugged and abandoned.	
CI78-1069, A, Aug. 3, 1978.....	Amoco Production Co., P.O. Box 3092, Houston, Tex. 77001.	El Paso Natural Gas Co., Many Gates field, Chaves County, N. Mex.	(16)	14.65
CI78-1070, B, Aug. 4, 1978.....	Teton Energy Co., Inc., 621 17th St., Suite 1520, Denver, Colo. 80923.	Northwest Pipeline Corp., Cathedral field, Rio Blanco County, Colo.	(17)	
CI78-1071, A, Aug. 4, 1978.....	Kerr-McGee Corp., P.O. Box 25861, Oklahoma City, Okla. 73125.	Transwestern Pipeline Co., Horseshoe Bend well No. 1, Eddy County, N. Mex.	(1)	14.65

[1] Applicant is willing to accept the applicable national rate pursuant to opinion No. 770, as amended.
[2] Applicant is filing under gas purchase contract dated Sept. 18, 1964, amended by letter agreement dated Mar. 20, 1978.
[3] Applicant is filing under gas purchase agreement dated Sept. 27, 1977, amended by amendment dated June 8, 1978.
[4] Applicant is filing under gas purchase agreement dated Jan. 26, 1978, amended by letter agreement dated June 19, 1978.
[5] Applicant is filing under gas purchase and sales agreement dated May 23, 1978.
[6] Applicant is filing under gas purchase contract dated May 1, 1978.
[7] The sale wellbore under the subject contract ceased gas deliveries in June 1968 and was plugged and abandoned October 1969. The contract expired under its own terms on Dec. 30, 1973. To the best of Applicant's knowledge, there are no physically recoverable reserves underlying the dedicated acreage.
[8] Economic depletion due to high pipeline pressure of Consolidated Gas Supply Corp. The remaining gas reserves to Columbia lower pressure pipeline.
[9] Pressure had decreased to point where gas from well could not enter purchaser's pipelines. All interstate use of Applicant's gas has ceased. Said well is plugged and the underlying leases expired.
[10] Applicant and Purchaser are affiliated.
[11] Sale to be continued under certificate authority issued to Texaco, Inc., the plant and unit operator, in Docket No. CI64-1138 and pursuant to the terms of Texaco, Inc. (Operator), et al., FERC gas rate schedule No. 328.
[12] Applicant is filing under gas purchase contract dated Apr. 7, 1978, amended by letter agreement dated June 22, 1978.
[13] Applicant is filing under gas purchase and sales agreement dated June 16, 1978.
[14] Applicant acquired its interest in the Hay Reservoir area from Davis Oil Co. Originally authorized under small producer docket No. CS71-468.
[15] Applicant is filing under gas purchase contract dated July 17, 1978.
[16] Applicant is filing under gas purchase agreement dated June 15, 1978.
[17] The acreage involved is in two small tracts which makes drilling difficult. Applicant has acquired through a trade a contiguous 160-acre tract which is more suitable for drilling and which Applicant will commit to the gas contract.
[18] Applicant also seeks the issuance of a certificate for the construction of approximately fifteen (15) miles of natural gas delivery facility from a point commencing at its platform No. 1 and going ashore across seabeds owned entirely by the State of Texas to a condensate reseparation center located at Texas State Highway No. 87 approximately three and one-half (3½) miles west of the Sabine River in Jefferson County, Tex. Superior has created a wholly owned subsidiary company called Tejas Pipeline Inc. to own and operate these facilities which will not receive any revenue from the transportation of natural gas delivered to Natural Gas Pipeline Co. of America, and Superior seeks a finding and order authorizing Superior to transfer the within described pipeline facility to its wholly owned subsidiary, Tejas Pipeline Inc.

Filing code: A—Initial service. B—Abandonment. C—Amendment to add acreage. D—Amendment to delete acreage. E—Total succession. F—Partial succession.

[FR Doc. 78-23723 Filed 8-24-78; 8:45 am]

[6740-02]

[Docket No. CS78-569 et al.]

C. E. LEITH, ET AL.

Applications for "Small Producer" Certificates [1]

AUGUST 18, 1978.

Take notice that each of the applicants listed herein has filed an application pursuant to section 7(c) of the Natural Gas Act and § 157.40 of the regulations thereunder for a "small producer" certificate of public convenience and necessity authorizing the sale for resale and delivery of natural gas in interstate commerce, all as more fully set forth in the applications which are on file with the Commission and open to public inspection.

Any person desiring to be heard or to make any protest with reference to said applications should on or before September 15, 1978, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, petitions to intervene or protests in accordance with the requirements of the Commis-

[1] This notice does not provide for consolidation for hearing of the several matters covered herein.

sion'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 proceedings. Persons wishing to become parties to a proceeding or to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure, a hearing will be held without further notice before the Commission on all applications in which no petition to intervene is filed within the time required herein if the Commission on its own review of the matter believes that a grant of the certificates is required by the public convenience and necessity. Where a petition for leave to intervene is timely filed, or where the Commission on its own motion believes that a formal heaing 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 applicants to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

Docket No.	Date filed	Applicant
CS78-569	7/3/78	C. E. Leith, 700 Farm Credit Banks Bldg., Wichita, Kans. 67202.
CS78-570	7/3/78	Leroy and Pauline A. Beckwith, 501 Northwest 13th St., Oklahoma City, Okla. 73103.
CS78-571	7/3/78	Bonray Oil & Gas Fund—1977, Ltd., P.O. Box 20746, Oklahoma City, Okla. 73156.
CS78-572	7/5/78	Sandlin Oil Corp., 1150 Petroleum Club Bldg., Denver, Colo. 80202.
CS78-573	7/6/78	Boling Production Co., Inc., 2016 Main St., No. 2203, Houston, Tex. 77002.
CS78-574	7/7/78	NICOR Exploration Co., 1700 West Ferry Rd., Naperville, Ill. 60540.
CS78-575	7/10/78	Wayne E. Glenn Associates, Inc., 4605 Post Oak Pl., Suite 102, Houston, Tex. 77027.
CS78-576	7/10/78	Texas Royalty Co., P.O. Box 789, Houston, Tex. 77001.
CS78-577	7/10/78	Petroleum Unlimited, Inc., 1331 Main Bldg., Houston, Tex. 77002.
CS78-578	7/10/78	Edward G. Powell, P.O. Box 21373, Shreveport, LA. 71120.
CS78-579	7/10/78	Michael F. Mahony, 406 Armstrong Bldg., El Dorado, Ark. 71730.
CS78-580	7/10/78	Joe H. Daniel, P.O. Box 1084, Jackson, Miss. 39205.
CS78-581	7/10/78	John B. Clark, P.O. Box 1084, Jackson, Miss. 39205.
CS78-582	7/10/78	Frank C. Horton, P.O. Box 1084, Jackson, Miss. 39205.
CS78-583	7/10/78	Thomas A. Bell, P.O. Box 1084, Jackson, Miss. 39205.
CS78-584	7/10/78	Curtis E. Coker, P.O. Box 1084, Jackson, Miss. 39205.
CS78-585	7/10/78	William G. New Associates, Inc., 5295 Galaxie Dr., Suite B, Jackson, Miss. 39206.
CS78-586	7/10/78	William G. New, 5295 Galaxie Dr., Suite B, Jackson, Miss. 39206.
CS78-587	7/10/78	Bruce T. Massey, Route 4, 505 Daniel Lane, Jackson, Miss. 39208.
CS78-588	7/10/78	Robert J. Shannon, Jr., Route 1, New Albany, Miss. 38652.
CS78-589	7/10/78	United Drilling Co. of Tyler, 1528-A N. NW. Loop 323, Tyler, Tex. 75704.
CS78-590	7/10/78	Mid-Mississippi Oil Corp., 220 North Timber St., Brandon, Miss. 39042.
CS78-591	7/10/78	Henry E. Ford, P.O. Box 70, Drew, Miss. 38737.
CS78-592	7/10/78	Robert D. Allen, 917 Audubon Point Dr., Brandon, Miss. 39042.
CS78-593	7/10/78	Ron C. Smith, 1300 Capital Towers, Jackson, Miss. 39201.
CS78-594	7/10/78	Richard E. Rhoden, M.D., 1052 Riverside Plaza, Jackson, Miss. 39208.
CS78-595	7/10/78	Monroe Allen, P.O. Box 175, Enterprise, Miss. 39330.
CS78-596	7/10/78	R. E. Williams, Suite 102, 3100 Walnut Grove Rd., Memphis, Tenn. 38111.
CS78-597	7/10/78	C. O. Wilcher, Hiway 488, Madden, Miss. 39109.
CS78-598	7/13/78	Western Wells Co., Box 561, Oklahoma City, Okla. 73101.
CS78-599	7/13/78	Pride Exploration, Inc., 1110 Beck Bldg., Shreveport, La. 71101.
CS78-600	7/13/78	CPC Exploration, Inc., Bank and Trust Tower No. 278, Suite 1905, Corpus Christi, Tex. 78477.
CS78-601	7/13/78	International Petro Associates, High Ridge Park, Stamford, Conn. 06905.
CS78-602	7/13/78	Amcan Oil Producers, High Ridge Park, Stamford, Conn. 06905.
CS78-603	7/10/78	Minuteman Drilling Fund, Ltd., 43 Woodmere Rd., North Brunswick, N.J. 08902.
CS78-604	7/17/78	Venture Exploration Joint Venture, 907 Philtower Bldg., Tulas, Okla. 74103.
CS78-605	7/17/78	Joseph K. Mahony, 406 Armstrong Bldg., El Dorado, Ark. 71730.
CS78-606	7/17/78	Tepco Engineering, Inc., P.O. Box 6, Alice, Tex. 78332.
CS78-607	7/17/78	SA-GU Corp., P.O. Drawer 2507, Corpus Christi, Tex. 78403.
CS78-608	7/17/78	Moore McCormack Oil & Gas Corp., 6400 North Central Expressway, Dallas, Tex. 75206.
CS78-609	7/20/78	Larry W. Curtis, 1121 Fidelity Plaza, Oklahoma City, Okla. 73102.
CS78-610	7/20/78	Ike Lovelady, Inc., P.O. Drawer 2666, Midland, Tex. 79702.
CS78-611	7/21/78	Jimmie T. Cooper, P.O. Box 55, Monument, N. Nex. 88265.
CS78-612	7/21/78	Indian Royalty Co., 4616 Greenville Ave., Dallas, Tex. 75206.
CS78-613	7/21/78	J. Marshall Nye, 1140 Northwest 63d, Suite 424, Oklahoma City, Okla. 73116.
CS78-614	7/21/78	Natural Gas Producers, Inc., 7364 South Darlington, Tulsa, Okla. 74136.
CS78-615	7/24/78	Holland Junction Exploration Co., Inc., Suite 1200, Citizens Bank Center, 100 North Central Expressway, Richardson, Tex. 75080.
CS78-616	7/24/78	Mole Operating Co., Inc., 1200 Citizens Bank Center, P.O. Box 1179, Richardson, Tex. 75080.
CS78-617	7/24/78	LGS Exploration, Inc., 530 Oil and Gas Bldg., New Orleans, La. 70112.
CS78-618	7/24/78	Louisiana General Services, Inc., 1233 Westbank Expressway, Harvey, La. 70058.
CS78-619	7/24/78	McGoldrick Oil Co., et al., 610 Beck Bld., Shreveport, La. 71101.
CS78-620	7/24/78	Gay A. Roane, P.O. Box 640, Duncan, Okla. 73533.
CS78-621	7/24/78	Phillips Production Co., 1500 Oliver Bldg., Pittsburgh, Pa. 15222.
CS78-622	7/24/78	Assets Administration & Management Inc., High Ridge Park, Stamford, Conn. 06905.
CS78-623	7/24/78	P & O Oil Corp., 1717 St. James Pl., Suite 602, Houston, Tex. 77056.
CS78-624	7/20/78	Petroleum Brokers, Inc., Suite 209, 1615 California St., Denver, Colo. 80202.
CS78-625	7/25/78	Concord Oil & Gas Corp., P.O. Box 829, Marietta, Ohio 45750.
CS78-626	7/25/78	Mohawk Oil Corporation—Project 3, P.O. Box 371, Lowell, Ohio 45744.
CS78-627	7/25/78	J & D Associates, P.O. Box 3052, Grand Junction, Colo. 81501.
CS78-628	7/25/78	P & O Oil Corp., 1717 St. James Pl., Suite 602, Houston, Tex. 77056.
CS78-629	7/28/78	Sunrise Exploration, 1200 Liberty Tower, Oklahoma City, Okla. 73102.
CS78-630	7/28/78	Perrin Oil Co., P.O. Box 17161, Wichita, Kans. 67217.
CS78-631	7/28/78	M. E. Norman, 58 Wansley Rd., Laurel, Miss. 39440.

Docket No.	Date filed	Applicant
CS78-632.....	7/28/78	Denmark Resources Inc., P.O. Box 517, Bismarck, N. Dak. 58501.
CS78-633.....	7/28/78	West Plains Royalty Co., Inc., P.O. Box 32483, Oklahoma City, Okla. 73132.
CS78-634.....	7/31/78	Oxy Petroleum, Inc. and the Permian Corp., 5000 Stockdale Highway, Bakersfield, Calif. 93309.
CS78-635.....	7/31/78	1977 Galbraith I Ltd., partnership, P.O. Box 1186, Maitland, Fla. 32751.
CS78-636.....	7/31/78	Public Service Co. of Oklahoma, P.O. Box 3008, Tulsa, Okla. 74101.
CS78-637.....	8/1/78	Barth Energy Corp., P.O. Box 45568, Houston, Tex. 77045.
CS78-638.....	8/1/78	Bonnie E. Hibbert, 700 4th Financial Center, Wichita, Kans. 67202.
CS78-639.....	8/1/78	James P. Madison, P.O. Box 510, Bastrop, La. 71220.
CS78-640.....	8/1/78	Sea Sand Oil Co., 917 Baker Bldg., Fort Worth, Tex. 76102.
CS78-641.....	8/1/78	Canadian American Resources Fund, Inc., 1976-1 partnership, 2500 Fort Worth National Bank Bldg., Fort Worth, Tex. 76102.
CS78-642.....	8/2/78	Canadian American Resources Fund, Inc., 1975-2 partnership, 2500 Fort Worth National Bank Bldg., Fort Worth, Tex. 76102.
CS78-643.....	8/3/78	Texas Energy Exploration, Inc., P.O. Drawer 1867, Austin, Tex. 78767.
CS78-644.....	8/3/78	Thomas Edward Moore, 1312 Midland Savings Bldg., Midland, Tex.
CS78-645.....	8/2/78	Howard E. Berry, P.O. Box 9998, North Station, Jackson, Miss. 39206.
CS78-646.....	8/4/78	Jeems. Bayou Production Corp., P.O. Box 639, Oil City, La. 71061.
CS78-647.....	8/4/78	John J. Coyle, et al., 2200 1st National Bank Bldg., Dallas, Tex. 75202.
CS78-648.....	8/4/78	E. B. Kime, Star Route, Lenapah, Okla. 74042.
CS78-649.....	8/4/78	Lifestyle Energy Corp., Suite 809, 100 North Central Expressway, Richardson, Tex. 75080.
CS78-650.....	8/7/78	Zinke & Philpy, Inc., 211 Chancellor Bldg., Midland, Tex. 79702.
CS78-651.....	8/7/78	Terry Scanlan, 14331 Broadgreen, Houston, Tex. 77079
CS78-652.....	8/7/78	Richard M. Flynn, 2411 Fountainview, Suite 100, Houston, Tex. 77057.
CS78-653.....	8/7/78	Cactus Bayou Production Co., partnership, 2900 Entex Bldg., Houston, Tex. 77002.
CS78-654.....	8/7/78	Alford-Signor Petroleum Corp., by: Mr. Chris Alford, 2203 Timberloch Pl., Suite 132, The Woodlands, Tex. 77380.
CS78-655.....	8/7/78	Charles J. Howard, M.D., 710 FM 1960 West, Houston, Tex. 77090.
CS78-656.....	8/7/78	B. B. Holt, M.D., 2900 Entex Bldg., Houston, Tex. 77002.
CS78-657.....	8/7/78	Texstar Sales, Inc., P.O. Box 38197, Houston, Tex. 77088.
CS78-658.....	8/7/78	Mr. Franklin C. Jones, 5425 Schumacher, Houston, Tex. 77055.
CS78-659.....	8/7/78	Lewis J. Wilson, Jr., M.D., P.A., F.A.C.O.G., 1720 Red Oak Dr., No. 202, Houston, Tex. 77055.
CS78-660.....	8/7/78	William K. MacTavish, D.D.S., 17200 Red Oak Dr., Suite 200, Houston, Tex. 77090.
CS78-661.....	8/7/78	Albert Lawrence Arcus, 15603 Valley Bend, Houston, Tex. 77009.
CS78-662.....	8/7/78	Dr. Floyd Hardimon, 1440 North Loop, Houston, Tex. 77009.
CS78-663.....	8/7/78	Edward Roberson, M.D., 710 FM 1960 West, Suite J, Houston, Tex. 77090.
CS78-664.....	8/7/78	Richard L. Mattews, D.D.S., 17200 Red Oak Dr., Suite 200, Houston, Tex. 77090.
CS78-665.....	8/7/78	Billy L. Johnson, P.O. Box 90216, Houston, Tex. 77090.
CS78-666.....	8/10/78	Kissinger 1977 Drilling Fund, Ltd., P.O. Box 22004, Denver, Colo. 80222.
CS78-667.....	8/7/78	H. M. Rovenger, 1322 Mercantile Bank Bldg., Dallas, Tex. 75201.
CS78-668.....	8/7/78	Universal Energy Fund, No. 6 Chestnut Court, Park Forest, Ill. 60466.
CS78-669.....	8/7/78	N. P. Energy Corp., a Texas corporation, 1399 South 7th East, Salt Lake City, Utah 84105.
CS78-670.....	8/9/78	Leland C. & Barbara E. Staab, d.b.a. Leba Oil Co., P.O. Box 267, Kimball, Nebr. 69145.
CS78-671.....	8/11/78	Tani Farms, 9744 Wilshire Blvd, PH, Beverly Hills, Calif. 90212.
CS78-672.....	8/11/78	Paul J. Ross, P.O. Box 178, Shreveport, La. 71161.
CS71-964.....	6/28/78	The estate of Alvin C. Hope, Bexar County National Bank, independent executor of the estate, Alvin C. Hope, Jr., Cousuelo Hope Woodward, and Louise B. Hope,[1] P.O. Box 300, San Antonio, Tex. 78291.

[1] Being noticed to reflect the substitution of the estate of Alvin C. Hope for the name of Alvin C. Hope due to his death and including Mr. Hope's two children and spouse who inherited under his Will properties falling into the small producer category.

[FR Doc. 78-23724 Filed 8-24-78; 8:45 am]

[3128-01]

Office of the Secretary

NUCLEAR WASTE MANAGEMENT

Meetings

AGENCY: Department of Energy.

ACTION: Notice of meetings on nuclear waste management.

SUMMARY: The Department of Energy will hold two small group meetings of Federal officials and selected State and local officials on August 30, 1978, in Washington, D.C., in response to the President's order to develop recommendations on management of nuclear wastes. These meetings are a continuation of the public participation process announced by the Department of Energy in 43 FR 30612 issued July 17, 1978. Discussions will focus on draft IRG working group reports concerning alternative technical strategies and Federal/State/local involvement.

FOR FURTHER INFORMATION CONTACT:

Tom Dennis, Office of Intergovernmental Affairs, Department of Energy, 1000 Independence Avenue NW., Washington, D.C. 20585, 202-252-6335.

SUPPLEMENTARY INFORMATION: The President has directed a comprehensive review of nuclear waste management and, on March 15th, he announced the formation of an Interagency Review Group (IRG) on Nuclear Waste Management. Using this governmentwide approach, the President is determined to resolve the issues related to nuclear waste management, and to do so with public involvement.

The principal objective of the IRG is to prepare a report for the President, setting forth recommendations for an overall decisionmaking and implementation process to deal with the Nation's nuclear wastes in a comprehensive manner.

The IRG will address the disposal of the four major types of nuclear wastes: Spent fuel, high level and transuranic wastes; low level wastes; uranium mill tailings; and decontamination and decommissioning wastes.

The IRG will be developing the following items for each major type of waste: A statement of Federal goals to be achieved in waste management; and a workplan describing how the Government will proceed in achieving the desired goals.

Each workplan will provide for:

A general strategic planning basis or rationale to be followed.

An overall schedule, including milestones for implementation of the workplan, which would include agency roles and assignments for rendering technical, regulatory, and program-

matic decisions, EIS schedules, legislative initiatives, criteria and regulations.

Identification of areas of uncertainty, their significance and the urgency of their resolution.

Research and development (R&D) needs, priorities and responsibilities necessary to resolve those uncertainties.

Identification of remaining decisions which, if not made, could constrain the effective resolution of those areas of uncertainty.

Establishment or clarification of compatible agency jurisdiction, regulation and enforcement authority.

Recommendations on near- and long-term agency resource requirements.

As part of the procedures of the IRG, six working groups have been established:

1. Alternative technology strategies.
2. Federal involvement (licensing/standards/criteria).
3. Defense waste (special issues).
4. Spent fuel storage/charges.
5. Transportation issues.
6. International issues.

On July 17, 1978, the Department of Energy issued a notice of public participation on nuclear waste management (43 FR 30612) announcing a series of meetings and discussions designed to insure public participation in the IRG process.

The purpose of this notice is to announce two additional small group meetings of Federal officials and selected State and local officials, being held as a continuation of the public participation process on nuclear waste management. These meetings are designed to provide opportunity for additional State and local input to the IRG on draft IRG working group reports concerning alternative technical strategies and Federal/State/local involvement, and are open to the public. The meeting dates, times and places are as follows:

Date: August 30, 1978.
Time: 9:00 am to 12 noon.
Location: Department of Energy, Room 8222C, 20 Massachusetts Avenue NW., Washington, D.C.
Date: August 30, 1978.
Time: 1 to 4 p.m.
Location: Department of Energy, Room 8222C, 20 Massachusetts Avenue NW., Washington, D.C.

An appropriate official will be designated to preside at the meetings. These will not be judicial or evidentiary-type hearings. Any person attending the meeting who wishes to make a statement or ask a question at the meeting may indicate his interest in doing so, in writing, to the presiding officer. The presiding officer will permit comments/questions from the audience as time limitations permit. Any person who wishes to submit written statements may do so. Written statements should be submitted to Tom Dennis, Office of Intergovernmental Affairs, Room 6A041, Department of Energy, 1000 Independence Avenue NW., Washington, D.C. 20585. Any further procedural rules needed for the proper conduct of the meetings will be announced by the presiding officer.

Transcripts of the meetings will be made and the entire record of the meetings, including the transcript, will be retained by DOE and made available for inspection at the Freedom of Information Office, Room 3116, Federal Building, 12th and Pennsylvania Avenue NW., Washington, D.C. between the hours of 8 a.m. and 4:30 p.m., Monday through Friday. Any person may purchase a copy of the transcript from the reporter.

Issued in Washington, D.C., on August 22, 1978.

WILLIAM S. HEFFELFINGER
Director of Administration.

[FR Doc. 78-23956 Filed 8-24-78; 8:45 am]

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 953-4]

ARIZONA SDWA PRIMARY ENFORCEMENT

Region IX; Approval of State Application for Arizona Drinking Water Primary Enforcement Responsibility

This public notice is issued pursuant to section 1413 of the Safe Drinking Water Act, Pub. L. 93-523, December 16, 1974, and § 142.10 of the National Interim Primary Drinking Water Regulations, published in the FEDERAL REGISTER on January 20, 1976.

An application has been received from the Deputy Director, Arizona Department of Health Services, dated June 15, 1978, requesting that the Arizona Department of Health Services be granted primary enforcement responsibility for the public water systems in the State of Arizona, in accordance with the provisions of the Safe Drinking Water Act.

I have determined that the Arizona Department of Health Services has met all conditions of the Safe Drinking Water Act and regulations promulgated pursuant to the Safe Drinking Water Act for the assumption of primary enforcement responsibility for public water systems in the State of Arizona. Specifically the State of Arizona:

(1) Has adopted drinking water regulations which are no less stringent than the National Interim Primary Drinking Water Regulations;

(2) Has adopted and will implement adequate procedures for the enforcement of such State regulations, including adequate monitoring, sanitary surveys, inspections, plan review, inventory of water systems, and adequate certified laboratory availability;

(3) Will keep such records and make such reports as required;

(4) If it permits variances or exemptions from the requirements of its regulations, will issue such variances and exemptions in accordance with the provisions of the National Interim Drinking Water Regulations; and

(5) Has adopted and can implement an adequate plan for the provision of safe drinking water under emergency conditions.

All documents relating to this determination are available for public inspection between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, at the following offices:

Bureau of Water Quality Control, Arizona Department of Health Services, 1740 West Adams Street, Phoeniz, Ariz. 85007.
Regional Administrator, Environmental Protection Agency, Region IX, 215 Fremont Street, San Francisco, Calif. 94105.

All interested parties are invited to submit written comments on this determination and may request a public hearing by writing to the above San Francisco address. Written comments and/or requests for a public hearing must be submitted on or before September 25, 1978. A request for a public hearing shall include the following information:

(1) The name, address, and telephone number of the individual, organization, or other entity requesting a hearing.

(2) A brief statement of the requesting person's interest in the Regional Administrator's determination and a summary of the information that the requesting person intends to submit at such hearing.

(3) The signature of the individual making the request; or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

Frivolous or insubstantial requests for a public hearing may be denied by the Regional Administrator. However, if a substantial request for a public hearing is made within thirty (30) days (September 25, 1978) after this notice, a public hearing will be held. The Regional Administrator will give further notice in the FEDERAL REGISTER and in a newspaper or newspapers of general circulation in the State of Arizona of any hearing to be held pursuant to a request submitted by an interested person, or on his own motion. Notice of the hearing shall be given not less than fifteen (15) days prior to the time scheduled for the hearing. In

addition to publication as described above, notice will be sent to the person requesting a hearing and to the State. Notice of the hearing will include a statement of the purpose of the hearing, information regarding the time and location for the hearing, and the address and telephone number of an office at which interested persons may obtain further information concerning the hearing.

After receiving the record of the hearing, the Regional Administrator will issue an order affirming or rescinding his determination. If the determination is affirmed, it shall become effective as of the date of the order.

If no timely and appropriate request for a hearing is received and the Regional Administrator does not elect to hold a hearing on his own motion, this determination shall become effective thirty (30) days after issuance of this initial decision.

Please bring this notice to the attention of any person known to you to have an interest in this determination.

Dated: August 17, 1978.

SHIELA M. PRINDIVILLE,
Acting Regional Administrator, Region IX, Environmental Protection Agency.

[FR Doc. 78-23850 Filed 8-24-78; 8:45 am]

[1505-01]

RECEIPT OF APPLICATION FOR PESTICIDE REGISTRATION

Date To Be Considered in Support of Applications

Correction

In FR Doc. 78-16318 appearing at page 25470 in the issue for Tuesday, June 13, 1978, under "APPLICATION RECEIVED—33000/547", in the first entry, "EPA Reg. No. 10120-18", make the following corrections:

(1) In the fifth line, "0.05%" should be corrected to read "0.10%".

(2) In the sixth line, "57.99%" should be corrected to read "57.00%".

(3) In the seventh line, "0.10%" should be corrected to read "0.05%".

[6560-01]

[OPP-180172A; FRL 954-5]

ALABAMA, ARKANSAS, FLORIDA, GEORGIA, LOUISIANA, NORTH CAROLINA, SOUTH CAROLINA, AND TEXAS

Applications To Use Ferriamicide To Control the Imported Fire Ant

On December 28, 1977 (42 FR 64734), the Environmental Protection Agency (EPA) published a notice of receipt of an application from the Mississippi Authority for Imported Fire Ant Control for a specific exemption to use Ferriamicide, a new formulation of Mirex, to control Imported Fire Ants. At that time, a 25-day period which invited comments from the public was announced. It was also stated that EPA anticipated that eight additional States were likely to apply for similar specific exemption requests for the use of Ferriamicide.

The purpose of this notice is to announce that EPA has now received applications from the States of Alabama, Arkansas, Florida, Georgia, Louisiana, North Carolina, South Carolina, and Texas. The proposed acreage and the amount of Ferriamicide bait requested from each of these States are as follows:

1. Alabama proposes to use 50,000 pounds until June 30, 1979;
2. Arkansas proposes to use 20,000 pounds in 10 counties along the Arkansas-Louisiana border from July 11, 1978, to June 30, 1979;
3. Florida proposes to use approximately 100,000 pounds during the period of July 1 through November 15, 1978, and 100,000 pounds between March 15 through June 30, 1979;
4. Georgia proposes to use 3,000,000 pounds on 3,000,000 acres until June 30, 1979;
5. Louisiana proposes to use 300,000 pounds in all 64 parishes (counties) from July 1, 1978, through June 30, 1979;
6. North Carolina proposes to use 8,000 pounds from July 1, 1978, through June 30, 1979. The acreage was not specified, but the Applicant stated that the Red Imported Fire Ant currently infests over 900,000 acres in 14 counties;
7. South Carolina proposes to use 60,000 pounds on 10,000,000 acres in 31 counties in the eastern half of the State through June 30, 1979; and
8. Texas proposes to use 3,500,000 pounds on over 42,000,000 acres in 93 counties from July 1, 1978, through June 30, 1979.

EPA has given tentative approval to Mississippi for the use of Ferriamicide to be applied to individual fire ant mounds and for limited ground broadcast to agricultural areas, parks and cemeteries. EPA will continue to accept any additional comments of a scientific nature *only* relating to the proposed use of Ferriamicide in States infested with Imported Fire Ants.

Persons interested in submitting scientific comments should send them to James Touhey, Chief, Emergency Response Section, Process Coordination Branch, Registration Division (TS-767), Office of Pesticide Programs, EPA, Room 315, East Tower, 401 M Street SW., Washington, D.C. 20460. All comments should bear the identifying notation "OPP-180172A." Comments received on or before September 18, 1978, shall be considered before it is determined whether a specific exemption will be granted. Comments received after this date will be considered only to the extent feasible consistent with the time limits imposed. All applications for specific exemptions, as well as all written comments filed according to this notice will be available for public inspection in the Emergency Response Section office at the above address from 8:30 a.m. to 4 p.m. on normal business days. It is suggested that persons interested in reviewing the comments call 202-755-4851 before visiting the EPA headquarters office, so that the comments may be made conveniently available for review purposes.

Statutory authority: Sec. 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 89 Stat. 751; U.S.C. 136(a) et seq.).

Dated: August 21, 1978.

DOUGLAS D. CAMPT,
Acting Deputy Assistant Administrator for Pesticide Programs.

[FR Doc. 78-24022 Filed 8-24-78; 8:45 am]

[6560-01]

[OPP—31019; FRL 954-7]

PESTICIDE PROGRAMS

Receipt of Application to Register a Pesticide Product Entailing a Changed Use Pattern

Montedison U.S.A., Inc., 1114 Avenue of the Americas, New York, N.Y. 10036, has submited to the Environmental Protection Agency (EPA) an application to register the pesticide product CIDIAL E-4 (EPA file symbol 39541-RN), which contains 46.5 percent of the active ingredient ethyl alpha [(dimethoxyphosphinothioyl) thio] benzeneacetate. The application received from Montedison U.S.A., Inc., proposes that the use pattern of this product be changed from technical chemical for reformulating into insecticide to an active ingredient in an insecticide formulation. The applicant also proposes that the product be classified for general use in citrus fruits.

Notice of receipt of this application does not indicate a decision by this Agency on the application. Interested persons are invited to submit written comments on this application to the Federal Register Section, Program Support Division (TS-757), Office of Pesticide Programs, Room 401, East Tower, 401 N Street SW, Washington, D.C. 20460. The comments must be received on or before September 25, 1978, and should bear a notation incidating the EPA file symbol 39541-RN. Comments received within the specified time period will be considered before a final decision is made; comments received after the specified time period will be considered only to the extent possible without delaying processing of the application. Specific questions concerning this application should be directed to Product Man-

ager (PM) 16, Registration Division (TS-767), Office of Pesticide Programs, at the above address or by telephone at 202-755-9315. The label furnished by Montedison U.S.C. Inc., as well as all written comments filed pursuant to this notice, will be available for public inspection in the Office of the Federal Register Section from 8:30 a.m. to 4:00 p.m. Monday through Friday.

Notice of approval or denial of this application to register CIDIAL E-4 will be announced in the FEDERAL REGISTER. Except for such material protection by section 10 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the test data and other information submitted in support of registration as well as other scientific information deemed relevant to the registration decision may be made available after approval under the provisions of the Freedom of Information Act. The procedures for requesting such data will be given in the FEDERAL REGISTER if an application is approved.

Dated: August 18, 1978.

HERBERT S. HARRISON,
Acting Director,
Registration Division.

[FR Doc. 78-24020 Filed 8-24-78; 8:45 am]

[6560-01]

[OPP—30152; FRL 954-8]

PESTICIDE PROGRAMS

Receipt of Application To Register a Pesticide Product Containing a New Active Ingredient

Monsanto Co., 800 North Lindbergh Boulevard, St. Louis, Mo. 63166, has submitted to the environmental Protection Agency (EPA) an application to register the pesticide product "machete herbicide" (EPA File Symbol 524-GET), containing 60 percent of the active ingredient butachlor [*N*-(butoxymethyl)-2-chloro-2',6'-diethylaceta- nilide] which has not been included in any previously registered pesticide products. The application proposes that the product be classified for general use for postemergent weed control in rice.

Notice of receipt of this application does not indicate a decision by the Agency on the application. Interested persons are invited to submit written comments on this application to the Federal Register Section, Program Support Division (TS-757), Office of Pesticide Programs, EPA, Room 401, East Tower, 401 M Street SW., Washington, D.C. 20460. The comments must be received on or before September 25, 1978, and should bear a notation indicating the EPA File Symbol "524-GET." Comments received within the specified time period will be considered before a final decision is made: comments received after the specified time period will be considered only to the extent possible without delaying processing of the application. Specific questions concerning this application should be directed to Product Manager (PM) 25, Registration Division (TS-767), Office of Pesticide Programs, at the above address or by telephone at 202-426-2632. The label furnished by Monsanto Co., as well as all written comments filed pursuant to this notice, will be available for public inspection in the office of the Federal Register Section from 8:30 a.m. to 4 p.m. Monday through Friday.

Notice of approval or denial of this application to register "machete herbicide" will be announced in the FEDERAL REGISTER. Except for such material protected by section 10 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the test data and other information submitted in support of registration as well as other scientific information deemed relevant to the registration decision may be made available after approval under the provisions of the Freedom of Information Act. The procedures for requesting such data will be given in the FEDERAL REGISTER if an application is approved.

Dated: August 18, 1978.

HERBERT S. HARRISON,
Acting Director,
Registration Division.

[FR Doc. 78-24019 Filed 8-24-78; 8:45 am]

[6560-01]

[OPP-50378; FRL 954]

PESTICIDE PROGRAMS

Experimental Use Permits

The Environmental Protection Agency (EPA) has issued experimental use permits to the following applicants. Such permits are in accordance with, and subject to, the provisions of 40 CFR Part 172, which defines EPA procedures with respect to the use of pesticides for experimental purposes.

No. 201-EUP-61. Shell Chemical Co., Washington, D.C. 20036. This experimental use permit allows the use of 3,024 pounds of the herbicide mixture 2-[[4-chloro-6-(ethylamino)-s-triazin-2-yl] amino]-2-methyl-propionitrile and 2-chloro-4(ethylamino)-6-(isopropylamino)-s-triazine on corn to evaluate control of various grasses and broadleaf weeds. A total of 10,500 acres is involved; the program is authorized only in the States of Alaska, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Montana, Nebraska, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, and Wisconsin. The experimental use permit is effective from May 17, 1978 to May 17, 1979. Permanent tolerances for residues of the active ingredients in or on corn have been established (40 CFR 180.307 and 180.220).

No. 1471-EUP-60. Elanco Products Co., Indianapolis, Ind. 46206. This experimental use permit allows the use of 210 pounds of the fungicide tricyclazole on rice to evaluate control of rice blast disease. A total of 200 acres is involved; the program is authorized only in the States of Arkansas, Louisiana, Mississippi, and Texas. The experimental use permit is effective from May 26, 1978 to May 26, 1979. This permit is being issued with the limitation that all treated crops are destroyed or used for research purposes only.

No. 707-EUP-92. Rohm & Haas Co., Philadelphia, Pa. 19105. This experimental use permit allows the use of 524 pounds of the fungicide d-butyl-d-phenyl-1*H*-imidazole-1-propanenitrile to evaluate control of the major diseases of roses. A total of 12.80 acres is involved; the program is authorized only in the States of Arkansas, California, Florida, Georgia, Illinois, Indiana, Louisiana, Michigan, Minnesota, Missouri, New Jersey, New York, Oregon, Pennsylvania, Tennessee, Texas, and Washington. The experimental use permit is effective from May 26, 1978 to May 26, 1979.

Interested parties wishing to review the experimental use permits are referred to Room E-315, Registration Division (TS-767), Office of Pesticide Programs, EPA, 401 M Street SW., Washington, D.C. 20460. It is suggested that such interested persons call 202-755-4851 before visiting the EPA Headquarters Office so that the appropriate permits may be made conveniently available for review purposes. These files will be made available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday.

STATUTORY AUTHORITY: Sec. 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136(a) *et seq.*).

Dated: August 18, 1978.

HERBERT S. HARRISON,
Acting Director,
Registration Division.

[FR Doc. 78-24021 Filed 8-24-78; 8:45 am]

[6560-01]

[OPP-33000/550; FRL 954-4]

PESTICIDE PROGRAMS

Receipt of Application for Pesticide Registration Data to be Considered in Support of Applications

On November 19, 1973, the Environmental Protection Agency (EPA) published in the FEDERAL REGISTER (39 FR 31862) its interim policy with respect to the administration of section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended ("Interim Policy Statement"). On January 22, 1976, EPA published in the FEDERAL REGISTER a document entitled "Registration of a Pesticide Product—Consideration of Data by the Administrator in Support of an Application" (41 FR 3339).

This document described the changes in the Agency's procedures for implementing section 3(c)(1)(D) of FIFRA, as set out in the Interim Policy Statement which were effected by the enactment of the amendments to FIFRA on November 28, 1975 (Pub. L. 94-140), and the regulations governing the registration and re-registration of pesticides which became effective on August 4, 1975 (40 CFR Part 162).

Pursuant to the procedures set forth in these FEDERAL REGISTER documents, EPA hereby gives notice of the applications for pesticide registration listed below. In some cases these applications have recently been received; in other cases, applications have been amended by the submission of additional supporting data, the election of a new method of support, or the submission of new "offer to pay" statements.

In the case of all applications, the labeling furnished by the applicant for the product will be available for inspection at the Environmental Protection Agency, Room 209, East Tower, 401 M Street SW., Washington, D.C. 20460. In the case of applications subject to the seciton 3 regulations which utilize either the 2(a) or 2(b) method of support specified in the Interim Policy Statement, all data citations submitted or referenced by the applicant in support of the application will be made available for inspection at the above address. This information (proposed labeling and, where applicable, data citations) will also be supplied by mail, upon request. However, such a request should be made only when circumstances make it inconvenient for the inspection to be made at the Agency offices.

Any person who (a) is or has been an applicant, (b) believes that data he developed and submitted to EPA on or after January 1, 1970, are being used to support an application described in this notice, (c) desires to assert a claim under section 3(c)(1)(D) for such use of his data and wishes to preserve his right to have the Administrator determine the amount of reasonable compensation to which he is entitled for such use of the data, or (d) wishes to assert confidential status under section 10 for his data, must notify the Administrator and the applicant named in the notice in the FEDERAL REGISTER of his claim by certified mail. Notification to the Administrator should be addressed to the Process Coordination Branch, Registration Division (TS-767), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460. Every such claimant must include, at a minimum, the information listed in the Interim Policy Statement of November 19, 1973.

Specific questions concerning applications made to the Agency should be addressed to the designated Product Manager (PM), Registration Division (TS-767), Office of Pesticide Programs, at the above address, or by telephone as follows:

PM 12 and 16—202/755-9315.
PM 21 and 22—202/426-2454.
PM 24—202/755-2196.
PM 31 and 32—202/426-2635.
PM 15 and 17—202/426-9427.
PM 23—202/755-1397.
PM 25—202/426-2632.

The Interim Policy Statement requires that claims for compensation be filed on or before October 24, 1978. EPA will not delay any registration pending the assertion of claims for compensation or the determination of reasonable compensation. Inquiries and assertions that data relied upon are subject to protection under section 10 of FIFRA, as amended, should be made within 30 days subsequent to publication of this notice. Registration will be delayed pending resolution of section 10 claims.

Dated: August 18, 1978.

HERBERT S. HARRISON,
Acting Director,
Registration Division.

APPLICATION RECEIVED 33000/550

EPA File Symbol 52-ELN. West Chemical Products, Inc., 42-16 West Street, Long Island City, NY 11101. TOTACIDE-28. Active Ingredients: Glutaraldehyde 2.0%. Method of Support: Application proceeds under 2(a) of interim policy. PM31

EPA Reg. No. 100-583. CIBA-GEIGY, Agricultural Division, P.O. Box 11422, Greensboro, N.C. 27409. DUAL 6E. Active Ingredients: Metolachlor: 2-chloro-*N*-(2-ethyl-6-methyl-phenyl)-*N*-(2-methoxy-1-methylethyl)acetamide 68.5%. Method of Support: Application proceeds under 2(b) of interim policy. Republished: Added use. PM24

EPA Reg. No. 100-590. CIBA-GEIGY, Agricultural Division. BICEP 4.5L. Active Ingredients: Atrazine: 2-chloro-4-ethylamino-6-isopropylamino-s-triazine 20.8%; Atrazine related compounds 1.1%; Metolachlor: 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy - 1 - methylethyl) acetamide 27.5%. Method of Support: Application proceeds under 2(b) of interim policy. Republished: Added use. PM25

EPA File Symbol 148-REAA. Thompson-Hayward Chemical Co., 5200 Speaker Road, Kansas City, Kans. 66106. DURSBAN ½% GRANULAR. Active Ingredients: Chlorpyrifos (0,0-diethyl 0-(3,5,6-trichloro-2-pyridyl) phosphorothioate) 0.5%. Method of Support: Application proceeds under 2(b) of interim policy. PM12

EPA File Symbol 148-REAT. Thompson-Hayward Chemical Co. DURSBAN 1% GRANULAR. Active Ingredients: Chlorpyrifos (0,0-diethyl 0-(3,5,6,-trichloro-2-pyridyl)phosphorothioate) 1%. Method of Support: Application proceeds under 2(b) of interim policy. PM12

EPA Reg. No. 239-2032. Chevron Chemical Co., Ortho Division, San Francisco, Calif. 94119. CHINCH BUG AND SOD WEBWORM CONTROL. Active Ingredients: 0,0,0,0-Tetrapropyl dithiopyrophosphate 3.2%. Method of Support: Application proceeds under 2(b) of interim policy. PM16

EPA Reg. No. 239-2186. Chevron Chemical Company. ORTHO PARAQUAT CL. Active Ingredients: Paraquat dichloride (1,1'-dimethyl-4-4'-bipyridinium dichloride) 29.1%. Method of Support: Application proceeds under 2(b) of interim policy. Republished: Amendment. PM25

EPA Reg. No. 352-354. E. I. Du Pont De Nemours & Co., Inc., Biochemicals Department, Wilmington, Del. 19898. BENLATE FUNGICIDE WETTABLE POWDER. Active Ingredients: Benomyl [methyl 1-(butylcarbamoyl) - 2 - benzimidazole- carbamate] 50%. Method of Support: Application proceeds under 2(b) of interim policy. Republished: Added use. PM22

EPA Reg. No. 359-659. Rhodia Inc., Agricultural Division, P.O. Box 125, Monmouth Junction, N.J. 08582. CHIPCO RONSTAR G. Active Ingredients: Oxadiazon [2-*tert*-butyl-4-(2,4-dichloro-5-isopropoxyphenyl)-delta 2-1,3,4-oxadiazolin-5-one] 2.0%. Method of Support: Application proceeds under 2(b) of interim policy. Republished: Added use PM24

EPA File Symbol 485-UI. Industrial Fumigant Co., 601 East 159th Street, Olathe, Kans. 66061. METHYL FUME. Active Ingredients: Methyl Bromide 100%. Method of Support: Application proceeds under 2(b) of interim policy. PM16

EPA Reg. No. 524-314. Monsanto Co., 800 North Lindbergh Boulevard, St. Louis, Mo. 63166. LASSO. Active Ingredients: Alachlor 45.1%. Method of Support: Application proceeds under 2(b) of interim policy. Republished: Amendment. PM25

EPA File Symbol 557-ROEL. Swift Agricultural Chemical Corp., 111 W. Jackson Boulevard, Chicago, Ill. 60604. GOLDEN VIGORO INSECT CONTROL PLUS LAWN FERTILIZER. Active Ingredients: Chloropyrifos (0,0-diethyl 0-(3,5,6-trichloro-2-pyridyl) phosphorothioate) 0.46%. Method of Support: Application proceeds under 2(b) of interim policy. PM12

EPA File Symbol 675-15-ZA. Lehn and Fink Industrial Products Division, National Laboratories, Sterling Drug Inc., Montvale, N.J. 07645. LEHN AND FINK INSTRUMENT GERMICIDE. Active Ingredients: Ethyl alcohol 4.640%; Soap 1.130%; 0-Phenylphenol 0.518%; 0-Benzyl-p-chlorophenol 0.252%; Isopropyl alcohol 0.083%; Tetrasodium ethylenediamine tetraacetate 0.072%. Method of Support: Application proceeds under 2(b) of interim policy. Republished: Formula change. PM32

EPA File Symbol 707-RUU. Rohm & Haas, Independence Mall West, Philadelphia, Pa. 19105. AMBERGARD XE-342. Active Ingredients: Silver Chloride 0.28%. Method of Support: Application proceeds under 2(a) of interim policy. PM31

EPA File Symbol 1159-ROO. Seacoast Laboratories, Inc., 257 Highway 18, East Brunswick, N.J. 08816. GRANULAR LAWN INSECTICIDE WITH DURSBAN. Active Ingredients: Chlorpyrifos [0,0-diethyl 0-(3,5,6-trichloro-2-pyridyl) phosphorothioate] 1.16%; Aromatic petroleum derivative solvent 0.65%. Method of Support: Application proceeds under 2(b) of interim policy. PM12

EPA File Symbol 1448-AN. Buckman Laboratories, Inc., 1258 North McLean Boulevard, Memphis, Tenn. 38108. BL WSCP-10. Active Ingredients: Poly [oxyethylene

(dimethyliminio) ethylene-(dimethyliminio) ethylene dichloride] 10.0%. Method of Support: Application proceeds under 2(b) of interim policy. PM32

EPA File Symbol 1448-AR. Buckman Laboratories, Inc. BL WSCP-15. Active Ingredients: Poly [oxyethylene (dimethyliminio) ethylene-(dimethyliminio)ethylene dichloride] 15.0 percent. Method of Support: Application proceeds under 2(b) of interim policy. PM32

EPA File Symbol 1448-AE. Buckman Laboratories, Inc. BL WSCP-20. Active Ingredients: Poly [oxyethylene (dimethyliminio) ethylene-(dimethyliminio)ethylene dichloride] 20.0 percent. Method of Support: Application proceeds under 2(b) of interim policy. PM32

EPA File Symbol 1448-AG. Buckman Laboratories, Inc. BL WSCP-30. Active Ingredients: Poly[oxyethylene(dimethyliminio)ethylene-(dimethyliminio)ethylene dichloride] 30.0 percent. Method of Support: Application proceeds under 2(b) of interim policy. PM32

EPA Reg. No. 1471-35. Elanco Products Co., Division of Eli Lilly & Co., P.O. Box 1750, Indianapolis, Ind. 46206. TREFLAN. Active Ingredients: Trifluralin (a,a,a-trifluoro-2,6-dinitro-n,n-dipropyl-p-toluidine) 44.5 percent. Method of Support: Application proceeds under 2(b) of interim policy. PM23

EPA File Symbol 1597-RL. Omaha Compound Co., 21st and Nicholas Streets, Omaha, Nebr. 68102. DEFIANCE ALGAECIDE NF. Active Ingredients: Poly [oxyethylene (dimethyliminio) ethylene-(dimethyliminio)ethylene dichloride] 10.0 percent. Method of Support: Application proceeds under 2(b) of interim policy. PM32

EPA File Symbol 1597—RA. Omaha Compound Co. DEFIANCE COOLING TOWER ALGAECIDE NF. Active Ingredients: Poly [oxyethylene (dimethyliminio) ethylene-(dimethyliminio)ethylene dichloride] 10.0 percent. Method of Support: Application proceeds under 2(b) of interim policy. PM32

EPA File Symbol 1812—EGR. Griffin Corp., Valdosta, Ga. 31601. NU-BAIT NO. 2. Active Ingredients: Methomyl (S-methyl-N-(methylcarbamoyl)oxy) thioacetimidate) 1.25 percent. Method of Support: Application proceeds under 2(b) of interim policy. PM12

EPA File Symbol 2564-L. Arrow Laboratories, P.O. Box 295, Fair Haven Station, New Haven, Conn. 06513. ALGO-1. Active Ingredients: n-Alkyl(60 percent C14, 30 percent C16, 5 percent C12, 5 percent C18)dimethylbenzyl ammonium chlorides 5 percent; n-Alkyl(68 percent C12, 32 percent C14)dimethyl ethylbenzyl ammonium chlorides 5 percent. Method of Support: Application proceeds under 2(b) of interim policy. Republished: Revised offer to pay. PM31

EPA Reg. No. 2596-49. Hartz Mountain Corp., Harrison, N.J. 07029. HARTZ 2 IN 1 COLLAR FOR CATS. Active Ingredients: 2-Chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate 13.7 percent. Method of Support: Application proceeds under 2(a) of interim policy. Republished: Formula change. PM15

EPA Reg. No 2596-50. Hartz Mountain Corp. HARTZ 2 IN 1 COLLAR FOR DOGS. Active Ingredients: 2-Chloro-1-(2,4,5,-trichlorophenyl)vinyl dimethyl phosphate 13.7 percent. Method of Support: Application proceeds under 2(a) of interim policy. Republished: Formula change. PM15.

EPA File Symbol 2935-URR. Wilbur-Ellis Co, P.O. Box 1286, Fresno, Calif. 93715. COPPER SULFATE CRYSTALS. Active Ingredients: ($CuSO_4$ $5H_2O$) 99 percent Min.; (Copper as Metallic, 25.2 percent Min.). Method of Support: Application proceeds under 2(b) of interim policy. PM24

EPA File Symbol 3772-UN. Earl May Seed & Nursery Co, North Elis Street, Shenandoah, Iowa 51601. EARL MAY DURSBAN 1/2G GRANULAR INSECTICIDE. Active Ingredients: Chlorpyrifos [O,O-diethyl O-(3,5,6-trichloro-2-pyridyl)phos- phorothioate] 0.5 percent. Method of Support: Application proceeds under 2(b) of interim policy. PM12

EPA File Symbol 4313-AG. Carroll Co., 2900 West Kingsley Road, Garland, Tex. 75041. CARROLL QUAT 9.0. Active Ingredients: n-Alkyl (60 percent C14, 30 percent C16, 5 percent C12, 5 percent C18)dimethyl benzyl ammonium chlorides 4.50 pecent; n-Alkyl (68 percent C12, 32 percent C14) dimethyl ethylbenzyl ammonium chlorides 4.50 percent; Sodium Carbonate 4.00 percent; Tetrasodium ethylenediamine tetraacetate 1.95 percent. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 4581-GGT. Pennwalt Corp, Decco Division, 900 First Avenue, P.O. Box C, King of Prussia, Pa. 19406 DECCO-BRAND CIPC TECHNICAL. Active Ingredients: Isopropyl-m-chlorocarbanilate (CIPC) 99.00 percent. Method of Support: Application proceeds under 2(b) of interim policy. PM25

EPA File Symbol 4959-EI. West Agro-Chimical, Inc. P.O. Box 1836, Shawnee-Mission, Kans. 66222. PRESERV-IT MILK SAMPLE PRESERVATIVE TABLETS. Active Ingredients: 1-(3-chloroallyl)-3,5,7,-triaza-1-azoniaadamantane chloride 38 percent. Method of Support: Application proceeds under 2(b) of interim policy. PM32

EPA File Symbol 5680-RO. W. G. Snee Co., Inc., 1430 South Peters Street, New Orleans, La. 70130. POWER-GUARD RD-10. Active Ingredients: Alkyl(C14, 50 percent, C12 40 percent, C16 10 percent) 10.00 percent; Ethanol 2.50 percent. Method of Support: Application proceeds under 2(b) of interim policy, Republished: Revised offer to pay. PM31

EPA File Symbol 6176-L. Livingston Industries Inc. 14550 West 99 Street, Lenexa, Kans. 66215. 3-D CONCENTRATED DETERGENT, SANITIZER FUNGICIDE, DISINFECTANT, DEODORIZER. Active Ingredients: n-Alkyl(60 percent C14, 30 percent C16, 5 percent C12, 5 percent C18) dimethyl benzyl ammonium chlorides 4.5 percent; n-Alkyl(68 percent C12, 32 percent C14)dimethyl ethylbenzyl ammonium chlorides 4.5 percent; Tetrasodium ethylenediamine tetraacetate 2.0 percent; Sodium Carbonate 4.0 percent. Method of Support: Application proceeds under 2(b) of interim policy. Republished: Revised offer to pay. PM31

EPA File Symbol 6889-RN. Palmetto Chemical and Supply Co., Inc., P.O. Box 1218, 600 Stitt Street, Monroe, NC. 28110. SPECTRA. Active Ingredients: n-Alkyl(60 percent C14, 30 percent C16, 5 percent C12, 5 percent C18)dimethylbenzyl ammonium chlorides 6.25 percent; n-Alkyl(68 percent C12, 32 percent C14)dimethylethylbenzyl ammonium chlorides 6.25 percent; Tetrasodium ethylenediamine tetraacetate 3.60 percent. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 8047-UE. Polychem, Inc., P.O. Box 10026, New Orleans, La. 70181. POLYCIDE CLQ ALGICIDE. Active Ingredients: Alkyl(C14, 90 percent; C12, 5 percent; C16, 5 percent)dimethyl dichlorobenzyl ammonium chloride 19.23 percent. Method of Support: Application proceeds under 2(b) of interim policy. Republished: Revised offer to pay. PM31

EPA File Symbol 8340-RR. Amercian Hoechst Corp., Agricultural Division, Sommerville, N.J. 08876. HOELON 3EC HERBICIDE. Active Ingredients: Methyl 2-[4-(2,4-dichlorophenoxy)phenoxy] propanoate 35.49 percent. Method of Support: Application proceeds under 2(a) of interim policy. PM23

EPA File Symbol 8340-RE. American Hoechst Corp. HOELON TECHNICAL. Active Ingredients: Methyl 2-[4-(2,4-dichlorophenoxy) phenoxy]propanoate 93 percent. Method of Support: Application proceeds under 2(a) of interim policy. PM23

EPA File Symbol 8901-EN. Kocide Chemical Corp., P.O. Box 45539, Houston, Tex. 77045. KOCIDE 6F. Active Ingredients: Cupric Hydroxide 37.5 percent. Method of Support: Application proceeds under 2(b) of interim policy. Republished: Revised offer to pay. PM22

EPA File Symbol 9091-U. Van Straaten Chemical Co., 630 West Washington Boulevard, Chicago, Ill. 60606. VAN STRAATEN CONDITIONER NO. 10. Active Ingredients: Poly [oxyethylene (dimethyliminio) ethylene (dimethyliminio) ethylene dichloride] 60.0 percent. Method of Support: Application proceeds under 2(b) of interim policy. PM32

[FR Doc. 78-24023 Filed 8-24-78; 8:45 am]

[6560-01]

[FRL 954-1]

POLYCHLORINATED BIPHENYLS

Approved PCB Disposal Facilities

On February 17, 1978, the U.S. Environmental Protection Agency published in the FEDERAL REGISTER the final rule for the "Disposal and Marking of Polychlorinated Biphenyls (PCBs)" (43 FR 7150). (This rule is required by section 6(e)(1) of the Toxic Substances Control Act (Pub. L. 94-469, 15 U.S.C. 2605(e)).)

Under this rule, disposal of many PCBs, as defined in the regulation, is prohibited subsequent to April 18, 1978, except at EPA approved facilities. All facility approvals will be granted in writing by the appropriate Regional Administrator in which the respective facility is located.

To date, the following facilities have been approved by EPA under the authority of §§ 761.40(d) and 761.41(c) of the PCB Disposal and Marking Regulation to dispose of PCBs:

EPA REGION II (26 Federal Plaza, New York, N.Y. 10007)

1. Facility: Newco Chemical Waste Systems, Inc.
Facility Address: 4626 Royal Avenue, Niagara Falls, N.Y. 14303.
Facility Telephone No.: 716-285-6944.
Type of Facility Approved: Chemical waste landfill.
Type of PCB Waste Handled: Capacitors (small and large); Properly drained transformers; Contaminated soil, dirt, rags, and other debris; Dredge spoils; Municipal sludges; Properly drained containers (drums).
Expiration Date of Approval: August 8, 1981.*
EPA Regional Office Contact: Wayne Pierre.
EPA Telephone No.: 212-264-0505.

EPA REGION IV (345 Courtland Street NE., Atlanta, Ga. 30308)

1. Facility: Waste Management of Alabama, Inc.
Facility Address: P.O. Box 1200, Livingston, Ala. 35470.
Facility Telephone No.: 205-652-9529.
Type of Facility Approved: Chemical waste landfill.
Type of PCB Waste Handled: Capacitors (small and large); Properly drained transformers; Contaminated soil, dirt, rags, and other debris; Dredge spoils; Municipal sludges; Properly drained containers (drums).
Expiration Date of Approval: Open-ended.*
EPA Regional Office Contact: Mr. James Scarbrough.
EPA Telephone No.: 404-881-3016.

EPA REGION X (1200 Sixth Avenue, Seattle, Wash. 98101)

1. Facility: Chem-Nuclear Systems, Inc.
Facility Address: P.O. Box 1269, Portland, Oreg. 97205—Main office (site located in Arlington, Oreg.).
Facility Telephone No.: 503-223-1912.
Type of Facility Approved: Chemical waste landfill.
Type of PCB Waste Handled: Capacitors (small and large); Properly drained transformers; Contaminated soil, dirt, rags, asphalt, and other debris; Properly drained containers (drums).
Expiration Date of Approval: January 1, 1980.
EPA Regional Office Contact: Mr. Roger Fuentes.
EPA Telephone No.: 206-442-1260.
2. Facility: Wes-Con, Inc.
Facility Address: P.O. Box 564, Twin Falls, Idaho 83301—Main office (site located in Grand View, Idaho).
Facility Telephone No.: 208-734-7711.
Type of Facility Approved: Disposal in missile silos.
Type of PCB Waste Handled: Capacitors (small and large); Properly drained transformers; Contaminated soil, dirt, rags, asphalt, and other debris; Properly drained containers (drums).
Expiration Date of Approval: January 1, 1980.
EPA Regional Office Contact: Mr. Roger Fuentes.
EPA Telephone No.: 206-442-1260.

*NOTE.—After January 1, 1980, PCB capacitors and contaminated soils, rags, and other debris cannot be disposed of in chemical waste landfills. A special provision does permit, without time limits, the disposal in chemical waste landfills of contaminated soil and debris resulting from spills or from old disposal sites that predate the PCB regulations.

Future notices, updating this list of approved facilities will be published in the FEDERAL REGISTER approximately every month. For further information on the EPA approval of these disposal facilities, please get in touch with the appropriate EPA Regional Office contact.

Dated: August 15, 1978.

G. M. DIETRICH,
Acting Deputy Assistant Administration for Solid Waste.

[FR Doc. 78-24017 Filed 8-24-78; 8:45 am]

[6560-01]

[FRL 954-2]

AMBIENT AIR MONITORING REFERENCE AND EQUIVALENT METHODS

Amendment to Equivalent Method for SO_2

Notice is hereby given that EPA, in accordance with 40 CFR Part 53 (40 FR 7044, February 18, 1975), has approved an amendment to SO_2 equivalent method number EQSA-1275-006 (FEDERAL REGISTER, Vol. 41, page 3893, January 27, 1976). While the designation number of the method remains the same, the method identification is amended to read as follows:

EQSA-1275-006, "Meloy Model SA 185-2A Sulfur Dioxide Analyzer", operated on the 0-0.5 p.p.m. range, with or without any of the following options:
S-1, Linearized Output
S-2, Modified Recorder Output
S-5, Teflon Coated Block
S-6A, Re-ignite Timer Circuit
S-7, Press to Read
S-11A, Manual Zero and Span
S-11B, Automatic Zero and Span
S-13, Status Lights
S-14, Output Booster Amplifier
S-14B, Line Transmitter Board
S-18, Rack Mount Conversion 18A, Rack Mount Conversion
S-21, Front Panel Digital Volt Meter
S-22, Remote Zero/Span Control and Status (Timer)
S-22A, Remote Zero/Span Control
S-23, Automatic Zero Adjust
S-23A, Automatic/Manual Zero Adjust
S-24, Dual Range Linearized Output
S-33, Remote Range Control and Status (Signals)
S-34, Remote Control
S-35, Front Panel Digit Meter with BCD Output
S-36, Dual Range Log-Linear Output
S-38, Sampling Mode Status;

or operated on the 0-1.0 ppm range with either option S-36 or options S-1 and S-24, with or without any of the other listed options.

The method is available from Meloy Laboratories, Inc., Instruments and Systems Division, 6715 Electronic Drive, Springfield, Va. 22151.

This change is made in accordance with 40 CFR 53.14, based on additional information submitted by the applicant subsequent to the original designation (41 FR 3893, January 27, 1976). As an equivalent method, this method is acceptable for use by States and other control agencies for purposes of § 51.17(a) of 40 CFR Part 51 ("Requirements for Preparation, Adoption, and Submittal of Implementation Plans") as amended on February 18, 1975 (40 FR 7042).

Additional information concerning the use of this designated method may be obtained from the original Notice of Designation (41 FR 3893) or by writing to: Director, Environmental Monitoring and Support Laboratory, Department E (MD-76), U.S. Environmental Protection Agency, Research Triangle Park, N.C. 27711. Technical questions concerning the method should be directed to the manufacturer.

Dated: August 22, 1978.

STEPHEN J. GAGE,
Assistant Administrator for Research and Development.

[FR Doc. 78-24018 Filed 8-24-78; 8:45 am]

[6712-01]

FEDERAL COMMUNICATIONS COMMISSION

[FCC 78-605; RM-2846, 3109]

NEW COMMUNITY EDUCATIONAL FIXED RADIO SERVICE AND LIMITED NON-COMMERCIAL LOCAL ORIGINATION THROUGH TELEVISION TRANSLATOR STATIONS

Memorandum Opinion and Order re Denial of Petition

Adopted: August 8, 1978.

Released: August 22, 1978.

By the Commission: Commissioner Washburn absent.

In the matters of establishment of a New Community Educational Fixed Radio Service in the 470 MHz to 930 MHz frequency bands and amendment of part 74 of the commission's rules to allow limited noncommercial local origination through television translator stations.

1. Here the Commission addresses two petitions for rulemaking. Each petition deals with the origination of programing by either television translators or by a form of low-power community-service television. As explained below, the Commission has decided to initiate today, in a separate proceeding, an inquiry (see notice of inquiry in BC docket 78-253, FCC 78-604, —— FCC2d —— (1978)) into the future role of low-power television, which also in-

cludes the operation of television translators. Many of the areas to be explored in the inquiry touch upon matters at issue in the subject two petitions. To the extent that the inquiry will address these areas, the petitions will be declared moot. In all other respects, and where petitioners seek immediate institution of certain rule amending proceedings—proceedings which we believe would be premature at this time due to the need for additional information and broader policy planning—the petitions will be denied. We have decided, however, to place these two petitions, and the comments received, in the record of the Commission's inquiry in BC docket 78-253.

2. Below is a brief description of the two petitions and the comments they have elicited. Following each summary we will explain the nature of our disposition of the petition as well as the rationale for our judgment.

RM-2846—"COMMUNICASTING"

3. The subject petition was submitted by the Center for Advance Study in Education (CASE) at the Graduate School and University Center of the City University of New York and the Communicasting Association of America, Inc. (CAA).[1] Petitioners seek the establishment of a new "communicasting" service and the use of certain frequencies in the 470 to 930 MHz band, with preference given to UHF television channels 70 through 83 (806 to 890 MHz). This communicasting service is described as one whereby low-power UHF transmission apparatus would be used to provide over-the-air community service broadcasting. This activity would involve the use of television "repeaters" which would pick up very low power signals from remote terminals and rebroadcast them to cover a community or small regional area. In this fashion, petitioners assert, communicasting could be used on an interactive basis to present educational, instructive and specialized programing.

4. Through the use of this low-power repeater technology, petitioners explain, there could be a number of receiving/sending stations in a community, each equipped with basic video gear and a small transmitter and antenna. Program matter or information transmitted from one of these multiple access stations then would be received by the repeater and retransmitted instantaneously on a UHF television channel, a signal which could be viewed not only at any other multiple access receiving/sending station but on any television reciever (with a typical UHF tuner) in the community. Petitioners maintain that the interactive capability of the system would add a new dimension to televised instructional and educational program delivery and afford a valuable vehicle for other information distribution and exchange purposes.

5. Petitioners and a variety of commenting parties maintain that communicasting would have operational advantages over ITFS[2] facilities in that the latter utilizes microwave signals which can only be received by those with special equipment. Communicasting, on the other hand, would result in an "open circuit" product viewable by anyone in the community.[3] A number of comments suggest that the advantages over ITFS also include the lower costs of transmission and, of course, reception equipment. The ITFS service, they contend, has been available only to financially affluent educational organizations which can afford the microwave equipment required. Certain ITFS licensees state their opinion that communicasting would allow them to serve a wider and more varied community.

6. The vast majority of the comments filed in response to the petition support the communicasting concept. Many contend that it would put unused electromagnetic spectrum to a valuable use. Several parties have offered a number of supportive suggestions, including the Commission's authorization of low-cost video generation gear, and the development of related technical standards that will foster the growth of the communicasting activity. Certain comments observed that the proposed communicasting service should not be construed as a "fixed" service but as a "broadcast" service since it would serve the general public and could utilize, generally, the existing allocation framework in most geographic areas. The "repeater" station, some note, could utilize unattended TV translator technology.

7. Several parties suggest a variety of community service uses for the proposed service. It is commented that communicasting could constitute the realization of cable television's "blue sky" promises through the use of the broadcast spectrum—all without the need to wire towns and cities. Aside from urban uses, many parties view the petitioners' proposals as being an integral part of rural telecommunications development. Several suggest that experimental and demonstration projects be established in both rural and urban settings.

8. Approximately 30 parties have offered support for the petitioners' proposals. This support ranges from a variety of educational institutions to amateur television operators to equipment suppliers and to health care and community service organizations. Generally favorable comment also was received from the Department of Health, Education, and Welfare, which urged that the Commission allow expanded television translator origination. The only comments in opposition were submitted by the Land Mobile Communications Council and the American Telephone & Telegraph Co. These oppositions argue that petitioners have shown insufficient public need or demand for the establishment of their proposed service or, more specifically, for their proposed use of frequency bands containing substantial land mobile allocations.

DISCUSSION

9. We have examined the matters set forth in the subject petition and several related comments, and find that they suggest an imaginative and potentially beneficial public service television concept. The service they describe under the term "communicasting" is but one form of low-power television use. And, as noted above, we have just opened up a broad inquiry into this entire low-power TV area. Many of the proposals set forth in the petition, and in the supportive comments, fit precisely within the scope of this inquiry.

10. As explained in our Notice, issued today, we believe there is a need for fact gathering and broad multi-issue policy planning—activities which are necessary prerequisites to the initiation of rulemaking proceedings designed to establish new low-power services. And although we will deny petitioners' request for initiation now of a rulemaking proceeding, this action should not be construed as a rejection of the "communicasting" concept. On the contrary, we believe that this type of communications activity is one which deserves considerable attention in the overall inquiry—a proceeding which later may be broadened to include the kind of rulemaking envisioned by petitioners. While we deny the petition now and correspondingly decline to grant a request for specific spectrum space reservation, it may be that, during the course of the Commission's inquiry, an experimental project could be undertaken, using a portion of the radio frequency spectrum, which could afford us and interested parties the opportunity to assess

[1] The Communicasting Association of America, Inc. is identified as a nonprofit organization dedicated to the use of the radio spectrum for educational and scientific multilateral communication.

[2] As defined in section 74.931 of the Commission's rules, the Instructional Television Fixed Service (ITFS) is one which uses microwave facilities (a "closed" system requiring special receiving gear) for the distribution of instructional or cultural information.

[3] Petitioners note that while the repeater's output would be on a UHF TV channel, the input from the multiple access stations could utilize nonbroadcast frequencies.

the facility and value of "communicasting." Parties commenting in response to our Notice of Inquiry may wish to address this matter and suggest mechanisms and parameters for such a demonstration project.

RM-3109—NONCOMMERCIAL ORIGINATION BY TRANSLATORS

11. This petition for rulemaking, filed by Dutchess Community College (Poughkeepsie, N.Y.), asks that we amend part 74 of the rules to permit television translator stations to originate limited noncommercial programming concerning health, education, public service and community affairs. Petitioner suggests that, in rural areas incapable of supporting conventional television broadcast facilities, originating translators would be a valuable means of providing locally-oriented programing. Rural viewers' television service, petitioner maintains, consisting of off-air and cable distributed reception of distant signals, does not provide local issue coverage. It is suggested that translator origination be limited to between 5 and 10 percent of the broadcast day and be limited to noncommercial matters. Under these limitations, petitioner asserts, most primary television broadcast stations would not be reluctant to grant continued rebroadcast consent.[4]

12. Petitioner submits that an originating translator could not only provide off-air service to the community but could serve as a local origination facility for subsequent carriage by area cable television systems. Dutchess suggests that these originating translators be limited to outputs of 100 or 1,000 watts and that they be allowed to utilize lower-cost program origination gear. Additionally, petitioner offers a detailed set of proposed part 74 amendments which it believes would be appropriate to implement its concepts.

13. Comments filed in response to this petition include those of the parties who submitted the "communicasting" petition (RM-2846), described above. These comments of CASE and CAA offer general support for the Dutchess petition but maintain that the time limitations suggested in RM-3109 are too stringent to allow the activities suggested in RM-2846.[5] The National Cable Television Association (NCTA) has filed comments which, in essence, repeat the matters asserted in NCTA's comments filed in RM-2751. (These comments are described thoroughly in the Memorandum Opinion and Order (FCC 78-606, —— FCC2d —— (1978)), adopted today, concerning, inter alia, RM-2751.) Basically, the NCTA suggests that no translator rulemaking be undertaken until the Commission completes a comprehensive inquiry into the relationship between cable and translators and establishes a program of "regulatory parity" between the two.

14. Also filed were comments of the Association of Maximum Service Telecasters (AMST). The AMST states that the RM-3109 proposal simply is one for "short-spaced drop-ins," and that it should be rejected. It asserts that viewers would receive a "second-class" service from these low-power facilities and that the public would attribute this "inferior" service to the UHF service generally. AMST also argues that these originating translators would deter the activation of UHF television station, be they "full-fledged" or satellities. The RM-3109 proposed limitation on translator origination (to between 5 and 10 percent of the broadcast day) is no limitation at all, according to AMST, since the "average" television station originates only 9.2 percent of its programming locally. Lastly, AMST contends that Dutchess has not demonstrated any pressing public need for such a service.

DISCUSSION

15. In a fashion similar to that explained concerning RM-2846, above, we feel that RM-3109 here include some useful concepts. However, and consistent with our RM-2846 decision, we conclude that any such specific rulemaking effort must be deferred until more generally policy issues have been settled. Thus, and while many of the proposals suggested by Dutchess will be addressed in our broader inquiry, its RM-3109 petition otherwise will be denied.

16. Accordingly, *It is ordered*, That the above-captioned petitions filed by the Center for Advance Study in Education at the Graduate School and University Center of the city of New York and the Communicasting Association of America, Inc. (RM-2846) and Dutchess Community College (RM-3109) are dismissed as moot, insofar as the matters presented in these petitions will be addressed in the Commission inquiry in BC docket 78-253.

17. *It is further ordered*, That the above-captioned petitions, in all other respects, are denied.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

[FR Doc. 78-23769 Filed 8-24-78; 8:45 am]

[4] See Section 74.784 of the Commission's rules.

[5] It should be noted, however, that the "communicasting" concept would not necessarily involve origination by a television "translator" licensed to rebroadcast a primary TV station.

[6712-01]

[FCC 78-606; RM-2751, 2826]

TELEVISION BROADCAST TRANSLATOR STATIONS AND OVERALL NATIONAL TELECOMMUNICATIONS POLICY

Memorandum Opinion and Order; Denying Petition for Rulemaking in Part

Adopted: August 8, 1978.

Released: August 24, 1978.

By the Commission: Commissioner Washburn absent.

In the matters of amendment of part 74 of the Commission's rules and regulations relative to public interest requirements to be imposed on television broadcast translator stations and request to institute inquiry to consider the present and future role of translators and cable systems in terms of an overall national telecommunications policy.

1. Before the Commission are two petitions, filed by Cablecom-General, Inc. (RM-2751), and Communications Services, Inc. (RM-2826), both cable television multiple system operators. As described in detail below, the substance of these two petitions relates, in large part, to the matters now at issue in a Commission inquiry (see notice of inquiry in BC docket No. 78-253, FCC 78-604, —— FCC 2d —— (1978)) initiated today. To the extent that the inquiry will address the matters set forth in the petitions, the petitions will be dismissed as moot. In other respects, and as explained in the following, the petitions will be denied.

2. The substantive positions of Cablecom-General, Inc. (Cablecom) and Communications Services, Inc. (CSI) are quite similar—as are the comments filed in each matter.[1] Both petitions referenced the Commission's then-pending rulemaking proceeding in docket 20539 and asked that Commission action in that proceeding, concerning, inter alia, the use of FM microwave to relay primary broadcast station and other material to translator stations, be held in abeyance pending an overall review of the Commission's translator policy and a determination of the role of translators in our national telecommunciations structure. As described infra, petitioners and certain commenting parties contend, in essence, that no further translator rulemaking action[2] should be

[1] Following the receipt of comments in RM-2826, CSI observed that its petition and the ensuing comments largely were duplicative of the petition and comments filed in tablecom's RM-2751. CSI suggested that the Commission merge the two proceedings.

[2] Reference also is made to television translator rulemaking petitions involving translator origination of emergency messages (RM-2740) and VHF translator origination of fund solicitation and acknowledgement messages (RM-2739). Today the Com-

Footnotes continued on next page

taken until the Commission establishes "regulatory parity" between translators and cable television. As explained in the report and order in docket 20539, FCC 77-836, 67 FCC 2d 209 (1977), the Commission recognized the arguments in the Cablecom and CSI petitions but concluded that the public interest would be better served by approval then, through rule amendment, of FM microwave relay to translators, and the consideration of broader policy matters in a subsequent forum.

3. It is the position of the two petitioners and several commenting parties that translators may undergo certain fundamental functional changes due to (1) the availability of FM microwave relay (docket 20539) and (2) the recent amendment to section 318 of the Communications Act. This statutory revision, as is relevant here, contemplates additional origination activity by translator stations.[3] These parties seem to contend that expanded unattended translator origination coupled with the signal importation facilitation of FM microwave relay (1) may have an adverse impact on cable television operation and penetration and (2) should be met with the Commission imposition of certain "public interest" requirements on translators. It is argued that the recently amended copyright law has added yet another "competitive advantage" for translators. The petitioners and certain cable television commentors note that most cable operators must pay a copyright "compulsory license" fee and that no copyright liability applies to most translators. Other commenting parties, including American Broadcasting Companies, Inc. (ABC) and the National Translator Association (NTA) point out that this copyright exemption applies only to translators which do not operate for profit and make no charges other than those needed to defray transmission and operational costs. They contend that copyright liability arises from the "commercial nature" activity of, for example, cable television, and note that a profit-making translator would be subject to complete copyright liability as opposed to cable's "nominal" compulsory license fee. Broadcast commentators suggest, in general, that petitioners' concern over regulatory and statutory changes is unwarranted, or at least premature, and not befitting the institution of the proceedings requested. They construe the arguments of petitioners and other cable-oriented parties as baseless and designed only to forestall the growth of a "free" broadcast medium which is just beginning to develop to its potential. The thrust of the petitions, they argue, is to impede the development of television translators by shackling them with a myriad of unnecessary constraints in order to protect the economic interests of cable television.

4. Aside from suggesting the need for an overall review and development of Commission translator policy, the petitioners and many commenting parties address several regulatory areas and present various views as to the need for Commission action. Below we list several of these regulatory areas and briefly summarize the basic positions of the parties.

Signal Carriage Regulation

5. The cable television parties suggest, in general, that the signal carriage limitations placed on cable systems in a particular market should apply with the same force to translators operating in the same market. Any decision to not apply such restrictions, they contend, should be accompanied by the rescission of these regulations as they apply to cable television. The NTA argues, in response, that translators do not and will not import distant signals because of the high costs of signal delivery. Broadcast parties find sufficient distinctions between translator and cable operation to merit differing regulatory requirements and point to section 74.732[4] as a "signal carriage" rule which already restricts the operation of translators. It is also noted that outside of the 35-mile specified zone of television broadcast stations, where most translators operate, no cable television signal carriage restrictions apply. Cable parties also question the propriety of the rule requiring carriage of 100-watt translators serving the cable community[5] and fear that an increase in the number of translators capable of demanding cable carriage may fill a system's channel capacity or independent station quota with programing of "no interest" to cable subscribers.

Nonduplication and Syndicated Exclusivity Protection

6. Cable parties argue that translators should be required to afford to local broadcast stations the same degree of nonduplication and syndicated program exclusivity protection required of cable systems. In the alternative they argue that the program protection requirements of cable television operators should be lifted if not made applicable to translators. Broadcast commentators first note that translators have been required to afford program protection to local broadcast stations[6] and that certain regulatory and marketplace restraints make unnecessary the kinds of regulations applied to cable. They maintain that translators must obtain retransmission consent[7] for rebroadcast of programing and that this consent, where is includes network programing, must be obtained from both the originating broadcast station and the network.[8] It is argued, by ABC and others, that network practice general-

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Footnotes continued from last page

mission has initiated a rulemaking proceeding (see notice of proposed rulemaking in BC docket No. 78-252, FCC 78-603, —— FCC 2d —— (1978)) looking toward authorization of these activities.

[3] Amended section 318 states, in pertinent part, that a licensed operator exemption applies to stations (translators) "* * * engaged *primarily* in the function of rebroadcasting the signals of broadcast station. (Emphasis added.) The amendment replaced the word "solely" with the underscored word "primarily." The Commission requested the statutory change.

[4] Section 74.732 of the Commission's rules provided, in pertinent part, as follows:

[5] See e.g. § 76.57(a)(2) of the Commission's rules.

§ 74.732 Eligibility and licensing requirements.

* * * * *

(d) A VHF translator will not be authorized to serve an area which is receiving satisfactory service from one or more UHF television broadcast stations or UHF translators unless, upon consideration of all applicable public interest factors, it is determined that, exceptionally, such intermixture of VHF and UHF service is justified.

(e) The licensee or permittee of a television broadcasting station, and applicant for a proposed new VHF translator whose application is financially supported by such licensee or permittee, or any person associated directly, will not be authorized to operate a VHF translator under any of the following circumstances:

(1) Where the proposed translator is intended to provide reception to places which are beyond the grade B contour of the television broadcast station proposed to be rebroadcast and within the grade B contour of another television broadcast station assigned to a different principal city: *Provided, however,* That this prohibition will not apply to translators using 100 watts on assignments listed in the Television Table of Assignments (§ 73.606(b) of this chapter).

(2) Where the proposed VHF translator is intended to provide reception to all or a part of any community located within the grade A contour of any other television broadcast station for which a construction permit or license has been granted and the programs rebroadcast by the proposed VHF translator will duplicate all or any part of the programs broadcast by such other television broadcast station or stations: *Provided, however,* That this will not proclude the authorization of a VHF translator intended to improve reception of the parent station's signal to any community, any part of the corporate limits of which is within the principal city service contour of such station. [Notes omitted].

[6] Commission decisions cited for this proposition include *KTVB, Inc.* 56 FCC 2d 895 (1975), reconsideration partially granted, FCC 76-200 (March 10, 1976); and *Mt. Mansfield Television, Inc.*, 41 FCC 2d 889 (1973).

[7] See section 325 of the Communications Act; section 74.784 of the Commission's rules.

[8] See *Porter Mountain Antenna TV Association*, 61 FCC 2d 67 (1976); *Storm King TV Association, Inc.*, 20 FCC 2d 348 (1969).

ly is to retain such discretion as to prevent one affiliate's "invasion," via translators, of the service area of another affiliated station. Comments also points to the nonduplication and syndicated exclusivity rule exceptions[9] granted to small cable systems and argue that translators are, "by their very nature," low budget, break-even operations which should not be subject to overly burdensome program protection requirements.

PROGRAM ORIGINATION

7. Cablecom and other cable representatives suggest that the Commission explore the possibility of requiring translators to originate a specific amount of "public service" programing if translator origination is to be allowed at all. Some draw the analogy to the cable television access channel requirements[10] and suggest that translators be required to provide program origination equipment and access time for public use. The National Cable Television Association (NCTA) suggests that the Commission establish time percentage parameters which will insure that translators will operate "primarily" as a rebroadcaster, as required by newly-revised section 318 of the Communications Act. An issue is raised by Cablecom as to whether translator origination should remove the access channel requirements[11] of a colocated cable system or the obligation of a nearby broadcaster to provide programing oriented to the needs of that locale. Certain broadcast and translator licensees insist that low-budget translator operations could not afford the costs of access services or the origination of substantial public service programing. An access obligation, they argue, is better suited to cable operations with multiple channel capacity and additional revenue sources including leased channel and subscription television service.

OWNERSHIP

8. In general, most cable television parties suggest, for reasons concerning media control, that the Commission consider barring broadcast stations and networks from having direct or indirect interests in translators or giving them financial support. Some cable comments only protest translator ownership by the primary or originating station. It is also recommended that the Commission reconsider its ban on cable ownership of translators operating in the cable community. Some broadcast comments assert that a complete bar of broadcast station support would spell the "death knell" for most translators and point to existing restrictions on broadcast station support of certain VHF translators (see section 74.732(e) of the Commission's rules.) Charges of broadcast media dominance through translators, they contend, are baseless since most translators are "merely passive repeaters."

SPECTRUM USAGE AND ALLOCATIONS

9. Cablecom proposes that the Commission place translators in the television broadcast allocations scheme. NCTA, in its comments to the Cablecom petition, suggests, as do other cable commenters, that the Commission consider confining translator operation to UHF frequencies, in the interim not authorize further VHF translators, and establish minimum spacing requirements for VHF translators. They believe that VHF translators are not needed as such service adequately could be rovided by cable and UHF translators.

TECHNICAL STANDARDS AND INTERFERENCE

10. Several cable operators have submitted comments concerning what they consider to be undue and harmful interference generated by translators. Many cite specific instances where translators allegedly have interferred with cable signal distribution or with broadcast signal reception at the cable headend. NCTA suggests that more vigorous technical standards be made applicable to translators, that an attended operation requirement be reinstated and that translator operators be required to select an output frequency that will not interfere with nearby cable television operations. It also suggests that the burden be placed on the translator licensee to resolve and eliminate any interference caused to a cable system or its subscribers. Other cable parties suggest, in more general terms, that the Commission review its policies concerning translator interference to cable operations. Broadcast and translator licensees contend that the problem of translator interference is minimal, at best, and that existing technical standards, applicable to translators, constitute effective and appropriate requirements.

APPLICATION NOTICE

11. Both petitioners and several cable comments argue that the rules be amended to require that actual written notice of translator applications be served on area cable system operations. NCTA suggests that all cable systems within 50 miles of the proposed or operating translator be given notice of any application to commence operation, raise power, or change output channel or location. Broadcast parties commenting on this contend that the existing Commission requirement of the publishing or posting of such a notification is sufficient and that additional notice is unnecessary.

DISCUSSION

12. We have examined the petitions and related comments filed in RM-2751 and RM-2826 and find that they have suggested certain useful areas for Commission inquiry. That is, and as set forth in today's notice of inquiry, supra, we will seek general comment on several matters such as translator signal carriage and local station program protection, the board area of program origination, translator ownership, spectrum usage and interference. We believe that these issues, and several others, must be addressed in any comprehensive examination of the national communications role of translator and low-power television transmission. But, while competitive considerations are germane to that inquiry, we do not believe that revision of the cable television rules nor the concept of "regulatory parity" between translators and cable television should be made specific elements of the proceeding. The purpose of that inquiry is to ascertain the potential function and regulation of low-power broadcast transmission (including translators), not cable television. We do not wish to develop, in that proceeding, a record of material in support of the retention, revision, or rescission of all or any of our cable television rules. Rather, we wish to obtain guidance as to the communications role and future regulation of TV translators and low-power television broadcasting. The Commission fully recognizes that cable television, translators and conventional broadcasting have the capacity to provide service to rural as well as urban areas. However, it is our view that these media are significantly dissimilar, in terms of, for example, program delievery, area of service, channel transmission capacity, and revenue generation as to warrant distinguishable treatment[12] in many of the regulatory areas of focus in the two subject petitions. Therefore, and while we will consider competitive factors in our overall inquiry, we do not solicit comments on the issues of regulatory parity per se between cable and translators (or between translators and conventional broadcasters) or the modification of our cable television rules.

13. Also, we do not believe the public interest would be served by imposing a

[9] See sections 76.95(b) and 76.161.

[10] See § 76.254, et seq.

[11] See the decision of the U.S. Court of Appeals for the Eighth Circuit in *Midwest Video Corp.* v. *FCC* (case No. 76-1496, decided February 21, 1978) which vacated the cable television access channel rules. The Commission has requested *certiorari* with the Supreme Court.

[12] See, e.g. *Community Television, Inc.* v. *Federal Communications Commission*, 404 F. 2d 771, 15 RR 2d 2001 (Tenth Circuit, 1969).

moratorium on all translator rulemaking, or licensing, until the culmination of the overall inquiry. Thus, we will deny that portion of the petitioners' request. Additionally, those portions of the subject petitions which request the immediate institution of specific cable television and/or translator rulemaking proceedings are denied, although many of the issues in those requests are incorporated in the broader inquiry.

14. Accordingly, *It is ordered*, That the above-captioned petitions filed by Cablecom-General, Inc. (RM-2751) and Communications Services, Inc. (Rm-2826), are dismissed as moot, insofar, as the matters presented in these petitions will be addressed in the Commission inquiry in BC Docket 78-253.

15. *It is further ordered*, That the above-captioned petitions, in all other respects, are denied.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

[FR Doc. 78-23961 Filed 8-24-78; 8:45 am]

[6712-01]

[FCC 78-613; BC Docket No. 254, File No. BR-2162; BC Docket No. 255, File No. BRH-742]

BLAIR COUNTY BROADCASTERS, INC.

Renewal of License; Designating Applications for Consolidated Hearing on Stated Issues

MEMORANDUM OPINION AND ORDER

Adopted: August 8, 1978.

Released: August 22, 1978.

By the Commission: Commissioner Washburn absent.

1. The Commission has before it for consideration the above-captioned applications and its inquiry into the operation by Blair County Broadcasters, Inc., licensee of stations WVAM and WVAM-FM, Altoona, Pa.

2. Information before the Commission raises serious questions as to whether the captioned applicant possesses the qualifications to be or to remain a licensee of the captioned stations. In view of these questions, the Commission is unable to find that a grant of the renewal applications would serve the public interest, convenience and necessity, and must, therefore, designatethe applications for hearing.

3. Accordingly, *it is ordered*, That the captioned applications are designated for a consolidated hearing pursuant to section 309(e) of the Communications Act of 1934, as amended, at a time and place specified in a subsequent order, upon the following issues:

(a) To determine whether, and if so the extent to which, the licensee has violated section 73.1205 of the Commission's rules regarding fraudulent billing practices, the degree of knowledge or participation in those practices by principals of the licensee, and the degree of supervision exercised by the licensee over the operation of the stations;

(b) to determine whether, and if so, the extent to which the licensee has made misrepresentations to the Commission and/or was lacking in candor regarding the billing practices of the stations; and

(c) To determine whether, in light of the evidence adduced under the preceeding issues, the applicant possesses the requisite qualifications to be or remain a licensee of the Commission, and whether a grant of the captioned applications would serve the public interest, convenience and necessity.

4. *It is further ordered*, That the Chief, Broadcast Bureau, is directed to serve upon the captioned applicant within thirty (30) days of the release of this order, a bill of particulars with respect to issues (a) and (b).

5. *It is further ordered*, That the Broadcast Bureau proceed with the initial presentation of evidence with respect to issues (a) and (b) and that the applicant then proceed with its evidence and have the burden of establishing that it possesses the requisite qualifications to be a licensee of the Commission and that a grant of its applications would serve the public interest, convenience and necessity.

6. *It is further ordered*, That to avail itself of the opportunity to be heard, the applicant herein, pursuant to section 1.221 of the Commission's rules, in person or by attorney, shall file with the Commission, within twenty (20) days of the mailing of this order, a written appearance in triplicate, stating an intention to appear on the date fixed for the hearing and present evidence on the issues specified in this order.

7. *It is further ordered*, That the applicant herein pursuant to section 311(a)(2) of the Communications Act of 1934, as amended, and § 1.594 of the commission's rules, shall give notice of the hearing within the time and in the manner prescribed in such rule and shall advise the Commission thereof as required by § 1.594(g) of the rules.

8. *It is further ordered*, That the Secretary of the Commission send copies of this order by certified mail—return receipt requested to Blair County Broadcasters, Inc., licensee of radio stations WVAM and WVAM-FM, Altoona, Pa.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

[FR Doc. 78-23960 Filed 8-24-78; 8:45 am]

[6712-01]

[SS Docket No. 78-258]

ALBERT H. GOULD

Application For Amateur Radio Station and Novice Class Operator Licenses; Designating Application for Hearing on Stated Issues

DESIGNATION ORDER

Adopted: August 14, 1978.

Released: August 21, 1978.

The Chief, Safety and Special Radio Services Bureau, has under consideration an application for an amateur radio station license and a novice class operator license filed by Albert H. Gould, 13761 Ward, Garden Grove, Calif. 92643, on February 13, 1978.

1. Gould was granted a citizens band radio service license on May 3, 1976. On June 21, 1976, Gould's station was operated on the frequency 27.146 MHz, which was not authorized for citizens band radio service stations (then known as class D of the citizens radio service), in willful violation of § 95.41(d) [1] of the Commission's rules; and, on that date, it was not identified by its assigned call sign, in willful violation of § 95.95(c) of the Commission's rules.

2. As a result of the violations on June 21, 1976, Gould was issued a notice of violation/notice of apparent liability to monetary forfeiture for $100 on July 15, 1976.

3. Despite the issuance of the abovementioned notice, Gould committed additional violations of the Commission's rules on February 24, 1977. He transmitted on the frequency 27.655 MHZ [2] which was not authorized for CB stations, in willful violation of section 95.455(a) of the Commission's rules. He failed to identify by assigned call sign at the beginning and end of transmissions, in willful violation of section 95.471(c) of the Commission's rules. He transmitted communications over more than 150 miles, in willful violation of section 95.501(b) of the Commission's rules.

4. These violations were the basis of an order revoking Gould's CB license (SS-105-78, issued July 6, 1978). The Order concluded that operation on unauthorized frequencies, such as Gould's, seriously interferes with the communications of legitimate users of the frequencies. It also concluded that Gould's failure to identify, frustrated

[1] Part 95 of the Commission's rules has been renumbered and revised. The rules referred to herein are those in effect at the time of the station operation.

[2] The frequency 27.655 MHz was assigned for use by stations of the U.S. Government.

the Commission's enforcement efforts by necessitating time consuming direction finding techniques to locate Gould's station.

5. In view of the findings and conclusions of the order of revocation (SS-105-78) issued on July 6, 1978, it cannot be determined that a grant of Gould's application would serve the public interest, convenience and necessity. Therefore, the Commission must designate the application for hearing. The factual matters adjudicated in the CB license revocation proceeding shall not be relitigated in this proceeding pursuant to the doctrine of collateral estoppel.

Accordingly, *it is ordered*, pursuant to section 309(e) of the Communications Act of 1934, as amended, and § 0.331 and 1.973 of the Commission's rules, that the captioned application is designated for hearing at a time and a place to be specified by subsequent order, upon the following issues:

(1) To determine the effect of the facts and conclusions contained in the order of revocation, issued July 6, 1978 (SS-105-78), upon the applicant's qualifications to be a licensee of the Commission.

(2) To determine, in the light of the evidence adduced under the foregoing issue, whether the applicant has the requisite qualifications to be a licensee of the Commission.

(3) To determine whether the public interest, convenience, and necessity would be served by a grant of the application for amateur radio station and novice class operator licenses.

It is further ordered, That to avail himself of the opportunity to be heard, the applicant herein, pursuant to § 1.221(c) of the Commission's rules, in person or by attorney, shall within 20 days of the mailing of this order, file with the Commission in triplicate a written appearance stating an intention to appear on the date fixed for hearing and to present evidence on the issues specified in the order. Failure to file a written appearance within the time specified may result in dismissal of the application with prejudice.

It is further ordered, That a copy of this order shall be sent by certified mail—return receipt requested and by regular mail to the licensee at his address of record as shown in the caption.

Chief, Safety and Special Radio Services Bureau.

GERALD M. ZUCKERMAN,
Chief, Legal, Advisory and Enforcement Division.

[FR Doc. 78-23959 Filed 8-24-78; 8:45 am]

[6712-01]

[FCC 78-620; SS Docket No. 78-259, File No. 40-MR-L-28 et al.]

GULF COAST COMMUNICATIONS, INC. ET AL.

Applications Designated for Consolidated Hearing on Stated Issues

In re applications of Gulf Coast Communications, Inc., P.O. Box 5067Y, Tampa, Fla. 33605, SS docket No. 78-259, file No. 40-M-RL-28, for renewal of license for public coast III-B maritime mobile radio station KUZ 383; Gulf Coast Communications, Inc., P.O. Box 5067Y, Tampa, Fla. 33605, SS docket No. 78-260, file No. 179-M-ML-54, for an additional working frequency for public coast III-B maritime mobile radio station KUZ 383; Dee Wetmore, d.b.a. Tampa Radio Marine Service, P.O. Box 18254, Tampa, Fla. 33605 (assignor) and General Telephone Co. of Florida, P.O. Box 110, Tampa, Fla. 33601 (assignee), SS docket No. 78-261, file No. 585-M-RL-111, for assignment of license of public coast III-B maritime mobile radio station KWB 426; Dee Wetmore, d.b.a. Tampa Radio Marine Service, P.O. Box 18254, Tampa, Fla. 33605, SS docket No. 78-262, file No. 61-M-L-66, for a new public coast III-B maritime mobile radio station at St. Petersburg Beach, Fla., on frequency 161.950 MHz; Dee Wetmore, d.b.a. Tampa Radio Marine Service, P.O. Box 18254, Tampa, Fla. 33605, SS docket No. 78-263, file No. 79-M-RL-116, for renewal of license for public coast III-B maritime mobile radio station KWB 426. Memorandum opinion and order.

Adopted: August 14, 1978.

Released: August 23, 1978.

By the Commission:

1. The Commission has before it for consideration the following matters and the pleadings and correspondence associated therewith: (1) Application of Gulf Coast Communications, Inc. (Gulf Coast), filed May 24, 1974, for and additional working frequency for class III-B public coast radio station KUZ 383 at Palmetto, Fla.; (2) applications filed August 20, 1974, by General Telephone Co. of Florida (General) and Dee Wetmore, d.b.a. Tampa Radio Marine Service (Wetmore) for consent to assignment of the licenses for class III-B public coast radio stations KTA 420 and KWB 426 at Tampa and St. Petersburg Beach, Fla., respectively, from Wetmore to General and the associated applications by General for licenses in the Maritime Mobile Service; (3) Gulf Coast's petition for order to cease and desist filed July 28, 1975, and directed against Wetmore; (4) Wetmore's petition for acceleration of license renewal or, in the alternative, for revocation of license, filed October 2, 1975, and directed against Gulf Coast; (5) Wetmore's motion for consolidation filed October 2, 1975; (6) letters dated February 18, 1976, from counsel for Wetmore and Gulf Coast transmitting an agreement which their respective clients has entered into and by which they attempted to withdraw their previously filed pleadings concerning the matters described in items (1) through (5), supra; (7) letter dated June 11, 1976, from the Acting Chief, Legal, Advisory and Enforcement Division, Safety and Special Radio Service Bureau, to counsel for Wetmore and General notifying them that the assignment application for KTA 420 was moot since Wetmore had failed to file a renewal application before the license for KTA 420 expired on May 28, 1976; and (8) an application filed by Wetmore on June 23, 1976, by which she seeks reinstatement of the license for KTA 420 and, if deemed necessary, waiver of section 81.303(b) of the rules; (9) Wetmore's application for renewal of class III-B public coast radio station KWB 426 filed on November 18, 1976; (10) Gulf Coast's application for renewal of license of KUZ 383. Palmetto, Fla.; filed February 9, 1978; and related pleadings and correspondence.[1]

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[1] Also before the Commission are the following related pleadings, and other matters: (a) Petition to dismiss or deny (1), filed July 8, 1974, by Wetmore; (b) Gulf Coast's opposition to (a), filed Sept. 10, 1974; (c) "formal protest" with respect to (2), filed Oct. 15, 1974, by Universal Radio Telephone Media & Westside Communications, Inc.; (d) petition to deny applications and for acceleration of station license renewals or, in the alternative, for institution of license revocation proceedings with respect to (2), filed Oct. 15, 1974; by Gulf Coast; (e) General's opposition to (d), filed Nov. 15, 1974; (f) Wetmore's opposition to (d), filed Dec. 16, 1974; (g) Gulf Coast's reply to (e) and (f), filed Jan. 20, 1975; (h) Gulf Coast's supplement to (d), filed July 28, 1975; (i) General's response to (h), filed Aug. 8, 1975; (j) Wetmore's opposition to (3), filed Aug. 19, 1975; (k) Wetmore's opposition to (h), filed Aug. 22, 1975; (l) Gulf Coast's reply to (j), filed Aug. 29, 1975; (m) Gulf Coast's reply to (j) and (k), filed Sept. 4, 1975; (n) Gulf Coast's opposition to (4), filed Nov. 26, 1975; (o) Gulf Coast's opposition to (5), filed Nov. 26, 1975; (p) Wetmore's reply to (n), filed Dec. 9, 1975; (q) Gulf Coast's amendment to (l) to specify 161.950 MHz (channel 27), filed June 1, 1976; (r) petition for reconsideration of (7), filed July 9, 1976, by Wetmore; (s) petition to deny (q), filed July 16, 1976, by Wetmore; (t) General's petition to deny (q), filed July 16, 1976; (u) Gulf Coast's opposition to (r), filed July 22, 1976; (v) Gulf Coast's petition to deny or dismiss (8), filed July 29, 1976; (w) Wetmore's reply to (u), filed Aug. 3, 1976; (x) petition to deny filed Aug. 4, 1976 by Universal Telephone Media Corp. & Westside Communications, Inc.; (y) Gulf Coast's opposition to (s) and (t), filed Aug. 6, 1976; (z) Wetmore's opposition to (v), filed Aug. 11, 1976; (aa) Wetmore's reply to (y), filed Aug. 18, 1976; (bb) General's reply to (y), filed Aug. 18, 1976; (cc) Gulf Coast's reply to (z), filed Aug. 31, 1976; (dd)

Footnotes continued on next page

2. Wetmore is the licensee of class III-B public coast radio station KWB 426. She was the licensee of class III-B station KTA 420 from May 28, 1971, until May 28, 176. She is also the licensee of Domestic Public Land Mobile Radio Service (DPLMRS) stations KFL 877 and KLF 659 and the holder of a construction permit for DPLMRS station KWU 335.

3. General is the licensee of class III-B public coast radio station KUZ 385 located at Clearwater, Fla., and class II-B public coast station WFA located at Medeira Beach and Indian Rocks, Fla. General is also the licensee of more than 20 point-to-point microwave stations, 7 DPLMRS stations, 10 telephone maintenance radio service stations, a local television transmission service station, and a business radio service station. All of these stations are located in Florida and most of them are in the Tampa-St. Petersburg area.

4. Gulf Coast is the licensee of class III-B public coast radio stations KUZ 383, Palmetto, Fla., KUZ 556, Cedar Key, Fla., and KYH 550, North Fort Myers, Fla.

5. In many of the pleadings filed by the captioned parties to this proceeding, the question of standing was discussed. The present status of the parties is that Wetmore and Gulf Coast are mutually exclusive applicants for channel 27 in the Tampa Bay area. Thus, they have standing with respect to one another as competing applicants. Accordingly, Wetmore's petitions to deny Gulf Coast's second working frequency application and its amendment of that application will be considered. No standing was required to file petitions to accelerate the renewal or institute revocation proceedings or petitions seeking a cease and desist order. Any complainant can file such petitions.

6. Gulf Coast in petitioning to deny the assignment applications of General and Wetmore in October 1974 claimed standing based on its allegation that the assignment was from a financially failing licensee to one which would be able to compete more effectively against it. It cited *Broadcast Enterprises, Inc.* v. *Federal Communications Commission*, 390 F. 2d 483, 12 RR 2d 2001 (D.C. Cir. 1968), in support of its request. The Commission, in *John Hay Whitney*, 28 FCC 2d 736, 21 RR 2d 807 (1971), stated that *Broadcast Enterprises, Inc., supra* at 739, mandated "a generous attitude in approaching standing questions where it is alleged a proposed assignee will be in a position to compete more effectively." Thus, Gulf Coast has standing to oppose the assignment applications.

7. General and Gulf Coast compete for revenues in the same market. Furthermore, grant of channel 27 to Gulf Coast would preclude General from obtaining the frequency from Wetmore through assignment as previously proposed. Therefore, economic injury may result to General if Gulf Coast's second working frequency application as amended is granted. Thus, General has standing to petition to deny the Gulf Coast's amendment. *Federal Communications Commission* v. *Sanders Brothers Radio Station*, 309 U.S. 470, 9 RR 2007 (1940); *Marian U. Moore*, 16 FCC 2d 351, 15 RR 2d 495 (1969); *John Hay Whitney*, 28 FCC 2d 736, 21 RR 2d 807 (1971). Having resolved the question of standing as it applied to Wetmore, General and Gulf Coast, standing will not be discussed infra each time it was raised in a pleading by the parties.

Universal's "Formal Protest" Against the Assignment Applications

8. On August 20, 1974, General filed the aforementioned assignment applications for Wetmore's licenses for KTA 420 and KWB 426. Universal Radio Telephone Media Corp. (Universal) filed a "formal protest" [2] to consent of the assignments on October 15, 1974. As the basis for its protest, Universal cited its prior joint venture agreement with Wetmore, and asserted that Wetmore was without authority to seek the assignment of her licenses to General. Universal further claimed the grant of the assignments to General would violate public policy in that General would obtain a virtual monopoly over the maritime public correspondence facilities.

9. In its protest, Universal did not discuss the question standing. From its submissions, it is clear that Universal's position vis-a-vis Wetmore and the applications is that of a party dissatisfied with previous business dealings with Wetmore.[3] However, Universal has not shown that direct and immediate economic injury will result from grant of the assignment. Therefore, it is not a party in interest. *J. J. C. Broadcasting Corp.*, FCC 2d (1972); *John W. Mowbray*, FCC 2d 35 RR 2d 418 (1975). Nonetheless, the matters raised by Universal, other than those dealing with its claims for monetary damages, will be considered as an informal complaint.

10. Universal submitted information and documents raising the possibility that control of Wetmore's radio business was transferred without advance Commission approval, as required by section 310 of the Communications Act of 1934, as amended, and section 1.924 of the Commission's rules. It appears that Universal signed a joint venture agreement with Wetmore on July 31, 1972. The agreement provided that Wetmore would transfer all of her radio common carrier and maritime mobile facilities and the licenses and permits therefor to a new corporation, Westside Communications, Inc. (Westside). Wetmore and Universal

Footnotes continued from last page
Wetmore's petition for conditional grant of (8), filed Oct. 20, 1976; (ee) letter application for joint interim operation, filed Nov. 2, 1976, by Gulf Coast; (ff) letter opposition to (ee), filed Nov. 4, 1976, by Wetmore; (gg) Gulf Coast's petition to deny (dd), filed Nov. 5, 1976; (hh) Wetmore's opposition to (gg), filed Nov. 11, 1976; (ii) Gulf Coast's letter reply to (ff), filed Nov. 19, 1976; (jj) Gulf Coast's reply to (hh), filed Nov. 23, 1976; (kk) Dec. 22, 1976; letter from Chief, Safety and Special Radio Services Bureau to Dee Wetmore; (ll) application for review of (kk), filed Jan. 6, 1977; (mm) Wetmore's letter request for interim operating authority, filed Jan. 6, 1977; (nn) amendment to application for interim operating authority, filed Jan. 10, 1977, by Gulf Coast; (oo) letter opposition to (mm), filed Jan. 25, 1977, by Gulf Coast; (pp) Gulf Coast's opposition to (ll), filed Jan. 21, 1977; (qq) petition for extraordinary and equitable relief, filed Jan. 21, 1977, by General; (rr) Gulf Coast's opposition to (qq), filed Feb. 17, 1977; (ss) motion to strike portion of (rr), filed Mar. 3, 1977, by General; (tt) application for review of (kk), filed Jan. 21, 1977, by Gulf Coast; (uu) Wetmore's opposition to (tt), filed Feb. 11, 1977; (vv) memorandum opinion and order (mimeo No. 80925) released jointly by the Chief, Common Carrier Bureau, and the Chief, Safety and Special Radio Services Bureau, on Apr. 20, 1977; (ww) application for review of (vv), filed May 20, 1977, by Gulf Coast; (xx) Wetmore's opposition to (ww), filed June 6, 1977; (yy) General's opposition to (ww), filed June 6, 1977; and (zz) Gulf Coast's reply to (xx) and (yy), filed June 16, 1977.

[2] Neither the Communications Act of 1934, as amended, nor the Commission's rules provide for a "formal protest." Sec. 309(d) of the Act provides that parties in interest may file petitions to deny applications.

[3] Universal, through Carlton Smith, filed a civil complaint against Wetmore on Dec. 13, 1972. The complaint sought specific performance of the agreement. The complaint was dismissed with prejudice on Jan. 19, 1973, since Smith was not at that time an officer of Universal and he did not have the authority to pursue the action in the name of the corporation. On Apr. 5, 1973, the remaining officers of Universal released Wetmore from the agreement. The order dismissing Smith's Dec. 1972 civil complaint was affirmed on Feb. 27, 1974.

Smith later became an officer in Universal. Universal then filed a "Complaint for Injunction: Specific Performance; Order to Show Cause; Action for Damages and Relief" in the Circuit Court of the Thirteenth Judicial Circuit in and for Hillsborough County, Fla. By the complaint, Universal sought to enjoin and restrain Wetmore and General from consummating the assignment of Wetmore's licenses, to require Wetmore to perform specifically her 1972 agreements with Universal, and to award Universal a judgment in an amount in excess of $50,000 from Wetmore for compensatory and punitive damages. This complaint was also dismissed and summary judgment was entered for Wetmore on Nov. 6, 1974. On appeal, the judgment was affirmed by the District Court of Appeal of Florida, Second District, on June 18, 1975.

would each receive 50 percent of the common voting shares of Westside but 2 percent of the common voting shares would be held in a voting trust to be voted by a third party mutually agreed upon by Wetmore and Universal.[4] The Agreement specified Wetmore's compensation for managing Westside as $12,000 for the first year of operation and at least $12,000 per year thereafter.

11. The joint venture agreement was apparently entered into on July 31, 1972. Paragraph 17 of the joint venture agreement provided that it could be terminated by mutual agreement of Wetmore and Universal or by vote of the shareholders including the voting trustee. The obligations of the parties to the agreement were made contingent upon the approval of the assignment of licenses by Wetmore to Westside by the Commission and the approval of appropriate State and local regulatory commissions and authorities.

12. In addition, Universal submitted minutes of a special meeting of subscribers, stockholders, and directors of Westside held on November 1, 1972. It appears that numerous actions relating to the operation, management, and control of Wetmore's radio facilities were taken at this meeting. For example, Westside authorized the payment of a salary of $1,000 per month to Mrs. Wetmore as president of Westside, the negotiation of the a 3- to 5-year lease for the premises which Mrs. Wetmore occupied at the time, the acquisition of property insurance on the assets of the business, the transfer of the ownership and the beneficiary of the life insurance policies on Mrs. Wetmore to Westside, continuation of negotiations between Wetmore on behalf of Westside and Mr. St. Philip concerning the sale of the two marine facilities, and the opening of a payroll account, a regular checking account and a special account for the purpose of negotiating a consolidation loan to pay off the short-term debts of the business.

13. Although Universal did not specify issues it believed were raised by its submission, those materials raise serious questions of unauthorized transfer of control. The Commission has defined "control," as the term is used in section 310(b) of the Communications Act of 1934, as amended, as: * * * any act which vests in a new entity or individual the right to determine the manner or means of operating the licensee and determining the policy that the licensee will pursue.[5]

The minutes of the meeting of November 1, 1972, imply that Westside was exercising authority over the dealings of Wetmore's business. It appears that Westside was determining both the means of operating Wetmore's business and the policy it would pursue. Thus, it appears that Wetmore may have relinquished control of her operation and Westside has assumed control of it as of November 1, 1972, and an apporpriate issue will be specified.

GULF COAST'S PETITION TO DENY APPLICATIONS

14. On October 15, 1974, Gulf Coast filed a petition to deny applications and for acceleration of station license renewals or, in the alternative, for institution of license revocation proceedings, which was directed against the assignment applications for KTA 420 and KWB 426. In its petition, Gulf Coast alleged that Wetmore had: (a) Violated section 605 of the Communications Act of 1934, as amended; (b) violated section 1.65 of the rules; (c) violated section 203 (b) and (c) of the Communications Act and her marine services tariff; (d) failed to turn over Federal excise taxes withheld to the Government; (e) violated section 81.191(c)(2) of the rules; and (f) increased her antenna height without the approval of the Commission, the Federal Aviation Administration, or the city of Tampa. Gulf Coast further asserted that General had engaged in anticompetitive practices. Finally, Gulf Coast contended that grant of the assignment applications would have an anticompetitive impact and would be contrary to the public interest. Each of Gulf Coast's allegations will be discussed separately.

15. In support of its claim that Wetmore violated section 605, Gulf Coast relies on a letter dated September 10, 1973, in which Wetmore, through her attorneys, complained to the Commission about the operation of Gulf Coast's public coast III-B radio station KUZ 383 and Tampa Bay Pilots' limited public coast III-B stations KAW 763 and KAW 767. Therein, Mrs. Wetmore stated that she had monitored the communications of those stations and related the content of specific communications.

16. In response, Wetmore claimed that Commission staff members had recommended that she monitor and record transmissions. She further asserted that although it was not clear whether the Commission's staff could delegate its authority to monitor communications for the purpose of enforcing the Commission's rules, if her actions constituted a violation of section 605, it was an innocent violation.

17. Wetmore's actions appear to be in violation of section 605 of the Communications Act of 1934, as amended,[6] and an issue, will be specified. However, Wetmore reported the results of her monitoring to the Commission. She did not divulge it to a person not authorized to monitor such communications. Her stated purpose for reporting the information was to persuade the Commission to investigate alleged wrongdoing. Accordingly, this matter will be considered with regard to her comparative qualifications only.

18. Gulf Coast asserted that Wetmore's failure to report the existence of the joint venture agreement with Universal in the assignment application constituted a violation of section 1.65 of the Commission's rules. In her December 16, 1974, opposition to Gulf Coast's petition to deny, Wetmore stated that Universal's civil complaints had been dismissed and the Universal's officers had released her from the joint venture agreement on April 5, 1973. Since the joint venture agreement with Universal was not in effect at the time of the filing of the instant assignment applications, Wetmore asserted she was not obligated to report the agreement.

19. In its January 20, 1975, reply, Gulf Coast argued that Wetmore had filed two applications[7] during the exist- ence of the joint venture agreement and that her failure to report the existence of the agreement was a violation of section 1.65.

20. Section 1.65 does not apply to the situation described by Gulf Coast. Section 1.65 requires an applicant to maintain the accuracy and completeness of the information in its application and to amend or request leave to amend its application if there is a change in any significant respect to the information in the application or if there is a change of potential decisional significance. Since the joint venture agreement was signed before the

[4] Wetmore and Universal were to each contribute 1 percent of their common voting shares to the voting trust.

[5] *Powell Crosley, Jr.*, FCC 3, 20, 3 RR 6, 23 (1945); *WHDH, Inc.*, 17 FCC 2d 856, 16 RR 2d 185 (1969).

[6] Sec. 605 has been the subject of various interpretations which have struggled to clarify its import. For instance, the Review Board has held that testimony by a petitioner relative to violations by an applicant, which violations were observed by the petitioner during its monitoring of the applicant's transmissions, is inadmissible at hearings. *Robert Flying Service, Inc.*, 30 FCC 2d 823, 22 RR 2d 467 (1971); *Business Aviation, Inc.*, 51 FCC 2d 855 (1975). Sec. 605 has been construed to prohibit the Commission itself from divulging to other governmental agencies the contents of a licensee's transmissions which were in furtherance of a criminal enterprise. *United States* v. *Sugden*, 226 F. 2d 281, *Aff'd without op.* 351 U.S. 961, 100 L. Ed 1449, 76, S.Ct. 709 (1955). However, it has also been held that sec. 605 is not violated where there was no element of privacy involved in the type of transmission at issue. *Brown* v. *C.A.B.*, 324 F. 2d 523 (6th Cir., 1963).

[7] Wetmore filed an application for a license to cover the construction of additional facilities for DPLMRS station KFL 877 (file No. 2112-C2-ML-73) on Aug. 25, 1972, and an application for an authorization to relocate public coast station KTA 420 (file No. 362-M-ML-33) on Mar. 8, 1973.

applications were filed, Wetmore could not have violated section 1.65 by not reporting the agreement in the aforementioned applications.

21. Regarding alleged violations of Wetmore's marine tariff and section 203 (b) and (c) of the Act,[8] Gulf Coast stated that effective October 12, 1973, Wetmore amended her Tariff F.C.C. No. 1 to require a $10 per vessel deposit before service would be rendered. According to Gulf Coast, this tariff was discriminatory with respect to transient vessels since they had no advance warning that Wetmore required a $10 deposit before rendering service. Furthermore, Gulf Coast alleged that Wetmore had required a $10 deposit before changing her tariff, based on a complaint letter received by the Commission on February 25, 1972, from S. C. Loveland Co., Inc. The letter from Loveland claimed that one of its tugs was refused service by Wetmore's marine operator because the tug did not have a Wetmore billing number. Gulf Coast also asserted that Wetmore did not refund deposits, contrary to her tariff.

22. In her opposition to Gulf Coast's petition to deny, Wetmore admitted that service was refused Loveland's tug but stated that the refusal was an isolated instance which was the culmination of a continuing problem between Wetmore and Loveland. Wetmore stated an apology had been made to Loveland and Loveland had not been refused service since that incident. Wetmore also stated that her revised tariff does not require the automatic refund of deposits, rather Wetmore has the option of refunding the deposit or crediting it to a subscriber's account before ceasing service to the subscriber. She denied that she has "consistently refused to make such refunds upon request." Wetmore attached to her response a copy of a letter from her attorney to the Commission dated March 14, 1973. In the letter, counsel stated that Wetmore requested the $10 registration fee from subscribers of her marine radio service but that she had not refused service if the fee had not been paid. Counsel also stated that "that fee perhaps should appear also in [her] tariff, * * *."

23. In its reply, Gulf Coast noted that Wetmore's promotional literature submitted with the petition to deny indicated that Wetmore had required a $10 deposit prior to service since at least December 1, 1971. Thus, Gulf Coast asserted, Wetmore had operated her marine stations in violation of her tariff for almost 2 years. Gulf Coast also claimed that Wetmore's refusal to serve the Loveland tug was not an isolated incident. No other examples were cited. It was Gulf Coast's contention that such refusals violated section 201(a) of the Act [9] [10] and that by requiring a deposit prior to service, which was not provided for in a tariff, Wetmore violated section 203 (b) and (c) of the Act. Gulf Coast further alleged that if Wetmore did not demand the deposit of all prospective users, she violated section 202(a) of the Act.[11] [12]

24. Wetmore stated that its refusal to provide service to the Loveland tug was an isolated instance. Gulf Coast did not submit any substantiation for its claim that Wetmore had refused service to other vessels. Gulf Coast's showing does not warrant specification of an issue. Gulf Coast also asserted that Wetmore did not demand the $10 deposit of all prospective users. However, Gulf Coast failed to submit any support for this allegation other than an affidavit of its vice president, James C. Pope, and it does not appear that he had personal knowledge of the facts alleged as required by section 309 of the Communications Act. Accordingly, the requested issue concerning Wetmore's alleged violation of section 202(a) of the Act will be denied.

25. It appears that Wetmore required the $10 deposit before her tariff was amended to allow her to require such a fee, in apparent violation of section 203 (b) and (c) of the Act. An issue will be specified inquiring into this matter.

26. Regarding Wetmore's Federal excise tax payments, Gulf Coast submitted the affidavit of Wetmore's former office manager Joyce R. Swindle, who claimed that Wetmore routinely withheld Federal excise tax payments from the Federal Government and did not pay the tax without a lien being attached. An unsworn statement by Charles Delk also claimed that withheld taxes were not paid to the Government. No consideration will be given the unsworn statement. Wetmore denied this allegation and stated that all taxes had been paid. The Swindle affidavit does not disclose a basis for her claimed knowledge that Wetmore failed to pay these withheld taxes to the Government. There is no indication that this matter fell within her responsibilities as office manager. Nor has Gulf Coast submitted any official documents, such as liens recorded against Wetmore. In light of the unsubstantiated nature of these allegations, no further inquiry is warranted. See *Sumiton Broadcasting Co., Inc.*, 15 FCC 2d 410 (Rev. Bd. 1968).

27. Gulf Coast also alleged that Wetmore failed to monitor the marine calling and distress channel 16 as required by § 81.191(c)(2). Gulf Coast relies on the unsworn statement of Delk to support this allegation. Wetmore denies this charge. Since this allegation was not supported by affidavit as required by Section 309 of the Communications Act, it will be given no further consideration.

28. Gulf Coast also alleged that Wetmore increased the height of her antenna tower during July and August 1972 without approval by the Commission, the city of Tampa, and the Federal Aviation Administration. In support of this allegation, Gulf Coast submitted an affidavit of its Vice-President Pope. In his affidavit Pope stated that, on July 24, 1972, he visually determined that the height of Wetmore's tower had been increased. He also related conversations he had with various other people regarding Wetmore's tower. Since affidavits of those persons were not submitted, no consideration will be given their purported statements. Pope further stated that, on July 28, 1972, the marine antenna was lowered so that the top of the antenna was 140 feet above the ground, and the tower was altered again as of August 22, 1972, although the height of the antenna was not increased. Gulf Coast also referred to a December 28, 1973, telegram from the Commission to Wetmore concerning the tower on which her antennas were mounted at that time.

29. Wetmore's license for KWB 426 was renewed on January 24, 1972, and it specified that the tower and supporting structure could not exceed 140 feet above ground level. Commission personnel observed Wetmore's antennas and tower on July 26, 1972, at which time the height of the antenna and tower exceeded the authorized 140 feet. However, within 2 days, according to Pope, the antenna on top of the tower was lowered so that it did not exceed the top of the tower and was in compliance with her authorization. The Commission's telegram of December 28, 1973, related to Wetmore constructing a tower for a community repeater. It had nothing to do with the marine stations.

30. Although it appears that for approximately 2 or 4 days in July 1972, Wetmore's antenna and supporting structure exceeded the 140-foot limitation on her station authorization, the short duration of the discrepancy renders inquiry into the matter unneces-

[8] Sec. 203(b) of the Communications Act of 1934, as amended, provides that tariffs shall be changed only after 90 days notice to the Commission and the public. Sec. 203(c) provides that, unless otherwise authorized by the Act, carriers shall operate their facilities in strict compliance with the tariffs they have filed with the Commission.

[9] Sec. 201(a) of the Act requires that a common carrier furnish its "communication service upon reasonable request therefor; [* * *."

[10] Since Gulf Coast did not request an issue regarding this matter in its petition, it is not being considered. Cf. *Midwest Television, Inc.*, 1 FCC 2d 1184 (Rev. Bd. 1965). Gulf Coast did not substantiate any violation of the Act.

[11] Sec. 202(a) of the Act states: It shall be unlawful for any common carrier to make any unjust or unreasonable discrimination in charges, practices, classifications, regulations, facilities, or services for or in connection with like communication service, directly or indirectly, by any means or device, or to make or give any undue or unreasonable preference or advantage to any particular person, class of persons, or locality, or to subject any particular person, class of persons, or locality to any undue or reasonable prejudice or disadvantage.

[12] Since gulf Coast did not request an issue regarding this matter in its petition, it is not being considered. Cf. *Midwest Television, Inc.*, 1 FCC 2d 1184 (Rev. Bd. 1965). gulf Coast did not substantiate any violation of the Act.

sary. Gulf Coast's request for initiation of revocation proceedings against Wetmore will also be denied. The matters which Gulf Coast has raised which warrant inquiry will be considered in this proceeding.

31. In her opposition, Wetmore asserted that Gulf Coast's petition was an example of "continuing efforts of Gulf Coast's principals to apply leverage against Tampa Radio to induce it to sell its marine facilities to Gulf Coast." These allegations are discussed *infra* at paras. 96, *et. seq.*

32. With respect to General's qualifications, in its petition to deny, Gulf Coast claimed that General has engaged in anticompetitive activities to the economic injury of Gulf Coast.[13] According to Gulf Coast, persons attempting to reach Gulf Coast's marine operator through General's telephone operators were connected with General's marine operator instead. Gulf Coast personnel purportedly confirmed this allegation by "spot checks." Gulf Coast stated it had filed repeated complaints with General about diversion of calls to no avail.

33. Gulf Coast also contended that General through its telephone directory listings and information section concerning marine services had engaged in anticompetitive practices to Gulf Coast's economic detriment. The general information section of General's 1974 telephone directory for Tampa under the heading "Mobile & Marine" instructed a caller to ask the operator for the marine operator for the desired area. According to Gulf Coast, this procedure invariably placed the caller in contact with General's marine operator. For information on other communications common carriers, the "Mobile & Marine" information directed the caller to the "yellow pages or other business guides." Gulf Coast claimed that this was designed to dissuade a caller from seeking additional information and was deceptive and misleading because marine mobile services are listed under the one yellow pages heading "Radiotelephone Common Carrier Communications Service with Mobile Units." Gulf Coast contended that General had refused to add a different heading in the yellow pages for "common carrier-Marine" or "Marine Radio Common Carrier," and since the term "mobile units" was associated with "land mobile units," the yellow pages heading was another example of an anticompetitive device used by General.

34. In addition, Gulf Coast speculated that in the future General might underprice its marine service and subsidize that service by revenues from its other communications services, thus using "its preferred status as the sole purveyor of landline telephone service in the Tampa Bay area to engage in anticompetitive activities . . ." to the detriment of Gulf Coast.

35. In its November 15, 1974, opposition to Gulf Coast's petition to deny, General stated it was unable to locate any record of a complaint by Gulf Coast to General's marine operator.[14] It further stated that it never had a policy of diverting traffic intended for Gulf Coast, and that its operators regularly referred callers to Gulf Coast's operators. General also claimed that its general information section and yellow pages listings for marine operators were not intended to be anticompetitive, and that the manner in which Gulf Coast was listed in the yellow pages was in conformity with standard practices throughout Florida. General changed the heading in 1974. Future directories would list Gulf Coast under the new heading of "Radiotelephone Communications," thus deleting the words "mobile units," which Gulf Coast found objectionable.

36. In its January 20, 1975, reply to the oppositions, Gulf Coast asserted that by changing the yellow pages heading General admitted that the original heading was improper. Gulf Coast also claimed that General had asked for a rate increase for its intrastate telephone services without a corresponding rate increase in its marine services thus indicating that underpricing and subsidization by General would be likely.

37. Gulf Coast also included two affidavits of its Vice President, James C. Pope. These affidavits related to Gulf Coast's charge that General's telephone operators diverted calls intended for Gulf Coast. In the first affidavit, Pope stated that Gulf Coast has placed a call from the Tug *Dixie Chief* to its local company office and the tug was waiting for a call back from the office. Gulf Coast later heard General's marine station calling for the *Dixie Chief* on channel 16. Pope called the *Dixie Chief's* local office and was told that the local office had asked that Gulf Coast place the call. Gulf Coast then placed the call to the *Dixie Chief* from its local office.

38. In his second affidavit, Pope related that from another city, he placed a call to a ship and requested that the call be handled by Gulf Coast and the local operator so informed the Tampa telephone operator; that the call was instead routed to General's marine operator; that Pope conducted similar test calls at other times with the same result;[15] and that General's traffic manager in Tampa had promised to correct the situation but had not done so.

39. With respect to the allegation that General directed calls, the only instance we will consider is the single test Pope stated he conducted personally and described specifically in his affidavit. The other instances of purported diversions were either not supported by specific factual allegations or, in the case of the *Dixie Chief*, were based on hearsay. Such allegations do not comply with the requirements of section 309(d) of the Communications Act of 1934, as amended. A practice or policy of diverting calls to its own public coast station would raise serious questions regarding General's qualifications. However, the single instance related by Gulf Coast and General's denial of such a practice makes inquiry into this matter unwarranted. Nor do the telephone directory and yellow pages information raise questions of unfair competitive practices. All the public coast stations were listed in the same fashion in the yellow pages, and the information section merely indicated that more information was available from landline operators.

40. On July 28, 1975, Gulf Coast filed a supplement to its petition to deny.[16] The Commission did not request Gulf Coast to file the supplement nor did it authorize the filing of the supplement. Thus, the supplement contravenes § 1.45(c) of the Commission's rules and it will not be considered.

Gulf Coast's Petition for Order to Cease and Desist Against Wetmore

41. On July 28, 1975, Gulf Coast filed a "Petition for Order to Cease and Desist" against Wetmore. Gulf Coast claimed that Wetmore's station had consistently attempted to establish radio contact with ship stations which were in communications with or attempting to communicate with Gulf Coast's station, in violation of § 81.312(a)(7) of the rules.[17] In support

[13] Gulf Coast's petition to deny was supported by an affidavit of its Vice-President, James C. Pope, who stated that he had personal knowledge of the facts alleged in the petition.

[14] General's opposition was supported by the affidavid of its Vice President Operations Staff, K. S. Durey, who stated that he had personal knowledge of the facts set forth in the opposition.

[15] Pope provided no details about any other alleged test calls.

[16] The supplement, *inter alia*, contained an unsworn letter about the difficulties one person had trying to contact Gulf Coast through General's telephone operators and a newspaper article dealing with alleged customer dissatisfaction with General's telephone service. The unsworn letter and the newspaper article will not be considered because they are not affidavits of persons having personal knowledge of the facts alleged.

[17] Section 81.312(a)(7) of the rules reads: A public coast station shall not attempt to communicate with a ship station that has specifically called another coast station until it becomes evident that the called station does not answer, or that communica-

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of this claim, Gulf Coast submitted excerpts from its logbooks. These log entries were made from January 10, 1975 through July 24, 1975. The entries were attributed to operators in Gulf Coast's employ. Gulf Coast's Vice President, James C. Pope, verified the pleading in an affidavit dated July 21, 1975. The discrepancy between the July 21, 1975 affidavit and the log entries which postdated it is discussed at para. 46, *infra*.

42. Wetmore filed an opposition to the cease and desist petition on August 19, 1975. Therein, Wetmore denied that her stations had operated in contravention of § 81.312(a)(7). She supplied signed statements [18] from her operators who were on duty at the times of the alleged violations. These statements, in general, denied "cutting in" on Gulf Coast and stated that Gulf Coast "cut in" on Wetmore. Wetmore also asserted that Pope's affidavit of July 21, 1975, purporting to verify the log entries of July 23 and 24, 1975, raised substantial questions concerning the authenticity of all of the log entries and whether Pope had signed a false affidavit.

43. In its August 29, 1975, reply to Wetmore's opposition to the petition for order to cease and desist, Gulf Coast stated that the date discrepancy between Pope's affidavit and the log entries accompanying its petition occurred because after execution of his affidavit, Pope sent counsel copies of the most recent log entries which he believed supported the allegations about Wetmore's rule violations and these entries were inadvertently included in the petition. Gulf Coast asserted that there was no intention to deceive the Commission.[19]

44. Gulf Coast asserted that no weight should be given the statements submitted by Wetmore because they were not affidavits; the employees' qualifications to discuss the matters alleged were not established; and some of the matters discussed were hearsay. Gulf Coast also claimed that it referred ships which did not have Gulf Coast's working channels to Wetmore. Gulf Coast further stated that: "In many of these situations, however, Wetmore's operators will interrupt in mid-conversation without allowing Gulf Coast's operator to complete the referral or to clear with the calling vessel." Gulf Coast claimed that Wetmore's operators frequently failed to answer calls addressed to her stations. Gulf Coast stated that its operators had been instructed to answer the calls for Wetmore after the second unsuccessful attempt by the calling vessel to contact Wetmore. Gulf Coast further claimed that whenever its operators did so respond, "invariably" Wetmore's operators interrupted and asked the vessel to switch to Wetmore's Channel 26. These claims were supported by affidavits from Pope and some of Gulf Coast's marine operators.

45. Gulf Coast also attached affidavits of four of the five operators whose log entries were included in the petition for a cease and desist order and the affidavits of two ship station owners. The two ship station owners stated that Wetmore's station interrupted conversations on Channel 16 (the calling channel) between their ships and Gulf Coast and told the ships to switch to Channel 26. Neither owner cited specific instances of this. Two Gulf Coast operators—Sheri Benjamine and Jerrine Hickman—did not affirm the accuracy of the log entries in the petition for a cease and desist order. They discussed other alleged instances of "cutting in." Rosemary Glover did affirm the accuracy of one of her two previously submitted log entries. She also mentioned a more recent incident of the same nature. Elsie Pope, who is also the office manager for Gulf Coast, did not discuss any specific instances of alleged "cut ins." The operators' affidavits submitted by Gulf Coast raise a substantial question of fact as to whether Wetmore violated § 81.312(a)(7) and an appropriate issue will be specified. At this juncture, the issuance of a cease and desist order is not warranted, and that petition will be denied.

46. The affidavit which Pope signed in support of the petition for a cease and desist order raises a serious question concerning Gulf Coast's qualifications to be or remain a Commission licensee. As stated *supra*, Pope's affidavit attested to the entire Petition. However, as submitted, the Petition included attachments which postdated Pope's affidavit. Despite Gulf Coast's proferred explanation of the sequence of events which led to the submission of the affidavit and attachments, a complete explanation is required. See *Post-Newsweek Stations, Florida, Inc.*, 54 FCC 2d 254 (Rev. Bd. 1975). Accordingly, an issue will be specified concerning the facts and circumstances surrounding the preparation and submission of that affidavit and its effect on Gulf Coast's qualifications.

WETMORE'S PETITION FOR RELIEF AGAINST GULF COAST

47. On October 2, 1975, Wetmore filed a Petition for Acceleration of License Renewal or, in the alternative, for Revocation of License directed against Gulf Coast and its license for Public Coast III-B station KUZ 383 at Palmetto, Fla.[20] Wetmore alleged that Gulf Coast violated section 605 of the Act when it disclosed the contents of Wetmore communications in Gulf Coast's petition for a cease and desist order. Wetmore asserted that Gulf Coast had committed other violations of section 605 as well, had violated § 81.312(a) (6) and (7) of the Commission's rules; [21] had engaged in anti-competitive conduct by overriding competitors' communcations; and had made misrepresentations or less-than-candid representations to this Commission. The affidavits of Samuel C. Lee and Billie Bonifay, two former Gulf Coast employees were submitted in support of these allegations.

48. Lee was employed as an electronic technician by Gulf Coast from February 1974 through August 1975. He stated that during his employment, Gulf Coast had a radio and an antenna which were used for monitoring Wetmore's public coast station KWB 426 on Channel 26. Lee stated that he was told that the radio was installed to monitor and tape the competition.

49. Bonifay was employed by Gulf Coast from July 1973 until July 1974 as a radio operator for Gulf Coast. According to Bonifay, Gulf Coast's operators were instructed to advise ships which initiated calls on Channel 16 without specifying a public coast station to switch to Channel 25, Gulf Coast's working channel. According to Bonifay, Gulf Coast monitored Wetmore's working channels and solicited business from Wetmore's customers. Bonifay also stated that she did not recall any instances of Wetmore's operators attempting to contact a vessel calling for KUZ 383 (Gulf Coast) on Channel 16.

50. In support of the allegation that Gulf Coast misrepresented facts to the Commission or was lacking in candor, Wetmore initially set forth the state-

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tion between the ship station and the called station cannot be carried on because of unsatisfactory operating conditions.

[18] Wetmore characterized the statements attached to the opposition as sworn affidavits. However, the attachments, with one exception, did not contain jurats. They were handwritten statements which apparently were dated and signed by the authors. Affixed to each statement was the signature and seal of a notary public, Mrs. Wetmore's son.

[19] This part of Gulf Coast's reply was supported by an affidavit of Pope who stated that he had personal knowledge of the facts sets forth in the petition.

[20] On that same date, Wetmore filed a Motion for Consolidation of her assignment applications, Gulf Coast's application for a second working channel for KUZ 383, and Wetmore's request for acceleration of Gulf Coast's renewal or revocation of its license.

[21] Section 81.312(a)(6) of the Commission's rules states: (6) Except in the event of an emergency involving safety, a public coast station, with respect to operation on any frequency which is used also by other coast stations within the same communication area, shall not answer, or attempt to answer, a ship station until the latter has transmitted the call sign or name of the particular coast station with which it desires to communicate.

ment in Gulf Coast's letter to the Commission of February 25, 1974, that its operators had been instructed to answer calls specifically directed to Wetmore's station only after the third unsuccessful attempt or the ship cleared without making contact. Wetmore contrasted that statement with the portion of Bonifay's affidavit which indicated that Gulf Coast's operators were instructed to respond promptly to all ships in order to get the call before the stations could establish contact. Samuel Lee's affidavit was also cited as support for Wetmore's allegations. Lee pointed out that Gulf Coast's signal could override other public coast station transmissions on the calling channel (channel 16). Wetmore claimed that Lee's affidavit established Wetmore's facilities were technically unable to interrupt Gulf Coast's transmissions and thus Gulf Coast's claims were misrepresentations. Wetmore further claimed that the Bonifay affidavit established that Gulf Coast had violated § 81.32(a) (6) and (7).

51. Wetmore also requested that harassment and abuse of process issues be specified against Gulf Coast. Wetmore cited as alleged harassment the August 9, 1972, letter from Gulf Coast's counsel to Wetmore's counsel (para. 91, *infra*) and Gulf Coast's referral of section 605 allegations concerning Wetmore to the U.S. Attorney in Tampa.

52. In its November 26, 1975, opposition to Wetmore's petition Gulf Coast responded to Lee's affidavit by denying that its Channel 26 monitor was ever connected to the tape recorder. Gulf Coast admitted that at some time it did tape some of Wetmore's transmissions on Channel 16 with the tape recorder in the belief that the recordings could be used to show Wetmore's violations. Gulf Coast claimed it did not violate section 605 of the Act since no use was made of the recordings.

53. Gulf Coast argued that Wetmore misinterpreted its original charge regarding "interruptions." Gulf Coast stated that its complaint was that a Wetmore operator keyed the Channel 16 transmitter and told a vessel to switch to Channel 26 after a Gulf Coast operator had told the vessel to switch to Channel 25 and released the key on Gulf Coast's transmitter. Gulf Coast stated that that practice by Wetmore's operators resulted in confusion to the vessel, a waste of time on Channel 16, and the diversion of calls from Gulf Coast to Wetmore.

54. With respect to the affidavit of Bonifay, Gulf Coast first stated that Bonifay was dismissed on June 25, 1974 because *inter alia*, she deliberately interfered with Wetmore's transmissions and argued with Wetmore's operators on Channel 16. Gulf Coast also claimed that its operators (including Bonifay) were instructed to answer promptly all calls not specifically addressed to Wetmore or General, and to answer calls addressed to Wetmore or General only after the third unsuccessful attempt by the caller or after the caller had cleared without contact. Gulf Coast admitted that it answered calls which may not have been properly addressed and thereby may have violated § 83.312(a)(6). However, it asserted that this practice was consistent with the public interest because each call is a potential emergency call. Gulf Coast further claimed that it notified the Commission of this operating procedure in a letter dated February 25, 1974, and since the Commission did not notify Gulf Coast of any objection to the practice, it assumed that continued operation in this manner was proper.

55. Regarding the section 605 allegations, Gulf Coast admitted monitoring Channels 26 and 27 and the subsequent mailing of a flier to calling vessels for a few weeks after Gulf Coast began its operation of KUZ 383. Gulf Coast claimed it did not realize this practice might be considered improper until Wetmore raised the charge. Affidavits of two persons who were operators on KUZ 383 in the summer of 1973 indicated that neither affiant engaged in the practice of sending out fliers to those vessels monitored on Channels 26 and 27; thus, according to Gulf Coast, the practice complained of had stopped by the summer of 1973.[22] Gulf Coast argued that its actions did not violate section 605 of the Act because Wetmore did not establish that Gulf Coast obtained customers from its fliers and therefore a beneficial use had not been demonstrated.

56. Gulf Coast also responded to the allegation that the log entries included in its July 28, 1975, petition for cease and desist order constituted a violation of section 605 of the Act. Gulf Coast stated that since it was a party to the communications, divulgence of the contents of the communications did not constitute a violation of section 605. Finally, Gulf Coast denied any harassment or abuse of process.

57. In a December 9, 1975, reply to Gulf Coast's opposition, Wetmore accused Gulf Coast of altering its position regarding Wetmore's conduct. In its petition for cease and desist order against Wetmore, Gulf Coast claimed:

> * * * interruptions have occurred after the ship station has already established contact with Gulf Coast's operator and a conversation is in progress.

In its reply to Wetmore's opposition, Gulf Coast claimed:

> * * * Wetmore's operators will interrupt in mid-conversation without allowing the Gulf Coast operator to complete the referral or to clear with the calling vessel.

Then, in its opposition to Wetmore's petition of October 2, 1975, Gulf Coast claimed:

> After Gulf Coast's operator has released the key of her Channel 16 transmitter and cleared the channel, * * *, Wetmore's operator keys her Channel 16 transmitter * * *.

58. The Commission will specify an issue concerning possible violations of section 605 of the Act by Gulf Coast based on its admitted monitoring of transmissions on Channels 26 and 27 between Wetmore and her customers in an attempt to obtain new customers for Gulf Coast's facility. The log entries by Gulf Coast do not warrant inquiry because Wetmore did not establish that Gulf Coast was not a party to the conversations reflected in the log entries.

59. Gulf Coast apparently had standing operating procedures that were in conflict with the provisions of § 81.312(a)(6) of the rules. Accordingly, an issue will be specified regarding this matter.

60. An issue is necessary regarding possible Gulf Coast misrepresentations concerning Wetmore and § 81.312(a)(7). Prior to Wetmore's assertion that Gulf Coast had the superior signal, Gulf Coast claimed that Wetmore operators interrupted conversations while they were in progress. Subsequently, Gulf Coast stated that disruptions occurred after Gulf Coast's operator released the transmitter key and cleared the channel. Accordingly, Gulf Coast apparently changed its allegations to comport with Wetmore's explanation. This raises questions of misrepresentation or lack of candor by Gulf Coast and issues will be specified.

Wetmore's Reinstatement and Renewal Applications

61. Wetmore's license for Public Coast III-B maritime mobile radio station KTA 420, St. Petersburg Beach, Fla., expired on May 28, 1976. Wetmore did not file a renewal application for the license for KTA 420 prior to that date. By letter received by the Commission on June 1, 1976, Gulf Coast amended its application for a second working channel for KUZ 383 [23] to Channel 27 (161.950 MHz), the channel on which KTA 420 had operated prior to expiration of that license on May 28, 1976.

62. On June 2, 1976, Wetmore submitted a mailgram which purported to be a renewal application for KTA 420. By a telegram dated June 7, 1976, Wetmore was informed that the mailgram application for renewal was inap-

[22] Gulf Coast did not state when the practice ended.

[23] As stated in paragraph 1, *supra*, Gulf Coast filed its additional working frequency application on May 24, 1974.

propriate. The mailgram was treated as a request for special temporary authority to operate in accordance with the terms of the expired license for KTA 420 (File No. 753-M-L89) and such temporary authority was granted by the telegram. By letter dated June 11, 1976, the Chief, Safety and Special Radio Services Bureau, notified Wetmore and General that the application for assignment of the license for KTA 420 was moot since the license has expired without a timely renewal application having been filed.[24] On June 16, 1976, Wetmore filed a renewal application for KTA 420. On June 23, 1976 Wetmore filed an application for reinstatement of the license[25] for KTA 420 and a telegram which asked for acceptance of her untimely filed renewal application *nunc pro tunc.*

63. Wetmore argued that her application for reinstatement of the license for KTA 420 be granted or that her so-called renewal application be accepted *nunc pro tunc.*[26] *Wetmore first contended that the bureau had dismissed the assignment application for Channel 27 by declaring it moot in the letter of June 11, 1976. She then asserted that the Commission has the authority to reinstate expired licenses, citing Lewel Broadcasting, Inc.,* 32 FCC 2d 39, 23 RR 2d 94 (1971); *Fred H. Whitely, Inc.,* 27 FCC 2d 624, RR 2d (1971); and *Melody Music, Inc.,* 2 FCC 2d 958, 6 RR 2d 973 (1966).

64. Wetmore further argued that significant public interest and equitable considerations in this case warranted reinstatement of the renewal application or acceptance of it *nunc pro tunc.* The public interest considerations Wetmore asserted were the continuation of her service to the public and maintaining the Commission's ability to make a comparison between the prospective assignee, General, and Gulf Coast for the facility. As equitable considerations, Wetmore stated that her failure to file timely renewal application was inadvertant; that she took immediate measures to achieve compliance with the rules once she discovered such failure; that she has served the Tampa Bay area boating public for 10 years; that a $70,000 contract was at stake; that her legal struggle with Gulf Coast had been extended and costly; and that but for a protracted administrative delay, the assignment would have been consummated prior to expiration of the license. Finally, Wetmore asserted that the Commission may not be hypertechnical and arbitrary in the application of its rules when the sanction imposed is as drastic as dismissal, citing *Natick Broadcast Associates, Inc.,* v *FCC.* 128 U.S. App. D.C. 203, 385 F. 2d 985 (1967).

65. Wetmore also claimed that *Committee for Open Media* v *FCC,* 543 F. 2d 861 (D.C. Cir. 1976), established that the Commission may accept a renewal application after expiration of the license and thereby continue the license in effect. She cited § 21.44 of the rules[27] governing Common Carrier licensees which states that a renewal application filed after expiration of the license will be considered under certain circumstances, and claimed that it demonstrated that the Commission could exercise its discretion without contravening section 307(d) of the Act, which specifies the term of a license. Wetmore claimed that the June 11, 1976, letter was a predetermination of the renewal and reinstatement applications and jeopardized Wetmore's contract to assign her marine facilities.

66. On July 22, 1976, Gulf Coast filed its opposition to the petition for reconsideration. Gulf Coast supported the Bureau's action. Gulf Coast also asserted that Wetmore had not been injured since the events resulted from her failure to file a timely renewal application, not from the Bureau dismissing the assignment application as moot. Gulf Coast asserted that Wetmore's claimed equitable considerations were irrelevant. In its July 29, 1976 petition to dismiss or deny Wetmore's application for reinstatement of the license for KTA 420, Gulf Coast contented that section 308(a) of the Communications Act of 1934, as amended, precludes the Commission from extending the term of Wetmore's license for KTA 420 beyond the date it expired, May 28, 1976. It also asserted that there is no provision in the Act or the rules for *nunc pro tunc* treatment of an application as Wetmore requested. In response to Wetmore's opposition to the petition to dismiss or deny, Gulf Coast argued that none of the cases cited by Wetmore supported *nunc pro tunc* treatment of her late filed renewal application.

67. By telegram dated December 3, 1976, Wetmore was granted temporary authority by the Chief, Safety and Special Radio Services Bureau, to operate on Channel 27 until an interim operator was selected. On December 22, 1976, the Chief, Safety and Special Radio Services Bureau, directed a letter to Mrs. Wetmore concerning the petition for conditional grant of either application for reinstatement or her application for renewal of the license for KTA 420.[28] The letter stated that since no renewal application was filed prior to the expiration of the license for KTA 420 on May 28, 1976, there was nothing to renew when the renewal application was subsequently filed and that Wetmore's renewal application filed on June 16, 1976, would be treated as an application for a new license. The letter also denied Wetmore's application for reinstatement of the license for KTA 420. The letter reiterated that Wetmore was granted authority to operate on Channel 27 pending the determination of who should render the interim operation needed until resolution of the mutually exclusive applications for that channel. The letter also stated that the cases which Wetmore cited in support of her claims were inapposite since in those cases, the licensees had filed timely renewal applications and thus did not allow their authorizations to lapse as did Wetmore.

68. The Bureau's determination that the assignment application will be dismissed as moot is affirmed. There is no rule governing public coast stations which allows filing of a renewal application after expiration of a license. We are not persuaded that there are any compelling public interest or equitable considerations warranting a departure from the usual requirement that a renewal application must be filed before expiration of license. As of the expiration date of the license for KTA 420, Wetmore had no license for that facility; she had nothing to assign.

69. As part of its July 29, 1976, petition to dismiss or deny Wetmore's application for reinstatement of the license for KTA 420 and its November 5, 1976, petition for conditional grant of its second working frequency application, Gulf Coast asserted that since Wetmore's application could only legally be considered as an application for a new station license, § 81.303(b) applied[29] and Wetmore had not dem-

[24] The June 11, 1976, letter asked Wetmore and General if the assignment application for KWB 426 was still being pursued in light of the determination that the application for assignment of KTA 420 was moot. In response General and Wetmore stated that the assignment applications for both Wetmore facilities were being pursued.

[25] This application was assigned File No. 61-M-L-66 and placed on public Notice Report No. 810 dated June 29, 1976.

[26] Wetmore took this position in her petition for reconsideration of the Bureau's June 11, 1976, determination that the assignment application for KTA 420 was moot; in her opposition to Gulf Coast's July 29, 1976, petition to dismiss or deny her application for reinstatement; and in her opposition to Gulf Coast's November 5, 1976, Petition for Conditional Grant of its second working frequency application.

[27] Wetmore cited § 21.34 but it appears that § 21.44 was intended.

[28] The grant of operating authority to Wetmore in the telegram of December 3, 1976, precluded grant of Gulf Coast's conditional grant request.

[29] Section 81.303(b) provides that: (b) When calculated in accordance with Subpart R of this Part, the service areas of two or more Class III-B public coast stations shall not be duplicated in more than 20 percent of the navigable waters within the service area of any station: *Provided, however,* That, (1) an application may be filed for a station to serve a boating locality in which

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onstrated compliance therewith. Gulf Coast also argued that there would be no valid basis for a waiver of § 81.303(b), and that since Wetmore was seeking the license only so she could assign it, it presented trafficking issues.

70. Wetmore filed oppositions to Gulf Coast's petitions. Wetmore argued that, even if § 81.303(b) were applicable, it should be waived because of "equitable considerations," including the facts that a renewal application was inadvertently not filed and that Wetmore had been pursuing the assignment application for a long period of time. Wetmore contended that § 81.303(b) is not intended to conserve spectrum (as Gulf Coast contended) but rather to insure viability of local stations. Wetmore asserted that § 81.303(b) had been waived with respect to the application of Gulf Coast's predecessor for less compelling reasons than presented here. *A. P. St. Philip, Inc.*, 40 FCC 2d 4, 26 RR 2d 1547 (1973). Finally Wetmore denied the trafficking allegation.

71. In reply, Gulf Coast disputed Wetmore's claim that the purpose of § 81.303(b) was to insure viability of stations. Gulf Coast contended that Wetmore had not demonstrated any basis for a waiver of § 81.303(b). According to Gulf Coast, Wetmore should have to make "more than just a routine, undocumented public interest showing," but had made no showing concerning the volume of traffic on her Channel 27 operation either prior to expiration of the license for KTA 420 or during the term of the STA.

72. The petition to deny will be denied except to the extent that an issue will be added to determine if Wetmore's application for Channel 27 complies with § 81.303(b) of the rules, and if not whether waiver of that rule is warranted. Clearly, Wetmore's application for Channel 27 at St. Petersburg Beach, Fla., can only be considered as an application for a new facility. As such, it must comply with § 81.303(b) of the rules. Nonetheless, in light of the fact that Wetmore had been operating a Channel 27 facility at St. Petersburg Beach for 5 years until her license for that facility expired on May 28, 1976, she will be afforded the opportunity to show that waiver of § 81.303(b) of the rules is warranted.

73. Gulf Coast's allegation that a trafficking issue is presented by Wetmore's applying for a license which she intends to assign will be rejected. The application for a new facility for Channel 27 was filed by Wetmore because she could not obtain renewal of the license for KTA 420, since she had allowed the license to expire without filing a renewal application. If she had filed a timely renewal application for KTA 420, there would be no question of trafficking. Thus, under the specific facts of this unique situation, we will not specify a trafficking issue.

Interim Operating Authority

74. On April 20, 1977, the Chief, Safety and Special Radio Services Bureau, and the Chief, Common Carrier Bureau, released a *Memorandum Opinion and Order* (Mimeo No. 80925) granting Wetmore interim authority to operate a Public Coast III-B station on 161.950 MHz (Channel 27). The order stated that grant to Wetmore would permit uninterrupted service on Channel 27 and would eliminate any confusion to the boating public that might be caused by a change in the operation of Channel 27. The order denied Gulf Coast's request for interim operating authority. The foregoing applications for review and the petition for extraordinary and equitable relief have been rendered moot by that order.

75. On May 20, 1977, Gulf Coast filed an Application for Review of that *Memorandum Opinion and Order*, Gulf Coast argued that the grant of Wetmore's application for interim authority without a comparative hearing violated Gulf Coast's *Ashbacker*[30] rights and its rights under section 309(e) of the Communications Act of 1934, as amended. Gulf Coast claimed that since the grant of interim authority to Wetmore precluded a grant to Gulf Coast of similar authority, a comparative hearing was required, and it contends that its proposal was "not given the benefit of any comparative evaluation."

76. Gulf Coast also asserted that grant to one applicant in the posture of this case violated Commission policy, citing *Community Broadcast Co.* v. *Federal Communications Commission*, 274 F. 2d 753 (1960); *Sandern of Iowa, Inc.*, 20 FCC 2d 546 (1969); *Cliften Forge Radio*, 34 FCC 2d 763 (1972); and *Billy D. Pirtle*, FCC 72-764, 25 R.R. 2d 205 (1972). Gulf Coast also asserted that the order did not comply with the requirement of section 555(e) of the Administrative Procedure Act ("the APA") that, when a petition is denied, the agency denying the petition must give notice of the denial together with a brief statement of the grounds therefor. Gulf Coast contended that the order in effect denied its petition to deny Wetmore's conditional grant proposal without providing any statement of the grounds for the denial and without even mentioning that petition.

77. Gulf Coast further alleged that the Bureaus committed prejudicial error by giving Wetmore a preference solely because she had been the existing operator on channel 27. Gulf Coast contented that there was no factual support for the finding that a grant to Wetmore would permit continued, uninterrupted service and would avoid confusion from a change in the operation of channel 27. Accordingly, Gulf Coast asserted that the only reason that Wetmore's application was granted was as a result of the Bureaus' giving her preference solely on the basis that she was the existing operator on channel 27. Finally, Gulf Coast asserted that Wetmore was ineligible to receive the grant of interim operating authority because she did not establish traffic loading on the channel to indicate her need for such a grant.

78. On June 6, 1977, Wetmore and General each filed oppositions to Gulf Coast's application for review. Wetmore contended that interim grants can be made without violating a party's *Ashbacker* rights, citing *Peoples Broadcasting Co.* v. *United States*, 93 U.S. App. D.C. 78, 209 F. 2d 286 (1953); and *ATS Mobile Telephone, Inc.*, 35 FCC 2d 443, 25 RR 2d 325 (1972). She maintained that where the public interest is clear and the subject of explicit findings, as in this case, such a grant may be made without a hearing. Furthermore, Wetmore denied that the grant of interim authority to one of two competing applicants was improper. She contended that since factors which might prejudice a "full and fair" comparative proceeding (i.e., the investment which an interim grantee would make and the possible advantage which an interim grantee might have as an applicant in the subsequent proceeding) were not present here, a grant of interim authority to one party is not improper. She stated that Gulf Coast cannot claim to have been prejudiced as she

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no station is located and which is at least 30 miles from an existing station serving primarily another locality, and for purposes of this rule section a boating locality is defined as a port, marina, or harbor with docking or servicing facilities for not less than 10 commercial or 50 noncommercial vessels that are equipped with radio; or (2) an application may be filed for a station having a service area which duplicates more than 20 percent of the service area of an existing station if the assigned channel occupancy of the existing station exceed 50 percent during the station's specified busiest hours of operation. An application based on channel use of an existing station and preposing duplication of more than 20 percent of the coverage area of the existing station, shall be accompanied by a record of monitorings or other satisfactory information to show that for any 4 days within a 10-consecutive-day period of station operation in each of 3 months immediately prior to the filing of the application, the assigned frequency, or frequencies, was in use for exchanging communications at least 50 percent of the 3 busiest hours of each day, of which not more than half of the use time may consist of waiting or setup time.

[30] *Ashbacker Radio Corp.* v. *FCC*, 326 U.S. 327 (1945).

will not have to make such an additional investment and because the Bureau's order of April 20, 1977, explicitly provided that the grant to Wetmore would not inure to her benefit or have any effect upon the ultimate disposition of the mutually exclusive applications. Moreoever, Wetmore noted that Gulf Coast had applied for such authority itself. Accordingly, she argued that Gulf Coast is taking an inconsistent position by objecting to the same sort of individual interim operating authority for which Gulf Coast has applied.

79. Wetmore also disputed Gulf Coast's contention that the Bureaus violated section 555(e) of the APA. She stated that it is clear from the memorandum opinion and order that the same public interest factors which provided the grounds for the grant of her interim application were also the grounds for the denial of Gulf Coast's petition to deny. Wetmore also maintained that she was not the recipient of any improper preference on the basis of her status as the existing operator. Citing *Consolidated Nine, Inc.* v. *Federal Communications Commission*, 131 U.S. App. D.C. 179, 403 F. 2d 585 (1968), she stated that existing operation is a factor entitled to weight. Furthermore, Wetmore stated that the findings relative to the confusion which could result from a grant of interim authority to Gulf Coast and the concern for uninterrupted service to the boating public were proper bases for the action. Wetmore further contended that "contrary to Gulf Coast's assertions, no showing of the volume of traffic on channel 27 is required under the Commission's rules" because she was not adding a second channel to an existing facility. She contended that her application is governed by section 81.301 of the Commission's rules which requires only that "the public interest, convenience or necessity would be served by a grant" of her application. Wetmore maintained that her application did make such a showing and that no requirement of a showing of channel loading was necessary.

80. General's opposition to application for review contained many of the same arguments as made by Wetmore. General contended that an interim grant of authority may be made without violating the parties' *Ashbacker* rights. General cited *Peoples Broadcasting Co.* v. *United States, supra*, to support its argument that a full hearing was not required and that such an interim authorization can be made without a hearing if it is clear that such a grant will serve the public interest. Such public interest was found by the Bureaus, General states, and therefore the grant was proper. General also asserted that while there is a policy against granting an individual request for interim operating authority among competing applicants, such an individual grant can be made if the public interest requires. General contended that the Bureaus made such a finding in this instance.

81. General also disputed Gulf Coast's contention that section 555(e) of the APA was violated. General argued that Gulf Coast's petition to deny Wetmore's conditional grant proposal was not dealt with in the Bureaus' April 20, 1977, order for the reason that the petition to deny was not filed against Wetmore's application for interim authority but rather against Wetmore's conditional grant request. According to General, the Bureaus were under no obligation to deal with Gulf Coast's petition to deny in the April 20, 1977, order, as Wetmore's conditional grant proposal had been denied on December 22, 1976, and was no longer under consideration. Finally, General argued that the fact of Wetmore's existing operation was entitled to be given weight and that no improper procedural preference was given Wetmore. General stated that the existing operation was only one of a number of factors weighed and accordingly the decision was proper.

82. In its June 16, 1977, reply, Gulf Coast admitted that a hearing is not required for the issuance of every temporary or short-term license, but maintained that *Peoples Broadcasting Co.* v. *United States, supra*, cited by both Wetmore and General in their oppositions, was not on point and that the interim authority granted Wetmore was no longer a "temporary measure" alleviating the need for an *Ashbacker* hearing. Gulf Coast further stated that the public interest was not made clear and it was not the subject of explicit findings in the action.

83. Gulf Coast's arguments with regard to the Bureau's grant of interim authority to Wetmore are without merit. Interim grants of authority may be made absent a hearing without violating the parties' *Ashbacker* rights. *Peoples Broadcasting Co.* v. *United States, supra; Beloit Broadcasters, Inc.* v. *Federal Communications Commission*, 125 U.S. App. D.C. 29, 365 F. 2d 962, 7 R.R. 2d 2155 (D.C. Cir. 1966); *Consolidated Nine, Inc.* v. *Federal Communications Commission, supra; WNJR Radio Company*, 34 FCC 2d 923 (1972). Furthermore, a grant of interim authority can be made without a hearing when it is clear that the public interest would be served by such a grant. *Beloit Broadcasters, Inc., supra.*

84. The Bureaus concluded, and we agree, that it is in the public interest to avoid any interruption in service to the boating public and to prevent any confusion to the boating public which would result from changing the operator of channel 27 in the Tampa Bay area.

85. Next, Gulf Coast claimed that its rights pursuant to Title 5 U.S.C. § 555(e) were violated because the order failed to specify the grounds for denial of Gulf Coast's petition to deny Wetmore's petition for conditional grant. Wetmore's conditional grant proposal was rejected by the Bureau in a letter dated December 22, 1976. The letter specifically refused to grant conditionally either Wetmore's application for reinstatement or application for renewal of the license for station KTA 420. Accordingly, Gulf Coast's petition was rendered moot by the Bureau's action of December 22, 1976, and there was no reason for the April 20, 1977, order to deal with it.

86. Gulf Coast also complained of a lack of factual support for the Bureaus' action because there was no showing made by Wetmore of the traffic on her channel 27 facility and there was no basis for the Bureaus to conclude that the existing VHF public coast station services in the Tampa Bay area could not adequately satisfy the need for service absent a channel 27 operation. These are issues to be resolved at a comparative hearing relative to the parties' various applications for a full-term license. In the instant situation, the Bureaus made sufficient factual findings to support their conclusion that the public interest would clearly be served by a continuation of the present operation pendente lite and made this the subject of explicit findings. That is the test to be applied, and that test was met. *Consolidated Nine, Inc.* v. *F.C.C., supra.* (See paragraphs 7 and 8 of the memorandum opinion and order released April 20, 1977.) Gulf Coast's assertion that, "it was prejudicial error for the Bureaus to give preference to Wetmore solely on the basis that she was the existing operator on Channel 27" is inaccurate in a number of regards. The statement presumes that such a preference was given. The cases cited by Gulf Coast relative to this argument[31] prohibit giving a procedural preference to the existing operator but explicitly permit the fact of present operation to be weighed. No preference procedural or otherwise, was accorded Wetmore. However, Wetmore's prior operation on channel 27 was entitled to and was given weight. Gulf Coast cannot claim prejudice in this regard since Wetmore's interim operation will not involve any further investment which could prejudice a selection of a regular licensee (if any) and because the Bureaus specifically noted that grant of interim operating authority would

[31] *Consolidated Nine, Inc.* v. *F.C.C., supra; Community First Corp.* v. *F.C.C.*, 403 F. 2d 578 (U.S. App. D.C., 1968).

have no effect upon the ultimate disposition of the matter and the grant would not inure to her benefit in the comparative aspect of this proceeding. Accordingly, Gulf Coast's application for review will be denied.

GULF COAST'S SECOND WORKING FREQUENCY APPLICATION

87. Gulf Coast filed an application for a second working frequency on May 24, 1974. The application was put on public notice June 6, 1974.[32] Wetmore filed a timely petition to deny the application on July 8, 1974. She claimed that Gulf Coast had not complied with the requirements of section 81.304(b)(22) of the rules, which states in pertinent part:

In assigning frequencies in the band 156–162 MHz to a class III–B public coast station, initial grants will be limited to one working frequency. An additional frequency may be assigned * * * if the channel occupancy of the assigned frequency, or frequencies, exceeds 40 percent during its specified busiest hours of operation. An application for assignment of an additional working frequency based on channel occupancy shall be accompanied by a record of monitorings, or other satisfactory information, to show that for any 4 days within a 10-consecutive-day period of station operation in each of 2 months immediately prior to the filing of the application, the assigned frequency, or frequencies, was in use for exchanging communications at least 40 percent of the 3 busiest hours of each day, of which not more than half of the use time may consist of waiting or setup time.

According to Wetmore, Gulf Coast was required to show that each hour or the three busiest hours of the four days met the requirements. Finally, Wetmore asserted that Gulf Coast had failed to establish its financial qualifications since it had not attached a current balance sheet and had not referenced which of its files contained a balance sheet on which it relied.

88. By letter dated September 9, 1974, Gulf Coast amended its application to submit an additional traffic loading study and a financial statement dated August 31, 1974. On September 10, 1974, Gulf Coast filed an opposition to petition to dismiss or deny. Gulf Coast stated that its additional traffic loading study demonstrated that its application met the requirements of section 81.304(b)(22) of the rules, and that the financial statement demonstrated that it could meet the anticipated costs of the proposed additional channel. By a letter dated January 27, 1975, Gulf Coast amended its application with an additional traffic loading study.

89. In order to determine if Gulf Coast's traffic loading study satisfies the requirements of section 81.304(b)(22), it is necessary to review the history of the section. The rules, as originally adopted in 1972, required an applicant:

* * * by a record of monitorings, or other satisfactory information, to show that for any three periods of 5 consecutive days of station operation, during the six month period immediately prior to the filing of the application, the assigned frequency, or frequencies, was in use for exchanging communications at least 40 percent of the time for any 12 hours of daily operation, of which not more than half of the use time may consist of waiting or setup time for calls.[33]

In adopting the rule, the Commission stated that average daily use was the criterion it would employ to determine if an applicant demonstrated the required need for the additional working frequency. In reconsidering the *Report and Order*,[34] the rule was amended to its present form (paragraph 87, *supra*). The rule now states in pertinent part that the channel occupancy must be "* * * at least 40 percent of the 3 busiest hours of each day, * * *." We recognize that the language of the ruled is somewhat confusing. To clarify the rule, we hold that the rule is to be applied on the basis of average daily use. Gulf Coast's channel loading showing meets that standard and complies with 81.304(b)(22). Since less than half of the use time on each day was set up time, Gulf Coast has met that requirement also.

90. In its application for a second working frequency, Gulf Coast had to demonstrate that it had sufficient funds available to construct and operate the proposed facility for 1 year without revenues.[35] Gulf Coast listed $7,300 as its estimated cost of equipping the proposed facility. The estimate appears to be reasonable. However, Gulf Coast did not estimate its first year operating expenses. Thus, an issue will be specified to ascertain Gulf Coast's first year of operation costs. On its August 31, 1974, balance sheet, Gulf Coast listed the following current assets and liabilities:

Cash	$4,095
Accounts receivable	4,308
Prepaid expenses	451
Total current assets	8,854
Accounts payable	241
Long-term debt due within 1 year	1,524
Total current liabilities	1,765

The degree of liquidity of Gulf Coast's accounts receivable was not indicated, so it cannot be considered a liquid asset.[36] Prepaid expenses is not a liquid asset. Accordingly, the only liquid asset which can be considered is cash in the amount of $4,095. Even without subtracting Gulf Coast's current liabilities, of $1,765, the amount falls short of Gulf Coast's own estimate of costs to construct and operate the proposed facility for 1 year without revenues. Therefore, and issue must be specified to determine if Gulf Coast has sufficient funds available to construct and operate the proposed facility.

GULF COAST'S AMENDMENT TO CHANNEL 27

91. Gulf Coast's June 1, 1976, amendment to change the frequency sought is a substantial amendment as defined by section 1.962(c) of the rules. Section 1.918(b) provides that when and application is mutually exclusive with another application, or when a petition to deny has been filed, an application to amend the application substantially must be filed not later than 30 days after the filing of the petition to deny or the public notice of the mutually exclusive application. Wetmore filed a petition to deny Gulf Coast's second working frequency application on July 8, 1974. Therefore, Gulf Coast would have had to amend by August 7, 1974. However, in August 1974, Gulf Coast could not have amended to channel 27 because Wetmore still has a license for channel 27 in Tampa.

92. Obviously, section 1.918(b) does not contemplate a situation where the amended frequency was not previously available. Under the unique facts of this proceeding, we will not apply 1.918(b) to bar the Gulf Coast amendment. Good cause exists for waiver of section 1.918(b) and the Commission, on its own motion, will waive the rule and accept Gulf Coast's amendment.[37]

93. On June 23, 1976, Gulf Coast filed a request for immediate grant of its application or for interim special temporary authority[38] with respect to its application for a second working frequency. Gulf Coast submitted a traffic study performed in May 1976 which it claimed demontrated that the traffic loading conditions on its station exceeded the requirements of section 81.304(b)(22) of the rules. Moreover, Gulf Coast stated that it would order

[32] By a letter received by the Commission on June 1, 1976, Gulf Coast amended its application for a second working frequency for KBZ 383 from 161.825 MHz (channel 84) to 161.950 MHz (channel 27).

[33] 35 FCC 2d 642 (1972).

[34] 37 FCC 2d 938 (1972).

[35] *West Indies Communications, Inc.*, 33 FCC 2d 851, 23 R.R. 2d 1002 (1972); *Ultravision Broadcasting Company*, 1 FCC 2d 544, 5 R.R. 2d 343 (1965).

[36] *Communico Oceanic Corp.* 38 R.R. 2d 821 (1976); *David Ortiz Radio Corp.*, 47 FCC 2d 28, 30 R.R. 2d 475 (1974); *Miami Broadcasting Corporation*, 9 FCC 2d 694, 10 R.R. 2d 1037 (1967).

[37] Neither Wetmore not Gulf Coast addressed the question of the applicability of section 1.918(b) to Gulf Coast's amendment.

[38] By a letter dated August 6, 1976, the Chief, Safety and Special Radio Services Bureau, denied Gulf Coast's requests for immediate grant of its application for a second working frequency or for interim special temporary operating authority.

a foreign exchange line to allow calls to and from St. Petersburg Beach at the single message unit rate.

94. On July 16, 1976, General filed its petition to deny amendment of pending application and request for immediate grant of application or for interim special temporary authority, which was in regard to Gulf Coast's amendment of June 1, 1976, and Gulf Coast's June 23, 1976, request. General objected to the requests claiming they would not increase the number of maritime mobile facilities in the Tampa Bay area and would revive the conflict that had existed between Gulf Coast and Wetmore; that grant of the amended application would exacerbate channel congestion; that General was ready to continue the channel 27 operation without a lapse in service, while Gulf Coast would have to construct a new facility; and that to allow Gulf Coast to obtain the license for operating channel 27 after General had an assignment application pending for some time would be an abuse of the administrative process.

95. On August 6, 1976, Gulf Coast filed an opposition to Wetmore's and General's petition to deny.[39] Gulf Coast argued that General's arguments that grant to Gulf Coast would not expand the number of facilities available in Tampa and would rekindle controversy were not grounds for refusal to grant an application (section 309(b) of the Act). On August 18, 1976, General filed its reply to Gulf Coast's opposition. General accused Gulf Coast of trying "to wiggle out of the settlement agreement."[40] General stated that the public interest would not be served by allowing Gulf Coast to overturn the agreement with Wetmore because of Wetmore's "oversight."

96. General has however, set forth no basis for denial of the amendment. Upon the expiration of the license for KTA 420 the frequency 161.950 MHz (channel 27) became available. The fact that a grant of Gulf Coast's amended application would not increase the number of maritime mobile public correspondence channels from that which existed before May 28, 1976, is not determinative. If channel congestion exists, applications meeting the requirements of section 81.304(b)(22) of the rules could be granted thus increasing the number of channels available. Nor is the so-called "settlement" between Gulf Coast and Wetmore or whether it has been breaqched a basis for denial of the amendment.

WETMORE'S HARASSMENT, ABUSE OF PROCESS, AND "STRIKE" ALLEGATIONS AGAINST GULF COAST

97. In her December 16, 1974, opposition to Gulf Coast's petition to deny the assignment applications, Wetmore asserted that the petition to deny was another instance of Gulf Coast's efforts to induce Wetmore to sell her marine facilities to Gulf Coast. The offers of purchase began in 1968. Counsel for Gulf Coast sent a letter dated August 9, 1972, to counsel for Wetmore which included another purchase offer. The letter stated as follows:

> As you are aware, A. P. St. Philip, Inc. has previously attempted to settle the controversy in the Tampa public coast station proceeding by offering to purchase at a reasonable price Mrs. Wetmore's marine station facilities at Tampa and St. Petersburg Beach, subject to the approval of the Federal Communications Commission, thereby avoiding what appears will be a costly, protracted hearing for both parties. This offer remains open.
>
> We would now like to know whether there is any genuine intent on Mrs. Wetmore's part to consider the acceptance of this offer as we are presently in the process of preparing for filing with the FCC a petition requesting the issuance of an order to show cause why Mrs. Wetmore's St. Petersburg Beach marine license should not be revoked, or in the alternative, for acceleration of her renewal filing under Section 81.43 of the Commission's Rules. In support of this petition, we have gathered a good deal of information and materials, documented and supported by affidavit, which we believe adequately demonstrate Mrs. Wetmore's lack of qualifications to continue to be a Commission licensee of her marine facilities and, quite possibly, her RCC facilities as well. These included, among others, evidence of improper operational practices, inadequate financial resources and serious violations of the Commission's rules and authorizations, only some of which have been uncovered by FCC investigative personnel. We also have reason to believe that exploration of the facts and materials now in our possession may lead to other areas of questionable licensee performance on Mrs. Wetmore's part.
>
> You will understand that we are most reluctant to file such a petition because our client has no quarrel or interest in your client's RCC operations which may nevertheless be jeopardized by the marine filing. If there is any *bona fide* prospect of settling this matter along the lines indicated above, therefore, we should be promptly so informed. For once the petition is filed and the allegations made, the FCC would very likely want to investigate the matter thoroughly and impose appropriate sanctions, including possible institution of license revocation proceedings—even though St. Philip were later to withdraw its petition as a condition of settlement. In other words, the damage done to Mrs. Wetmore by the filing of the petition may not thereafter be easily undone; and could pose a severe impediment to any possible future composition of the differences between Mrs. Wetmore and St. Philip.
>
> We are willing to let you view, without copying, the information and materials in our possession which we intend to use in support of the petition—if there is any reasonable prospect of accommodation at this point. However, we must have Mrs. Wetmore's decision in the matter prior to August 21, 1972, so that we may promptly proceed with the filing of the petition in the event that there is no genuine prospect of settlement.

98. Wetmore asserted that the letter was tantamount to a threat that Gulf Coast would challenge her qualifications with the Commission unless she agreed to sell the facilities to Gulf Coast. Other purchase offers were purportedly made in November 1972, May 1973, and September 1974. Wetmore contended that her September 1974 refusal precipitated the petition to deny. She cited the foregoing as the basis for her assertions that Gulf Coast was harassing her and abusing the Commission's processes.

99. Gulf Coast responded to the allegations in its January 20, 1975, reply to the oppositions to its petition to deny. Gulf Coast claimed the purchase offers were privileged negotiations to settle litigation. According to Gulf Coast, the August 9, 1972, letter was being taken out of context by Wetmore. Gulf Coast stated that the conflict arose when Wetmore protested the application for a new public coast station at Palmetto, Fla., filed by A. P. St. Philip, Gulf Coast's predecessor in interest. Gulf Coast claimed that while the application was in a hearing status, St. Philip offered to buy Wetmore's marine facilities because such a purchase "would avoid the disclosure at the impending hearing of a number of factors which St. Philip believed reflected adversely on Wetmore's qualifications to remain a Commission licensee." On reconsideration the Commission granted the application without hearing.[41] Gulf Coast asserted that Wetmore rekindled the controversy when she petitioned to dismiss or deny its application to establish marine control and repeater stations at Palmetto and Tampa and its application for a second working channel for Palmetto on January 14 and July 8, 1974, respectively. Gulf Coast characterized the petitions as without merit and as having been filed to harass Gulf Coast

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[39] Wetmore's petition to deny is discussed at para. 101, infra.

[40] ON February 18, 1976, Wetmore and Gulf Coast filed with the Commission a request to withdraw their pleadings filed against one another and an executed agreement regarding the manner in which they would conduct their future operations, which they claimed would alleviate previous problems between them. However, as the Commission stated in *Midcontinent Broadcasting Co.*, 57 FCC 2d 285 (1975): "The withdrawal of a pending petition to deny does not afford a licensee a shield from an inquiry * * *. All allegations set forth by petitioners are examined in order to determine if any substantial and material question of fact has been raised as to whether a grant of the challenged application would serve the public interest, convenience and necessity."

[41] *A. P. St. Philip, Inc.*, 40 FCC 2d 4 (1973).

and impede its growth in the Tampa Bay area. Gulf Coast next asserted that its offer to purchase Wetmore's marine facilities in mid-1974 was accepted in principle. During the mid-1974 negotiations, counsel for Gulf Coast purportedly told counsel for Wetmore that he was concerned that Wetmore's past and continuing infirmities as a licensee would delay the assignment applications.

100. On October 2, 1975, Wetmore filed a petition for acceleration of license renewal, or in the alternative, for revocation of license against Gulf Coast. In the petition, she sought a harassment issue against Gulf Coast based on the August 9, 1972, letter and the alleged harassment she set forth in the opposition to Gulf Coast's petition to deny. She also claimed that Gulf Coast's referral to the U.S. Attorney in Tampa of its section 605 allegation against Wetmore was unnecessary, unreasonable, and an abuse.

101. Wetmore also asserted that Gulf Coast abused the Commission's processes. She claimed that Gulf Coast filed its petitions against her to pressure her into selling her stations and to prevent General from acquiring her stations and by so doing abused the Commission's processes. She asserted that Gulf Coast had made false charges against her, citing the section 605 and section 81.312(a) (6) and (7) issues which Gulf Coast requested. Wetmore contended that "the sequence of Gulf Coast's repeated filings" was additional evidence of its abuse of the Commission's processes. Concerning Gulf Coast's supplement to its petition to deny filed July 28, 1975, Wetmore stated that the reason Gulf Coast gave for filing the supplement was that certain matters had come to its attention only recently and could not have been pleaded in the October 15, 1974, petition to deny. Wetmore noted that the allegations about her alleged violations of section 81.312(a)(7) of the rules were based on log entries as early as January 10, 1975, and that Gulf Coast had claimed the violations had occurred routinely for an extended period of time. Wetmore rhetorically questioned why Gulf Coast waited until July 28, 1975, to file the supplement if the foregoing were true. She further asserted that Gulf Coast's August 18, 1975, opposition to Wetmore's request for 10 additional days to respond to Gulf Coast's petition for a cease and desist order was indicative of Gulf Coast's conduct. According to Wetmore, not only did Gulf Coast file unauthorized supplemental pleadings and levy false charges but it also sought to deny its competitor the opportunity to respond. In support of her position Wetmore cited *California Motor Transport Co.* v. *Trucking Limited*, 404 U.S. 508 (1971).

102. Gulf Coast filed its opposition to Wetmore's petition on November 2, 1975. Gulf Coast contended that Wetmore had not shown that Gulf Coast's filings constituted harassment as described in the Review Board in *Chronicle Broadcasting Co.*, 19 FCC 2d 240, 16 R.R. 2d 1014 (1969). Gulf Coast stated that it opposed the grant of the assignment applications to demonstrate that the assignments could not be approved because Wetmore was an unqualified licensee, thus making the frequencies available for application by Gulf Coast. It was also alleged that Gulf Coast and Wetmore had filed the same number of protests against each other's applications. Gulf Coast asserted that its allegations had been well documented while Wetmore's had not been.

103. On July 16, 1976, Wetmore petitioned to deny Gulf Coast's amendment of its second working frequency application filed June 1, 1976. In the petition, she incorporated by reference her October 2, 1975, petition concerning Gulf Coast's qualifications and her reply pleading dated December 9, 1975. Wetmore alleged that Gulf Coast's channel 27 amendment constituted a strike application as defined in *Grenco, Inc.*, 28 FCC 2d 166 (1971). Therein, the Commission held that a strike application is one whose principal or incidental motive or purpose is to obstruct or delay another application. The Commission further indicated four guidelines to determine if an application is a strike application: (1) The timing of the application; (2) the economic and competitive benefit occurring from the application; (3) the good faith of the applicant; and (4) questions concerning a frequency study.

104. With respect to timing, Wetmore stated that Gulf Coast filed the amendment on the first business day after the licensee for KTA 420 expired. The license expired on May 28, 1976. The amendment was signed on May 26, 1976. Gulf Coast's June 23, 1976, STA request to operate on channel 27 contained traffic studies dating back to May 22, 1976. The foregoing showed that the studies were done to support an STA request for channel 27 not channel 84, according to Wetmore. She further asserted that Gulf Coast's amendment to channel 27 was inconsistent with its allegation that there was an emergency need for a second working channel. She claimed that Gulf Coast intended to file for her channel before it could have known that the license had expired, thus demonstrating its intent to obstruct the assignment. According to Wetmore, Gulf Coast would have benefited more from maintaining its channel 84 application than amending to channel 27. By amending to channel 27, Gulf Coast allegedly would face a lengthy delay due to a comparative hearing and the possibility of losing in the hearing. In Wetmore's view, this also demonstrated that Gulf Coast's motivation was to obstruct or delay the assignment.

105. With respect to the good faith aspect of the test set forth in *Grenco, supra*, Wetmore stated that Gulf Coast's STA request for Channel 27 was "*prima facie* evidence of bad faith." Wetmore contended that Gulf Coast chose an "occupied frequency," which would delay a solution to the public's need for another marine working frequency in Tampa Bay. Wetmore finally claimed that the totality of facts in this proceeding established Gulf Coast's obstructive motive for the amendment to Channel 27.

106. Gulf Coast filed its opposition to Wetmore's petition to deny on August 6, 1976.[41] Gulf Coast contended that Wetmore's petition to deny was untimely since she had withdrawn her previous protests to its additional working frequency application as part of the settlement agreement of February 1976. Gulf Coast asserted that Wetmore could only attack the amendment, not matters previously raised and abandoned, and that Wetmore was abusing the Commission's processes by attempting to raise old matters.

107. Regarding Wetmore's "strike" allegation, Gulf Coast stated that, pursuant to § 81.37, a timely renewal application by Wetmore had to be filed between February 28 and April 28, 1976.[42] During May, Gulf Coast decided to file an amendment to specify Channel 27 on June 1, 1976, unless it learned that Wetmore had filed an application by that date. Gulf Coast contended that the amendment was prepared and executed prior to June 1 so it could be filed on that date, and that Gulf Coast recognized the possibility that it could file the amendment on June 1 and later find out that Wetmore had filed an application prior to June 1. Had that occurred, Gulf Coast claimed, it would have withdrawn the amendment voluntarily rather than go through a comparative hearing. Gulf Coast reasoned that if Wetmore filed

[41] The pleading was verified by an affidavit of Gulf Coast's vice president, James C. Pope, who stated that he had personal knowledge of the facts set forth in the pleading.

[42] Section 81.37 of the Commission's rules provides, in pertinent part, that: "All applications for renewal of license must be made during the license term and should be filed within 90 days but not later than 30 days prior to the end of the license term." Since Wetmore's license for KTA 420 was to expire on May 28, 1976, Wetmore was required to file her renewal application between February 28 and April 28, 1976.

after June 1, there would be no comparative hearing because Wetmore's application would be barred by § 81.303(b).

108. Gulf Coast also asserted that its good faith in this matter was demonstrated by the fact that Channel 27 had a higher priority than Channel 84 pursuant to § 81.304(b)(22) and that more ships in the area were equipped with 27 than 84. Gulf Coast further argued that its amendment could not have been intended to impede the Wetmore-General assignment application since the subject license had expired. Gulf Coast suggested that Wetmore could end the dispute by amending her "reinstatement application" to specify Channel 84, which would result in Gulf Coast withdrawing its petition to dismiss or deny the application. Gulf Coast asserted that Wetmore's continued specification of Channel 27 demonstrated her bad faith and that her application was a strike application designed to obstruct Gulf Coast's application. Gulf Coast also denied that any of its actions breached the "settlement agreement," and argued that Wetmore had abused the Commission's processes by filing allegations, then withdrawing them, then trying to reinstate them.

109. Wetmore stated in an August 18, 1976, reply that her petition to deny was filed within 30 days of the public notice of the amendment, so it was timely, and that her petition was limited to the amendment. She stated she incorporated her earlier pleadings to show Gulf Coast's bad faith and to show that the amendment was filed at least in part to obstruct or delay the assignment.

110. In response to Gulf Coast's argument that its amendment could not have been for strike purposes, Wetmore argued that *Sumiton Broadcasting Company, Inc.*, 15 FCC 2d 40 (1968), established that there could be a strike application where the target application had not yet been filed because (in her words) "the focal point of the 'strike' inquiry is the filer's purpose.* * *" Wetmore argued that Gulf Coast's entire course of conduct was designed to: "(1) file on top of Wetmore (or at least run that risk); (2) capitalize upon its adversary's obvious inadvertent oversight before such oversight might be corrected; (3) time the filing after the expiration date to avoid the appearance of a 'strike' purpose."

111. Wetmore argued that Gulf Coast's statement that it would have withdrawn its application had Wetmore filed a renewal application prior to expiration of KTA 420 was an admission that the settlement agreement bound Gulf Coast not to hinder the assignment of Channel 27 to General. therefore, Wetmore asserted, Gulf Coast was obligated not to interfere in her attempt to reinstate the license for KTA 420 so that she could assign it and Gulf Coast's amendment breached this agreement and demonstrated Gulf Coast's bad faith.

112. Wetmore also argued that § 81.304(b)(22) did not require Gulf Coast to apply for the higher priority frequency when it became available, because the boating public had access to Channels 26 and 27 over KWB 426 and KTA 420, satisfying the priority scheme of § 81.304(b)(22) in the Tampa Bay area.

113. Regarding Gulf Coast's claim that her application for channel 27 constituted a strike filing, Wetmore stated that she had "custody of channel 27 for more than 5 years" and still retained "custody of the channel under STA;" that she serves the 900 vessels registered to KWB 426 and the former KTA 420 and another 750 transient vessels; and that the Commission's grant of an STA to her in order to avoid confusion to the users of channel 27 revealed that she could not have been manifesting bad faith by not amending to channel 84.

114. Wetmore's request for the specification of an harassment issue will be denied. Such an issue is appropriate when one party in a proceeding has engaged in an unnecessary, unreasonable, and abusive investigation of another party to the proceeding or witnesses in a proceeding. See, *Chronicle Broadcasting Co.*, 19 FCC 2d 240, 16 RR 2d 1014 (1969); *National Broadcasting Company, Inc.*, 21 FCC 2d 195, 18 RR 2d 74 (1970); and *WIOO, Inc.*, FCC 73R-338, 28 RR 2d 685 (1973). Wetmore has provided no evidence that Gulf Coast pursued such a course of action in the collection of the material it claimed to have in the letter of August 9, 1972, or in the gathering of material which it submitted in the various pleadings it filed in this proceeding.

115. However, the letter of August 9, 1972, from counsel for Gulf Coast to counsel for Wetmore does raise serious questions concerning Gulf Coast's qualifications. It appears that Gulf Coast was threatening Wetmore that, unless she accepted Gulf Coast's offer of purchase, Gulf Coast would file with the Commission whatever material and information it had accumulated against Wetmore. In *Home Service Broadcasting Corp.*, 24 FCC 2d 192 (1970), the Review Board noted its concern with the conduct of an applicant which withheld information from the Commission which the applicant believed to be pertinent to a competing applicant's character qualifications. The information had been withheld during the pendency of settlement negotiations between the two applicants. The Board stated:

> Moreover, the Board is constrained to point out that a serious problem is raised by Natick's "unilaterial" delay in filing this motion because of the pendency of settlement negotiations. The Board looks askance at Natick's deliberate withholding of information that it believed to be pertinent to Home Service's character qualifications during the pendency of settlement negotiations. Not only does such action constitute and inadequate basis for a delay in filing a request for a character qualification issue, but it could lead to serious abuses of the Commission's process, i.e., use of the knowledge of misconduct as leverage for obtaining an agreement to dismiss, or, if the misconduct were never brought to the Commission's attention, approval of reimbursement to a dismissing applicant whose misconduct should be a bar to reimbursement. *Id.*, at 193.

The Board concluded that conduct of that nature "* * * cannot be condoned, for it facilitates an abuse of the Commission's processes." *Id.*, at 196. From all of the foregoing, it appears that Gulf Coast attempted to use whatever information it had about Wetmore's character qualifications to improve its position in purchase negotiations and failed to notify the Commission of the information in its possession for 2 years. Inquiry into Gulf Coast's conduct in this regard is warranted and appropriate issues will be specified.

116. Wetmore's request for a strike issue against Gulf Coast will be granted. Gulf Coast's conduct beginning with the August 9, 1972, letter as set forth above raises substantial questions concerning Gulf Coast's motives in amending to channel 27. Due to the conflicting representations before us, it is necessary to resolve this matter in the hearing.

117. On August 4, 1976, Westside Communications, Inc., and Universal Radio Telephone Media Corp., filed a petition to deny Gulf Coast's application. They claimed standing based on the joint venture agreement of July 1972 between Universal and Wetmore. However, as discussed previously, the joint venture agreement has been declared a nullity. Universal and Westside Communications, Inc., do not have standing with respect to Gulf Coast's application or amendment because they have made no showing of economic injury if Gulf Coast's application as amended is granted. Moreover, the petition was filed more than 30 days after the public notice of the amendment. Accordingly, it was untimely. Since the petition was untimely and the petitioners lack standing, it will not be considered and it will be dismissed.

118. On November 18, 1976, Wetmore filed a renewal application for KWB 426, Tampa, Fla. The application was put on public notice on November 26, 1976. The application was assigned file No. 79-M-RL-116. Be-

cause the issues specified with respect to Wetmore in this proceeding concern her basic qualifications to be a licensee, the renewal application will be made part of this proceeding.

CONSOLIDATION

119. Wetmore also filed a motion to consolidate on October 2, 1975. She sought consolidation of her assignment applications, Gulf Coast's application for a second working frequency, and her petition for institution of renewal or revocation proceedings against Gulf Coast. Wetmore stated that consolidation would serve administrative convenience and that substantially the same issues are involved in these matters, since if Gulf Coast lacks the qualifications to retain its public coast license, it would not be qualified to obtain an additional marine frequency.

120. Gulf Coast filed an opposition to Wetmore's motion to consolidate on November 26, 1975. Gulf Coast asserted that Wetmore's petition for accelerated renewal or revocation would be disposed of without a hearing thus obviating the need to consolidate it for hearing with the applications. Gulf Coast also claimed that since it had established that its traffic loading would meet the requirements of § 81.304(b)(22), there would be no need for a hearing on its second working frequency application.

121. On February 9, 1978, Gulf Coast filed an application for renewal of license for KUZ-383. In light of the questions regarding Gulf Coast's qualifications discussed above, that application will also be designated for hearing in this proceeding.

122. As indicated above, Wetmore and Gulf Coast now have mutually exclusive applications pending. Accordingly, all matters which we believe warrant consideration will be dealt with in a consolidated proceeding.

123. Since the applications of Wetmore and Gulf Coast for authority to operate a Public Coast III-B Maritime Mobile Radio Station on 161.950 MHz in the Tampa Bay area are mutually exclusive, a comparative issue will also be specified so as to determine which of the applications should be granted, if both applicants demonstrate they are otherwise qualified to be licensees.

Accordingly, *it is ordered*, That, pursuant to section 309(e) of the Communications Act of 1934, as amended, the above-captioned applications are designated for hearing in a consolidated proceeding at a time and place to be specified in a subsequent order, upon the following issues:

(A) With respect to Dee Wetmore d.b.a. Tampa Radio Marine Service:

(1) To determine the facts and circumstances surrounding the operation, management, ownership, and control of radio stations KTA-420 and KWB-426 during the period July 1, 1972, through April 30, 1973.

(2) To determine, in light of the evidence adduced pursuant to issue (A)(1), whether Dee Wetmore violated section 310(b) of the Communications Act of 1934, as amended and § 1.924 of the Commission's rules and, if so, the effect on her basic or comparative qualifications.

(3) To determine the facts and circumstances surrounding Dee Wetmore's monitoring and use on disclosure, if any, of conversations between Gulf Coast and other parties.

(4) To determine, in light of the evidence adduced pursuant to issue (A)(3), whether Dee Wetmore violated section 605 of the Communications Act of 1934, as amended, and, if so, the effect on her comparative qualifications.

(5) To determine whether Dee Wetmore required deposits prior to providing service.

(6) To determine, in light of the facts adduced pursuant to issue (A)(5), whether Dee Wetmore violated section 203 (b) and (c) of the Communications Act of 1934, as amended, and, if so, the effect on her basic or comparative qualifications.

(7) To determine, whether Dee Wetmore violated § 81.312(a)(7) of the Commission's rules, and, if so, the effect on her basic or comparative qualifications.

(8) To determine whether Dee Wetmore's application for a new public coast III-B station on 161.950 MHz complies with § 81.303(b) of the Commission's rules, and, if not, whether the requirements thereof should be waived.

(B) With respect to Gulf Coast Communications, Inc.

(1) To determine the facts and circumstances surrounding the preparation and execution of James C. Pope's July 21, 1975, affidavit and its filing as part of Gulf Coast Communications, Inc.'s "Petition for Order to Cease and Desist."

(2) To determine the facts and circumstances surrounding Gulf Coast Communications, Inc.'s monitoring and use or disclosure, if any, of conversations between Dee Wetmore d.b.a. Tampa Radio Marine Service and other parties.

(3) To determine, in light of the evidence adduced pursuant to issue (B)(2), whether Gulf Coast Communications, Inc. violated section 605 of the Communications Act of 1934, as amended, and, if so, the effect on its basic or comparative qualifications.

(4) To determine whether Gulf Coast violated § 81.312(a)(6) of the Commission's rules, and if so, the effect on its basic or comparative qualifications.

(5) To determine whether Gulf Coast Communications, Inc. in its July 28, 1975, "Petition for Order To Cease and Desist," made misrepresentations or was less than candid in its representations to the Commission concerning alleged interruptions by Wetmore, and, if so, the effect on its requisite qualifications.

(6) To determine Gulf Coast Communications, Inc.'s first year operating costs for the proposed second working frequency.

(7) To determine Gulf Coast Communications, Inc.'s available net liquid assets, to construct and operate the proposed facility.

(8) To determine, in light of the evidence adduced pursuant to Issues (B)(6) and (B)(7), whether Gulf Coast is financially qualified.

(9) To determine whether Gulf Coast Communications, Inc. withheld information regarding Dee Wetmore's qualifications from the Commission and/or used such information in an attempt to enhance its private interests in connection with its efforts to purchase stations KTA 420 and KWB 426 and, if so, the effect on its requisite qualifications.

(10) To determine whether Gulf Coast Communications, Inc.'s June 1, 1976, amendment to its application for a second working frequency was filed for the principal or incidental purpose of obstructing or delaying the application of Dee Wetmore for a new Public Coast III-B Maritime Mobile radio station at St. Petersburg Beach, Fla., or frequency 161.950 MHz, and, if so, the effect on its requisite qualifications.

(C) To determine which applicant for 161.950 MHz would provide the public with better public coast station service based on the following considerations:

(1) Coverage area and potential users therein;

(2) Availability of other public coast station services in the coverage area;

(3) Hours of operation;

(4) Rates and charges;

(5) Ability to participate actively in the safety system;

(6) Personnel available to operate the station and their experience in marine communications; and

(7) Interconnection with landline facilities.

(D) To determine, in light of the evidence adduced pursuant to the foregoing issues which, if any, of the above-captioned applications should be granted.

It is further ordered, That the burden of proceeding with the introduction of evidence with respect to issues A(1), B(2), B(4), B(5), B(6), B(7), B(9), and B(10) shall be on Dee Wetmore; the burden of proceeding with the introduction of evidence with respect to issues A(3), A(5), A(7), and

A(8), shall be on Gulf Coast Communications, Inc.; the burden of proof on every issue shall be on the applicant to which it pertains.

It is further ordered, That the Petition To Dismiss or Deny filed July 8, 1974, by Dee Wetmore is granted to the extent reflected above and is denied in all other respects.

It is further ordered, That the amendment to its application for a second working frequency filed September 9, 1974, by Gulf Coast Communications, Inc. is accepted.

It is further ordered, That the amendment to the application for assignment of license KWB 426 filed September 10, 1974, by General Telephone Co. of Florida is accepted.

It is further ordered, That the "Formal Protest" filed October 15, 1974, by Universal Radio Telephone Media and Westside Communications, Inc. is denied.

It is further ordered, That the Petition To Deny Applications and for Acceleration of Station License Renewals or, In the Alternative, for Institution of License Revocation Proceedings filed October 15, 1974, by Gulf Coast Communications, Inc. is granted to the extent reflected above and is denied in all other respect.

It is further ordered, That the amendment to its application for a second working frequency filed January 27, 1975, by Gulf Coast Communications, Inc. is accepted.

It is further ordered, That the Supplement To Petition To Deny Applications and for Acceleration of Station License Renewals or, in the Alternative, for Institution of License Revocation Proceedings filed July 28, 1975, by Gulf Coast Communications, Inc. is accepted.

It is further ordered, That the Petition for Order to Cease and Desist filed July 28, 1975, by Gulf Coast Communications, Inc. is denied.

It is further ordered, That the Petition for Acceleration of License Renewal or, in the Alternative, for Revocation of License filed October 2, 1975, by Dee Wetmore is denied.

It is further ordered, That the Motion for Consolidation filed October 2, 1975, by Dee Wetmore is granted to the extent reflected above and is denied in all other respects.

It is further ordered, That the amendment to its application for a second working frequency filed June 1, 1976, by Gulf Coast Communications, Inc. is accepted.

It is further ordered, That the Petition for Reconsideration filed July 9, 1976, by Dee Wetmore is denied.

It is further ordered, That the Petition To Deny filed July 16, 1976, by Dee Wetmore is denied.

It is further ordered, That the Petition To Deny Amendment of Pending Application and Request for Immediate Grant of Application or for Interim Special Operating Authority filed July 16, 1976, by General Telephone Co. of Florida is denied.

It is further ordered, That the Petition To Dismiss or Deny filed July 29, 1976, by Gulf Coast Communications, Inc. is granted to the extent reflected above and is denied in all other respects.

It is further ordered, That the Petition To Deny Application filed August 4, 1976, by Westside Communications, Inc. and Universal Radio Telephone Media Corp. is denied.

It is further ordered, That the Application for Review filed January 6, 1977, by Dee Wetmore is denied.

It is further ordered, That the Petition for Extraordinary and Equitable Relief filed January 21, 1977, by General Telephone Co. of Florida is denied.

It is further ordered, That the Application for Review filed January 21, 1977, by Gulf Coast Communications, Inc. is denied.

It is further ordered, That the amendment filed January 28, 1977, by Dee Wetmore is accepted.

It is further ordered, That the Motion to Strike filed March 3, 1977, by General Telephone Co. of Florida is denied.

It is further ordered, That the Application for Review filed May 20, 1977, by Gulf Coast Communications, Inc. is denied.

It is further ordered, That to avail themselves of the opportunity to be heard, the applicants herein, pursuant to § 1.221(c) of the Commission's rules, in person or by attorney, shall within twenty (20) days of the release of this Order, file with the Commission in triplicate a written appearance stating an intention to appear on the date fixed for hearing and to present evidence on the issues specified in the Order.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

[FR Doc. 78-23957 Filed 8-24-78; 8:45 am]

[6712-01]

[FCC 78-548]

MEMORANDUM OF UNDERSTANDING WITH EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

AGENCY: Equal Employment Opportunity Commission and Federal Communications Commission.

ACTION: Memorandum of understanding.

SUMMARY: The Equal Employment Opportunity Commission and the Federal Communications Commission have entered into a memorandum of understanding to establish a joint working relationship to eliminate employment discrimination on the basis of race, sex, national origin, religion, and color at broadcasting stations. The memorandum is intended to eliminate conflict and duplication of effort by the two agencies in administering their respective statutes, the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e et seq., and the Communications Act of 1934, as amended, 47 U.S.C. 151 et seq.

EFFECTIVE DATE: September 25, 1978.

FOR FURTHER INFORMATION CONTACT:

Issie L. Jenkins, Deputy General Counsel, Equal Employment Opportunity Commission, 2401 E Street NW., Washington, D.C. 20506, 202-634-6400 between the hours of 9 a.m. and 5:30 p.m. or Richard Shiben, Chief, Renewal and Transfer Division, Federal Communications Commission, 1919 M Street NW., Washington, D.C. 20554, 202-632-6993 between the hours of 8 a.m. and 4:30 p.m.

SUPPLEMENTARY INFORMATION:

Adopted: July 27, 1978.

Released: August 21, 1978.

In the matter of Memorandum of understanding between the Federal Communications Commission and the Equal Employment Opportunity Commission; Report and order.

By the Commission:

1. The Federal Communications Commission [hereinafter FCC] and the Equal Employment Opportunity Commission [hereinafter EEOC] have under consideration their proposed memorandum of understanding, 43 FR 12936 (March 28, 1978), as well as comments filed by several interested parties.[1]

2. The proposed memorandum sought to formalize a system of cooperation and coordination between the two agencies. In the past such collaboration was intermittent and informal. Indeed, although directed toward a common goal and covering much the same area, each agency charted an independent course, and only occasionally did one agency use the expertise and information of the other. Thus, after extensive negotiations, both agencies agreed to a tentative plan of cooperation and coordination to increase the effectiveness of each agency's equal employment responsibilities and reduce possible duplication of effort.

[1] Appendix A lists those parties filing comments. We will consider all the comments even though many were filed a few days after the time alloted by the public notice.

3. As proposed, the memorandum contained three major parts involving the exchange of information, the handling and referral of discrimination complaints and an automatic inquiry of broadcasters' employment practices by the FCC upon an EEOC finding of reasonable cause and a failure of the parties to conciliate their differences.[2] Initially, the agencies agreed that they would share "any information relating to a broadcast employer's employment policies and practices which may assist each agency in carrying out its responsibilities." This information would include stations' annual employment reports, compliance review reports and investigative files.

4. In addition, the agencies agreed that the FCC would become "an agent of the EEOC" for the "sole purpose" of receiving charges of employment discrimination. The date of filing with the FCC, then, would be deemed to be the date of filing with the EEOC. To effectuate this, the FCC agreed that when it gets a "charge" which comes within its and the EEOC's jurisdicaiton, it would forward the complaint to the EEOC. Further, if the EEOC received a charge which fell without its jurisdiction but within the FCC's jurisdiction, it would refer the matter to the FCC "which will process the complaint in accordance with its own rules, policies and procedures." And if the EEOC got a complaint which fell within both its jurisdiction and the FCC's the EEOC would "process the charge in accordance with its normal procedures." Also, the EEOC promised to send the FCC "quarterly reports to keep the FCC informed of charges against broadcasters."

5. Finally, the memorandum proposed an automatic letter inquiry of certain broadcasters' employment practices. The EEOC agreed to notify the FCC when a reasonable cause determination was made against a broadcaster. In addition, where a reasonable cause finding was made by the EEOC and the complainant and broadcaster failed to settle their dispute through the EEOC's conciliation process, the proposed memorandum required the FCC to send a letter [3] to the broadcaster noting the failure of conciliation and ordering the licensee to "submit any additional comments you wish to make relating to your employment policies and practices to show a grant of your application (or a continuation of your present license) would be in the public interest." The letter then recited the possible action which might be taken ranging from grant of a pending renewal application to designation for hearing. The letter also stated that the FCC might impose "any other appropriate sanction (e.g., forfeiture or revocation)."

6. Pursuant to the public notice, the two Commissions received comments from a variety of organizations. Many of the commentors agreed with the objectives and operation of the proposed memorandum. One, for example, hoped that the accord would "significantly reduce the duplicative efforts by the two agencies as well as the paperwork required for the broadcasters" and that the outlined process would "insure that all charges are investigated and that charge processing is consistent." Most of the groups also suggested changes for expanding the scope of the memorandum. Other groups, particularly broadcasting industry representatives, questioned the fundamental fairness of the proposed agreement. We have considered all the comments, and in light of them, we will amend the proposed memorandum as detailed below.

AUTHORITY

7. At least one commentor appeared to argue that the two agencies lacked the authority to enter into such an agreement of cooperation and that the FCC lacked the statutory power to impose forfeitures for equal employment violations. Further, some commentors argued that the proposed memorandum was unlawful since it proposed to cover broadcast licensees but not "nonbroadcast licensees" and since it altered past FCC treatment of EEOO actions.

8. We are confident that the FCC the EEOC have the authority to enter into the proposed memorandum of understanding. Any explanation of the Commissions' power to enter into such an agreement must begin, we feel, with an examination of the Commissions' respective powers concerning discriminatory employment practices. The EEOC's authority is drawn directly from the Civil Rights Act of 1964, 42 U.S.C. §§ 2000e-5 et seq. (1970), and includes the general power to prevent unlawful discrimination through the Commission's mediation and conciliation.[4] The FCC's authority is more indirect, but no less sound. In establishing the FCC Congress charged the Commission with the regulation of interstate and foreign commerce in order to establish a communications service for all people of the United States. 47 U.S.C. § 151 (1970). Indeed, the Commission is empowered to grant licenses only after determining that the public interest, convenience and necessity will be served by the grant. 47 U.S.C. § 309(a) (1970). Just over a decade ago the Commission, in recognition of the historical exclusion of some groups from the Broadcasting industry, concluded that no one who discriminates against employees or potential employees on the basis of race, color, sex, national origin or religion could be said to be operating in the public interest. *Petition for Rulemaking to Require Broadcast Licensees to Show Nondiscrimination in Their Employment Pratices,* 13 FCC 2d 766 (1968). Since then, the FCC has adopted and enforced various rules forbidding such discrimination [5] not as part a broad mandate to regulate employment discrimination but to assure on an overall basis that the Commission's licensees engage in employment policies and practices which are compatible with their responsibilities as public trustees. *Nondiscrimination in the Employment Policies and Practices of Broadcast Licensees,* 60 FCC 2d. at 229-30. Moreover, this responsibility has been recognized by the courts. In *N.A.A.C.P.* v. *F.P.C.,* 425 U.S. 662 (1976), the Supreme Court noted that the FCC had a responsibility to assure that diverse views, including minority

[2] Generally, the EEOC is charged with investigating complaints "filed by or on behalf of a person * * * alleging that an employer * * * has engaged in an unlawful employment practice." 42 U.S.C. § 2000e-5(b) (1970). These employment practices including failure or refusal "to hire or to discharge * * * or otherwise discriminate" against any individual "because of the individual's race, color, religion, sex, or national origin." 42 U.S.C. § 2000e-2(a)(1) (1970). During the EEOC's investigation the respondent is to be offered an opportunity to submit a statement of its position or evidence with respect to the allegations. 29 CFR § 1601.15(a). If on the basis of its investigation the EEOC finds that "there is reasonable cause to believe that the charge is true, the EEOC shall endeavor to eliminate any such alleged unlawful employment practice by informal methods of conference, conciliation, and persuasion." 42 U.S.C. § 2000e-5(b) (1970). If the complainant and respondent fail to reach some agreement, then the EEOC or the "person aggrieved" may "bring a civil action against any respondent" other than a governmental agency. 42 U.S.C. § 2000e-5(f)(1) (1970). The EEOC's district directors are also empowered to issue determinations as to reasonable cause. 29 CFR § 1601.21(d). The EEOC's rules also provide that the information gathered by the agency shall remain confidential except "such earlier disclosure to the charging party, the respondent, witnesses, and representatives of interested Federal * * * agencies as may be appropriate or necessary to the carrying out of the Commission's functions." 29 CFR § 1601.26.

[3] A model letter was appended to the proposed memorandum.

[4] See supra note 2.

[5] For a history of the Commission's equal employment policies, see *Nondiscrimination in the Employment Policies and Practices of Broadcast Licensees,* 60 FCC 2d 226, 227-30 (1976). It has been suggested that the FCC's authority in equal employment may be unique among Federal agencies in that such regulation "allows minority groups to participate in the vital industry function of informing the public and thereby molding public opinion." Implementation of Equal Employment Opportunity by the Independent Regulatory Commissions Through the Power to Act in the Public Interest: Two Divergent Views, 17 Wm. & Mary L. Rev. 332, 358 (1975).

views, are expressed in programming and included in programming decisions. 425 U.S. at 670 n. 7. And the court of appeals has suggested that FCC employment analysis is appropriate in order to uncover practices which "raise questions about the character qualifications of the licensee." *National Organization for Women* v. *F.C.C.*, 181 U.S. App. D.C. 65, 80, 555 F. 2d 1002, 1017 (D.C. Cir. 1977); *accord Bilingual Bicultural Coalition on Mass Media, Inc.* v. *F.C.C.*, Civil Nos. 75-1855 & 75-2181 (D.C. Cir. May 4, 1978). Thus, we feel that the Commission's authority to prevent employment discrimination is well grounded.

9. Given this recognized responsibility, the FCC retains, as in other areas of its authority, expansive powers to deal with employment discrimination. See, e.g., *National Broadcasting Co.* v. *U.S.*, 319 U.S. 190, 218-19 (1943). Indeed, the Communications Act specifically authorizes the Commission to promulgate such rules or issue such orders "as may be necessary in the execution of its functions," 47 U.S.C. § 154(i) (1970), as well as to institute inquiries concerning "which any questions may arise under any of the questions may arise under any of the provisions of this Act, or relating to the enforcement of any of the provisions of this Act." 47 U.S.C § 403 (1970). Similarly, the EEOC is empowered to "cooperate with and, with their consent, utilize regional, State, local, and other agencies." 42 U.S.C. § 2000e-4(g)(1) (1970). It is under these broad powers, then, that the two Commissions have determined that the public interest can best be served by their formal cooperation and coordination.

10. Further, we believe that this situation is analogous to Reynolds, Metals, Co. v. *Rumsfeld*, 417 F. Supp. 365 (E.D. Va 1976), *aff'd in part and rev'd in part*, 564 F. 2d 663 (4th Cir. 1977), where the court upheld the authority of the EEOC and Labor Department's Office of Federal Contract Compliance Programs (OFCCP) to enter into a similar memorandum of understanding.[6] There, the district court found—and the court of appeals agreed—that the memorandum should stand since it was designed to assist the two agencies in their common goal of eliminating employment discrimination and sense no specific law prevented the two agencies from entering into such an agreement. 417 F. Supp. at 368.[7]

11. In addition, we believe that the FCC has the authority under the Communications Act to impose forfeitures in the equal employment area. The Commission has maintained equal employment rules since 1970, e.g., 47 CFR §§ 73.125, 73.599 & 73.793 (1977), and the Communications Act clearly provides the Commission with express authority to assess forfeitures against any broadcast station which "willfully or repeatedly" violates "any rule or regulation of the Commission prescribed under authority of this Act." Pub. L. No. 95-234 (Feb. 21, 1978).

12. Moreover, we must also reject the contention that the proposed agreement unlawfully singles our broadcast licensees for FCC scrutiny. Equal protection of the laws does not prohibit governmental agencies from making distinctions but rather prohibits those agencies from making arbitrary or unreasonable distinctions. E.G., *Railway Express Agency* v. *New York*, 356 U.S. 106, 110 (1949). We believe, as we and the courts have historically recognized, that broadcasters have unique problems and responsibilities in the area of equal employment. For example, broadcasters have a special obligation to insure that minority voices are heard in program selection. E.g., *N.A.A.C.P.* v. *F.P.C.*, 425 U.S. at 670 n. 7. Therefore, we decline, as we have consistently declined, to approach the peculiar discrimination problems of the businesses we regulate in the same manner. Rather, we will continue to deal separately with their respective employment discrimination problems. Compare *Nondiscrimination in the Employment Policies and Practices of Broadcast Licensees*, 60 FCC 2d 226 (1977), with *Amendment of the Commission's Rules to Require Community Antenna Television Systems and Community Antenna Relay Station Licensees to Show Nondiscrimination in Their Employment Practices*, 34 FCC 2d 186 (1972).

Sharing of Information

13. At least one commentor argued that the proposed agreement would violate the privacy rights attaching to information which the EEOC uncovers in its investigation. However, we disagree since the Civil Rights Act prohibits only "public" disclosure, 42 U.S.C. § 2000e-8(e) (1970), and not disclosure to a governmental agency. Indeed, the EEOC's rules specifically provide for disclosure of information to agencies. 29 CFR § 1601.20 (1977).[8] Nor do we intend to circumvent the meaning of the Civil Rights Act by doing indirectly what the EEOC is prevented from doing directly. the FCC has specifically agreed in the momorandum to respect the EEOC's confidentiality provisions, and we believed that the sharing of information will not necessarily lead to public disclosure. However, in view of the comments, we will emphasize the nondisclosure provision of the memorandum by placing it in part I of the agreement; in this way there should be no mistake that we intend the confidentiality provision to apply to all shared information which is protected by the Civil Rights Act.[9]

14. One commentor also noted that the memorandum's provision for quarterly reports to be made by the EEOC to keep the FCC informed of discrimination charges against broadcasters was located in a paragraph dealing with the processing of charges which come within the jurisdiction of both the FCC and EEOC. In order to emphasize that the quarterly reports will contain all pending EEOC charges against broadcasters, the wording of provision has been clerified and moved to part I of the momorandum.

Agency

15. One commentor suggested that the agency relationship envisioned by the proposed memorandum is invalid, but we must reject this contention. We emphasize that the relationship indicated by the agreement is strictly limited: the FCC agrees only to become a conduit for formal discrimination charges falling within the EEOC's jursdiction. In this regard, then, the relationship is similar to the one approved by the *Reynolds* court. 564 F. 2d at 667-69. Further, it involves no delegation of any authority between

[6] The agency relationship was the only part of the EEOC-OFCCP memorandum which was invalidated by the district court. 417 F. Supp. at 362. However, the court of apeals disagreed and upheld the agency relationship envisioned by the agreement. 564 F. 2d at 670. See also infra at para. 15. The OFCCP, like the FCC, has powers beyond more conciliation and mediation. In fact, the office is authorized to withheld, suspend or terminate Federal contracts or assistance programs.

[7] We also note that President Carter recently order the EEOC to initiate cooperative programs, "including the development of memorandum of understanding between agencies, designed to improve the coordination of equal employment opportunity compliance and enforcement" and ordered all Federal agencies to cooperate with and assist the EEOC in its efforts. Exec. Order No. 12067, 43 FR 28967 (July 5, 1978).

[8] While legislative history on the nondisclosure provision is scarce, it seems that there was no intention to prohibit Federal agencies from securing and using information gathered by the EEOC. For example, Senator Humphrey, in introducing the compromise bill which ultimately became the Civil Rights Act, noted that the nondisclosure porvision of the Act was "not intended to hamper Commission investigations or proper cooperation with other State and Federal agencies, but rather is aimed at the making available to the general public of unproven charges." 110 Cong. Rec. 12723 (1964).

[9] We do feel, however, that the nondisclosure provisions of the Civil Rights Act prevent the suggestion from one commentor that the quarterly reports to be furnished by the EEOC to the FCC should also be placed in broadcasters' public files. This of course, will not prevent the FCC from developing its own public information concerning discrimination complaints.

the FCC and the EEOC. Indeed, the referral of complaints to the EEOC is specifically made "in addition to any separate action [the FCC] may make * * * within the context of [the Communications Act's] public interest finding." And the EEOC retains the authority to "process the charge in accord with its normal procedures" where the EEOC has jurisdiction. Thus, we find the limited agency relationship envisioned by the proposed accord to be valid.[10]

PROPOSED INQUIRY

16. Most of the criticism of the memorandum focused on the proposed inquiry triggered by a failure of conciliation.[11] The proposed inquiry, many commentors argued, would lead to a denial of "due process" in the sense that an inquiry would raise a presumption of discrimination based on an interlocutory finding of the EEOC. Further, many commentors argued that the timing and automatic nature of the inquiry would put undue pressure on broadcasters to conciliate claims whatever the merits to avoid "further entanglement with the FCC." Thus, the effect would be to "wholly deprive broadcast licensees of due process to which they are entitled under the Civil Rights Act."

17. Moreover, many broadcasters complained of the breadth of the proposed inquiry. As one noted, the proposed inquiry would be directed to broadcasters' overall employment policies rather than the "facts and circumstances surrounding the specific discrimination charges." On the other hand, one commentor worried that any inquiry into the specific charges would usurp the funtions of the EEOC.

18. In addition, one commentor described the envisioned procedure as "an open invitation to duplicative proceedings" since even after an independent FCC inquiry is begun the complainant or the EEOC could sue the broadcaster in Federal court on the same facts which trigger the FCC's inquiry. Thus, one commentor recommended that the FCC defer action until the case "has been tried and a decision rendered"; on the other hand, if the case is not taken to Federal court, the FCC "has little cause to embark on its own investigation." Similarly, many broadcasters argued that the memorandum is a departure from past FCC case law and cited decisions in which the Commission has conditioned renewal on the "final outcome" of an EEOC matter in recognition of the "interlocutory stages of an EEOC complaint proceeding."

19. We largely disagree with the criticisms of the proposed inquiry. We are concerned, however, that the wording of the memorandum may appear to pressure broadcasters to conciliate EEOC complaints, and we are also concerned in reevaluating the memorandum that the automatic inquiry may unduly restrict the FCC and lead to unwarranted duplicative efforts. Accordingly, we will revise various sections of the memorandum as detailed below.

20. We feel that the proposed memorandum in no way violates broadcasters' due process rights under the Communications Act or Civil Rights Act. However, we also feel that too much emphasis is given in the memorandum to the possible timing of an FCC inquiry. We realize that the EEOC's processes are by nature informal and conciliatory and that an EEOC finding of reasonable cause coupled with failure of conciliation does not raise a legal presumption of employment discrimination. *E.g., Fekete* v. *U.S. Steel Corp.*, 424 F.2d 331, 336 (3rd Cir. 1970). Indeed, in any resulting Federal court action, the trial takes on the character of an action de novo in which the complainant "must carry the initial * * * burden * * * of establishing a prima facie case of racial discrimination." *McDonnell Douglas Corp.* v. *Green*, 411 U.S. 792, 802 (1973). Therfore, we do not seek to give undue deference to a failure of conciliation. However, we do feel that this point in many cases will represent both a convenient and reasonable time for the FCC's involvement. For example, failure of conciliation marks the end of the EEOC's conciliatory efforts and, if the case is not pursued, will afford the FCC the most complete information regarding the facts of the complaint. However, we emphasize that it is the information gathered by the EEOC rather than the EEOC's procedural touchstones in which the FCC will be interested. Thus, it is possible in some cases for an FCC inquiry—based on information from the EEOC and other sources—to take place even before the EEOC's conciliatory process ends. *Report on Uniform Policy as to Violations by Applicants of Laws of the United States, 1 R.R., Part 3, 91.495 (1951); 42 F.C.C. 2d 399 (1973).*

21. We agree with some of the commentors who point out that an automatic inquiry may lead to duplicative efforts since the complainant or the EEOC may bring an action in Federal district court even after failure of conciliation. In order to alleviate this possibility of duplication, therefore, we will amend the memorandum to indicate that while the FCC will notify a broadcaster of the Commission's awareness of failure of conciliation, the FCC may in its discretion await final outcome of a court proceeding and may condition any action on a final court determination. It should be noted, however, that situations may arise in which the Commission may act before a court decision. *Id.*[12]

22. Further, on reevaluation we are concerned that the proposed memorandum is too inflexible in requiring a letter inquiry concerning a broadcaster's overall employment policies whenever there is a failure of conciliation. That is, we believe that the FCC should be able to fashion the areas of inquiry to the circumstances of the particular case and not be constrained to conduct only a general inquiry. Accordingly, we will amend the memorandum to indicate that the scope and type of FCC inquiry—including the letter of inquiry approach—will remain in the Commission's discretion.[13]

OTHER MATTERS

23. One commentor suggested that the memorandum establish a definite period of time in which the FCC would be required to complete review of information gathered through the proposed inquiry. However, we think the suggestion is impractical given the FCC's limited staff and the detailed investigation and analysis which may be required in some cases.

24. One commentor said that the FCC should routinely inform the EEOC when a broadcaster does not meet applicable FCC processing standards. We do not feel that it is necessary to detail the types of information which may be exchanged although we

[10] One commentor suggested that the provision of Part III of the memorandum in which the EEOC agrees to provide technical assistance and guidance as requested by the FCC is an ultra vires act. However, we reject this assertion since the EEOC is not prohibited from sharing its expertise with other agencies in order to permit uniformity of policy; indeed, the EEOC has recently been authorized to coordinate the equal employment efforts of all Federal agencies. Exec. Order No. 12067, 43 FR 28967 (July 5, 1978).

[11] As the memorandum now reads, the FCC staff would be required to send a letter of inquiry requesting "additional comments you may wish to make relating to your employment policies and practices" when notified that a complainant and broadcaster had failed to conciliate their differences throught the EEOC's processes. See supra note 2. This letter would be sent automatically even if the case which triggered the inquiry were taken to Federal court.

[12] Accordingly, we do not believe that the memorandum is inconsistent with those decisions, cited by some commentors, in which the Commission has conditioned renewal on whatever action it may wish to take after a "final determination" of an outstanding EEOC complaint. *E.g., Newhouse Broadcasting Corp.* 61 F.C.C. 2d 528, 539-40 (1976). Moreover, cases such as *Newhouse* never precluded collateral FCC investigation of employment matters in appropriate cases.

[13] This flexibility will also allow the Commission, as one commentor suggested, to investigate past discrimination where appropriate.

note that the memorandum is broad enough to permit the routine sharing of this information. We feel that experience will best indicate the specific information which will be useful to each agency, and we will establish procedures for the routine sharing of this information insofar as our resources permit.

25. One commentor pointed out that the list of possible FCC actions contained in Part IV of the memorandum is different from that contained in the appended sample letter. This difference was inadvertent and has been corrected to reflect the full range of possible actions which the FCC may take.

26. One commentor mentioned that the memorandum does not state what would happen if the EEOC is unable to complete its investigation prior to the license expiration date. However, we do not deem it necessary to provide for this contingency since the FCC under its current procedures may at any time under the Communications Act call the license into question and conduct its own inquiry.

27. Finally, one commentor suggested that the memorandum was meaningless because the FCC considers only systemic issues while the EEOC does not consider class issues. However, we disagree since the information obtained by the EEOC in the course of its investigation of an individual complaint will be helpful to the FCC in directing the FCC's attention to areas which may require further inquiry. Moreover, the EEOC does consider systemic issues of discrimination through Commissioner's charges, and it also considers issues arising in an individual charge which are by nature class issues.

28. Accordingly, *it is ordered*, That the Memorandum of Understanding between the Equal Employment Opportunity Commission and the Federal Communications Commission as set forth in the attached Appendix B is adopted and will become effective 30 days after its publication in the FEDERAL REGISTER.

29. *It is further ordered*, That this proceeding is terminated.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

APPENDIX A

The following organizations filed comments on the proposed memorandum of understanding:

Center for National Review
Women Employed
National Women's Employment Project
KWHW Radio, Inc., KNOR Radio, Inc., and KWON Radio, Inc.
United States Commission on Civil Rights
National Association of Broadcaster
N.A.A.C.P. Legal Defense and Educational Fund, Inc.
National Council of La Raza
Metromedia, Inc.
American Broadcasting Cos., Inc.
Storer Broadcasting Co.
Pierson, Ball & Dowd
Citizens Communications Center (on behalf of itself, National Black Media Coalition, National Organization for Women, Black Citizens for Fair Media, National Council of La Raza and National Citizens Committee for Broadcasting)
N.A.A.C.P. Special Contribution Fund
Maryland-District of Columbia-Delaware Broadcasters Association, Inc.

APPENDIX B

MEMORANDUM OF UNDERSTANDING

The following represents a memorandum of understanding relating to nondiscrimination in employment at radio and television broadcasting stations as defined in section 3 (o) and (dd) of the Communications Act of 1934, as amended, 47 U.S.C. 153 (o) and (dd), [1] and has been agreed to by the Equal Employment Opportunity Commission, hereinafter the EEOC, and the Federal Communications Commission, hereinafter the FCC.

The EEOC, pursuant to title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e (hereinafter title VII), has jurisdiction to identify and eliminate discriminatory employment policies and practices at employment units, including broadcasting stations. The FCC, under the Communications Act of 1934, as amended, 41 U.S.C. 151 et seq., has jurisdiction to regulate interstate and foreign commerce by wire and radio in the public interest, and has found its regulatory jurisdiction also to include authority to identify and eliminate discriminatory employment policies and practices at broadcasting stations. It has adopted rules and procedures desinged to assure equal employment opportunities to all persons without regard to their race, color, religion, national origin or sex. Its authorization to do so has been recongized by the Supreme Court. *N.A.A.C.P.* v. *F.P.C.*, 425 U.S. 662 (1976). Both the EEOC and FCC share a common goal—the elimination of discriminatory employment policies and practices at broadcasting stations, including both commercial and noncommercial educational (public) broadcasting stations. In pursuit of this common goal, and to promote efficiency and eliminate potential conflict and duplication, the EEOC and FCC hereby agree as follows:

I. EXCHANGE OF INFORMATION

Both the EEOC and FCC shall make available for inspection and copying to appropriate officials from the other agency any information relating to a broadcast employer's employment policies and practices which may assist each agency in carrying out its responsibilities. Such information shall include, but no necessarily be limited to, affirmative action programs, annual employment reports (FCC form 395), complaints investigative files, conciliation or compliance agreements, and compliance review reports and files.

Additionally, the EEOC will send to the FCC quarterly reports to keep the FCC informed of all charges against broadcasters. With respect to all information obtained from the EEOC, the FCC agrees to preserve the confidentiality provisions of sections 706(b) and 709(e) of title VII of the Civil Rights Act of 1964, as amended.

II. DISCRIMINATION COMPLAINTS

The EEOC has responsibility to investigate charges of discrimination filed with it. The EEOC hereby designates the FCC as an agent of the EEOC for the sole purpose of receipt of such charges. For the purpose of determining the timeless of charge under title VII of the Civil Rights Act of 1964, as amended, the date the matter was received by the FCC shall be deemed to be the date it was received by the EEOC.

III. PROCESSING DISCRIMINATION COMPLAINTS

It an individual files a charge with either the EEOC or FCC alleging discrimination in employment by a broadcaster, the EEOC and FCC shall proceed as follows:

(a) If the EEOC receives the charge but the broadcast employer does not fall within the jurisdiction of the EEOC pursuant to title VII, and also not within the jurisdiction of a State or local agency to which the EEOC defers such charges pursuant to section 706 of the Civil Rights Act of 1964 (hereinafter section 706 agency), the EEOC will forward the charge to the FCC, which will process the compliant in accordance with its own rules, policies, and procedures. Upon request, the EEOC shall provide technical advice and guidance to the FCC in their investigation of such complaints. The EEOC shall also notify the charging party that it has forwarded the complaint to the FCC. The EEOC shall furnish to the appropriate office of the FCC a list of section 706 agencies and their jurisdictional limits.

(b) If the FCC receives a charge which falls both within its own jurisdiction and within the jurisdiction of the EEOC or a section 706 agency, the FCC shall, in addition to any separate action it may take to investigate such charges within the context of the public interest finding it must make on any broadcast application: (i) Date stamp the charge and refer it to the appropriate EEOC office or the appropriate section 706 agency; (ii) notify the complianant that is has done so; and (iii) notify the broadcaster that the compliant has been referred to the EEOC, indicating that the FCC has asked the EEOC to inform it of the results of the case processing.

(c) If the EEOC receives a discrimination charge against a broadcaster which is within the jurisdiction of both the EEOC and the FCC, the EEOC will process the charge in accord with its normal procedures. The EEOC shall make a reasonable effort to investigate the charge prior to the broadcast station's license expiration date as established in section 73.34 of the FCC's rules and regulations.

IV. ACTION ON DISCRIMINATION COMPLAINTS

The EEOC will notify the FCC by letter of all reasonable cause determinations on discrimination charges involving a broadcaster, and upon specific request will provide the FCC with any additional information regarding the determination. However, nothing herein is intended to require or force licensees to enter into conciliation agreements or to affect the legal rights of

[1] While the FCC has jurisdiction over other communications by wire and radio, e.g., common carrier and cable television, this memorandum of understanding is limited to broadcasting

the complainants. Likewise, nothing herein is intended to discourage a licensee from entering into a conciliation agreement if its so desires or to affect the legal rights of the EEOC.

When the EEOC makes a determination on a discrimination complaint involving a broadcaster, and there is a failure of conciliation, the EEOC will so notify the FCC. Thereafter, consistent with its usual practice of compiling a full and complete record prior to reaching any determination on an issue, the FCC will send the licensee a letter (similar to the attached document) inviting the licensee's comments on specific areas of FCC concern. Based upon a review of the broadcaster's response and any other information on file relating to its employment policies and practices, the FCC, within its statutory discretion, shall detemine what administrative action may be appropriate. Other than a regular grant of a pending application, such action may include:

(a) Grant of a renewal for a short-term period;

(b) Grant of a renewal subject to certain conditions (with appropriate monitoring);

(c) Grant of a renewal for a short-term period subject to certain conditions (with appropriate monitoring);

(d) Imposition of a monetary forfeiture (see 47 U.S.C. § 503(b)); or

(e) Designation of the license or application for hearing pursuant to either section 312 or 309 of the Communications Act, 47 U.S.C. §§ 312, 309.

Upon disposition of the case, the FCC shall notify the EEOC. Furthermore, should the EEOC or the complainant elect to pursue the matter in the Federal courts, the FCC retains discretion to defer consideration of the case until a determination is reached by the courts. Likewise, in given circumstances the FCC retains its discretion to proceed with appropriate administrative actions prior to a final court determination.

V. LIAISON AND MONITORING

To provide for more effective exchange of complete information so that both agencies will be utilized to the maximum effectiveness in the public interest, each agency will designate a liaison officer to serve as the primary source of contact. These liaison officers will be responsible for currently informing each other of proposed proceedings and of internal developments in areas of joint concern to the extent that such information is not privileged. Additionally, the parties shall conduct reviews of the implementation of this agreement to assure proper effectuation. In this regard, liaison meetings between appropriate senior officials of both agencies to exchange views on matters of common interest and responsibility shall be held from time to time as determined by such liaison officers to be necessary.

Designated liaison officers:

(a) Equal Employment Opportunity Commission—The Executive Director or his designee.

(b) Federal Communications Commission—The General Counsel or his designee.

VI. AMENDMENT AND TERMINATION

This agreement, when signed by both parties, covers an indefinite period of time and may be modified by or expanded with the mutual consent of both parties or terminated by either party upon thirty (30) days' advance written notice.

Approved and accepted for the Equal Employment Opportunity Commission.

ELEANOR HOLMES NORTON,
Chair, Equal Employment Opportunity Commission.

Approved and accepted for the Federal Communications Commission.

CHARLES D. FERRIS,
Chairman, Federal Communications Commission.

ATTACHMENT A

DEAR ———: The Federal Communications Commission has been advised that the Equal Employment Opportunity Commission has determined in (EEO Case No.) that there is reasonable cause to believe that (licensee) has discriminated against (affected class/party) by (type of discrimination) in violation of Title VII of the Civil Rights Act of 1964, as amended. We have also been advised that there has been a failure of conciliation.

While the FCC does not directly enforce Title VII of the Civil Rights Act, it does consider broadcasters' employment policies and practices under its own public interest mandate and non discrimination regulation. These regulations require each broadcast station licensee to afford equal employment opportunity to all qualified persons, and hiring, placement and promotion, and related benefits on the basis of race, color, religion, national orgin, or sex.

The Commission is now in the process of reviewing your equal employment opportunity practices including the reasonable cause to believe finding. In order that we may have a complete understanding of your compliance with our equal employment opportunity rules you are requested to submit comments on the following matters: (Here the Commission will specify matters of particular concern).

Based upon a review of any such comments, which should be submitted within thirty (30) days of the date of receipt of this letter, and other information on file concerning your employment policies and practices, we will determine what further action, if any, is necessary, including: (1) grant of your license renewal application; (ii) grant of your license renewal for a short-term period; (iii) grant of your license renewal application subject to certain conditions; (iv) grant of your license renewal application for a short-term period subject to certain conditions; (v) in the case of substantial and material questions of fact, designation of your application for evidentiary hearing to determine what action should be taken; or (vi) imposition of any other appropriate sanction (e.g., forfeiture, revocation).

If you have any additional questions, please feel free to write or call the Chief of the Renewal Branch, Broadcast Bureau.

Sincerely yours,

RICHARD J. SHIBEN,
Chief, Renewal and Transfer Division, Broadcast Bureau.

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

MEMORANDUM OF UNDERSTANDING WITH THE FEDERAL COMMUNICATIONS COMMISSION

Notice is hereby given that on August 3, 1978, the Equal Employment Opportunity Commission approved a memorandum of understanding between the EEOC and the Federal Communications Commission. The memorandum which was adopted appears above as an appendix to the report and order of the FCC on this subject.

The EEOC has considered the comments received in response to the publication of the proposed memorandum on March 28, 1978, and has adopted the discussion of those comments which appears in the report and order of the FCC. The EEOC hereby makes a specific affirmation that it has the authority under Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e-4(g)(1), and under Executive Order 12607 (June 30, 1978) to enter into this memorandum of understanding and to render such advice and assistance to the FCC as it may request in handling matters of equal employment opportunity.

In addition, the EEOC also specifically finds that the sharing of information with the FCC will not result in disclosure to the public prohibited by sections 706(b) and 709(e) of Title VII. The sharing of information with another Government agency in carrying out that agency's duties with respect to equal employment opportunity is not prohibited by Title VII. In addition, FCC has agreed to respect the confidentiality provisions of Title VII.

As indicated in the report and order of the FCC, the EEOC has designated the FCC its agent for the receipt of charges. The date of receipt of a charge by FCC will be deemed the date of receipt of the charge by EEOC for the purpose of determining whether the charge has been received within 180 or 300 days, as applicable, after the act of discrimination.

This memorandum of understanding will become effective September 25, 1978.

Dated: August 7, 1978.

ELEANOR HOLMES NORTON,
Chair, Equal Employment Opportunity Commission.

[FR Doc. 78-23958 Filed 8-24-78; 8:45 am]

[4110-92]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Federal Council on the Aging

SPECIAL AGING POPULATIONS COMMITTEE

Meeting

The Federal Council on the Aging was established by the 1973 amendments to the Older Americans Act of 1965 (Pub. L. 93-29, 42 U.S.C. 3015) for the purpose of advising the President, the Secretary of Health, Education, and Welfare, the Commission on Aging, and the Congress, on matters relating to the special needs of older Americans.

Notice is hereby given pursuant to the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C. app. 1, sec. 10, 1976) that the Council's Committee on Special Aging Populations will hold a meeting on September 15 from 9:30 a.m. to 5 p.m., Room 4254, HEW-North Building, 330 Independence Avenue SW., Washington, D.C. 20201.

The agenda will consist of a review of committee functions and responsibilities; staff report on definition of age categories and special aging populations; recommendations on the Elderly Minority Report; review of mandated studies; consideration of committee resources.

Further information on the Council may be obtained from the FCA Secretariat, Federal Council on the Aging, Washington, D.C. 20201, telephone 202-245-0441. FCA meetings are open for public observation.

NELSON H. CRUIKSHANK,
Chairman,
Federal Council on the Aging.

AUGUST 18, 1978.

[FR Doc. 78-23937 Filed 8-24-78; 8:45 am]

[4110-02]

Office of Education

NATIONAL ADVISORY COUNCIL ON THE EDUCATION OF DISADVANTAGED CHILDREN

Meeting

Notice is hereby given, pursuant to Pub. L. 92-463, that the National Advisory Council on the Education of Disadvantaged Children will meet in Knoxville, Tenn., on Friday, September 15 and Saturday, September 16, 1978. On September 15, the Council members will conduct site visits to various Knoxville title I schools from 8:30 a.m. to 4:30 p.m.; and, the regular Council meeting will be held on September 16, from 8:30 a.m. to 1:30 p.m. (location to be announced at a later date).

The National Advisory Council on the Education of Disadvantaged Children is established under section 148 of the Elementary and Secondary Act (20 U.S.C. 2411) to advise the President and the Congress on the effectiveness of compensatory education to improve the educational attainment of disadvantaged children.

The members will be conducting the site visit for the purpose of gathering additional information needed to finalize their special report on Urban Education, after which they have scheduled a full Council meeting to review all draft materials for final inclusion in this report scheduled to be issued on September 30, 1978.

The meeting will be open to the public. Because of limited space, all persons wishing to attend should call for reservations by September 11, 1978, area code 202-724-0114 and speak with Mrs. Lisa Haywood.

Records shall be kept of all Council proceedings and shall be available for public inspection at the Office of the National Advisory Council on the Education of Disadvantaged Children located at 425 Thirteenth Street NW., Suite 1012, Washington, D.C. 20004.

Signed at Washington, D.C., on August 22, 1978.

ROBERTA LOVENHEIM,
Executive Director.

[FR Doc. 78-23900 Filed 8-24-78; 8:45 am]

[4110-92]

Office of the Secretary

NATIONAL ADVISORY COUNCIL ON SERVICES AND FACILITIES FOR THE DEVELOPMENTALLY DISABLED

Meeting

The National Advisory Council on Services and Facilities for the Developmentally Disabled was established by section 133(a)(1) of Pub. L. 91-517, which was signed October 30, 1970, to advise the Secretary with respect to any regulations promulgated or proposed to be promulgated by him in the implementation of the Act and to study and evaluate programs authorized by the Act with a view to determining their effectiveness in carrying out the purposes for which they were established.

Notice is hereby given, pursuant to Pub. L. 92-463, that the National Advisory Council on Services and Facilities for the Developmentally Disabled will hold a meeting on September 11, 12, and 13, 1978. The meeting will be held in Room 727-A, Hubert H. Humphrey Building, Department of Health, Education, and Welfare, 200 Independence Avenue SW., Washington, D.C., from 9 a.m. to 5 p.m.

Agenda: Annual Report to Congress; Reorganization; Status of Legislation; Research and Evaluation Strategy; and Reports on Projects of National Significance and Contracts.

This meeting is open for public observation.

Further information on the Council may be obtained from Mr. Francis X. Lynch, Executive Secretary, National Advisory Council on Services and Facilities for the Developmentally Disabled, Room 3070, Mary Switzer Building, 330 C Street SW., Washington, D.C. 20201, telephone 202-245-0335.

FRANCIS X. LYNCH,
Executive Secretary.

AUGUST 17, 1978.

[FR Doc. 78-23936 Filed 8-24-78; 8:45 am]

[4110-07]

Social Security Administration

ADVISORY COUNCIL ON SOCIAL SECURITY

Appointment and Public Meeting

AGENCY: Advisory Council on Social Security, HEW.

ACTION: Notice is hereby given of public meetings of the Advisory Council on Social Security and the Panel of Actuaries and Economists.

SUMMARY: Notice is given pursuant to Pub. L. 92-463, that the Advisory Council on Social Security established pursuant to section 706 of the Social Security Act, as amended, will meet on Monday, September 18, 1978, from 9 a.m. to 5 p.m. in room 800 of the Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, D.C. The meeting will be devoted to the topic of social security disability insurance.

There will be a meeting of the Advisory Council's panel of actuaries and economists on Tuesday, September 19, 1978, from 9 a.m. to 12 noon in room 503A, Hubert H. Humphrey Building. The panel will continue its review of the economic and actuarial assumptions used in social security cost projections.

These meetings are open to the public. Individuals and groups who wish to have their interest in the social security program taken into account by the Council may submit written comments, views, or suggestions to Mr. Lawrence H. Thompson.

FOR FURTHER INFORMATION CONTACT:

Mr. Lawrence H. Thompson, Executive Director of the Advisory Council, P.O. Box 17054, Baltimore, Md. 21235. Telephone inquires should be directed to Mr. Edward F. Moore, telephone No. 301-594-3171.

(Catalog of Federal Domestic Assistance Program Nos. 13.800-13.805, Social Security Programs.)

Dated: August 21, 1978.

LAWRENCE H. THOMPSON,
Executive Director, Advisory Council on Social Security.

[FR Doc. 78-23946 Filed 8-24-78; 8:45 am]

[4210-01]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Federal Disaster Assistance Administration

[FDAA-3066-EM; Docket No. NFD-639]

NEW YORK

Emergency Declaration and Related Determinations

AGENCY: Federal Disaster Assistance Administration, HUD.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of New York (FDAA-3066-EM), dated August 7, 1978, and related determinations.

DATED: August 7, 1978.

FOR FURTHER INFORMATION CONTACT:

A. C. Reid, Program Support Staff, Federal Disaster Assistance Administration, Department of Housing and Urban Development, Washington, D.C. 20410, 202-634-7825.

NOTICE: Pursuant to the authority vested in the Secretary of Housing and Urban Development by the President under Executive Order 11795 of July 11, 1974, and delegated to me by the Secretary under Department of Housing and Urban Development Delegation of Authority, Docket No. D-74-285; and by virtue of the act of May 22, 1974, entitled "Disaster Relief Act of 1974" (88 Stat. 143); notice is hereby given that on August 7, 1978, the President declared an emergency as follows:

I have determined that the adverse impact of chemical wastes lying exposed on the surface and associated chemical vapors emanating from the Love Canal Chemical Waste Landfill in the city of Niagara Falls, N.Y., is of sufficient severity and magnitude to warrant a declaration of an emergency under Pub. L. 93-288. I therefore declare that such an emergency exists in the State of New York.

Notice is hereby given that pursuant to the authority vested in the Secretary of Housing and Urban Development under Executive Order 11795, and delegated to me by the Secretary under Department of Housing and Urban Development Delegation of Authority, Docket No. D-74-285, I hereby appoint Mr. Norman Steinlauf of the Federal Disaster Assistance Administration to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following area of the State of New York to have been adversely affected by this declared emergency:

The city of: Niagara Falls.

(Catalog of Federal Domestic Assistance No. 14.701, Disaster Assistance)

WILLIAM H. WILCOX,
Administrator, Federal Disaster Assistance Administration.

[FR Doc. 78-23968 Filed 8-24-78; 8:45 am]

[4210-01]

[FDAA-561-DR; Docket No. NFD-638]

TEXAS

Major Disaster and Related Determinations

AGENCY: Federal Disaster Assistance Administration, HUD.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Texas (FDAA-561-DR), dated August 3, 1978, and related determinations.

DATED: August 3, 1978.

FOR FURTHER INFORMATION CONTACT:

A. C. Reid, Program Support Staff, Federal Disaster Assistance Administration, Department of Housing and Urban Development, Washington, D.C. 20410, 202-634-7825.

NOTICE: Pursuant to the authority vested in the Secretary of Housing and Urban Development by the President under Executive Order 11795 of July 11, 1974, and delegated to me by the Secretary under Department of Housing and Urban Development delegation of authority, docket No. D-74-285, and by virtue of the Act of May 22, 1974, entitled "Disaster Relief Act of 1974" (88 Stat. 143); notice is hereby given that on August 3, 1978, the President declared a maor disaster as follows:

I have determined that the damage in certain areas of the State of Texas resulting from severe storms and flooding, beginning about August 1, 1978, is of sufficient severity and magnitude to warrant a major disaster declaration under Pub. L. 93-288. I therefore declare that such a major disaster exists in the State of Texas.

Notice is hereby given that pursuant to the authority vested in the Secretary of Housing and Urban Development under Executive Order 11795, and delegated to me by the Secretary under Department of Housing and Urban Development delegation of authority, docket No. D-74-285, I hereby appoint Mr. Joe D. Winkle of the Federal Disaster Assistance Administration to act as the Federal Coordinating Officer for this declared major disaster.

I do hereby determine the following areas of the State of Texas to have been adversely affected by this declared major disaster.

The counties of: Bandera, Kendall, and Kerr.

(Catalog of Federal Domestic Assistance No. 14.701, Disaster Assistance.

WILLIAM H. WILCOX,
Federal Disaster Assistance Administration.

[FR Doc. 78-23967 Filed 8-24-78; 8:45 am]

[4210-01]

[FDAA-561-DR; Docket No. NFD-640]

TEXAS

Amendment to Notice of Major Disaster Declaration

AGENCY: Federal Disaster Assistance Administration, HUD.

ACTION: Notice.

SUMMARY: This notice amends the notice of major disaster declaration for the State of Texas (FDAA-561-DR), dated August 3, 1978.

DATED: August 5, 1978.

FOR FURTHER INFORMATION CONTACT:

A. C. Reid, Program Support Staff, Federal Disaster Assistance Administration, Department of Housing and Urban Development, Washington, D.C. 20410, 202-634-7825.

NOTICE: The notice of major disaster for the State of Texas dated August 3, 1978, is hereby amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of August 3, 1978.

The counties of: Haskell and Shackleford.

(Catalog of Federal Domestic Assistance No. 14.701, Disaster Assistance.)

WILLIAM H. WILCOX,
Administrator, Federal Disaster Assistance Administration.

[FR Doc. 78-23969 Filed 8-24-78; 8:45 am]

[4210-01]

[FDAA-561-DR; Docket No. NFD-641]

TEXAS

Amendment to Notice of Major Disaster Declaration

AGENCY: Federal Disaster Assistance Administration, HUD.

ACTION: Notice.

SUMMARY: This notice amends the notice of major disaster declaration for the State of Texas (FDAA-561-DR), dated August 3, 1978.

DATED: August 7, 1978.

FOR FURTHER INFORMATION CONTACT:

A. C. Reid, Program Support Staff, Federal Disaster Assistance Administration, Department of Housing and Urban Development, Washington, D.C. 20410, 202-634-7825.

NOTICE: The notice of major disaster for the State of Texas dated August 3, 1978, is hereby amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of August 3, 1978.

The county of Young.

(Catalog of Federal Domestic Assistance No. 14,701, Disaster Assistance.)

WILLIAM H. WILCOX,
Administrator, Federal Disaster Assistance Administration.

[FR Doc. 78-23970 Filed 8-24-78; 8:45 am]

[4210-01]

[FDAA-561-DR; Docket No. NFD-642]

TEXAS

Amendment to Notice of Major Disaster Declaration

AGENCY: Federal Disaster Assistance Administration, HUD.

ACTION: Notice.

SUMMARY: This notice amends the notice of major disaster declaration for the State of Texas (FDAA-561-DR), dated August 3, 1978.

DATED: August 11, 1978.

FOR FURTHER INFORMATION CONTACT:

A. C. Reid, Program Support Staff, Federal Disaster Assistance Administration, Department of Housing and Urban Development, Washington, D.C. 20410 202-634-7825.

NOTICE: The notice of major disaster for the State of Texas dated August 3, 1978, as amended on August 5, 1978, and August 7, 1978, is hereby further amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of August 3, 1978.

The counties of: Throckmorton and Stephens.

(Catalog of Federal Domestic Assistance No. 14,701, Disaster Assistance.)

WILLIAM H. WILCOX,
Administrator, Federal Disaster Assistance Administration.

[FR Doc. 78-23971 Filed 8-24-78; 8:45 am]

[4210-01]

Office of Secretary

[Docket No. D-78-505]

ASSISTANT SECRETARY FOR NEIGHBORHOODS, VOLUNTARY ASSOCIATIONS AND CONSUMER PROTECTION

Delegation of Authority

AGENCY: Department of Housing and Urban Development.

ACTION: Delegation of authority.

SUMMARY: The Secretary is delegating to the Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection certain authority to implement and administer a program of energy efficient performance standards for new residential and commercial buildings.

EFFECTIVE DATE: August 25, 1978.

Section A. *Authority delegated.* The Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection is hereby delegated under Title III of the Energy and Conservation and Production Act of 1976, 42 U.S.C. 6831 *et seq.*, the power and authority of the Secretary of Housing and Urban Development to implement and to administer a program of performance standards for new residential and commercial buildings.

Section B. *Authority excepted.* There is excepted from the authority delegated under section A the power to:

1. Sue and be sued.

Section C. *Authority to redelegate.* The Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection is authorized to redelegate to employees of the Department and to agents of the Department any of the power and authority delegated under section A of this delegation, except the authority to issue rules and regulations.

Issued at Washington, D.C., August 21, 1978.

PATRICIA ROBERTS HARRIS,
Secretary of Housing and Urban Development.

[FR Doc. 78-23965 Filed 8-24-78; 8:45 am]

[1505-01]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AA-6697-A through AA-6697-E]

ALASKA NATIVE CLAIMS SELECTION

Correction

In FR Doc. 78-21977 appearing at page 35116 in the issue for Tuesday, August 8, 1978, make the following corrections:

(1) In the middle column of page 35117, under T. 78 S., R. 126 W., Sec. 26, "* * * U.S. Survey 520 * * *" should have read "* * * U.S. Survey 5520 * * *".

(2) In the same column, under T. 76 S., R. 128 W., "Secs. 26, 27, and 18;" should have read "Secs. 26, 27, and 28;".

(3) In the third column of page 35117, the second to the last land description (the eighteenth line from the top of the column), "T. 78 S., R. 131 W." should have read "T. 77 S., R. 131 W.".

(4) In the first column of page 35118, paragraph "d.", "(EIN 3a C4)" should have read "(EIN 3b C4)".

[4310-84]

[NM 34268]

NEW MEXICO

Application

AUGUST 17, 1978.

Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the act of November 16, 1973 (87 Stat. 576), El Paso Natural Gas Co. has applied for a cathodic protection station right-of-way across the following land:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 25 S., R. 14 W.,
Sec. 20, W½SE¼.

This cathodic protection station will be used for natural gas operations across 0.225 of a mile of public land in Grant County, N. Mex.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 1420, Las Cruces, N. Mex. 88001.

RAUL E. MARTINEZ,
Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-23902 Filed 8-24-78; 8:45 am]

[4310-84]

[NM 34151]

NEW MEXICO

Application

AUGUST 17, 1978.

Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the act of November 16, 1973 (87 Stat. 576), Transwestern Pipeline Co. has applied for one 4-inch natural gas pipeline right-of-way across the following land:

NEW MEXICO PRINCIPAL MERIDAN, NEW MEXICO

T. 24 S., R. 34 E.,
Sec. 18, SW¼NE¼.

This pipeline will convey natural gas across 0.20 of a mile of public land in Lea County, N. Mex.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of

whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 1397, Roswell, N. Mex. 88201.

RAUL E. MARTINEZ,
Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-23903 Filed 8-24-78; 8:45 am]

[4310-84]

[NM 34157]

NEW MEXICO

Application

AUGUST 17, 1978.

Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the act of November 16, 1973 (87 Stat. 576), Phillips Petroleum Co. has applied for one 4½-inch natural gas pipeline right-of-way across the following land:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 17 S., R. 27 E.,
Sec. 10, NE¼NW¼ and NW¼NE¼.

This pipeline will convey natural gas across 0.060 of a mile of public land in Eddy County, N. Mex.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 1397, Roswell, N. Mex. 88201.

RAUL E. MARTINEZ,
Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-23904 Filed 8-24-78; 8:45 am]

[4310-84]

[NM 34165]

NEW MEXICO

Application

AUGUST 17, 1978.

Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the act of November 16, 1973 (87 Stat. 576), El Paso Natural Gas Co. has applied for one 4½-inch natural gas pipeline right-of-way across the following land:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 29 N., R. 7 W., Sec. 19, lots 6, 7 and SE¼NW¼.
T. 29 N., R. 8 W., Sec. 24, NE¼SE¼.

This pipeline will convey natural gas across 0.409 mile of public lands in Rio Arriba and San Juan Counties, N. Mex.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 6770, Albuquerque, N. Mex. 87107.

RAUL E. MARTINEZ,
Acting Chief, Branch of Lands, and Minerals Operations.

[FR Doc. 78-23905 Filed 8-24-78; 8:45 am]

[4310-84]

[NM 34161 and 34164]

NEW MEXICO

Applications

AUGUST 17, 1978.

Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the act of November 16, 1973 (87 Stat. 576), El Paso Natural Gas Co. has applied for three 4½-inch natural gas pipelines and related facilities rights-of-way across the following lands:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 18 S., R. 31 E.,
Sec. 33, SE¼NE¼;
Sec. 34, SW¼NW¼ and NW¼SW¼.
T. 21 S., R. 32 E.,
Sec. 8, S½N½;
Sec. 9, SW¼NE¼ and S½NW¼.

These pipelines will convey natural gas across 1.984 miles of public lands in Eddy and Lea Counties, N. Mex.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the applications should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 1397, Roswell, N. Mex. 88201.

RAUL E. MARTINEZ,
Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-23906 Filed 8-24-78; 8:45 am]

[4310-84]

[NM 34170]

NEW MEXICO

Application

AUGUST 18, 1978.

Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the act of November 16, 1973 (87 Stat. 576), Southern Union Gathering Co. has applied for one 20-inch natural gas pipeline right-of-way across the following lands:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 28 N., R. 11 W.,
Sec. 12, lot 4 and SW¼SW¼;
Sec. 13, NW¼NW¼.
T. 29 N., R. 11 W.,
Sec. 27, SW¼SE¼;
Sec. 34, N½NE¼, SE¼NE¼ and NE¼SE¼;
Sec. 35, lots 3, 4 and NW¼SW¼.

This pipeline will convey natural gas across 1.85 miles of public lands in San Juan County, N. Mex.

This purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 6770, Albuquerque, N. Mex. 87107.

RAUL E. MARTINEZ,
Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-23907 Filed 8-24-78; 8:45 am]

[4310-84]

[NM 34171]

NEW MEXICO

Application

AUGUST 18, 1978.

Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the act of November 16, 1973 (87 Stat. 576), Northwest Pipeline Corp. has applied for one 4½-inch natural gas pipeline right-of-way across the following land:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 31, N., R. 6 W.,
Sec. 13, NW¼SW¼.

This pipeline will convey natural gas across 0.131 of a mile of public land in Rio Arriba County, N. Mex.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of

whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 6770, Albuquerque, N. Mex. 87107.

RAUL E. MARTINEZ,
Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-23908 Filed 8-24-78; 8:45 am]

[4310-84]

[Wyoming 64680]

WYOMING

Application

AUGUST 18, 1978.

Notice is hereby given that pursuant to section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 185), the Colorado Interstate Gas Co. of Colorado Springs, Colo., filed an application for a right-of-way to construct a 6⅝ inch pipeline for the purpose of transporting natural gas across the following described public lands:

SIXTH PRINCIPAL MERIDIAN, WYOMING

T. 19 N., R. 98 W.,
Sec. 36, N½NE¼.

The proposed pipeline will transport natural gas produced from the Table Rock unit well No. 36 located in the NW¼ of section 31, T. 19 N., R. 97 W., into an existing natural gas pipeline located in the N½ of section 36, T. 19 N., R. 98 W., Sweetwater County, Wyo.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved and, if so, under what terms and conditions.

Interested persons desiring to express their views should do so promptly. Persons submitting comments should include their name and address and send them to the District Manager, Bureau of Land Management, 1300 Third Street, P.O. Box 670 Rawlins, Wyo. 82301.

HAROLD G. STINCHCOMB,
Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-23909 Filed 8-24-78; 8:45 am]

[4310-84]

[Wyoming 64675]

WYOMING

Application

AUGUST 19, 1978.

Notice is hereby given that pursuant to section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 185), the Cities Service Gas Co. of Oklahoma City, Okla., filed an application for a right-of-way to construct a 4½-inch pipeline for the purpose of transporting natural gas across the following described public lands:

SIXTH PRINCIPAL MERIDIAN, WYOMING

T. 21 N., R. 93 W.,
Sec. 34. NE¼SW¼ and NW¼SE¼.

The proposed pipeline will transport natural gas from their 5-mile gulch well No. 5 to a point of connecting with their gathering line within section 34, T. 21 N., R. 93 W., Sweetwater County, Wyo.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved and, if so, under what terms and conditions.

Interested persons desiring to express their views should do so promptly. Persons submitting comments should include their name and address and send them to the District Manager, Bureau of Land Management, 1300 Third Street, P.O. Box 670, Rawlins, Wyo. 82301.

HAROLD G. STINCHCOMB,
Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-23910 Filed 8-24-78; 8:45 am]

[4310-84]

[M 34985(ND)]

NORTH DAKOTA

Coal Lease Offering by Sealed Bid and Oral Auction

AUGUST 16, 1978.

U.S. Department of the Interior, Bureau of Land Management, Montana State Office, Granite Tower, 222 North 32d Street, P.O. Box 30157, Billings, Mont. 59107. Notice is hereby given that coal resources in the lands described below located in Burke County, N. Dak., are being offered to the qualified bidder of the highest cash amount per acre. The minimum acceptable bid is $25 per acre. Offerings will be by sealed bid to be followed by oral auction starting at the level of the highest sealed bid received. The offer is being made as a result of an application filed by Baukol-Noonan, Inc. The sale will be held at 2 p.m., September 15, 1978, in the conference room on the sixth floor of the Granite Tower Building. At that time all sealed bids will be opened and read and the oral auction conducted. The successful high bidder will be notified in writing after the State director has made his determination. No bids received after 2 p.m., September 15, 1978, will be considered. Sealed bids may not be modified or withdrawn unless such modification or withdrawal is received before the date, time, and place set for the opening of such bids. The Department of the Interior reserves the right to reject any and all bids, and also the right to offer the lease to the next highest qualified bidder if the successful bidder fails to obtain the lease for any reason. If any bid is rejected, the deposit made on the day of the sale will be returned. Payment of the bonus shall be on a deferred basis, one-fifth due on the day of the sale, and the balance in equal annual installments on the next four anniversary dates of the lease. The successful bidder is obligated to pay for the newspaper publications of this Notice.

Qualified bidder. In addition to the qualification requirements in 43 CFR 3502, a qualified bidder other than the applicant who has not met short-term criteria, will have to meet the criteria set out in the decision *Natural Resources Defense Council, et al.* v. *Royston C. Hughes, et al.*, Civil Action No. 75-1749, in the U.S. District Court for the District of Columbia, dated September 27, 1977, as amended on June 14, 1978. Any documents presented to support the position that the bidder meets the criteria of the order, as amended, must be enclosed with the sealed bid or presented on the day of the sale.

Warning to bidders. In accordance with the Federal Coal Leasing Amendments Act of 1975, it will be necessary that the high bidder, as a prospective lessee, disclose the nature and extent of his coal holdings to the Department of Justice before issuance of the lease. A lease will not be issued to a bidder who holds or controls more than 46,080 acres of Federal coal leases in any one State or 100,000 acres of Federal coal leases in the United States.

Coal offered. The coal resources to be offered are located in Burke County, N. Dak., near the community of Larson. The area consists of the following tract: T. 162 N., R. 94 W., 5th P.M., Section 14, W½NE¼, containing 80.00 acres. The coal resources offered are limited to the Noonan bed. The Conservation Division, Geological Survey, has reported that the tract contains 587,000 tons of recoverable coal. The coal resources are within the undefined Larson known recoverable coal resource area.

Rental and royalty. A lease issued as a result of this offering will provide for payment of an annual rental of $3 per acre or fraction thereof and a royalty payable to the United States at the rate of 12½ percent of the value of coal mined by strip mining methods. The value of coal shall be determined in accordance with 30 CRF 211.63.

Public comments. The public is invited to submit written comments to the Bureau of Land Management on the fair market value of the tract to be sold. Public comments should be sent to the State Director, Bureau of Land Management, at the address given above, to arrive no later than September 8, 1978.

Notice of availability. All case file documents and written comments submitted by the public on fair market value or royalty rates, except those portions identified as proprietary by the commenter, and meeting exemptions stated in the Freedom of Information Act, will be available for public inspection at the Bureau of Land Management Office, at the address given above. Copies of the detailed statement and proposed coal lease are also available from that office.

ROLAND F. LEE,
Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-23901 Filed 8-24-78; 8:45 am]

[4310-84]

[Nev-025474]

NEVADA

Airport Lease Amendment

AUGUST 15, 1978.

Notice is hereby given that pursuant to the Act of May 24, 1928 (49 U.S.C. 211-214), the Unincorporated Town of Jackpot, Nev., has applied to amend its existing airport lease, serial number Nev-025474, to include the following described lands:

MOUNT DIABLO MERIDIAN, NEVADA

T. 47 N., R. 64 E.
Sec. 1, S½SE¼SE¼SW¼, S½SW¼SW¼SE¼, S½SE¼SW¼SE¼.

The purpose of this notice is to inform the public that the filing of this application segregated the described public lands from all other forms of appropriation under the public land laws.

Interested persons desiring to express their views should promptly send their comments together with their name and address to the Elko District Manager, Bureau of Land Management, 2002 Idaho Street, Elko, Nev. 89801.

WM. J. MALENCIK,
Chief, Division of Technical Services.

[FR Doc. 78-23940 Filed 8-24-78; 8:45 am]

[4310-55]

Fish and Wildlife Services

ALASKA

Application for Pipeline Right-of-Way

Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by Pub. L. 93-153, approved November 16, 1973 (87 Stat. 576), Alaska Pipeline Co. has applied for a twenty (20) foot wide pipeline right-of-way across the following lands:

KENAI NATIONAL MOOSE RANGE

Kenai National Moose Range within the existing Sunken Island Lake Road and Swanson River Road rights-of-way located generally sixteen (16) miles east of the city of Kenai, Alaska, and more specifically T. 6 N., R. 9 W., Sections 21, 22, 23, 24, 25, 26, 35, and 36 Seward Meridian.

This 3.5-4.5 inch pipeline will convey natural gas across six (6) miles of the Kenai National Moose Range, Kenai Peninsula Borough, Alaska.

The purpose of this notice is to inform the public that the U.S. Fish and Wildlife Service will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their comments to the Refuge Manager, Kenai National Moose Range, P.O. Box 500, Kenai, Alaska 99611, 907-283-4877.

JAMES E. FRATES,
Refuge Manager, Kenai National Moose Range.

[FR Doc. 78-23911 Filed 8-24-78; 8:45 am]

[4410-01]

DEPARTMENT OF JUSTICE

Attorney General

[AAG/A Order No. 9-78]

PRIVACY ACT OF 1974

Notice of System of Records

Notice is hereby given that pursuant to the provisions of the Privacy Act of 1974 the Department of Justice proposes to establish a new system of records to be maintained by the Civil Division.

The Swine Flu Administrative Claim File System (JUSTICE/CIV-004) is a new system of records for which no public notice consistent with the provisions of 5 U.S.C. 552a(e)(4) has been published in the FEDERAL REGISTER.

Interested persons are invited to submit written comments on those portions of the notice which describe the routine uses. Comments may be submitted in writing to the administrative Counsel, Office of Management and Finance, Room 1118, Department of Justice, Washington, D.C. 20530. All comments must be received on or before September 25, 1978. No oral hearings are contemplated.

A report of the proposed system has been provided to the Director, Office of Management and Budget, to the President of the Senate, and to the Speaker of the House of Representatives.

Dated: August 16, 1978.

KEVIN D. ROONEY,
Assistant Attorney General for Administration.

JUSTICE/CIV-004

System name:

Swine Flu Administrative Claim File System.

System location:

Civil Division, U. S. Department of Justice, 521 12th Street NW., No. 804, Washington, D.C, 20530.

Categories of individuals covered by the system:

Any and all parties making administrative claims for damages resulting from the administration of the swine flu vaccine, whose claims have been referred by the Department of Health, Education, and Welfare for handling by the Civil Division, will have identifying data contained in this system.

Categories of records in the system:

(1) The main record of the system is the administrative claim filed which is retained on each claim under the jurisdiction of the Civil Division and constitutes the official record of the Department of Justice. All record material relating to a claim is retained in the file. Each claim is assigned a number in sequential order from the date of the filing. (2) Alphabetical and numerical indices are utilized as a means of access to the proper file by the cross-referencing of the names of all claimants with the file number. Index cards are used in these indices. (3) A docket card index is maintained on each claim in order to follow the progress of all swine flu claims and to obtain statistical data for periodic and fiscal reports. However, all information contained on the cards has been taken from the record material contained in the official file.

Authority for maintenance of the system:

General authority to maintain the system is contained in 5 U.S.C. 301 and 44 U.S.C. 3101. The particular system was established by authority of 28 CFR 0.77(f) which authority was delegated to the Civil Division pursuant to a memorandum from the Deputy Attorney General, dated July 17, 1974.

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

Any record pertaining to any swine flu administrative claim in the Civil Division may be disseminated to any other component of the Department of Justice, including the FBI and the U.S. Attorneys' offices, for use in connection with the consideration of that claim or matter or any other claim, case or matter under consideration by the Civil Division or any other component of the Department of Justice. A record maintained in this sysem of records may be disseminated as a routine use of such record as follows: (1) A record relating to a claim or matter that has been referred by the Department of Health, Education, and Welfare for investigation, or that involves a claim or matter within the jurisdiction of an agency, or where the agency or officials thereof are a party to litigation or where the agency or officials may be affected by a claim or matter may be disseminated to such agency to notify the agency of the status of the claim or matter or any decision or determination that has been made, or to make such other inquiries and reports as are necessary during the processing of the claim or matter; (2) a record may be disseminated to the public, news media, trade associations, or organized groups, when the purpose of the dissemination is educational or informational, provided that the record does not contain any information identifiable to a specific individual other than that necessary to identify the matter and is not an unwarranted invasion of privacy or where the information has previously been filed in a judicial or administrative office, including the clerk of the court; (3) in any claim in which there is an indication of a violation or potential violation of law, whether civil, criminal or regulatory in nature, the record in question may be disseminated to the appropriate Federal, State, local, or foreign agency charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law; (4) in the course of investigating the potential or actual violation of any law, whether civil, criminal, or regulatory in nature, or during the course of a trial or hearing, or the preparation for a trial or hearing for such violation, a record may be disseminated to a Federal, State local, or foreign agency, or to an individual or organization, if there is reason to believe that such agency, individual or organization possesses information relating to the investigation, trial, or hearing and the dissemination is reasonably necessary to elicit such information or to obtain the cooperation of a witness or an informant; (5) a record relating to a claim or matter may be disseminated in an appropriate Federal, State, local, or foreign court or grand jury proceeding in accordance with established constitutional, substantive, or procedural law or practice; (6) a record relating to a claim or matter may be disseminated to a Federal, State, or local administrative or regulatory proceeding or hearing in accordance with the procedures governing such proceeding or hearing; (7) a record relating to a claim or matter may be disseminated to an actual or potential party or his attorney for the purpose of negotiation or discussion of such matters as settlement of the claim or matter, or for formal or informal discovery proceedings.

Release of information to the news media: Information permitted to be released to the news media and the public pursuant to 28 CFR 50.2 may be made available from systems of records maintained by the Department of Justice unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

Release of information of Members of Congress: Information contained in systems of records maintained by the Department of Justice, not otherwise required to be released pursuant to 5 U.S.C. 552, may be made available to a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of and at the request of the individual who is the subject of the record.

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

Release of information to the National Archives and Records Service (NARS): A record from a system of records may be disclosed as a routine use to NARS in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

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

Storage:

The claim files utilize standard file jackets and are retained in standard file cabinets; (2) the alphabetical and numerical index cards, as well as the docket cards, are retained in standard file cabinets.

Retrievability:

The files and docket cards must be retrieved by file number. The file number can be ascertained from the alphabetical index if the name of the administrative claimant is known.

Safeguards:

Information contained in the system is unclassified. No personalized information about a claim or claimant will be given to anyone other than the claimant, his attorney, or authorized representative. Requests for such information will not be given by telephone unless the caller can provide sufficient information to identify himself as one authorized to receive personalized information. Nonpersonal or generalized information will be given to any requester. Information in the system is regarded as sensitive pursuant to Department rules and procedures. Department rules and procedures are in force to insure that only departmental attorneys and their authorized agents have access to the information.

Retention and disposal:

When a claim file is closed by the legal section, it is sent to the Federal Records Center for retention in accordance with the authorized record disposal schedule for the classification of the case. Such schedules are approved by the National Archives. After the designated period has passed, the file is destroyed. However, the index and docket cards are not purged and are retained for as long as practicable.

System manager(s) and address:

Assistant Attorney General, Civil Division; U.S. Department of Justice, 10th and Constitution Avenue NW., Washington, D.C. 20530.

Notification procedure:

Address inquiries to Chief, Torts Section, Civil Division, U.S. Department of Justice, 10th and Constitution Avenue NW., Washington, D.C. 20530.

Record access procedures:

A request for information concerning the swine flu administrative claims of the Civil Division should be submitted in writing, with the envelope and letter clearly marked "Privacy Act Request". The request should include the file number and/or names of any claimants known to the requester. The requester should also provide a return address for transmitting the information. Such access requests should be submitted to the system manager listed above. Requests may also be made by telephone. In such cases the caller will be referred to the attorney of record. The attorney, in turn, may require an official written request.

Contesting record procedures:

Individuals desiring to contest or amend information maintained in the system should direct their request to the system manager listed above. The request should clearly state what in-

formation is being contested, the reasons for contesting it, and the proposed amendment to the information sought.

Record source categories:

All swine flu claimants are sources of information. Such information is either contained in the record material in the case files or has been extracted from that record material and put onto docket and index cards.

Systems exempted from certain provisions of the act:

None.

[FR Doc. 78-23955 Filed 8-24-78; 8:45 am]

[4510-24]

DEPARTMENT OF LABOR

Bureau of Labor Statistics

BUSINESS RESEARCH ADVISORY COUNCIL'S COMMITTEE ON MANPOWER AND EMPLOYMENT

Meeting

The BRAC Committee on Manpower and Employment will meet at 9:30 a.m., September 14, 1978, at the General Accounting Office Building, in Room 2106, 441 G Street NW., Washington, D.C. The agenda for the meeting is as follows:

1. The establishment survey (790 program):
   (a) Review of current program.
   (b) Possible program changes.
   (c) Conceptual differences between 790 and CPS surveys.
2. Job vacancy program.
3. National Commission on Employment and Unemployment Statistics:
   (a) Summary of major issues and options presented to NCEUS in hearings and meetings.
   (b) Current information on feasibility and cost of implementing above items.

This meeting is open to the public. It is suggested that persons planning to attend this meeting as observers contact Kenneth G. Van Auken, Executive Secretary, Business Research Advisory Council, area code 202-523-1559.

Signed at Washington, D.C., this 22d day of August 1978.

JANET L. NORWOOD,
Acting Commissioner of Labor Statistics.

[FR Doc. 78-23984 Filed 8-24-78; 8:45 am]

[4510-30]

Employment and Training Administration

EMPLOYMENT TRANSFER AND BUSINESS COMPETITION DETERMINATIONS UNDER THE RURAL DEVELOPMENT ACT

Applications

The organizations listed in the attachment have applied to the Secretary of Agriculture for financial assistance in the form of grants, loans, or loan guarantees in order to establish or improve facilities at the locations listed for the purposes given in the attached list. The financial assistance would be authorized by the consolidated Farm and Rural Development Act, as amended, 7 U.S.C. 1924(b), 1932, or 1942(b).

The act requires the Secretary of Labor to determine whether such Federal assistance is calculated to or is likely to result in the transfer from one area to another of any employment or business activity provided by operations of the applicant. It is permissible to assist the establishment of a new branch, affiliate or subsidiary, only if this will not result in increased unemployment in the place of present operations and there is no reason to believe the new facility is being established with the intention of closing down an operating facility.

The act also prohibits such assistance if the Secretary of Labor determines that it is calculated to or is likely to result in an increase in the production of goods, materials, or commodities, or the availability of services or facilities in the area, when there is not sufficient demand for such goods, materials, commodities, services, or facilities to employ the efficient capacity of existing competitive commercial or industrial enterprises, unless such financial or other assistance will not have an adverse effect upon existing competitive enterprises in the area.

The Secretary of Labor's review and certification procedures are set forth at 29 CFR Part 75. In determining whether the applications should be approved or denied, the Secretary will take into consideration the following factors:

1. The overall employment and unemployment situation in the local area in which the proposed facility will be located.

2. Employment trends in the same industry in the local area.

3. The potential effect of the new facility upon the local labor market, with particular emphasis upon its potential impact upon competitive enterprises in the same area.

4. The competitive effect upon other facilities in the same industry located in other areas (where such competition is a factor).

5. In the case of applications involving the establishment of branch plants or facilities, the potential effect of such new facilities on other existing plants or facilities operated by the applicant.

All persons wishing to bring to the attention of the Secretary of Labor any information pertinent to the determinations which must be made regarding these applications are invited to submit such information in writing within two weeks of publication of this notice to: Deputy Assistant Secretary for Employment and Training, 601 D Street NW., Washington, D.C. 20213.

Signed at Washington, D.C., this 21st day of August 1978.

ERNEST G. GREEN,
Assistant Secretary for Employment and Training.

APPLICATIONS RECEIVED DURING THE WEEK ENDING AUGUST 18, 1978

Name of applicant and location of enterprise and principal product or activity: D & J Enterprises, Clearwater, Minn.—Retail shopping center.

[FR Doc. 78-23785 Filed 8-24-78; 8:45 am]

[4510-30]

EMPLOYMENT OPPORTUNITIES PILOT PROGRAM

Selection of Sponsors

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: This is an announcement of the welfare reform employment demonstration program. The purpose of this announcement is to notify the public of the selection of prime sponsors to operate the pilot projects to be carried out under the program.

FOR FURTHER INFORMATION CONTACT:

Jodie T. Allen, Special Assistant to the Secretary for Welfare Reform, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210, 202-523-9184.

SUPPLEMENTARY INFORMATION:

SITE SELECTION FOR THE EMPLOYMENT OPPORTUNITIES PILOT PROGRAM

INTRODUCTION

The Secretary of Labor announces his intention to begin negotiations with the following prime sponsors (under the Comprehensive Employment and Training Act) for the purpose of securing agreements with these sponsors to serve as the sites for the employment opportunities pilot program:

PRIME SPONSORS SELECTED, SUBJECT TO NEGOTIATIONS, AS SITES FOR THE EMPLOYMENT OPPORTUNITIES PILOT PROGRAM

Lowell Consortium, Massachusetts, Balance of Union County, N.J. (including Elizabeth City), Pittsburgh, Pa., Mobile Consortium, Alabama, Balance of State—North Carolina (part), Eastern Kentucky CEP (part), Columbus Consortium, Ohio, Marathon County, Wis., Baton Rouge, La., Coastal Bend Manpower Consortium, Texas, Balance of State—Missouri (part), Weld County, Colo., Long Beach, Calif., and Balance of State—Washington (part).

If the Department does not reach satisfactory agreement with any of the above named prime sponsors or if the prime sponsors fail to fulfill the conditions of the proposed planning grants, the Secretary may choose to designate an alternate prime sponsor to become a pilot project site.

A description of the purposes of the pilot program and the site selection process follows. A more detailed documentation of the site selection process, including specific reasons for the selection of each prime sponsor, is available for inspection in room 3402, 601 D Street NW., Washington, D.C. 20213.

PURPOSES OF THE PILOT PROGRAM

The employment opportunities pilot program is being conducted to prepare for national implementation of the jobs component of the program for better jobs and income (PBJI), the President's proposal for welfare reform. The President has requested $200 million for fiscal year 1979 from Congress for the purpose of implementing the pilot program.

The intent of PBJI and the pilot program is to assure, insofar as it is possible, job opportunities to the eligible population. Primary earners in families with children will be eligible for subsidized job or training placement and job search assistance. Childless couples and single persons may receive job search assistance. Approximately 35,000 jobs will be allocated. The number of jobs allocated to each site will be based upon the estimated demand for jobs within the prime sponsor area. The estimated demand was calculated from a computerized microsimulation model.

The pilot program will test the effects of the program on the labor market, verify the accuracy of the computer-based estimates of job demand, study problems associated with particular types of labor markets including seasonality and the use of migrant labor, and develop and pretest administrative structures. These goals influence the site selection process described below.

In addition, the program will develop and evaluate alternative methods of creating employment and training opportunities, evaluate the adequacy of overhead allocations, test various methods of improving private sector placements, and develop management information and program monitoring systems.

Prime sponsors selected to participate in the pilot program will be required to verify eligibility of participants including those eligible under PBJI, develop procedures for providing intensive job search assistance, and insure the creation of adequate numbers of productive job and training opportunities.

Average wages paid to participants will be determined by the Department of Labor according to the area wage index in the CETA program. All job participants will receive no less than the minimum wage. Maximum allowable wages will also be established. Prime sponsors will receive the average wage determined for the prime sponsor plus a percentage of this wage for overhead for each full-time equivalent position. Prime sponsors may split full-time equivalent positions in order to provide part-time positions.

Within these constraints, prime sponsors will have considerable discretion to create jobs in the public or nonprofit sectors and to fund institutional or on-the-job training opportunities with public or private organizations.

An extension research and evaluation effort will be conducted in all the demonstration sites.

SITE SELECTION PROCESS

The site selection process began with a proposed funding level adequate to support 50,000 job and training positions.

The purpose of the pilot program, as described above, placed three kinds of requirements on site selection.

1. The administrative structures in each region must be tested.

2. Each site must be allocated enough jobs to supply the estimated demand.

3. Sites must be representative of the predominant kinds of labor markets.

The site selection process involved four separate phases. Each of the first three phases was based on a different set of criteria.

The fourth phase involved a combination of the criteria from the other phases as well as other additional criteria. Each of the three above requirements was addressed during one or more of the phases.

The first phase criteria concentrated on size and type of site and geographic representation. The second phase focused on labor market and demographic characteristics, the third on administrative suitability given the experimental nature of the program, and the fourth phase on the national representativeness of various combinations of sites.

PHASE I

During the first phase, Employment and Training Administration (ETA) personnel in conjunction with staff from the Office of the Secretary selected 138 prime sponsors based upon the following criteria:

CRITERIA—PHASE I

1. *Geographic representativeness and regional office involvement.* At least on site in each of the 10 Federal regions was selected in order to insure geographic representativeness and to familiarize each regional offfice with the new program.

2. *Minimize the number of separate sites.* Given the intense evaluation and survey efforts planed for the projects, it was important to minimize the number of regions wherein more than one non-contiguous prime sponsor was selected. Overall, it was not expected that more than 15 separate sites would be chosen.

3. *Regional job allocations.* Each of the Federal regions were allocated job slots on the basis of the estimated regional demand for the welfare reform jobs. If more than one site was assigned to a region, the number of jobs allocated to the region was divided between the sites. Sites were chosen so that the estimated demand for jobs was between 50 and 130 percent of the site's allocation. This amount of variation was necessary in order to satisfy other parameters of site selection.

4. *Type of site in each region.* The distribution of the welfare reform job participants by place of residence was estimated for each Federal region. Place of residence was defined as: large SMSA[1] (one of 98 largest)[2] small SMSA, and outside SMSA. For each region a "type of site" was designated consistent with the "place of residence" for a plurality of the job participants. For example, in region I, 30 percent of the job participants live in large SMSA's, 39 percent in small SMSA's and 31 percent outside SMSA's. Because of plurality of the job participants would reside in small SMSA areas, the region was allocated a small SMSA site.

In addition, two prime sponsors were considered for regions II, IV, V, VI, and IX. In region II where 70 percent of the jobs will be taken by people

[1] SMSA—standard metropolitan statistical area. SMSA's are used to identify labor markets.

[2] Census data used for the microsimulation model was only available for the 98 largest SMSA's.

living within large SMSA's the possibility of combining two smaller contiguous prime sponsors within a large SMSA was considered as well as the possibility of having one large prime sponsor operate the pilot site. Both an SMSA site and a non-SMSA site were allocated to regions IV and V because each of these regions were estimated to have more SMSA and more non-SMSA job participants than any other region.

Region VI was assigned two sites because the region encompasses two distinctly different geographic areas, the South and the Southwest. During phase I, the possibility for both a central city and a suburban site was allowed in region IX (the latter because of the dominate residential pattern in California).

5. *Sites under investigation.* Prime sponsors currently under investigation by the Department of Labor were excluded from consideration where the investigation raised serious doubts about the sponsors ability to develop a program.

The following chart shows the required type of site and size of site by region.

Criteria Applied—Phase I

DOL region	Job allocation	Size of site limitations**
I	2,650	Smaller SMSA* (1,325 to 3,445 jobs).
II	5,750	Large SMSA* (2,875 to 7,475 jobs).
III	4,750	Large SMSA (2,375 to 6,175 jobs).
IV	10,800	Large SMSA (1,620 to 8,986 jobs). Outside SMSA (rural) (1,944 to 9,828 jobs).
V	9,850	Large SMSA (2,562 to 7,850) jobs outside SMSA.**
VI	5,700	SMSA (798 to 4,965 jobs). Outside SMSA (940 to 5,335 jobs).
VII	2,150	Outside SMSA (1,075 to 2,795 jobs).
VIII	1,400	Outside SMSA (700 to 1,820 jobs).
IX	5,450	Large SMSA (1,362 to 7,085 jobs).
X	1,450	Out side SMSA (725 to 1,885 jobs).

*Larger SMSA's are one of the 98 largest.

**A memo describing the procedure for setting size limitations in regions with multiple sites is included in the detailed documentation.

PHASE II

During the second phase staff from the Office of the Secretary attempted to select 50 sites that were repersentative of their respective region in terms of labor market and demographic characteristics. The factors listed below were selected because they are thought to be those most important in determining the demand for lower wage public jobs. The use of these factors also indentify sites which are representative of the region.

CRITERIA—PHASE II

Regional and demographic characteristics:

1. Average wage level (1975 data).
2. Unemployment rate (1977 data).
3. Percent nonwhite (1977 data).
4. Percent of Spanish heritage (1970 data—U.S. Census definition).
5. Welfare benefit (1978 AFDC plus food stamp guarantee).
6. Pecent poor (1970 and 1975 data).

Other factors:

7. Sites which are the center of a labor of a labor market or which encompass an entire labor market were strongly preferred. Diverse economies were also preferred.
8. Preference was given to those sites whose job estimate came closest to the regional allocation.
9. Preference was given to sites wherein a monthly reporting project is to be operated by the Department of Health, Education, and Welfare. The monthly reporting project is testing administrative features of welfare reform. Part of the purpose of the pilot program is to develop administrative structures for welfare reform. Thus it is necessary to have a site located in a monthly reporting project area to develop coordination between the job program and the cash assistance program.
10. Sites receiving large amounts of funds (tier I) for the youth entitlement project were excluded, since the addition of an employment opportunities pilot program could overburden the prime sponsor, causing both programs to suffer.
11. It was desirable to obtain a mix of prime sponsor types (e.g., consortia, balance of state).
12 Preference was given to prime sponsors where it was known that there are special features or characteristics that the demonstration project should examine, for example, seasonal labor markets.
13. As previously stated each site was to represent either a large SMSA, small SMSA, or outside SMSA area within its region. In addition, the total combination of sites was to include, if possible, each of the following: Large Eastern city; large Southern city; rural South; rural Appalachia; Midwest city; Sunbelt city; rural West; Western city and suburb; and seasonal/migrant labor.

In phase II, the above criteria were used to compare each prime sponsor against all other prime sponsors of the type (e.g., large SMSA) within the region. Consequently, comparisons across regions as to the representativeness of sites are not valid. In some regions, the phase I list of sites contained several prime sponsors which are very representative of the region. In these regions, stricter limits around the quantitative criteria (e.g., unemployment rate) were employed during the screening process than was the case in regions where fewer, less representative sites appeared on the phase I list. One or a combination of factors could result in the inclusion or exclusion of any particular prime sponsor.

PHASE III

In phase III, staff from the Office of the Secretary as well as ETA staff met with each ETA Regional Administrator who identified those sites from phase II recommendations which would be most appropriate selections for pilot sites given the experimental nature of the program and other employment and training factors.

In a few regions, sites that had not been recommended by the national office during phase II were evaluated to insure that sponsors with special features were not overlooked and to provide additional back-up sites where necessary. Thus six sites which had not been recommended in phase II, were recommended as potential sites in phase III.

PHASE IV

Various combinations of sites which were recommended during phase III were analyzed as to their national representativeness in phase IV. Preference was given to combinations of sites which require approximately 35,000 jobs. In addition preference was given to sites which contained all or most of the respective labor market. The site combinations were evaluated (through the use of weighted averages) according to the following criteria:

CRITERIA—PHASE IV

1. The national unemployment rate and a wide spread in rates to include high unemployment and low unemployment areas.
2. The national average wage level (for larger SMSA's and others) and a wide spread in wages.
3. A wide spread in welfare benefits and a mix of aid to families with dependent children and aid to families with dependent children and unemployed fathers states.
4. The national nonwhite percentage (for SMSA's and non-SMSA's).
5. The national Spanish percentage.
6. The metropolitan/nonmetropolitan population distribution.
7. A mix of CETA prime sponsors by type (e.g., consortium, balance of state).
8. The total number of jobs.

The Department of Labor also intends to conduct a controlled dispersed sample experiment in Philadelphia, Pa. Philadelphia was selected from among the 10 largest cities which characteristically have high proportions of minorities, high unemployment rates, high percentages of poor

families with children, and large welfare populations. Philadelphia was selected because its unemployment rate is among the highest as is the percent of minorities, percent of poor families with children and the percent on welfare. Philadelphia also suffers from fiscal stress and is representative of the 10 largest cities with respect to average wage and welfare benefits.

Final site selections were approved by the Secretary of Labor.

Signed: August 18, 1978.

RAY MARSHALL,
Secretary of Labor.

[FR Doc. 78-23786 Filed 8-24-78; 8:45 am]

[4510-28]

Office of the Secretary

[TA-W-3301]

ALBERTO, INC., BALTIMORE, MD.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3301: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on March 7, 1978, in response to a worker petition received on February 21, 1978, which was filed by the Amalgamated Clothing & Textile Worker's Union on behalf of workers and former workers producing men's tailored clothing at Alberto, Inc., Baltimore, Md.

During the course of the investigation, it was revealed that Alberto produced only men's dress coats and jackets and Mennonite dress coats.

The notice of investigation was published in the FEDERAL REGISTER on March 17, 1978 (43 FR 11277). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Alberto, its customers, the U.S. International Trade Commission, U.S. Department of Commerce, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met the following criterion has not been met:

Increases in imports of articles like or directly competitive with those produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Alberto assembles men's tailored made to measure dress coats and sport coats and Mennonite (religious sect) dress coats for apparel manufacturers and men's custom tailor shops on a contract basis. The Department surveyed Alberto's customers. Respondents to the survey did not import men's apparel.

CONCLUSION

After careful review of the facts obtained in the investigation, I determine that all workers at Alberto, Inc., Baltimore, Md. are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 17th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23799 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3247]

ALTOONA SHOE, INC., ALTOONA, PA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3247: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on February 27, 1978, in response to a worker petition received on February 7, 1978, which was filed on behalf of workers and former workers producing ladies' casual shoes at Altoona Shoe, Inc., Altoona, Pa.

The notice of investigation was published in the FEDERAL REGISTER on March 14, 1978 (43 FR 10648). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Altoona Shoe, Inc., its customers, the U.S Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of women's and misses' nonrubber footwear, excluding athletic footwear, increased from 190.7 million pairs in 1975 to 195.5 million pairs in 1976, and then decreased to 181.8 million pairs in 1977. The ratio of imports to domestic production remained virtually constant from 1975 to 1976 and then increased from 114.0 percent in 1976 to 119.2 percent in 1977.

A Department survey, conducted with customers who purchased shoes produced by Altoona Shoe, Inc., revealed that customers increased imports of ladies' casual shoes from 1975 to 1976 and from 1976 to 1977, while decreasing purchases from Altoona Shoe, Inc.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with ladies' casual shoes produced by Altoona Shoe, Inc., Altoona, Pa. contributed importantly to the decline in sales and production and to the total or partial separation of workers at that firm. In accordance with the provisions of the Act, I make the following certification:

All workers at Altoona Shoe, Inc., Altoona, Pa. who became totally or partially separated from employment on or after June 10 1977 are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 17th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23800 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3401]

CHINO MINES DIVISION OF KENNECOTT COPPER CORP., HURLEY, N. MEX., SILVER CITY, N. MEX. MINE

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3401: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 22, 1978 in response to a worker petition received on March 8, 1978 which was filed by the United Steelworkers of America on behalf of workers and former workers producing copper ore and refined copper at the Chino Mines Division of Kennecott Copper Corp., Hurley, N. Mex.

The notice of investigation was published in the FEDERAL REGISTER on April 7, 1978 (43 FR 14775). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Kennecott Copper Corp., Metals Week, Metal Bulletin, American Metal Market, the U.S. Department of the Interior, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

U.S. imports of refined copper increased from 147 thousand short tons in 1975 to 384 thousand short tons in 1976 and 391 thousand short tons in 1977.

The ratio of imported refined copper to domestic production increased from 8.6 percent in 1975 to 21.0 percent and 22.2 percent, respectively, in 1976 and 1977.

While imports of refined copper had increased by 161 percent in 1976 compared to 1975 and by 2 percent in 1977 compared to 1976, domestic demand increased at only a fraction of those rates. Inventory levels of domestic and imported copper on consignment at domestic refineries in December 1976 were 31.4 percent above December 1975 levels and 143.2 percent above December 1974 levels. Kennecott and other domestic producers of refined copper lost substantial sales in 1977 because of the excessive inventories of domestic and imported refined copper.

Imports of copper are affected by the differential between the domestic producers' price for copper and the world price established by the LME (London Metal Exchange). When the LME price drops more than the estimated transportation costs of 5-8 cents per pound below the domestic producers' price, the demand for imported copper increases. The yearly average LME price for copper in 1977 was 10 cents below the yearly average domestic producers' price. During May and June 1977 the LME price was almost 11 cents per pound below the domestic producers' price and in July and August 1977 the LME price was almost 12 cents per pound below the domestic producers' price. At the same time, the abundant supply of copper stocks in the forseeable future provides no reason for domestic consumers of copper to maintain ties with domestic producers for purposes of a guarantee against copper shortages. Consequently, in 1977, when many domestic copper producers curtailed production because of the depressed market price for copper, imports of refined copper increased.

Price pressure from imported copper has reduced the ability to profitably mine domestic ore and convert it to copper concentrate and refined copper. Industry sources state that the weighted average production costs of the lowest cost domestic copper mines are 63 cents per pound. The weighted average costs for the highest cost domestic copper mines are $1.05 per pound. Thus, with a domestic market price of 60 cents per pound, domestic producers lose, on the average, 3 to 45 cents on each pound of copper they choose to sell.

The Chino Mines Division's decision to lay off workers in March 1978 was based mainly on an attempt to minimize losses which the company could not avoid were it to run at normal production levels at the current market prices for copper.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with refined copper produced by the Chino Mines Division of Kennecott Copper Corp., Hurley, N. Mex. including the Silver city, N. Mex. mine contributed importantly to the decline in sales and to the total or partial separation of workers of that division of the firm. In accordance with the provisions of the act, I make the following certification:

All workers of the Chino Mines Division of Kennecott Copper Corp., Hurley, N. Mex. including the Silver City, N. Mex. mine who became totally or partially separated from employment on or after March 1, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 18th day of August 1978.

James F. Taylor,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-23801 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3025]

CLEVELAND CAP SCREW, CLEVELAND, OHIO; ATLANTA, GA.; CHICAGO, ILL.; AND JENKINTOWN, PA.

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3025: Investigation regarding certification of eligibility to apply for workers adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 6, 1978 in response to a worker petition received on January 23, 1978 which was filed on behalf of workers and former workers producing, standard and nonstandard cap screws at Cleveland Cap Screw, Cleveland, Ohio.

The notice of investigation was published in the Federal Register on February 17, 1978 (43 FR 7064). No public hearing was requested and none was held.

The information upon which the determinations were made was obtained principally from officials of Cleveland Cap Screw, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. With respect to workers employed at the production facility in Cleveland, without regard to whether any of the other criteria have been met, the following criterion has not been met:

that a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated.

The Department's investigation revealed that the average number of workers engaged in employment related to the production of bolts increased in 1977 compared to 1976. Employment of production workers increased during three of the four quarters of 1977. Workers formerly producing standard fasteners at the Cleveland plant were absorbed into production of specialty items.

With respect to workers engaged in employment related to the marketing and warehousing of standard bolts, at Cleveland Cap Screw facilities in Atlanta, Ga.; Chicago, Ill.; and Jenkintown, Pa., all of the group eligibility requirements of section 222 of the Act have been met.

U.S. imports of standard bolts increased both absolutely and relative to domestic production from 1975 to 1976 and from 1976 to 1977. U.S. imports of standard bolts increased absolutely during the first quarter of 1978 compared to the first quarter of 1977.

Several customers of Cleveland Cap Screw who were surveyed increased purchases of imported standard fasteners while reducing purchases from Cleveland Cap Screw. Reduced sales of standard fasteners resulting from increased import competition caused Cleveland Cap Screw to terminate production of standard fasteners in early 1978. The termination of production of standard fasteners at the Cleveland plant caused the closure of three regional facilities of Cleveland Cap

Screw devoted solely to the sale and distribution of standard fasteners.

CONCLUSIONS

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with standard bolts produced at Cleveland Cap Screw, Cleveland, Ohio contributed importantly to the decline in sales and production of standard fasteners and to the separation of workers engaged in employment related to the marketing and warehousing of such fasteners from the company's regional facilities. In accordance with the provisions of the act, I make the following certification:

All workers employed at the Atlanta, Ga.; Chicago, Ill.; and Jenkintown, Pa. facilities of Cleveland Cap Screw, who became totally or partially separated from employment on or after January 1, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

I further determine that workers at Cleveland Cap Screw, Cleveland, Ohio plant are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-23802 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3686]

FORMFLEX FOUNDATIONS, INC., SADDLE BROOK, N.J.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3686: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on May 8, 1978, in response to a worker petition received on April 28, 1978, filed on behalf of workers and former workers producing ladies' and girls' brassieres and ladies' girdles.

The notice of investigation was published in the FEDERAL REGISTER on May 26, 1978 (43 FR 22793). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Formflex Foundations, Inc., and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

that a significant number or proportion of the workers in such workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated.

Employment at the Saddle Brook plant increased in 1977 compared to 1976 and also increased in the first 4 months of 1978 compared to the same period in 1977.

CONCLUSION

After careful review, I determine that all workers of Formflex Foundations, Inc., Saddle Brook, N.J., are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 17th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23803 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3722]

G. C. ZARNAS & CO., INC., BETHLEHEM, PA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3722: Investigation regarding certification of eligibility to apply for worker adjustment asistance as prescribed in section 222 of the Act.

The investigation was initiated on May 16, 1978, in response to a worker petition received on April 27, 1978, which was filed by the Painter's District Council No. 4 on behalf of workers and former workers providing industrial painting services at G. C. Zarnas & Co.

The notice of investigation was published in the FEDERAL REGISTER on June 27, 1978 (43 FR 27923). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from G. C. Zarnas & Co. and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Act must be met. The Department has determined that services are not "articles" within the meaning of section 222 of the Act, and the independent firms for which the subject firm provides services cannot be considered to be the "workers' firm."

The Department's investigation revealed that G. C. Zarnas & Co. is a New York corporation which provides maintenance painting services for a major steel company under a competitively awarded contract. Workers at G. C. Zarnas & Co. are engaged in providing painting services and do not produce an article within the meaning of section 222(3) of the Act.

G. C. Zarnas & Co. and its customer have no controlling interest in one another. All workers engaged in providing maintenance painting services at G. C. Zarnas & Co. are employed by that firm. All personnel action and payroll transactions are controlled by G. C. Zarnas & Co. personnel. All employment benefits are provided and maintained by G. C. Zarnas & Co. Workers are not at anytime under employment or supervision by any customers of G. C. Zarnas Co. Thus, G. C. Zarnas must be considered "the workers' firm."

CONCLUSION

After careful review I determine that all workers at G. C. Zarnas & Co., Bethlehem, Pa., are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 17th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23804 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3688]

GLORIA COAT CORP., MORRISTOWN, N.J.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3688: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on May 8, 1978, in response to a worker petition on April 28, 1978, which was filed by the International Ladies' Garment Workers Union on behalf of workers and former workers producing ladies' coats and raincoats at Gloria Coat Corp., Morristown, N.J.

The notice of investigation was published in the FEDERAL REGISTER on May 26, 1978 (43 FR 22793-5). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Gloria Coat Corp., its customers (manufacturers), the U.S Department of Commerce, the U.S. International Trade Commission, the National Cotton Council of America, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. The investigation revealed that all of the group requirements have been met.

Imports of women's, misses', and children's coats and jackets increased from 2,252,000 dozen in 1976 to 2,723,000 dozen in 1977. Imports decreased from 590,000 dozen to 572,000 dozen in the first quarter of 1978 compared to the first quarter of 1977. The ratio of imports to U.S. production increased from 48.3 percent in 1976 to 54.9 percent in 1977.

The two customers representing the majority of sales of Gloria Coat Corp., increased imports of ladies' coats and raincoats and reduced orders with Gloria Coat Corp. in 1977 and 1978. Both of these customers (manufacturers) were certified by the Department of Labor as eligible to apply for adjustment assistance in 1978.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with ladies' coats and raincoats produced at Gloria Coat Corp., Morristown, N.J., contributed importantly to the declines in sales and production and to the total or partial separation of the workers of that firm. In accordance with the provisions of the act, I make the following certification:

All workers of Gloria Coat Corp., Morristown, N.J., who became totally or partially separated from employment on or after June 12, 1977 are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 17th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23805 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3028; TA-W-3029]

HANNA NICKEL MINING CO. AND HANNA NICKEL SMELTING CO., RIDDLE, OREG.

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3028 and TA-W-3029: Investigations regarding elegibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigations were initiated on February 6, 1978, in reponse to a worker petition received on January 17, 1978, which was filed by the United Steel workers of America on behalf of workers and former workers producing ferronickel ore at Hanna Nickel Mining Co., Riddle, Oreg., and on behalf of workers and former workers producing ferronickel pigs at Hanna Nickel Smelting Co., Riddle, Oreg. Production is fully intergrated between the two companies, which are subsidiaries of the Hanna Mining Co.

The notice of investigation was published in the FEDERAL REGISTER on February 17, 1978 (43 FR 7064). No public hearing was requested and none was held.

The information upon which the determinations were made was obtained principally form the Hanna Mining Co., the U.S. Department of Commerce, the U.S. International Trade Commission, the U.S. Department of Interior, the American Metal Market, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met with respect to workers producing ferronickel or at Hanna Nickel Mining Co.:

that a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated.

The Department's investigation revealed that the average number of production workers engaged in employment related to the production of ferronickel ore at the Hanna Nickel Mining Co. increased 22.1 percent from 1975 to 1976, increased 6.0 percent from 1976 to 1977, and increased 5.7 percent during January through May 1978 as compared to January through May 1977. Weekly hours worked by production workers were not reduced at any time during this period.

With respect to workers producing ferronickel pigs, all of the group eligibility requirements of section 222 of the act have been met.

U.S. imports of nickel declined from 70,095 short tons in 1975 to 61,821 short tons in 1976, and then increased to 82,782 short tons in 1977. The ratio of imports to domestic production declined from 491.1 percent in 1975 to 474.0 percent in 1976 and then increased to 674.0 percent in 1977.

Nickel producers worldwide have been affected by a global glut of nickel. Total world stocks are estimated at a level equal to 9 or 10 months of world requirements. This vast surplus has caused a decline in the price of nickel. Imports of nickel increased to a level nearly seven times greater than domestic production in 1977, as domestic consumers turned incresingly to foreign sources. Consequently, Hanna Nickel Smelting Co., which accounts for the bulk of domestic nickel production, experienced declining sales in 1977 and January 1978, necessitating cutbacks in production and employment.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with ferronickel pigs produced by Hanna Nickel Smelting Co., Riddle, Oreg., contributed importantly to the decline in sales and production and to the separation of workers at that company. In accordance with the provisions of the Act, I make the following certification:

All workers at Hanna Nickel Smelting Co., Riddle, Oreg., who became totally or partially separated from employment on or after January 1, 1977, and before February 27, 1978, are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974. Workers separated from employment on or after February 27, 1978, are denied eligibility.

I further determine that all workers at Hanna Nickel Mining Co., Riddle, Oreg., are denied eligibility to apply for trade adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-23806 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3696]

INTERNATIONAL MILL SERVICE, INC., NEWPORT, ARK.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3696: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on May 11, 1978 in response to a worker petition received on May 1, 1978, which was filed on behalf of all workers of the Newport, Ark. facility of International Mill Service, Inc., who recover waste material from the steel making process and produce scrap metal.

The notice of investiagation was published in the FEDERAL REGISTER on May 30, 1978 (43 FR 23036). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from International Mill Service, Inc. and Department files.

In order to make an affirmative determination and issue a certifcation of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met.

Without regard to whether any of the other criteria have been met, the following criterion has not been met:

that increased imports of articles like or directly competitive with those produced by the firm or subdivision contributed importantly to the separations or threat thereof, and to the absolute decrease in sales or production.

International Mill Service (IMS) employees at the Newport facility are under contract with Tennessee Forging Steel's Newport, Ark. plant. IMS removes from the furnace area the spillage (slag) produced in the steelmaking process. The slag is hauled by IMS truck drivers to a work site provided by the mill, where it is dumped and allowed to cool. The slag is processed and scrap metal is reclaimed. The scrap metal is returned to the furnace and recycled into steel. The slag and scarp metal are owned by Tennessee Forging Steel. There is no corporate relationship between International Mill Service, Inc. and its customers.

International Mill Service is involved in the production of scrap metal of which imports are negligible. IMS is under contract to Tennessee Forging's Newport, Ark. plant for this specialized production of scrap metal. When the Newport plant reduced its output of steel the need for production of scrap metal declined accordingly. The reduction in scrap metal production was caused by decreased production of steel at Tennessee Forging's Newport plant.

CONCLUSION

After careful review, I determine that all workers at the Newport, Ark. facility of International Mill Service, Inc. be denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 17th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23807 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3480]

JARMEL FABRICS, INC., NEW YORK, N.Y.

Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3480: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on April 6, 1978 in response to a worker petition received on March 24, 1978, which was filed on behalf of workers and former workers producing double knit polyester fabric at Jarmel Fabrics, Inc., New York, N.Y.

The notice of investigation was published in the FEDERAL REGISTER on April 25, 1978 (43 FR 17550). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Jarmel Fabrics, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met the following criterion has not been met:

that increased imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

U.S. imports of manmade knit fabric decreased from 83 million square yards in 1975 to 67 million square yards in 1976 to 61.8 million square yards in 1977.

Customers surveyed reported no import purchases in 1976, 1977 or 1978.

CONCLUSION

After careful review I determine that all workers of Jarmel Fabrics, Inc., New York, N.Y. are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 17th day of August 1978.

HARRY J. GILMAN,
Acting director, Office of Foreign Economic Research.

[FR Doc. 78-23808 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3402]

KENNECOTT REFINING CORP., BALTIMORE, MD.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3402: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on March 22, 1978 in response to a worker petition received on March 7, 1978 which was filed by the United Steelworkers of America on behalf of workers and former workers producing refined copper at the Kennecott Refining Corp., Baltimore, Md.

The notice of investigation was published in the FEDERAL REGISTER on April 7, 1978 (43 FR 14775). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Kennecott Refining Corp., Metals Week, Metal Bulletin, American Metal Market, the U.S. International Trade Commission, the U.S. Department of Commerce, the U.S. Department of Interior, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of refined copper increased from 147,000 short tons in 1975 to 384,000 short tons in 1976 and 391,000 short tons in 1977.

The ratio of imported refined copper to domestic production increased from 8.6 percent in 1975 to 21.0 percent and 22.2 percent, respectively, in 1976 and 1977.

While imports of refined copper had increased by 161 percent in 1976 compared to 1975 and by 2 percent in 1977 compared to 1976, domestic demand increased at only a fraction of those rates. Inventory levels of domestic and imported copper on consignment at domestic refineries in December 1976 were 31.4 percent above December 1975 levels and 143.2 percent above December 1974 level. Kennecott and other domestic producers of refined copper lost substantial sales in 1977 because of the excessive inventories of domestic and imported refined copper.

Imports of copper are affected by the differential between the domestic producers price for copper and the price established by the LME (London Metal Exchange). When the LME price drops, more than the estimated transportation costs of 5-8 cents per pound below the domestic producers price, the demand for imported copper increases. During May and June 1977, the LME price was almost 11 cents per pound below the domestic producers price and in July and August 1977, the LME price was almost 12 cents per pound below the domestic producers price. At the same time, the abundant supply of copper stocks in the foreseeable future provides no reason for domestic consumers of copper to maintain ties with domestic producers for purposes of a guarantee against copper shortages. Consequently in 1977, when many domestic copper producers curtailed production because of the depressed market price for copper, imports of refined copper increased.

Price pressure from imported copper has reduced the ability to profitably mine domestic ore and convert it to copper concentrate and refined copper. Industry sources state that the weighted average production costs of the lowest cost domestic copper mines are 63 cents per pound. The weighted average costs for the highest cost domestic copper mines are $1.05 per pound. Thus, with a domestic market price of 60 cents per pound, domestic producers lose, on the average, 3 to 45 cents on each pound of copper they chose to sell.

The Kennecott Refining Corp.'s decision to lay off workers beginning in July 1977 was based mainly on an attempt to minimize losses which the company could not avoid were it to run at normal production levels at the current market prices for copper.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with refined copper produced by the Kennecott Refining Corp., Baltimore, Md., contributed importantly to the decline in production and to the total or partial separation of workers at that firm. In accordance with the provisions of the Act, I make the following certification:

All workers at Kennecott Refining Corp., Baltimore, Md., who became totally or partially separated from employment on or after July 19, 1977 are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-23809 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3467]

L. & S. FASHIONS, INC., AMITYVILLE, N.Y.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3467: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on April 4, 1978, in response to a worker petition received on March 27, 1978, which was filed on behalf of workers and former workers producing women's coats at L. & S. Fashions, Inc., Amityville, N.Y.

The notice of investigation was published in the FEDERAL REGISTER on April 28, 1978 (43 FR 18360). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from L. & S. Fashions, Inc., its customers, the National Cotton Council of America, the U.S Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of women's and misses' and children's coats and jackets increased in 1975 to 1,517 thousand dozen, increased in 1976 to 2,252 thousand dozen, and increased in 1977 to 2,723 thousand dozen.

U.S. imports of women's, misses' and children's raincoats increased in 1975 to 191 thousand dozen, increased in 1976 to 261 thousand dozen and decreased in 1977 to 242 thousand dozen.

The ratio of imports to domestic production of women's, misses' and children's coats and jackets increased in 1975 to 38.9 percent and increased in 1976 to 57.5 percent. The ratio of imports to domestic production of women's, misses' and children's raincoats increased to 36.8 percent in 1975 and increased to 50.4 percent in 1976.

A survey of the manufacturer which contracts all of the production of L. & S. Fashions, Inc. revealed that the manufacturer decreased orders from L. & S. Fashions, Inc. and increased purchases of imports in 1977 and 1978.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with women's coats produced by L. & S. Fashions, Inc., Amityville, N.Y. contributed importantly to the total or partial separation of workers at the plant. In accordance with the provisions of the Act, I make the following certification:

All workers at L. & S. Fashions, Inc., Amityville, N.Y. who became totally or partially separated from employment on or after March 21, 1977 are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-23810 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3280]

MANUFACTURING GROUP, INC., GREENSBORO, N.C.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3280: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 1, 1978 in response to a worker petition received on February 21, 1978 which was filed on behalf of workers and former workers producing texturized polyester yarn, at Manufacturing Group, Inc, Greensboro, N.C.

The notice of investigation was published in the FEDERAL REGISTER on March 11, 1978 (43 FR 10649). No

public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Manufacturing Group Inc., its customers, the American Textile Manufacturers Institute, the National Cotton Council, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met.

that increases of imports of articles like or directly competitive with articles produced by the firm or subdivison have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Manufacturing Group, Inc., Greensboro, N.C. produced texturized yarn. The petition alleges that increased imports of apparel adversely affected production and employment at Manufacturing Group, Inc. Imported apparel cannot be considered to be like or directly competitive with texturized yarn. Imports of yarn must be considered in determining import injury to workers producing texturized yarn.

The ratios of U.S. imports of all yarns (spun and texturized) to domestic production and consumption reached a peak in the most recent 5-year period at 3.2 percent in 1973. Since 1973, the ratios have been 2 percent or less.

The Department surveyed a sample of Manufacturing Group's customers. The survey results indicated that customers which imported yarn also increased purchases from the subject firm in 1977 compared to 1976.

CONCLUSION

After careful review I determine that all workers of Manufacturing Group, Inc., Greensboro, N.C., are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 17th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23811 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3751]

MIAMI-INSPIRATION HOSPITAL INC., MIAMI, ARIZ.

Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3751: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on May 23, 1978 in response to a worker petition received on May 8, 1978, which was filed on behalf of workers and former workers providing hospital, medical, and surgical services at Miami-Inspiration Hospital, Miami, Ariz.

The notice of investigation was published in the FEDERAL REGISTER on June 6, 1978 (43 FR 24633). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Miami-Inspiration Hospital and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. The Department has determined that services are not "articles" within the meaning of section 222 of the act and that independent firms for which the subject firm provides services cannot be considered the "workers' firm."

Miami-Inspiration Hospital was founded in July, 1965 and is incorporated in Arizona. The hospital is not affiliated with any other company.

Miami-Inspiration consists of a 54 bed hospital, a professional office building and dormitory facilities. All equipment in the hospital complex is owned by Miami-Inspiration Hospital, Inc. Miami-Inspiration Hospital is engaged in providing medical/surgical services under the direction of physicians and in accordance with state and federal licensure and regulations. Workers at the Miami-Inspiration Hospital provide medical/surgical services and do not produce an article within the meaning so section 222(3) of the act.

The majority of the patients at Miami-Inspiration Hospital come from the two copper mining companies in the area. Miami-Inspiration Hospital and the mining companies have no controlling interest in each other.

All workers performing hospital, medical, and surgical services are employed by Miami-Inspiration Hospital, Inc. All personnel and payroll transactions are controlled by the hospital. All employment benefits are provided and maintained by Miami-Inspiration Hospital. Workers are not at any time under the supervision of either of the mining companies. Thus, Miami-Inspiration Hospital must be considered the "workers' firm."

CONCLUSION

After careful review, I determine that all workers at Miami-Inspiration Hospital, Inc., Miami, Ariz. be denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 17th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23812 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3495]

HORACE T. POTTS STEEEL SERVICE CENTER PHILADELPHIA, PA.

Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3495: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on April 11, 1978 in response to a worker petition received on March 24, 1978 which was filed on behalf of all workers engaged in the cutting, buying, and selling of steel at Horace T. Potts Steel Service, Philadelphia, Pa.

The notice of investigation was published in the FEDERAL REGISTER on May 2, 1978 (43 FR 18791). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Horace T. Potts Steel Service and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. The Department has determined that services are not "articles" within the meaning of section 222 of the Act.

The Department's investigation revealed that the Erie Avenue and D Street facility of Horace T. Potts Steel Service is a Steel center. It purchases carbon steel, alloy steel, tool steel, and

stainless steel. It then sells these to customers in the quantities and sizes specified. Some items are sheared or sawed to size while others are shipped unaltered. Workers at the Erie Avenue and D Street facility are engaged in processing, shipping and distribution activities and do not perform any production functions.

CONCLUSIONS

After careful review, I determine that all workers at the Erie Avenue and D Street facility of Horace T. Potts Steel Service Center, Philadelphia, Pa. are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 17th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23813 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3794]

RENCO MANUFACTURING, INC., LONG BRANCH, N.J.

Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on May 31, 1978, in response to a worker petition which was filed on behalf of all employees of Renco Manufacturing, Inc., Long Branch, N.J.

The notice of investigation was published in the FEDERAL REGISTER on June 20, 1978 (43 FR 40243). No public hearing was requested and none was held.

During the course of the investigation, it was established that all employees of Long Branch Manufacturing, Long Branch, N.J., were previously certified eligible for adjustment assistance benefits on November 23, 1977. (See notice of determination for TA-W-2184.) Renco Manufacturing is the successor firm of Long Branch Manufacturing. Both firms produced the same product for the same contractor and occupied the same plant and used principally the same group of workers. All workers of Renco Manufacturing are therefore eligible to apply for benefits under the certification issued for workers of Long Branch Manufacturing.

The existing certification will expire on November 23, 1979 unless terminated by the Secretary of Labor. Since workers newly separated, totally or partially, are covered by the existing certification provided such separation occurred on or after the impact date (August 13, 1976), a new investigation would serve no purpose. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 17th day of August 1978.

HAROLD A. BRATT,
Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-23814 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3740]

ROCKLAND WEAVING, BALTIMORE, MD.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3740: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on May 18, 1978, in response to a worker petition received on May 16, 1978, which was filed on behalf of workers and former workers producing greige goods and some synthetic cotton at Rockland Weaving, Baltimore, Md. The investigation revealed that the workers produced cotton and synthetic greige fabric.

The notice of investigation was published in the FEDERAL REGISTER on June 13, 1978 (43 FR 25498). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Rockland Industries, Inc., the American Textile Manufacturers Institute, the National Cotton Council of America, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

that increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threats thereof, and to the absolute decline in sales or production.

U.S. imports of cotton greige fabric decreased absolutely in 1977 compared to 1976. The ratio of imports to domestic production decreased in the first three quarters of 1977 compared to the same period in 1976.

U.S. imports of manmade fiber greige fabric decreased in 1977 compared to 1976. The ratio of imports to domestic production has been less than 1 percent each year from 1972 through 1976.

CONCLUSION

After careful review, I determine that all workers of Rockland Weaving, Balitimore, Md., are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-23815 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3628]

ROSEMARY FASHION COAT CO., HOBOKEN, N.J.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3628: Investigation regarding eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on May 8, 1978, in response to a worker petition received on April 28, 1978, which was filed by the International Ladies' Garment Workers Union on behalf of workers and former workers producing coats and raincoats at Rosemary Fashion Coat Co., Hoboken, N.J. During the course of the investigation it was discovered that Rosemary Fashion Coat Co. only produced ladies' coats.

The notice of investigation was published in the FEDERAL REGISTER on May 26, 1978 (43 FR 22793). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Rosemary Fashion Coat Co, its customers (manufacturers), the U.S. Department of Commerce, the U.S. International Trade Commission, the National Cotton Council of America, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Act must be met. The Department's investigation revealed that all of the criteria have been met.

U.S. imports of women's, misses', and children's coat and jackets increased from 2,252 thousand dozen in 1976 to 2,723 thousand dozen in 1977. Imports declined from 590 thousand

dozen in the first quarter of 1977 to 572 thousand dozen in the first quarter of 1978. The ratio of imports to domestic production increased from 48.3 percent in 1976 to 54.9 percent in 1977.

The Department conducted a survey of the principal manufacturers for which Rosemary Fashion Coat Co. worked in 1976 and 1977. Manufacturers that accounted for a majority of sales in 1977 reduced purchases from Rosemary Fashion Coat Co. in 1977 and 1978 and increased purchases of imports in the fiscal year ending in April 1978 as compared to the fiscal year ending April 1977.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with ladies' coats produced at Rosemary Fashion Coat Co., Hoboken, N.J., contributed importantly to the decline in sales and to the separation of workers at the plant. In accordance with the provisions of the Act, I make the following certification:

All workers of Rosemary Fashion Coat Co., Inc., Hoboken, N.J., who became totally or partially separated from employment on or after September 1, 1977, are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 17th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23816 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3578]

UNITED SPORTSWEAR, SOMERVILLE, MASS.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3578: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on May 4, 1978, in response to a worker petition received on April 28, 1978, which was filed on behalf of workers and former workers producing ladies' sportswear at United Sportswear, Sommerville, Mass.

The notice of investigation was published in the FEDERAL REGISTER on May 23, 1978 (43 FR 22087). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of United Sportswear and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

that sales or production, or both, of the firm or subdivision have decreased absolutely.

United Sportswear, a contract stitcher, produces ladies' sportswear for apparel manufacturers. Primarily slacks and skirts are produced.

Sales and production at United Sportswear are equal. Production, in terms of value, increased from 1976 to 1977 and in the first 5 months of 1978 compared to the same period in 1977. Production increased in each quarter of 1977 and in the first quarter of 1978 when compared to the respective quarter of the previous year.

Average employment at United Sportswear increased from 1976 to 1977 and remained stable in the first 5 months of 1978 compared to the same period in 1977.

CONCLUSION

After careful review I conclude that all workers at United Sportswear, Somerville, Mass., are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-23817 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3049]

UNITED STATES STEEL CORP., SUPPLY DIVISION, NEWARK, N.J.

Notice of Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3049: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on February 6, 1978, in response to a worker petition received on January 16, 1978, which was filed by the United Steelworkers of America on behalf of all workers selling steel products at the United States Steel Service Center, Newark, N.J.

The notice of investigation was published in the FEDERAL REGISTER on February 17, 1978 (43 FR 7064). No public hearing was requested and none was held.

The information upon which the determination was made was obatained principally from officials of the United States Steel Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met the following criterion has not been met:

that increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

The Department conducted a survey of some customers of the Newark Service Center. This survey revealed that most of the responding customers of the Newark Supply Division purchased no imports in 1976 and none purchased any imports in 1977 or in the first 2 months of 1978.

CONCLUSIONS

After careful review I determine that all workers of the United States Steel Corp., Supply Division, Newark, N.J., are denied eligibility to apply for trade adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-23818 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3050]

UNITED STATES STEEL CORP., SUPPLY DIVISION, PITTSBURGH, PA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3050: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on February 6, 1978, in response to a worker petition received on January 16, 1978, which was filed by the United Steelworkers of America on behalf of all workers selling steel products at the Steel Supply Division, Pittsburgh, Pa., Service Center.

The notice of investigation was published in the FEDERAL REGISTER on February 17, 1978 (43 FR 7064). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the United States Steel Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met the following criterion has not been met:

that increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separation, or threat thereof, and to the absolute decline in sales or production.

The Department of Labor conducted a survey of some customers of the Pittsburgh, Supply Division. This survey revealed that these customers purchased no imports from 1976 to 1977 and in the first quarter of 1978.

CONCLUSION

After careful review I determine that all workers of the United States Steel Corp., Steel Supply Division, Pittsburgh, Pa., are denied eligibility to apply for trade adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-23819 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3090, 3091, 3133]

UNITED STATES STEEL CORP., CANISTEO DISTRICT, COLERAINE, MINN.; VIRGINIA-EVELETH DISTRICT, VIRGINIA, MINN.; HIBBING-CHISHOLM DISTRICT, HIBBING, MINN.

Negative Determinations Regarding Eligibility To Apply for Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3090, 3091, 3133: Investigations regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

Investigation TA-W-3090 was initiated on February 7, 1978, in response to a worker petition received January 27, 1978, which was filed by the United Steelworkers of America on behalf of all workers engaged in the mining and beneficiation of iron ore at the United States Steel Corp., Canisteo District in Coleraine, Minn.

The notice of investigation was published in the FEDERAL REGISTER on February 24, 1978 (43 FR 7744). No public hearing was requested and none was held.

Investigation TA-W-3091 was initiated on February 7, 1978, in response to a worker petition received on January 26, 1978, which was filed by the United Steelworkers of America on behalf of all workers engaged in the mining and benefication of iron ore at the United States Steel Corp., Hibbing-Chisholm District, in Hibbing, Minn.

The notice of investigation was published in the FEDERAL REGISTER on February 24, 1978 (43 FR 7744). No public hearing was requested and none was held.

Investigation TA-W-3133 was initiated on February 15, 1978, in response to a worker petition received on February 2, 1978, which was filed by the United Steelworkers of America on behalf of all workers engaged in the mining and beneficiation of iron ore at the United States Steel Corp., Virginia-Eveleth District, in Virginia, Minn.

The notice of investigation was published on February 28, 1978 (43 FR 8209). No public hearing was requested and none was held.

The information upon which these determinations were made was obtained principally from officials of the United States Steel Corp., the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

that increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Declines in employment and production at the petitioning mines are a result of the depletion of the ore in these mines. As the production of natural ore at these mines has declined, United States Steel Corp. has increased taconite production in the area.

Imports of iron ore, pellets, and sinter declined absolutely in 1977 compared to 1976. Although imports increased relative to domestic production in 1977 this is due primarily to a strike within the domestic mining industry in 1977 which seriously affected domestic production.

CONCLUSION

After careful review I determine that all workers of the following United States Steel Corp. mining districts: Canisteo District, Coleraine, Minn.; Hibbing-Chisholm District, Hibbing, Minn.; and Virginia-Eveleth District, Virginia, Minn.; are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-23820 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3530; TA-W-3531]

VICTORY BEEF CO., INC., PATERSON, N.J.; BORDENTOWN, N.J.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3530 and 3531: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on April 18, 1978, in response to a worker petition received on April 11, 1978, which was filed on behalf of workers and former workers slaughtering and packaging meat at the Paterson, N.J., and Bordentown, N.J., plants of Victory Beef Co., Inc.

The notice of investigation was published in the FEDERAL REGISTER on May 2, 1978 (43 FR 18789). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Victory Beef Co., its customers, the U.S. International Trade Commission, the U.S. Department of Agriculture, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the

Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Imports of table beef and veal increased from 32 million pounds in 1976 to 44 million pounds in 1977. Imports then decreased from 13 million pounds in the first quarter of 1977 to 12 million pounds in the first quarter of 1978.

The ratio of imports of table beef and veal to domestic production increased from 0.15 percent in 1976 to 0.21 percent in 1977. Imports of table beef and veal did not exceed 0.29 percent of domestic production in any year from 1973 through 1977.

None of the customers of Victory Beef who were surveyed purchased imported veal.

CONCLUSION

After careful review, I determine that workers of the Paterson, N.J., and Bordentown, N.J., plants of Victory Beef Co., Inc., are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-23821 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-2918]

WESTINGHOUSE ELECTRIC CORP., SMALL MOTOR DIVISION, LIMA, OHIO

Negtive Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-2918: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 11, 1978, in response to a worker petition received on December 30 1977, which was filed by the International Union of Electrical, Radio & Machine Workers on behalf of workers and former workers producing fractional horsepower a.c. motors at the Lima, Ohio, plant of Westinghouse's Small Motor Division.

The notice of investigation was published in the FEDERAL REGISTER on January 27, 1978 (43 FR 3776). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Westinghouse Electric Corp., and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

that a significant number or porportion of the workers in the worker's frim, or an appropriate subdivision there of, have become totally or partially separated, or are threatened to become totally or partially separated.

In May 1977, Westinghouse announced that during 1978 and 1979 the Small Motor Division would completely phase out the motor production line at the Lima, Ohio, plant and would relocate these motor production activities at company plants in Juarez, Mexico, and Union City, Ind.

The Department's investigation revealed that employment of production workers in the Small Motor Division at the Lima plant increased steadily from the second through the fourth quarters of 1977. Monthly employment either remained stable or increased from July 1977 through February 1978. Employment in January-February 1978 was higher than in the same period of 1977. Furthermore, there were no permanent layoffs from March 1977 through February 1978. Despite the announced plans to relocate production decisions regarding future layoffs have not been made.

CONCLUSION

After careful review, I determine that workers of the Lima, Ohio, plant of Westinghouse's Small Motor Division are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 17th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23822 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3065]

WILBUR B. DRIVER, CO., 1875 McCARTER HIGHWAY, NEWARK, N.J.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3065: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 6, 1978, in response to a worker petition received on January 13, 1978, which was filed by the United Steelworkers of America on behalf of workers and former workers producing alloy strip and wire at Wilbur B. Driver Co., Newark, N.J. The petition identified the workers' plant at 1875 McCarter Highway. The investigation revealed that workers produced nickel alloy wire.

The notice of investigation was published in the FEDERAL REGISTER on February 17, 1978 (43 FR 7064). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Wilbur B. Driver Co., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met. The investigation has revealed that all of the requirements have been met.

Evidence developed during the course of the investigation revealed that the impact of imports of nickel alloy wire in the domestic market has been substantial. U.S. imports of nickel alloy wire increased absolutely and relative to domestic production and consumption in 1976 compared to 1975, and increased in 1977 compared to 1976.

A survey of Wilbur B. Driver's customers indicated that some customers have increased purchases of imported nickel alloy wire and decreased purchases from the subject firm during the period 1975 through 1977.

CONCLUSION

After careful review of the facts obtained in the investigation I conclude that increases of imports of articles like or directly competitive with nickel alloy wire produced at the 1875 McCarter Highway plant of Wilbur B. Driver Co., Newark, N.J. contributed

importantly to the declines in sales and production and to the separations of workers at that firm. In accordance with the provisions of the act, I make the following certification:

All workers engaged in employment related to the production of nickel alloy wire at the 1875 McCarter Highway, Newark, N.J. plant of Wilbur B. Driver Co. who became totally or partially separated from employment on or after January 9, 1977, are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-23823 Filed 8-24-78; 8:45 am]

[4510-23]

[Secretary of Labor's Order 11-78]

DELEGATION OF AUTHORITY ON INTERNAL LABOR-MANAGEMENT RELATIONS MATTERS

AUGUST 12, 1978.

1. *Purpose.* To delegate authority and assign responsibility for administering the Department's internal labor-management relations program.

2. *Directives affected.* Secretary's Order 13-72 is canceled. The Employee Handbook and all other instructions and memoranda are superseded to the extent that they are inconsistent with the authority delegated by this order.

3. *Authority of the Secretary.* The Secretary of Labor has the final authority for internal labor-management relations within the Department; such authority, including that as discussed particularly and delegated herein, also includes, but is not limited to, the establishment of negotiation parameters.

4. *Internal Labor-Management Relations Committee.* There is hereby established by this order within the Department of Labor an Internal Labor-Management Relations Committee.

a. *Purpose.* The purpose of the Committee shall be to advise on the development and establishment of internal labor-management policy and program within the Department.

b. *Membership.* The membership of the Committee shall consist of the deputy or his/her designee to each Assistant Secretary, the Solicitor of Labor, the Commissioner of the Bureau of Labor Statistics, and the Deputy Under Secretary for International Affairs, and such other persons as may be designated by the Assistant Secretary for Administration and Management. The Director, Office of Labor-Management Relations, shall serve as chairperson.

5. *Delegation of authority and assignment of responsibility.*

a. *The Assistant Secretary for Administration and Management* is delegated authority and assigned responsibility for administering the Department's internal labor-management relations program, which shall be carried out by the Director, Office of Labor-Management Relations, OASAM, who will be responsible for its development, coordination, and management and who is authorized to:

(1) Act as the Department's representative in dealing with all unions representing Department of Labor employees, except in dealings with the National Union of Compliance Officers representing LMSA employees, which shall be the responsibility of the Assistant Secretary for Labor-Management Relations, coordinated with the Director, Office of Labor-Management Relations, OASAM.

(2)(a) Establish, in conjunction with Agency heads, a management preparations committee and a management negotiating team, reflecting the bargaining units for which collective bargaining agreements are to be negotiated; these committees and teams shall actively participate with the Director in preparation for and conduct of the bargaining process. With respect to the Labor-Management Services Administration and the National Union of Compliance Officers bargaining relationship, the preparations committee and bargaining teams specified herein shall be constituted by the Labor-Management Services Administration and they shall have on them a member(s) from the Office of Labor-Management Relations.

(b) Negotiate, sign, and administer all collective bargaining agreements covering Department of Labor employees, including any amendments, corrections, alterations, substitutions and/or changes thereto—except that with respect to the Labor-Management Services Administration and the National Union of Compliance Officers bargaining relationship, this authority is delegated to the Labor-Management Services Administration—and, as may be necessary, represent the Department of Labor's position on all matters coming before the Federal Service Impasses Panel or any successor agency.

(3) Act as final approving official on all collective bargaining agreements covering Department of Labor employees, including any amendments, corrections, alterations, substitutions and/or changes thereto, subject to applicable laws, Executive Order 11491, as amended, existing published departmental policies and regulations (unless the Department has granted an exception to a policy or regulation), and regulations of other appropriate authorities. Prior to final approval being given to any of the foregoing instruments, the Solicitor of Labor will review the instrument(s) as to its (their) legal sufficiency.

(4) Establish, in consultation with Agency heads and other appropriate DOL executives, and represent the Department of Labor's internal labor-management positions on the appropriateness of bargaining unit, unfair labor practice cases, and other formal and informal proceedings on internal labor-management matters before the U.S. Civil Service Commission, the Federal Labor Relations Council, and the Federal Service Impasses Panel and any successor agencies. In exercising such representational authority, the Director (OLMR) shall utilize the legal services of the Office of the Solicitor to represent the Department in third party proceedings.

(5) Consult, as appropriate, with recognized unions representing Department of Labor employees holding national consultation rights with the Department of Labor, and consult with the national headquarters of recognized unions on departmentwide issues.

(6) Issue, in consultation with Agency heads and other appropriate DOL executives, interpretations of all collective bargaining agreements covering Department of Labor employees, except as to the Labor-Management Services Administration and the National Union of Compliance Officers agreement; this activity shall be performed by the Labor-Management Services Administration in consultation with the Office of Labor-Management Relations.

(7) Advise Agency heads on final-step grievances arising from negotiated grievance procedures at the last step prior to arbitration; determine whether a dispute arising out of a collective bargaining agreement covering Department of Labor employees shall be submitted to binding arbitration; and establish and represent the Department of Labor's position in arbitration cases. In the case of the Labor-Management Services Administration and National Union of Compliance Officers Agreement, the Labor-Management Services Administration and the Office of Labor-Management Relations shall jointly (a) determine whether a grievance shall be submitted to binding arbitration and (b) establish and represent the Department's position in arbitration cases. In exercising such representational authority, the Director (OLMR) shall utilize the legal services of the Office of the Solicitor to represent the Department before arbitrators.

(8) Develop the Department's internal labor-management relations training program and conduct it in conjunction with Agency/Regional labor relations officers and training personnel.

(9) Evaluate management's internal labor relations activities in the Agencies and regions.

(10) Develop systems of intra-management consultation and communication on internal labor-management relations matters providing, as necessary and appropriate, assistance and advice to managers and supervisors at all levels of the Department.

(11) Provide training and functional direction to persons designated to handle internal labor-management relations in each Agency of the Department of Labor; and

(12) Assist the Regional Administrators—OASAM in designating person(s) responsible for handling internal labor-management matters, and provide training and functional direction to persons so designated.

b. *Agency Heads* will be responsible for implementing uniformly the internal labor-management relations program based on the advice of the Department's Internal Labor-Management Relations Committee, exercising responsibility for seeing that collective bargaining agreements are observed; assuring that supervisors and managers discharge their labor-management responsibilities in the most constructive manner possible; providing information to the Office of Labor-Management Relations on the nature of problem areas requiring policy or interpretation, and proposals for consultation and contract negotiations; and for participation either directly, or indirectly through their designees, with the Office of Labor-Management Relations in the work of the Internal Labor-Management Relations Committee and in other intra-management consultations.

c. *Regional Administrators—OASAM* will be responsible for overseeing in their regions the operation of the internal labor-management relations program of the Department; for providing information to the Office of Labor-Management Relations on the nature of field problem areas requiring policy or interpretation, and proposals for field consultation and contract negotiation.

RAY MARSHALL,
Secretary of Labor.

[FR Doc. 78-23983 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-2940, 2940A, 2940B]

BLOOMSBURG MILLS, INC., LOCK HAVEN, PA., BLOOMSBURG, PA., ABBEVILLE, S.C.

Negative Determination Regarding Application for Reconsideration

By letter postmarked July 28, 1978, the International Vice President of the United Textile Workers of America requested administrative reconsideration of the Department of Labor's negative determination regarding eligibility to apply for worker adjustment assistance in the case of workers and former workers of Bloomsburg Mills, Inc., at its Lock Haven, Pa., plant, Bloomsburg, Pa., plant, and Abbeville, S.C., plant. The determination was published in the FEDERAL REGISTER on July 7, 1978 (43 FR 29367).

Pursuant to 29 CFR 90.18(c), reconsideration may be granted under the following circumstances:

(1) If it appears, on the basis of facts not previously considered, that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts previously considered; or

(3) If, in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justifies reconsideration of the decision.

In his application, the International Vice President of the union stated that imported apparel contributed importantly to the separations of workers engaged in the production of fabric, namely, that imports of apparel are directly competitive with the fabric. The Department does not agree. This issue has already been settled by the court. In a case arising under the Trade Expansion Act of 1962, *United Shoe Workers* vs. *Bedell*, 506 F. 2d 174, the United States Court of Appeals for the District of Columbia Circuit construed the term "like or directly competitive." The issue in this case was whether imported finished women's shoes were like or directly competitive with domestic components of women's shoes, in this case shoe counters (stiffeners which are placed around the heel of the shoe).

The court traced the legislative history of the term in the Trade Expansion Act and in prior trade agreements legislation. The court concluded that a shoe counter is not likely or directly competitive with a shoe. Similarly, fabric is not like or directly competitive with apparel.

CONCLUSION

After review of the application and the investigative file, I conclude that there has been no error or misinterpretation of fact or misinterpretation of the law which would justify reconsideration of the Department of Labor's prior decision. The application is, therefore, denied.

Signed at Washington, D.C., this 18th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23986 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-2238]

EASTSIDE SPORTSWEAR, INC., PATERSON, N.J.

Revised Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor issued a Notice of Negative Determination on January 18, 1978, which was published in the FEDERAL REGISTER on January 31, 1978 (43 FR 4135), regarding eligibility to apply for adjustment assistance applicable to former workers producing ladies' coats at Eastside Sportswear, Inc., Paterson, N.J.

On the basis of additional information provided by workers of Eastside Sportswear, Inc., and on its own motion, the Office of Trade Adjustment Assistance agreed to reconsider the denial and initiated a review investigation.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. It is concluded that all requirements have been met.

The original investigation had established the fact that: Average employment of production workers had decreased 61.8 percent in the first quarter of 1977, compared to the like period in 1976, and had ceased completely by March 5, 1977; production had decreased 57.1 percent during the first quarter of 1977, compared to the same quarter in 1976, and had ceased in March 1977; and that imports of women's, misses', and children's coats and jackets increased absolutely and relative to domestic production in 1976, compared to 1975, and increased absolutely in the first 6 months of 1977, compared to the like period in 1976.

Eastside Sportswear was a contractor producing ladies' coats under contract from manufacturers. One manufacturer accounted for approximately 90 percent of Eastside's production. This manufacturer wholly owned another company with which it shared the same physical facilities. This subsidiary, which sold to the same customers, began to order imported ladies' coats during 1977 and by December of that year had imported a substantial amount. In addition, it was determined that Eastside's principal manufacturer experienced decreased sales in 1977 compared to 1976. A survey of customers of the manufacturer indicated that some customers had switched to imports in 1977.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with the ladies' coats produced at Eastside Sportswear, Inc., contributed importantly to the total or partial separations of the workers of that firm. In accordance with the provisions of the Trade Act of 1974, I hereby issue the following revised determination:

All workers at Eastside Sportswear, Inc., Paterson, N.J., engaged in employment related to the production of ladies' coats who became totally or partially separated from employment on or after November 6, 1976, are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23987 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3193]

FRANK SALTZ & SONS, INC. PASSAIC, N.J.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3193: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 22, 1978, in response to a worker petition received on February 6, 1978, which was filed by the Amalgamated Clothing & Textile Workers Union on behalf of workers and former workers producing men's tailored clothing at Frank Saltz & Sons, Inc., Passaic, N.J. During the course of the investigation it was established that women's tailored sportcoats are also produced at the firm.

The Notice of Investigation was published in the FEDERAL REGISTER on March 3, 1978 (43 FR 8863). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Frank Saltz & Sons, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated.

The workers of Frank Saltz & Sons were certified as eligible to apply for adjustment assistance on February 27, 1976 (TA-W-521). That certification expired on February 27, 1978.

Average employment of production workers at Frank Saltz & Sons increased 13.8 percent in 1977 compared to 1976. There were no layoffs and no reduction in hours worked at the company since the expiration of the certification. Average employment increased each month from February through May 1978.

CONCLUSION

After careful review I determine that all workers of Frank Saltz & Sons, Inc., Passaic, N.J., are denied eligibility to apply for trade adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23988 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-2823]

GEORGE'S MANUFACTURING CO., INC., BOSTON, MASS.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2823: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on December 28, 1977, response to a worker petition received on December 12, 1977, which was filed on behalf of workers and former workers producing women's dresses and sportswear at George's Manufacturing Co., Inc., Boston Mass.

The notice of investigation was published in the FEDERAL REGISTER on January 10, 1978 (43 FR 1554). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of George's Manufacturing Co., Inc., its customers, the U.S. Department of Commerce, the National Cotton Council of America, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Act must be met. Without regard to whether any of the other criteria have been met the following criterion has not been met.

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threats thereof, and to the absolute decline in sales or production.

The Department's investigation revealed that manufacturers which contract orders with George's Manufacturing Co., Inc., do not purchase imported garments and do not employ foreign contractors to produce the garments. During the periods in which the manufacturers decreased orders with George's Manufacturing Co., Inc., they increased orders with other domestic firms.

CONCLUSION

After careful review I determine that all workers at George's Manufacturing Co., Inc., Boston, Mass., are denied eligibility to apply for adjustment assistance under Title II, Chapter 2, of Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23989 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3120]

MOODY II, WALTHAM, MASS.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor presents the results of TA-W-3120: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on February 13, 1978, in response to a worker petition received on January 26, 1978, which was filed on behalf of workers and former workers producing samples of women's clothing at Moody II, Waltham, Mass.

The notice of investigation was published in the FEDERAL REGISTER on February 24, 1978 (43 FR 8208). No

public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Moody II, Puritan Fashion Corp., and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Moody II is a division of Puritan Fashions which produces samples and duplicates for the Verona and Forever Young divisions of Puritan. Verona and Forever Young produce ladies' dresses (including pants suits). Due to the seasonal nature of producing samples, the Moody II factory experiences layoffs throughout the year.

The ratio of imports to domestic production for ladies' dresses declined from 1976 to 1977. The impact of imports in the domestic market for women's and misses' dresses has been small and did not change appreciably from 1975 to 1976 and from 1976 to 1977. From 1975 to 1976 the ratio of imports to domestic production remained constant at 4.5 percent while imports increased by only 2.2 percent in absolute terms. Imports fell by 11 percent in 1977 compared to 1976.

Industry analysts indicate that imports of dress samples were negligible from 1975 to 1977. Commercial drawings of apparel or textile designs are imported. However, such items can not be considered like or directly competitive with dress samples.

CONCLUSION

After careful review, I determine that all workers at Moody II, Waltham, Mass. are denied eligibility to apply for adjustment assistance under title II, chapter 2, fo the Trade Act of 1974.

Signed at Washington, D.C., 18th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23993 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3264]

RCA CORP., SOLID STATE DIVISION, SOMERVILLE, N.J.

Notice of Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3264: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 27, 1978 in response to a worker petition received on February 15, 1978 which was filed by the International Union of Electrical, Radio and Machine Workers on behalf of workers and former workers producing semiconductors at the Somerville, N.J. plant of the RCA Corp., Solid State Division. The Department's investigation revealed that approximately half of the Somerville facility performs administrative services for the Solid State Division, while the other half is engaged in research development and pilot production activities. The Somerville plant also housed a machine shop which made dies, molds, and other equipment for both the Somerville plant and an overseas facility of RCA Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on March 14, 1978 (43 FR 10648). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of RCA Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met. With respect to workers engaged in research, development, and pilot production, and workers in the machine shop without regard to whether any of the other criteria have been met the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

On June 30, 1977 the Department of Labor denied a petition for trade adjustment assistance on behalf of workers and former workers at the Somerville, N.J. facility of the RCA Corp., Solid State Division (see TA-W-1662).

The Department concluded under TA-W-1662 that layoffs in the first quarter of 1977 were attributable to RCA transferring production of power transistors for heart pacer units and silicon-on-sapphire integrated circuits from the Somerville, N.J. plant to other domestic facilities.

Production workers at the Somerville plant are employed in research, development, and pilot production activities. The Somerville plant does not engage in volume production, but engineers and designs new products for the Solid State Division of RCA. When these new products are successfully developed at Somerville, full scale production is commenced at other RCA plants.

Layoffs of production workers since the first quarter of 1977 at RCA's Somerville, N.J. plant have occurred in the machine shop. The machine shop has historically performed support activities for the Somerville facility and for an RCA manufacturing plant in Malaysia. The support activities for the Malaysia plant included making dies, molds, fixtures for transistors, and modifying and repairing equipment for use in manufacturing semiconductor devices. In November 1977, an RCA plant in Taiwan began performing the support activities for the Malaysia plant, previously performed by the Somerville machine shop. The workload for the machine shop in Somerville, N.J. has been reduced due to the loss of work generated from the plant in Malaysia. The functions now performed in Taiwan are solely for the production of machinery and equipment used to manufacture semiconductors in Malaysia. The machinery and equipment produced in Taiwan is not imported into the United States by RCA.

CONCLUSION

After careful review, I determine that production workers engaged in research, development, and pilot production activities and workers in the machine shop of the Somerville, N.J. plant of RCA Corp. Solid State Division be denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23990 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3003]

SHARON STEEL CORP., FARRELL, PA., PLANT, FARRELL, PA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3003: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 31, 1978, in response to a worker petition received on January 10, 1978, which was filed by the United Steelworkers of America on behalf of all workers producing low and high carbon strip and forging steel at the Farrell, Pa., plant of the Sharon Steel Corp.

The investigation revealed that the correct name of the plant at which the petitioning workers are employed is the Farrell, Pa., plant of the Sharon Steel Co., which is a subsidiary of NVF, Inc. The investigation also revealed that the plant only produces the following products:

1. Carbon and alloy semi-finished steel of forging quality.
2. Carbon hot and cold rolled sheet and strip.
3. Alloy hot and cold rolled sheet and strip.
4. Coated sheet.

The notice of investigation was published in the FEDERAL REGISTER on February 17, 1978 (43 FR 7067). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Sharon Steel Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met the following criterion has not been met with regard to workers producing carbon and alloy semi-finished steel of forging quality, alloy hot and cold rolled sheet and strip and coated sheet.

That sales or production, or both, of such firm or subdivision have decreased absolutely.

Production of each of these products increased in 1977 compared to 1976 in both quantity and value. Sales of these products were determined to be equivalent to production data after making adjustments for inventory changes and changes in product mix.

It is further concluded that the following criterion has not been met with regard to workers producing carbon hot and cold rolled sheet and strip:

That increases of imports of articles like or directly competitive with articles produced by such workers' firm or an appropriate subdivision thereof contributed importantly to such total or partial separation, or threat thereof, and to such decline in sales or production.

The U.S. Department of Labor conducted a survey of customers of the Farrell, Pa., plant of the Sharon Steel Co. that purchased carbon steel sheet and strip in 1976 and 1977. Responses from the survey indicated that between 1976 and 1977 most customers either increased purchases from Sharon Steel or those decreasing purchases also decreased import purchases.

It was further determined that decreases in production of carbon steel sheet and strip between 1976 and 1977 were attributable to Sharon Steel Corp. business decisions and was not associated with competition from imports.

CONCLUSION

After careful review, I determine that all workers at the Sharon Steel Corp., plant in Farrell, Pa., are denied eligibility to apply for adjustment assistance under title II, chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23991 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3063]

UNITED STATES STEEL CORP., AMERICAN BRIDGE DIVISION, AMBRIDGE, PA.

Revised Certification of Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor issued a certification of eligibility to apply for adjustment assistance on July 26, 1978, applicable to workers and former workers producing fabricated structural steel at the Ambridge, Pa., plant of the American Bridge Division of the United States Steel Corp. The Notice of Certification was published in the FEDERAL REGISTER on August 1, 1978 (43 FR 33846).

At the request of the petitioner, a further investigation was made by the Director of the Office of Trade Adjustment Assistance. A review of the case revealed that a significant number of the workers were separated from employment immediately prior to the impact date of July 31, 1977, and were not covered by the certification.

The intent of the certification is to cover those workers at the Ambridge, Pa., plant of the American Bridge Division of the United States Steel Corp., who were affected by the decline in the production of fabricated structural steel related to import competition. The certification, therefore, is revised providing a new impact date of July 22, 1977.

The revised certification applicable to TA-W-3063 is hereby issued as follows:

All workers at the Ambridge, Pa., plant of the American Bridge Division of the United States Steel Corp., who became totally or partially separated from employment on or after July 22, 1977, are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of August 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-23992 Filed 8-24-78; 8:45 am]

[4510-28]

[TA-W-3745]

RELATIVE INCREASES OF IMPORTS

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance; Correction

In Federal Register Docket 78-15519 appearing at pages 24633 and 24634 in the FEDERAL REGISTER of June 6, 1978, line 4 of the appendix, Butte Knitting Mills (workers), Walnut Ridge, Ariz., should be changed to read:

Lawrence Manufacturing Co. (workers), Walnut Ridge, Ark.

Signed at Washington, D.C., this 11th day of August 1978.

HAROLD A. BRATT,
Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-23985 Filed 8-24-78; 8:45 am]

[7590-01]

NUCLEAR REGULATORY COMMISSION

Regulatory Guide

Notice of Issuance and Availability

The Nuclear Regulatory Commission has issued a guide in its Regulatory Guide Series. The series has been developed to describe and make available to the public methods acceptable to

the NRC staff of implementing specific parts of the Commission's regulations and, in some cases, to delineate techniques used by the staff in evaluationg specific problems or postulated accidents and to provide guidance to applicants concerning certain of the information needed by the staff in its review of applications for permits and licenses.

Regulatory Guide 1.68, Revision 2, "Initial Test Programs for Water-Cooled Nuclear Power Plants," is a generic guide that describes the scope and depth of initial test programs acceptable to the NRC staff for light-water-cooled nuclear power plants. Included are three appendices that provide (A) representative listing of the plant structurers, systems, and components and the design features and performance capability tests that should be demonstrated, (B) information on inspections performed by the NRC Office of Inspection and Enforcement, and (C) guidance on preparation of procedures to conduct the tests. This guide was revised as the result of public comment and additional staff review.

Separate, more specific guides are developed to provide detailed guidance in the conduct of initial test programs for particular systems and are issued in a series designated 1.68.X. Two of these guides are now available: Regulatory Guide 1.68.1, Revision 1, "Preoperational and Initial Startup Testing of Feedwater and Condensate Systems for Boiling Water Rector Power Plants," and Regulatory Guide 1.68.2, Revision 1, "Initial Startup Test Program to Demonstrate Remote Shutdown Capability for Water-Cooled Nuclear Power Plants."

Comments and suggestions in connection with (1) items for inclusion in guides currently being developed or (2) improvements in all published guides are encouraged at any time. Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, attention: Docketing and Service Branch.

Regulatory guides are available for inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. Requests for single copies of issued guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future guides in specific division should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, attention: Director of Technical Information and Document Control. Telephone requests cannot be accommodated. Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

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

Dated at Rockville, Md., this 17th day of August 1978.

For the Nuclear Regulatory Commission.

ROBERT B. MINOGUE,
Director, Office of Standards Development.

[FR Doc. 78-23859 Filed 8-24-78; 8:45 am]

[7590-01]

[Docket No. 50-289]

METROPOLITAN EDISON CO., ET AL.

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. DPR-50, issued to Metropolitan Edison Co., Jersey Central Power & Light Co., and Pennsylvania Electric Co. (the licensees), which revised technical specifications for operation of the Three Mile Island Nuclear Station, Unit No. 1 (the facility) located in Dauphin County, Pa. The amendment is effective as of its date of issuance.

The amendment revises the technical specifications to change the method of surveillance testing of the reactor internal vent valves.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment. Prior public notice of this amendment 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 February 3, 1978, as supplemented April 18, and July 7, 1978, (2) amendment No. 42 to license No. DPR-50, 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, Box 1601 (Education Building), Harrisburg, Pa. 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 Operating Reactors.

Dated at Bethesda, Md., this 16th day of August 1978.

For the Nuclear Regulatory Commission.

ROBERT W. REID,
Chief, Operating Reactors Branch No. 4, Division of Operating Reactors.

[FR Doc. 78-23858 Filed 8-24-78; 8:45 am]

[3110-01]

OFFICE OF MANAGEMENT AND BUDGET

CLEARANCE OF REPORTS

List of Requests

The following is a list of requests for clearance of reports intended for use in collecting information from the public received by the Office of Management and Budget on August 18, 1978 (44 U.S.C. 3509). The purpose of publishing this list in the FEDERAL REGISTER is to inform the public.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number(s), if applicable; the frequency with which the information is proposed to be collected; and indication of who will be the respondents to the proposed collection; the estimated number of responses; the estimated burden in reporting hours; and the name of the reviewer or reviewing division or office.

Requests for extension which appear to raise no significant issues are to be approved after brief notice thru this release.

Further information about the items on this daily list may be obtained from the Clearance Office, Office of Management and Budget, Washington, D.C. 20503, 202-395-4529, or from the reviewer listed.

NEW FORMS

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service:

Application for Nutrition Education Demonstration and Development Projects—Grants, AD-623, annually, State educational agencies, Budget Review Division, 395-4775.

Residential Child Care Institution Survey, single-time, 400 residential child care institutions—10 percent of universe, Office of Federal Statistical Policy and Standard, 673-7956.

Model Food Stamp Forms, on occasion, 240 food stamp applicants and State agencies, Clearance Office, 395-3772.

Forest Service:

Organization Management Assistance Survey, on occasion, 6,000 a sampling of

50 percent or more SF agency employees, vol., Clearance Office, 395-3772.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service:
Master Facility Inventory—Complement Survey, on occasion, 300 health facilities in area prob. sample and not listed in MFI, Clearance Office, 395-3772.
Health Resources Administration:
Survey of Dental Benefit Plans, 1978, single-time, 8350 underwriters of dental insurance and administration of dental benefit plan, Office of Federal Statistical Policy and Standard, 673-7956.

REVISIONS

DEPARTMENT OF ENERGY

Annual Report for Public Utilities and Licensees (class C and D), FPC-1-F, annually, jurisdictional class C and D public electric utilities, 12 responses, 498 hours, C. Louis Kincannon, 395-3211.

U.S. CIVIL SERVICE COMMISSION

Personnel Research Questionnaire 78-6, CSC 1339 and 1339A, on occasion, applicants for Federal employment, 100,000 responses, 16,667 hours, Laverne V. Collins, 395-3214.

DEPARTMENT OF ENERGY

Annual Report for Licensees for Privately Owned Major Projects (Utility and Industrial), FPC-9, annually, major privately owned hydro-electric licensees, 600 responses, 16,800 hours, C. Louis Kincannon, 395-3211.
Annual Report for Electric Utilities, Licensees and Others (class A and B), FPC-1, annually, jurisdictional class A and B public electric utilities, 289 responses, 414,282 hours, C. Louis Kincannon, 395-3211.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Health Care Financing Administration (Medicare):
Determining Level of Care Required by Patient in Skilled Nursing Facility, HCFA-1922, on occasion, profit and nonprofit direct dealing skill nursing facilities, 25,000 responses, 6,250 hours, Clearance Office, 395-3772.
Professional Standards Review Organization Routine Federal Reporting Requirements, HCFA-111; 112,121; 122,131; 135,141; and 142J, quarterly, Funded Cond. PSRO's and Stay Hosp. Dele. PSRO Rev. Respon., 13,200 responses, 68,000 hours, Human Resources Division, Richard Eisinger, 395-3532.
Office of Human Development, National Day Care Home Study: Caregiver and Parent Interview Instruments, on occasion, family day care providers and day care consumers, 1,500 responses, 2,135 hours, Office of Federal Statistical Policy and Standard, 673-7956.

DEPARTMENT OF LABOR

Employment Standards Administration, Certification by School Official, CM-981, on occasion, school officials, 1,000 responses, 250 hours, Clearance Office, 395-3772.

EXTENSIONS

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service, Monthly Report of the Special Supplemental Food Program for Women, Infants, FNS-187, monthly, State agencies, 804 responses, 402 hours, Ellett, C. A., 395-6132.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

National Institutes of Health, Effects of Contraceptive Steroids on Blood Pressure—Southeastern Georgia Study, single time, contraceptive steriods on blood pressure, 13,200 responses, 6,600 hours, Clearance Office, 395-3772.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Housing Production and Mortgage Credit Construction Complaint and Covering Letter by Owner, FHA-2556, on occasion, homeowners of new homes, 16,000 responses, 4,000 hours, Clearance Office, 395-3772.

DEPARTMENT OF THE INTERIOR

Bureau of Mines:
Natural Sodium Compounds, 6-1234-MA, monthly, producer of natural sodium compounds, 106 responses, 80 hours, Office of Federal Statistical Policy and Standard, 673-7956.
Crude Iodine—Production, Consumption, and Stocks, 6-1297-A, annually, producers and consumers, 44 responses, 22 hours, Office of Federal Statistical Policy and Standard, 673-7956.
Lime (Production), 6-1221-M, monthly, producers of lime, 2,196 responses, 1,098 hours, Office of Federal Statistical Policy and Standard, 673-7956.
Strontium, 6-1197-A, annually, producers, 28 responses, 21 hours, Office of Federal Statistical Policy and Standard, 673-7956.

DAVID R. LEUTHOLD,
Budget and Management Officer.

[FR Doc. 78-24027 Filed 8-24-78; 8:45 am]

[3190-01]

OFFICE OF THE SPECIAL REPRESENTATIVE FOR TRADE NEGOTIATIONS

ORDERLY MARKETING AGREEMENTS WITH REPUBLICS OF CHINA AND KOREA

The following letter, concerning administration of the orderly marketing agreement with the Republic of China and the Republic of Korea, has been sent to the Commissioner of Customs:

OFFICE OF THE SPECIAL REPRESENTATIVE FOR TRADE NEGOTIATIONS,
EXECUTIVE OFFICE OF THE PRESIDENT,
Washington, D.C., August 8, 1978.

Hon. ROBERT CHASEN,
Commissioner, U.S. Customs Service, Department of the Treasury, Washington, D.C.

DEAR MR. COMMISSIONER: By letters of March 20, 1978 and March 30, 1978,[1] you were directed to provide for certain amounts of footwear from the Republic of China and the Republic of Korea subject to restraints to be entered in excess of the restraint level, as provided for in paragraph (g) of headnote 3 of Subpart A, part 2 of the Tariff Schedules of the United States. Also pursuant to that authority, the same amount that was carried forward in each category was to be subtracted from that category in the second restraint year.

Since the total amount provided in those letters to be entered in excess of the quota was not entered in the first restraint year, the amount by which the second restraint year quota is reduced should be the absolute amount entered which exceeded the first restraint year quota, as provided in headnote 3, paragraph (g).

Therefore, pursuant to paragraph (6) of Proclamation No. 4510 of June 22, 1977 the letters to you of March 20 and March 30, 1978 are amended as follows:

Letter of March 20, second paragraph:

"Accordingly, pursuant to operative paragraph (6) of Proclamation No. 4510, of June 22, 1977, you are hereby requested to increase the first-year restraint level applicable to non-rubber footwear imports entering under TSUS item Nos. 923.90, 923.91, and 923.92 by six percent, and to decrease the restraint levels applicable to each of those TSUS categories in the second restraint year by the absolute amount by which the category was exceeded in the first restraint year."

Letter of March 30, second sentence of second paragraph:

"You are further requested to decrease the restraint levels applicable to each category during the succeeding restraint year by the absolute amount by which the level in that category is exceeded in the first restraint year."

This amendment is effective August 25, 1978.

Sincerely,

ROBERT S. STRAUSS.

RICHARD RIVERS,
General Counsel.

[FR Doc. 78-23767 Filed 8-24-78; 8:45 am]

[1] See 43 FR 12770, Mar. 27, 1978 and 43 FR 14367, Apr. 5, 1978.

[8010-01]

SECURITIES AND EXCHANGE COMMISSION

[File No. 81-335; Administrative Proceeding File No. 3-5510]

BURDOX, INC.

Application and Opportunity for Hearing

AUGUST 17, 1978.

Notice is hereby given that Burdox, Inc. ("Applicant") has filed an application pursuant to section 12(h) of the Securities Exchange Act of 1934, as amended (the "1934 Act") for an order exempting Applicant from the provisions of sections 13 and 15(d) of that Act.

The application states, in part:

1. The Applicant became subject to the periodic reporting requirements of section 15(d) of the 1934 Act for its common stock in 1973.

2. Applicant's registration under section 12(g) of the 1934 Act, effective in 1967, was terminated as of May 16, 1978.

3. Gas Accumulator Corp. acquired 98.4 percent of Applicant's common stock pursuant to a tender offer which expired on January 20, 1978.

4. On April 27, 1978 a merger was consummated whereby the Applicant became wholly-owned by Gas Accumulator Corp.

As a result of the merger, Gas Accumulator Corp. owns the entire equity interest in the Applicant. All of the common stock outstanding prior to the merger has been canceled.

In the absence of an exemption, Applicant would be required to file a report on form 10-K for the period ended February 28, 1978. Applicant believes that its request for an order exempting it from the provisions of sections 13 and 15(d) of the Act is appropriate in view of the facts that it is now a wholly-owned subsidiary and it has no publicly held securities, it would be unduly burdensome to the management and employees, it would be unnecessarily time consuming and expensive, and it would not appear to serve the public interest or provide for the protection of investors.

For a more detailed statement of the information presented, all persons are referred to the application which may be examined at the Commission's Public Reference Section, 1100 L Street NW., Washington, D.C. 20549.

Notice is further given that any interested person, not later than Sept. 11, 1978 may submit to the Commission in writing his view or any substantial facts bearing on this application or the desirability of a hearing thereon. Any such communication or request should be addressed to Secretary, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549, and should state briefly the nature of the interest of the person submitting such information or requesting the hearing, the reason for such request, and the issues of fact and law raised by the application which he desires to controvert. Persons who request a hearing or advice as to whether a hearing is ordered will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof. At any time after said date, an order granting the application may be issued upon request or upon the Commission's own motion.

For the Commission, by the Division of Corporation Finance, pursuant to delegated authority.

SHIRLEY E. HOLLIS,
Assistant Secretary.

[FR Doc. 78-23851 Filed 8-24-78; 8:45 am]

[8010-01]

[Rel. No. 10366; 812-4323]

FIRST MULTIFUND FOR DAILY INCOME, INC.

Order for Hearing on Application for Exemption

AUGUST 18, 1978.

Notice is hereby given that First Multifund for Daily Income, Inc. ("Applicant"), 32 East 57th Street, New York, N.Y. 10022, registered under the Investment Company Act of 1940 ("Act") as an open-end, diversified, management investment company, filed an application on June 7, 1978, for an order of the Commission, pursuant to section 6(c) of the Act, exempting Applicant from the provisions of rule 2a-4 thereunder as interpreted by Investment Company Act Release No. 9786 ("Release No. 9786"), to the extent necessary to permit Applicant to value its assets on an "amortized cost" basis. By a letter from its counsel dated July 8, 1978, Applicant has also requested that the exemption it has requested be granted on a temporary basis. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

Applicant states that it is a no-load, "money market" fund designed to offer to public investors the benefits of participation in a money market fund whose portfolio consists exclusively of obligations issued or guaranteed by the U.S. Government, its agencies, or the Nation's 10 largest commercial banks, Applicant further states that its shares are offered directly to public investors without brokers or salesmen, and that its assets are managed by First Multifund Advisory Corp.

According to the application, as of December 31, 1977, Applicant had nets assets of $12,613,140 and its portfolio consisted exclusively of certificates of deposits and bankers' acceptances of the 10 largest banks in the Nation. Applicant represents that at the close of each business day the income derived from instruments in its portfolio, net of expenses, is declared as a dividend to Applicant's shareholders and credited to each shareholder's account. Applicant further represents that these dividends are paid monthly to Applicant's shareholders except where a shareholder advises Applicant's servicing agent, Bradford Trust Co., of such shareholder's election to have such dividends reinvested in additional shares.

Applicant asserts that no bona fide market exists to provide readily available quotations with respect to the value of the money market instruments within Applicant's portfolio. Applicant further asserts that, in any event, Applicant purchases these money market instruments with the intention of holding such money market instruments to maturity, or of holding any cash equivalent or replacement instrument to maturity. Applicant further states that the maturity dates of the respective money market instruments within its portfolio are scheduled in such a way that such money market instruments will mature in sufficient quantity and frequency to provide the necessary cash to meet Applicant's obligations, including redemption of Applicant's shares. On the basis of the foregoing, Applicant states that its board of directors concluded that any attempt to "mark to market" as a basis for valuing the money market instruments within Applicant's portfolio would be unfair to Applicant's shareholders because such valuation would be based on estimates, guesses, and speculation, rather than the amortized cost of each such money market instrument.

Applicant states that an action is currently pending in the U.S. Court of Appeals for the District of Columbia Circuit alleging that the Commission has no authority under the laws enacted by Congress to deprive Applicant's directors of their right and duty to determine the fair value of Applicant's portfolio on the basis of amortized cost, that being, according to Applicant, their good faith determination of the best method of determining fair value. Nonetheless, Applicant requests an order of the Commission, pursuant to section 6(c) of the Act, exempting Applicant from the provisions of rule 2a-4 thereunder as interpreted by Release No. 9786 to the extent necessary to permit it to value its assets on the basis of amortized cost. As noted above, Applicant has also requested that its application be granted on a temporary basis.

Rule 2a-4 adopted under the Act provides, as here relevant, that the "current net asset value" of a redeemable security issued by a registered investment company used in computing its price for the purposes of distribution and redemption shall be an amount which reflects calculations made substantially in accordance with the provisions of that rule, with estimates used where necessary or appropriate. Rule 2a-4 further provides that portfolio securities for which market quotations are readily available shall be valued at current market value, and other securities shall be valued at fair value as determined in good faith by the board of directors.

Section 6(c) of the Act provides, in part, that the commission may, upon application, exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision or provi-

sions of the Act or any rule thereunder, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

According to the application, Applicant believes it has a constitutional and lawful right to value the money market instruments within its portfolio on the basis of amortized cost. Applicant further states that it believes that it would be contrary to the best interests of its shareholders and disruptive of its operations to change from the amortized cost method of valuation to the method known as "marking to market", since that would involve, according to Applicant, estimates, guesses and speculation as to what might be the value of a given money market instrument in a non-existent market.

On May 31, 1977, the Commission issued an interpretation (Investment Company Act Release No. 9786) of rule 2a-4 promulgated under the Act which, among other things, stated the Commission's views that: (1) It is inconsistent generally with the provisions of rule 2a-4 for "money market" funds to value their assets on an amortized cost basis, ignoring market factors, and (2) it is inconsistent with the provisions of rule 2a-4 for such funds to "round off" calculations of their net asset values per share to the nearest 1 cent on a share value of $1. Thereafter, on April 12, 1978, the Commission ordered a consolidated hearing (Investment Company Act Release No. 10201) with respect to ten applications filed by 13 money market funds pursuant to section 6(c) of the Act, requesting exemptions from the provisions of section 2(a)(41) of the Act and rules 2a-4 and 22c-1 thereunder, either to permit them to value their assets on an amortized cost basis, or to permit them to calculate their net asset values to the nearest one cent on a $1 share. That hearing is presently scheduled to commence on September 6, 1978.[1]

It appears to the Commission that it is appropriate in the public interest and consistent with the protection of investors to hold a hearing with respect to the application herein. Accordingly,

It is ordered, pursuant to section 40(a) of the Act, that a hearing be held on the application under the applicable provisions of the Act and rules of the Commission thereunder.

It also appears to the Commission that this application and the applications under consideration in *InterCapital Liquid Asset Fund, Inc., et al.*, note 1 herein, involve common questions of law and fact. Accordingly,

It is further ordered, pursuant to rule 10 of the Commission's rules of practice (17 CFR 201.10), that the hearing on this application be joined for hearing of all matters in issue with the hearing on *InterCapital Liquid Asset Fund, Inc., et al.*, and that such proceedings be, and hereby are, consolidated.

Any person other than the Applicant desiring to be heard or otherwise wishing to participate in this proceeding is requested to file with the Secretary of the Commission his application pursuant to rule 9(c) of the Commission's rules of practice (17 CFR 201.9(c)), setting forth the nature and extent of his interest in the proceeding and any issues of law or fact which he desires to controvert or any additional issues which he deems raised by the application or by this notice and order. A copy of such request shall be served personally or by mail upon the Applicant at the address noted above, and proof of such service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. Persons filing an application to participate or be heard will receive notice of the date and place of the hearing and any adjournments thereof, as well as other actions of the Commission involving the subject matter of the proceeding.

The Commission's Division of Investment Management ("Division") has advised the Commission that, based upon examination of the application, the following matters are presented for consideration, without prejudice to the Division's specifying additional matters and questions upon further examination:

1. To what extent, if any, dilution of money market fund shareholders' interests may occur by reason of use of amortized cost valuation;

2. Under what circumstances and conditions, if any, is the requested exemption appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act; and

3. Under what circumstances and conditions, if any, should an order be issued granting Applicant's request for an exemption on a temporary basis.

It is further ordered that at the aforesaid hearing attention also be given to the foregoing matters.

It is further ordered that the Secretary of the Commission shall give notice of the aforesaid hearing by mailing a copy of this notice and order by certified mail to the Applicant; that notice to all other persons be given by publication of this notice and order in the "SEC Docket"; and that an announcement of the aforesaid hearing shall be included in the "SEC News Digest."

By the Commission.

SHIRLEY E. HOLLIS,
Assistant Secretary.

[FR Doc. 78-23852 Filed 8-24-78; 8:45 am]

[1] In the Matter of InterCapital Liquid Asset Fund, Inc., *et al.* (Administrative Proceeding File No. 3-5431). See, Investment Company Act Release No. 10201, April 12, 1978.

[8010-01]

[File No. 81-316; Administrative Proceeding File No. 3-5506]

GRAHAM MAGNETICS INC.

Application and Opportunity for Hearing

AUGUST 17, 1978.

Notice is hereby given that Graham Magnetics Inc. ("Applicant") has filed an application pursuant to section 12(h) of the Securities Exchange Act of 1934, as amended (the "1934 Act"), for an order granting Applicant an exemption from the provisions of section 15(d) of the 1934 Act.

The Applicant states, in part:

1. On November 29, 1977, Applicant merged with and became a wholly owned subsidiary of Carlisle Corp. As a result of the merger, Applicant no longer has any publicly owned common stock.

2. The Applicant has filed with the Commission a form 10-Q for the period ended September 30, 1977, and Carlisle Corp. has filed a form 8-K to reflect the merger.

Applicant argues that the granting of the exemption would not be inconsistent with the public interest or the protection of investors.

For a more detailed statement of the information presented, all persons are referred to said application which is on file in the offices of the Commission at 500 North Capitol Street, Washington, D.C. 20549.

Notice is further given that any interested person not later than September 11, 1978 may submit to the Commission in writing his views or any substantial facts bearing on this application or the desirability of a hearing thereon. Any such communication or request should be addressed:

Secretary, Securities and Exchange Commission, 500 North Capitol Street NW., Washington, D.C. 20549, and should state briefly the nature of the interest of the person submitting such information or requesting the hearing, the reason for such request, and the issues of fact and law raised by the application which he desires to controvert. At any time after said date, and order granting the application may be issued upon request or upon the Commission's own motion.

For the Commission, by the Division of Corporation Finance, pursuant to delegated authority.

SHIRLEY E. HOLLIS,
Assistant Secretary.

[FR Doc. 78-238 Filed 8-24-78; 8:45 am]

[8010-01]

[File No. 81-356; Administrative Proceeding File No. 3-5450]

HARTE-HANKS SOUTHERN COMMUNICATIONS, INC.

Application and Opportunity for Hearing

AUGUST 17, 1978.

Notice is hereby given that Harte-Hanks Southern Communications, Inc. ("New Southern") has filed an application pursuant to section 12(h) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") for an order exempting the company from filing the form 10-K for the fiscal year ending December 31, 1978, the interim forms 10-Q, and all other reports required under section 15(d) of the Exchange Act.

New Southern's application discloses in part:

1. New Southern, a wholly owned subsidiary of Harte-Hanks Communications, Inc., was formed as part of a plan of merger with Southern Broadcasting Co., whereby the latter would be merged into a wholly-owned subsidiary of New Southern. Under the terms of the merger, New Southern issued 8 percent guaranteed installment notes due 1988 (the "Notes") in exchange for the outstanding stock of Southern Broadcasting Co. As a result of this merger, Southern Broadcasting Co. is now wholly owned by New Southern, which in turn is wholly owned by Harte-Hanks Communications, Inc.

2. Audited financial statements for Harte-Hanks Communications, Inc. for the year ended December 31, 1976 on a consolidated basis, and unaudited financial statements for the period ended June 30, 197 were presented to shareholders in the proxy statement sent to the shareholders of Southern Broadcasting Co. in connection with the merger. New Southern will continue the business of Southern Broadcasting Co.

3. At no time did New Southern have more than approximately 170 shareholders; its assets consist of $1,000 in cash and its liabilities are represented by shareholder's equity of $1,000.

4. Harte-Hanks Communications, Inc. is reporting company under section 12(g) of the 1934 Act, and is the guarantor and co-issuer of the notes. The guarantee is unconditional, and, in the event of default, the holders of the notes may proceed directly against Harte-Hanks Communications, Inc.

For a more detailed statement of the information presented, all persons are referred to said application which is on file in the offices of the Commission at 500 North Capitol Street NW., Washington, D.C. 20549.

Notice is further given that any interested person no later that September 11, 1978 may submit to the Commission in writing his view or any substantial facts bearing on this application or the desirability of a hearing thereon. Any such communication or request should be addressed: Secretary, Securities and Exchange Commission, 500 North Capitol Street NW., Washington, D.C. 20549, and should state briefly the nature of the interest of the person submitting such information or requesting the hearing, the reason for such request, and the issues of fact and law raised by the application which he desires to controvert. At any time after said date, an order granting the application may be issued upon request or upon the Commission's own motion.

For the Commission, by the Division of Corporation Finance, pursuant to delegated authority.

SHIRLEY E. HOLLIS,
Assistant Secretary.

[FR Doc. 78-23854 Filed 8-24-78; 8:45 am]

[8010-01]

[Rel. No. 10365; 812-4319]

INVESTORS DIVERSIFIED SERVICES, INC. ET AL.

Filing of Application for an Order of the Commission Exempting Certain Transactions

AUGUST 17, 1978.

Notice is hereby given that Investors Diversified Services, Inc. ("IDS"), IDS Tower, Minneapolis, Minn. 55402; a diversified financial services company, Investors Syndicate of America, Inc. ("Fund"), a wholly owned subsidiary of IDS registered under the Investment Company Act of 1940 ("Act") as a face-amount certificate company, and Tower Mortgage Corp. ("Tower"), a wholly owned subsidiary of IDS engaged in the mortgage banking business (hereinafter collectively referred to as "Applicants"), filed an application pursuant to section 6(c) of the Act, on May 30, 1978, and an amendment thereto on July 31, 1978, for an order of the Commission granting an exemption from the provisions of section 17(a) of the Act to permit the sale of Government National Mortgage Association mortgage-backed securities ("GNMA's") by Tower to the Fund.

Applicants state that the Fund is engaged in the issuance of face-amount certificates, the servicing of its outstanding certificates, and the investment of its assets, in mortgages and other investments of the kind which life insurance companies are permitted to invest in or hold under the provisions of the Insurance Code for the District of Columbia ("Qualified Investments") and which the Fund is required to maintain pursuant to the Act in respect to its outstanding certificates. Applicants state that as of December 31, 1977, such Qualified Investments were in the amount of $1,101,119,828 which included GNMA's in the amount of $48,441,780.

Applicants also state that Tower, which was organized in 1976, is engaged on a national basis in the mortgage banking business including the origination, purchase, sale, and servicing of mortgages; and that it is one of the major issuers of GNMA's. Applicants state that on December 31, 1977, Tower was servicing a portfolio of $305,665,920 in mortgages for companies in the IDS group, including the Fund; and that on this date Tower was servicing a portfolio of $512,256,709 in mortgages for others including $193,858,462 of GNMA's. As of December 31, 1977, Tower and its predecessor had issued a total of $292,576,208.63 of GNMA's. Applicants further state that Tower does not sell mortgages or GNMA's to the Fund.

Applicants state that Tower services mortgages, provides recordkeeping and management services for mortgages owned by the Fund, pursuant to service and management agreements between the Fund and Tower. According to the application, Tower is the successor to certain activities of IDS Mortgage Corp. ("IDSMC") a subsidiary of IDS. By an order dated November 13, 1974 (Investment Company Act Release No. 8580), the Commission, pursuant to section 6(c) of the Act, granted an exemption from the provisions of section 17(a) of the Act to permit the sale of GNMA's by IDSMC to the Fund.

Applicants represent that IDS, the parent company of the Fund and Tower, comprises with its subsidiaries a diversified financial services organization engaged in the businesses of (1) selling and issuing face-amount certificates (through the Fund); (2) providing investment advisory and administrative services to, and distribution of the securities of, investment companies; (3) securities brokerage; (4) life insurance and annuities; (5) mortgage banking (through Tower); (6) ownership of real properties; and (7) providing investment advisory services to pension funds and pools of privately owned capital. Applicants state that by virtue of their common control by IDS, Tower is an affiliated person of the Fund. Applicants state that the Fund desires to purchase GNMA's directly from Tower as Qualified Investments, and that Tower desires to sell GNMA's directly to the Fund, on a continuing basis at various times in the future. Applicants seek an order of exemption from section 17(a) of the Act to permit such transactions on the terms set forth below.

Applicants state that GNMA's are issued by an approved issuer pursuant to section 306(g) of the National Hous-

ing Act and related provisions of such Act, whereby the issuer makes the timely payment of principal and interest on securities based on and backed by a pool of mortgages which are insured under the National Housing Act of title V of the Housing Act of 1949, or which are insured or guaranteed under the Servicemen's Readjustment Act of 1944 or chapter 37 of title 38, United States Code. Such timely payment of principal and interest is guaranteed by the Government National Mortgage Association. Applicants also state that during the life of the issue of such securities the issuer received one-half percent per annum and is required to pay a guaranty fee of six one-hundredth of 1 percent per annum to the Government National Mortgage Association, as well as a custodian fee to the custodian. The issuer is required to service the mortgages in pools collateralizing the GNMA's, remit monthly payments of principal and interest to the security holders whether or not such payments have been collected by the issuer, and perform such duties as are required by the agreements with and regulations of the Government National Mortgage Association. According to the application, IDS is custodian for mortgage documents relating to mortgages in pools collateralizing GNMA's issued by Tower. In accordance with the terms of the custodial agreements between IDS and Tower, IDS receives a fee of $2 per mortgage per year.

Applicants state that the price of GNMA's is determined on the open market and is dependent on prevailing interest rates for alternative investments; and that the profit or loss to the issuer of GNMA's is represented by the difference between the sale price less the mortgage acquisition price, any fees required by Government National Mortgage Association, and any other fees, commissions, or other expenses incurred in the sale of GNMA's. Applicants also state that approximately 60 government securities dealers maintain an active market in trading GNMA's. Applicants propose that the price to be paid by the Fund to Tower in connection with a sale of GNMA's shall be based on the current market price then available and shall be no higher than the price at which the Fund could purchase such securities from other recognized dealers or issuers. As evidence of such price, the Fund will obtain three bona fide offers for such securities at each sale. Under this pricing mechanism, purchases of GNMA's by the Fund from Tower will be made at a price no higher than the lowest price at which the Fund can purchase them from other recognized dealers or issuers.

Applicants represent that the Fund intends to purchase GNMA's for investment purposes and that the Fund will have no participation in the offering of GNMA's as an issuer, underwriter, dealer, or manager and will not share in any profits or losses of such offering. Applicants represent further that Tower will be acting as a principal and not as an agent or broker in connection with such sales and that IDS will not act as principal, agent, or broker in connection with GNMA's which Tower sells to the Fund as discussed herein.

Applicants submit that it will be advantageous to both the Fund and Tower if the Fund is able to purchase GNMA's directly from Tower because both parties anticipate obtaining advantageous prices under this procedure. In addition, it will be advantageous for the Fund to be able to purchase GNMA's directly from Tower because of its close relationship to and familiarity with the operating methods of Tower. Applicants submit that Tower will benefit by the direct sales through expansion of its GNMA market to include the Fund.

Section 17(a) of the Act provides, in pertinent part, that it shall be unlawful for any affiliated person of a registered investment company, or any affiliated person of such a person, acting as principal, knowingly to sell to or to purchase from such registered company any security or other property, subject to certain exceptions not relevant here. Section 17(b) of the Act provides that the Commission, upon application, may exempt a proposed transaction from the provisions of section 17(a) of the Act if the evidence establishes that the terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and that the proposed transaction is consistent with the policy of each registered investment company concerned and with the general purposes of the Act.

Section 6(c) of the Act provides, in pertinent part, that the Commission, by order upon application, may conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of the Act, or of any rule or regulation thereunder, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicants request that the Commission issue an order, pursuant to section 6(c) of the Act, exempting from the provisions of section 17(a) of the Act, the sales of GNMA's by Tower to the Fund. Applicants submit that the facts as stated above clearly establish that the terms of the proposed sales of GNMA's by Tower to the Fund, including the consideration to be paid and received, are reasonable and fair and do not involve overreaching on the part of any person concerned and that the proposed sales are consistent with the policy of the Fund as recited in its registration statement and reports filed under the Act. Further, Applicants submit that the exemption hereby applied for is appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Notice is further given that any interested person may, not later than September 11, 1978, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the application accompanied by a statement as to the nature of his interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicant at the address stated above. Proof of such service (by affidavit, or in the case of an attorney at law by certificate) shall be filed contemporaneously with the request. As provided by rule 0-5 of the rules and regulations promulgated under the Act, an order disposing of the application herein will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons, who request a hearing or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

SHIRLEY E. HOLLIS,
Assistant Secretary.

[FR Doc. 78-23855 Filed 8-24-78; 8:45 am]

[8010-01]

[Rel. No. 10363; 811-2830]

LA CROSSE COOLER HOLDING CORP.

Filing of Application for an Order Declaring That Applicant Has Ceased To Be an Investment Co.

AUGUST 17, 1978.

Notice is hereby given that La Crosse Cooler Holding Corp. ("Applicant"), 2809 Losey Boulevard South, La Crosse, Wis. 54601, registered under

the Investment Company Act of 1940 (the "Act") as a closed end, nondiversified management investment company, filed an application on July 18, 1978, pursuant to section 8(f) of the Act, for an order of the Commission declaring that Applicant has ceased to be an investment company as that term is defined in the Act. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

Applicant was incorporated in the State of Wisconsin in 1945 under the name La Crosse Cooler Co. and thereafter until January 4, 1978, engaged in the business of manufacturing refrigeration devices including coin-operated, soft drink vending machines and institutional and restaurant equipment. The application states that on January 4, 1978, pursuant to shareholder approval, the operating assets of Applicant were transferred to La Crosse Cooler Subsidiary, Inc., a wholly owned subsidiary of Applicant, which assumed all of Applicant's liabilities. Thereafter, on January 20, 1978, the name of Applicant was changed to La Crosse Cooler Holding Corp. The application also states that on April 19, 1978, also pursuant to shareholder approval, the Applicant's wholly owned subsidiary was sold for a cash consideration of $2,280,738.13. The proceeds of this sale, together with the liquid assets retained by Applicant when its operating assets were transferred to the subsidiary, aggregated $3,352,230, which represented a liquid book value of $9 for each of Applicant's 372,470 shares of common stock then outstanding. Applicant states that it presently has no debts or other liabilities except for legal and accounting fees for which bills have not yet been received, and that it is not a party to any pending litigation, or administrative proceedings.

Applicant registered under the Act on April 25, 1978, by a filling a notification of registration on form N-8A with the Commission. On May 12, 1978, Applicant transmitted to its shareholders an offer to purchase its outstanding common stock for $9 per share. Applicant states that pursuant to such offer it has purchased 134,245 shares of its outstanding common stock through the close of business on July 10, 1978, and that the 238,225 shares of its common stock remaining outstanding are beneficially owned by 85 shareholders of record. Applicant represents that at the date of filing this application the outstanding securities of Applicant are beneficially owned by not more than 100 persons. In addition, it is represented that as of that date, no "company," as such term is defined in the Act, owned of record or was known by Applicant to own beneficially, 10 percent or more of the outstanding voting securities of Applicant. The application also states that Applicant is not making and does not presently propose to make a public offering of its securities.

On the basis of the above information Applicant maintains that it is not presently an "investment company" as that term is defined in the Act.

Section 3(c)(1) of the Act provides, in pertinent part, that any issuer whose outstanding securities (other than short-term paper) are beneficially owned by not more than 100 persons and which is not making and does not presently propose to make a public offering of its securities is not an investment company within the meaning of the Act.

Section 8(f) of the Act provides, in pertinent part, that whenever the Commission, on its own motion or upon application, finds that a registered investment company has ceased to be an investment company, it shall so declare by order, and upon the effectiveness of such order the registration of such company shall cease to be in effect.

Notice is further given that any interested person may, not later than September 11, 1978, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the application accompanied by a statement as to the nature of his interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicant at the address stated above. Proof of such service (by affidavit, or in the case of an attorney at law by certificate) shall be filed contemporaneously with the request. As provided by rule 0-5 of the rules and regulations promulgated under the Act, an order disposing of the application herein will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons, who request a hearing or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

SHIRLEY E. HOLLIS,
Assistant Secretary.

[FR Doc. 78-23856 Filed 8-24-78; 8:45 am]

[8010-01]

[Rel. No. 20676; 70-6199]

NEW ORLEANS PUBLIC SERVICE, INC.

Proposal To Issue Short-Term Notes to Banks

AUGUST 18, 1978.

Notice is hereby given that New Orleans Public Service, Inc. ("NOPSI"), 317 Baronne Street New Orleans, La. 70160, a wholly owned subsidiary of Middle South Utilities, Inc., a registered holding company, has filed an application-declaration with this Commission pursuant to the Public Utility Holding Company Act of 1935 ("Act"), designating sections 6 and 7 of the Act and rule 50(a)(2) promulgated thereunder as applicable to the proposed transaction. All interested persons are referred to the application-declaration, which is summarized below, for a complete statement of the proposed transaction.

NOPSI proposes to issue and sell short term securities in the form of promissory notes ("notes") to various commercial banks from time to time through December 31, 1979, to meet its interim financing requirements. The maximum aggregate principal amount of notes outstanding at any one time shall not exceed the lesser of $20,000,000 or 10 percent of NOPSI's capitalization, which is the maximum amount of unsecured borrowings permissible under the provisions of NOPSI's restated articles of incorporation without the consent of the preferred shareholders. Applying this formula to NOPSI's capitalization at June 30, 1978, including $10,000,000 of first mortgage bonds, 3¼ percent series due 1978, an aggregate principal amount of $22,005,701 of promissory notes would be issuable. The maximum amount proposed herein will not be increased without the filing by NOPSI of a post-effective amendment hereto notifying the Commission of any such increase and the issuance by the Commission of a further order with respect thereto.

NOPSI's current construction program is expected to result in expenditures of approximately $25,000,000 in 1978 and $26,750,000 in 1979. Additionally, it is anticipated that during 1979 NOPSI will be required to provide about $4,600,000 as prepaid rent to the city of New Orleans to be used by the city for the purchase of new fare boxes for NOPSI's transit vehicles and 185 new buses. The net proceeds to be

received by NOPSI from the issuance and sale of the notes will be applied principally to NOPSI's construction program, to the prepayment of the aforesaid rent and to the payment at maturity of $10,000,000 aggregate principal amount of its first mortgage bonds, 3¼ percent series due October 1, 1978. As the notes mature, they will be renewed (but to mature not later than September 30, 1980) or repaid out of funds then available to NOPSI from its operations or derived from the issuance and sale of long-term debt. NOPSI presently contemplates that permanent financing will be undertaken in the last quarter of 1978.

The notes would be in the form of unsecured promissory notes customarily used by the lending banks. NOPSI presently has outstanding $4,000,000 in aggregate principal amount of unsecured notes consisting of a $2,000,000 note held by the Hibernia National Bank in New Orleans and a $2,000,000 note held by the First National Bank of Commerce in New Orleans. Both of these notes mature on or before October 18, 1978, bear interest at the rate of 9 percent per annum and are prepayable in whole or in part at any time without premium. The notes would be issued by NOPSI to the banks listed below in aggregate amounts not to exceed the maximum amounts listed below, would be due not more than 9 months from date of issuance, bear interest at the prime commercial bank rate in effect at the lending bank at the time of issuance or renewal, and be prepayable in whole or in part at any time without premium:

	Present loans	Proposed maximum additional loans	Maximum loans to be outstanding
Whitney National Bank of New Orleans		$8,100,000	$8,100,000
Hibernia National Bank in New Orleans	$2,000,000	1,500,000	3,500,000
First National Bank of Commerce in New Orleans	2,000,000	1,000,000	3,000,000
National American Bank of New Orleans		2,400,000	2,400,000
The Chase Manhattan Bank (N.A.)		3,000,000	3,000,000
Total	4,000,000	16,000,000	20,000,000

Accounts are maintained with the above-mentioned banks, from whom borrowings are proposed to be made, and, although balances in some of these accounts may be deemed to be compensating balances, these accounts are working accounts and fluctuations in their balances do not reflect or depend upon fluctuations in the amounts of bank loans outstanding. NOPSI does not have any commitments to maintain compensating balances with the above banks and no commitment fee is involved for any of the proposed borrowings.

The fees, commissions and expenses to be incurred in connection with the proposed transaction are estimated to be less than $4,000. It is stated that no State of Federal Commission, other than this Commission, has jurisdiction over the proposed transaction.

Notice is further given that any interested person may, not later than September 12, 1978, request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of fact or law raised by the filing which he desires to controvert; or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request should be served personally or by mail upon the applicants-declarants at the above-stated address, and proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. At any time after said date, the application-declaration, as filed or as it may be amended, may be granted and permitted to become effective as provided in rule 23 of the general rules and regulations promulgated under the Act, or the Commission may grant exemption from such rules as provided in rules 20(a) and 100 thereof or take such other action as it may deem appropriate. Persons who request a hearing or advice as to whether a hearing is ordered will receive any notices or orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

SHIRLEY E. HOLLIS,
Assistant Secretary.

[FR Doc. 78-23857 Filed 8-24-78; 8:45 am]

[8025-01]

SMALL BUSINESS ADMINISTRATION

[License No. 06/06-0199]

ALLIANCE CAPITAL CORP.

Notice of Surrender of License To Operate as a Small Business Investment Company

Notice is hereby given that Alliance Capital Corp. (Alliance), 4321 North Central Expressway, Dallas, Tex. 75205, pursuant to the provisions of section 107.105 of the regulations governing small business investment companies (13 CFR 107.105 (1978)), has surrendered its license to operate as a small business investment company (SBIC).

Alliance was incorporated under the laws of the State of Texas to operate solely as an SBIC under the Small Business Investment Act of 1958, as amended (15 U.S.C. 661 et seq.) (the Act) and it was issued license No. 06/06-0199 by the Small Business Administration on June 19, 1978.

Under the authority vested by the Act and the rules and regulations promulgated thereunder, the surrender of the license of Alliance is hereby accepted and accordingly, it is no longer licensed to operate as an SBIC.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies.)

Dated: August 18, 1978.

PETER F. MCNEISH,
Deputy Associate Administrator for Investment.

[FR Doc. 78-23862 Filed 8-24-78; 8:45 am]

[8025-01]

REGION V ADVISORY COUNCIL MEETING

Public Meeting

The Small Business Administration Region V Advisory Council, located in the geographical area of Columbus, Ohio, will hold a public meeting on Thursday, September 14, 1978, from 9 a.m. until 2 p.m., at the Imperial House—Arlington, 1335 Dublin Road, Columbus, Ohio, to discuss such business as may be presented by members, staff of the Small Business Administration, or others present.

For further information, write or call Frank D. Ray, District Director, U.S. Small Business Administration, Federal Building and U.S. Courthouse, 85 Marconi Boulevard, Columbus, Ohio 43215, 614-469-7310.

Dated: August 21, 1978.

K. DREW,
Deputy Advocate for Advisory Councils.

[FR Doc. 78-23865 Filed 8-24-78; 8:45 am]

[8025-01]

REGION V ADVISORY COUNCIL MEETING

Public Meeting

The Small Business Administration Region V Advisory Council, located in the geographical area of Minneapolis, Minn., will hold a public meeting on Tuesday, September 12, 1978, from 10 a.m. to 2 p.m., at the Bluff House, Control Data Corporation, 3315 East Old Shakopee Road, Bloomington, Minn., to discuss such business as may be presented by members, staff of the Small Business Administration, or others present.

For futher information, write or call Paul W. Jansen, District Director, U.S. Small Business Administration, Plymouth Building, Room 530, 12 South Sixth Street, Minneapolis, Minn. 55402, 612-725-2928.

Dated: August 21, 1978.

K DREW,
Deputy Advocate for Advisory Councils.

[FR Doc. 78-23886 Filed 8-24-78; 8:45 am]

[8025-01]

REGION VI ADVISORY COUNCIL MEETING

Public Meeting

The Small Business Administration Region VI Advisory Council, located in the geographical area of Dallas, Tex., will hold a public meeting on Thursday, October 5, 1978, from 9:30 a.m. to 2 p.m., in the third floor Board Room of the National Bank of Commerce, 1525 Elm Street, Dallas, Tex., to discuss such business as may be presented by members, staff of the Small Business Administration, or others present.

For further information, write or call Emly S. Atkinson, District Director, U.S. Small Business Administration, 1100 Commerce Street, Dallas, Tex. 75202, 214-749-2706.

Dated: August 21, 1978.

K DREW,
Deputy Advocate for Advisory Councils.

[FR Doc. 78-23867 Filed 8-24-78; 8:45 am]

[8025-01]

REGION VI ADVISORY COUNCIL MEETING

Public Meeting

The Small Business Administration Region VI Advisory Council, located in the geographical area of Lubbock, Tex., will hold a public meeting on Wednesday, September 20, 1978, from 8:30 a.m. to 4:30 p.m. at the Reddy Room, Southwestern Public Service Co., 1120 Main Street, Lubbock, Tex., to discuss such business as may be presented by members, staff of the Small Business Administration, or others present.

For further information, write or call Philip J. O'Jibway, District Director, U.S. Small Business Administration, 712 Federal Office Building and U.S. Courthouse, 1205 Texas Avenue, Lubbock, Tex. 79401, 806-738-7462.

Dated: August 21, 1978.

K DREW,
Deputy Advocate for Advisory Councils.

[FR Doc. 78-23868 Filed 8-24-78; 8:45 am]

[8025-01]

REGION X ADVISORY COUNCIL MEETING

Public Meeting

The Small Business Administration Region X Advisory Council, located in the geographical area of Portland, Oreg., will hold a public meeting on Friday, September 22, 1978, at 9:30 a.m. (P.s.t.), at the U.S. National Bank of Oregon Board Room, Third Floor, Broadway and Oak Streets, Portland, Oreg., to discuss such business as may be presented by members, staff of the Small Business Administration, or others present.

For further information, write or call J. Don Chapman, District Director, U.S. Small Business Administration, Federal Building, Room 676, 1220 Southwest Third Avenue, Portland, Oreg. 97204, 503-423-3461.

Dated: August 21, 1978.

K DREW,
Deputy Advocate for Advisory Councils.

[FR Doc. 78-23869 Filed 8-24-78; 8:45 am]

[8025-01]

[Declaration of Disaster Loan Area No. 1516]

NEW YORK

Declaration of Disaster Loan Area

Richmond County and adjacent counties within the State of New York constitute a disaster area as a result of damage caused by heavy rain and flooding which occurred on August 12, 1978. Eligible persons, firms, and organizations may file applications for loans for physical damage until the close of business on October 19, 1978, and for economic injury until the close of business on May 18, 1979, at:

Small Business Administration, District Office, 26 Federal Plaza, Room 3100, New York, N.Y. 10007.

or other locally announced locations.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: August 18, 1978.

PATRICIA M. CLOHERTY,
Acting Administrator.

[FR Doc. 78-23863 Filed 8-24-78; 8:45 am]

[8025-01]

[Declaration of Disaster Loan Area No. 1514]

SOUTH DAKOTA

Declaration of Disaster Loan Area

The following two counties and adjacent counties within the State of South Dakota constitute a disaster area as a result of natural disaster as indicated:

County, natural disaster(s), and date(s)

Marshall; high winds and tornadoes; June 16, 1978.
Marshall; hail storm and heavy rains; June 22, 1978.
Marshall; heavy rain; June 6, 1978 and June 29, 1978.
Union; high wind, hail, and heavy rain; July 5, 1978.

Eligible persons, firms, and organizations may file applications for loans for physical damage until the close of business on October 16, 1978, and for economic injury until the close of business on May 17, 1979, at:

Small Business Administration, District Office, Eighth and Main Avenue, Sioux Falls, S. Dak. 57102.

or other locally announced locations.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: August 17, 1978.

H. A. THEISTE,
Acting Administrator.

[FR Doc. 78-23864 Filed 8-24-78; 8:45 am]

[4810-31]

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

[Notice No. 78-9; Reference: ATF O 1100.90]

ASSISTANT DIRECTOR (REGULATORY ENFORCEMENT)

Delegation of Authority; Correction

In FR Doc. 78-17390 appearing on page 27271 in the FEDERAL REGISTER of June 23, 1978, the heading of the document which reads "[Notice No. 78-9; Reference: ATF O 1100.]" is corrected to read "[Notice No. 78-9; Reference: ATF O 1100.90]".

Signed: August 19, 1978.

JOHN G. KROGMAN,
Acting Director.

[FR Doc. 78-23875 Filed 8-24-78; 8:45 am]

[4810-31]

[Notice No. 78-7; Reference: ATF O 1100.87]

DELEGATION TO THE ASSISTANT DIRECTOR (REGULATORY ENFORCEMENT) OF AUTHORITIES OF THE DIRECTOR IN 27 CFR, PART 213, DISTRIBUTION AND USE OF TAX-FREE ALCOHOL

Delegation Order; Correction

In FR Doc. 78-16750 appearing on page 26174 in the FEDERAL REGISTER of June 16, 1978, the heading of the document which reads "[Notice No. 78-7; Reference: ATF O 1100]" is corrected to read "[Notice No. 78-7; Reference: ATF O 1100.87]".

Signed: August 19, 1978.

JOHN G. KROGMAN,
Acting Director.

[FR Doc. 78-23874 Filed 8-24-78; 8:45 am]

[4830-01]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

FORM 940, EMPLOYER'S ANNUAL FEDERAL UNEMPLOYMENT TAX RETURNS

Proposed Revision

AGENCY: Internal Revenue Service, Department of the Treasury.

ACTION: Notice of proposed revision of Form 940, Employer's Annual Federal Unemployment Tax Return, for 1979.

SUMMARY: As part of their forms simplification effort, the Internal Revenue Service is asking for public comments on a proposed extensive revision of Form 940, Employer's Annual Federal Unemployment Tax Return, for 1979. After considering all comments and suggestions, the Service will decide whether to adopt the proposed revision for 1979.

DATE: Written comments and suggestions should be mailed or delivered by November 2, 1978.

ADDRESS: Written comments and suggestions should be mailed or delivered to the Chairman, Tax Forms Coordinating Committee, Internal Revenue Service, Room 5577, 1111 Constitution Avenue NW., Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT:

Mr. Robert I. Brauer, 1111 Constitution Avenue NW., Washington, D.C. 20224. Telephone: 202-566-6150 (not a toll-free telephone number).

SUPPLEMENTARY INFORMATION: The proposed revision is simpler to complete for employers who (1) pay contributions to the unemployment compensation fund of only one State, (2) pay all contributions to the State by the due date (or extended due date) of Form 940, and (3) have no exemption from State contributions for wages subject to Federal unemployment tax. A majority of employers are in this category. They will not have to complete the tentative credit part of the return and will have a simplified tax computation. They will figure their tax by miltiplying net taxable wages by .007 and adding any required reduction in credits.

Employers who make payments to more than one State, make payments after the due date of Form 940, or have any part of their net taxable wages subject to Federal unemployment tax exempted from State contributions, will continue to complete the tentative credit and the tax computation parts of the return as in past years.

Tax return preparers and employers are cautioned not to make any program changes based on the proposed revision before it is adopted.

This document does not meet the criteria for significant regulations set forth in paragraph 8 of the proposed Treasury Directive appearing in the FEDERAL REGISTER for Wednesday, May 24, 1978.

Dated: August 21, 1978.

JOHN L. WITHERS,
Assistant Commissioner, Technical.

Form **940**
Department of the Treasury
Internal Revenue Service

Employer's Annual Federal Unemployment Tax Return

1979

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I	
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If incorrect, make any necessary change ▶

Name (as distinguished from trade name)

Trade name, if any

Address and ZIP code

Calendar Year
1979

Employer identification number

A Are you required to pay contributions to only one State? . . . . . ☐ Yes ☐ No

If you check the "Yes" box, enter the name of the State to which you are required to pay contributions . . . ▶

B Have you paid all required contributions to your State unemployment fund by the due date of Form 940? . . . . . ☐ Yes ☐ No

If you check the "Yes" box, enter amount of contributions timely paid to your State unemployment fund . . ▶

Part I Computation of Taxable Wages (To be Completed by All Taxpayers)

1 Total remuneration (including exempt remuneration) paid during the calendar year for services of employees

Exempt Remuneration	Amount paid
2 Exempt remuneration. (Explain each exemption shown, attaching additional sheets if necessary) ▶	
3 Remuneration in excess of $6,000. Enter only the excess over the first $6,000 paid to individual employees exclusive of exempt amounts entered on line 2. Do not use State wage limitation	

4 Total exempt remuneration (add column b, lines 2 and 3) . . . . . .

5 Total taxable wages (subtract line 4 from line 1) . . . . . ▶

Part II Complete Only if You Checked the "Yes" Boxes in Items A and B Above

1 FUTA tax. Multiply the wages on line 5, Part I by .007 and enter here . . . . . .

2 (Name of State) wages included on line 5, Part I ▶ $ ..... multiplied by .006 . . .

3 Total (add lines 1 and 2) . . . . . .

4 Less: Total Federal tax deposited from line 5, Part IV . . . . . .

5 Balance due (subtract line 4 from line 3—this should not be over $100). Pay to Internal Revenue Service . . ▶

6 Overpayment (subtract line 3 from line 4) . . . . . ▶

Part III Complete If You Checked the "No" Box in Item A or Item B Above

1 Gross FUTA tax. Multiply the wages on line 5, Part I by .034 . . . . . .

2 Maximum credit. Multiply the wages on line 5, Part I by .027 . . . . . .

3 Enter the smaller of the amount on: { line 11, Part V / Line 2, above } . . . . . .

4 (Name of State) wages included on line 5, Part I ▶ $ ..... multiplied by .006 .

5 Credit allowable (subtract line 4 from line 3) . . . . . .

6 Net FUTA tax (subtract line 5 from line 1) . . . . . .

7 Less: Total Federal tax deposited from line 5, Part IV . . . . . .

8 Balance due (subtract line 7 from line 6—this should not be over $100). Pay to Internal Revenue Service . . ▶

9 Overpayment (subtract line 6 from line 7) . . . . . ▶

If no longer in business at end of year, write "Final" here . . . . . ▶

Under penalties of perjury, I declare that I have examined this return, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct, and complete, and that no part of any payment made to a State unemployment fund claimed as a credit was or is to be deducted from the remuneration of employees.

Date ▶ Signature ▶ Title (Owner, etc.) ▶

263-038-1 Form **940** (197)

Part IV Record of Federal Tax Deposits for Unemployment Tax (Form 508)

	a. Quarter	b. Liability by period	c. Date of deposit	d. Amount of deposit
1	First			
2	Second			
3	Third			
4	Fourth			

5 Total Federal tax deposited (add column d, lines 1 through 4) . . . . . ▶

Part V Computation of Tentative Credit—See Instructions

Name of State 1	State reporting number as shown on employer's State contribution returns 2	Taxable payroll (As defined in State act) 3	Experience rate period 4 From—	Experience rate period 4 To—	Experience rate 5	Contributions had rate been 2.7% (col. 3×2.7%) 6	Contributions payable at experience rate (col. 3×col. 5) 7	Additional credit (col. 6 minus col. 7) 8	Contributions actually paid to State 9
10 Totals . . . . . ▶									

11 Total tentative credit (add line 10, columns 8 and 9) . . . . . ▶

Effective January 1, 197 8–

(1) Wage base increases to $6,000;

(2) Coverage extended to certain agricultural and domestic service employees; and

(3) U.S. Virgin Islands employers are subject to FUTA.

General Instructions

For more detailed information on which employers must file, the types of payments defined by law as wages, and the kind of services covered by the Federal Unemployment Tax Act (FUTA), see **Publication 15,** Circular E, Employer's Tax Guide, available at any Internal Revenue Service office. **Publication 539,** Withholding Taxes and Reporting Requirements, has examples and a filled in copy of Form 940.

Purpose of Form 940.—Use it for the annual reporting of tax under FUTA, which is **paid only by the employer.** The tax rate is 3.4 percent on the first $6,000 of wages paid to each employee during 197 .

Who Must File.—In general, every employer who during 197 or 197 paid wages of $1,500 in any calendar quarter or at any time had one or more employees in any 20 calendar weeks must file. Count all regular, temporary, and part-time employees. A partnership should not count its partners. If a change of ownership or other transfer of the business occurs during the year, each employer who meets the $1,500 a quarter or one or more employees in 20 weeks tests must file, but neither should report wages paid by the other. Organizations described in section 501(c)(3) are not required to file.

Generally, beginning in 1978, employers who (1) paid cash wages of $20,000 or more to agricultural workers during any calendar quarter in 197 or 197 ; or (2) employed 10 or more agricultural workers during some portion of a day (whether or not at the same time) for at least one day during any 20 different weeks in 197 or 197 . (Aliens admitted to the U.S. on a temporary basis to perform agricultural labor are excluded until January 1, 1980.); or (3) paid cash wages of $1,000 or more in any calendar quarter in 197 or 197 for domestic service in a private home, local college club, or a local chapter of a college fraternity or sorority will be required to file Form 940.

If you receive a form and are not liable for Federal unemployment tax for 197 , write "Not Liable" across the front and return it to the IRS. If you are no longer in business at the end of the year, write "Final" on the line above the signature line.

If you sold or transferred the business during the year, attach a statement showing the name, address, and employer identification number (if known) of the new owner.

Once you have filed a Form 940, we will send you a preaddressed form near the end of the year. If you do not receive it, request one from any IRS office in time to file.

Due Date.—Form 940 for 197 is due by January 31, 19 . If you made timely deposits in full payment of the tax due, you have until February 10, 19 , to file.

Where to File.—

If your principal business, office, or agency is located in ▼	File with the Internal Revenue Service Center at ▼
New Jersey, New York City and counties of Nassau, Rockland, Suffolk, and Westchester	Holtsville, NY 00501
New York (all other counties), Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont	Andover, MA 05501
District of Columbia, Delaware, Maryland, Pennsylvania	Philadelphia, PA 19255
Alabama, Florida, Georgia, Mississippi, South Carolina	Atlanta, GA 31101
Michigan, Ohio	Cincinnati, OH 45999
Arkansas, Kansas, Louisiana, New Mexico, Oklahoma, Texas	Austin, TX 73301
Alaska, Arizona, Colorado, Idaho, Minnesota, Montana, Nebraska, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming	Ogden, UT 84201
Illinois, Iowa, Missouri, Wisconsin	Kansas City, MO 64999
California, Hawaii	Fresno, CA 93888
Indiana, Kentucky North Carolina, Tennessee, Virginia, West Virginia	Memphis, TN 37501

If you have no legal residence or principal place of business in any Internal Revenue Service district, or if your principal place of business is in Puerto Rico or the U.S. Virgin Islands, file Form 940 with the Internal Revenue Service Center, Philadelphia, PA 19255.

Deposit Requirements.—Deposit Federal unemployment tax in an authorized financial institution or a Federal Reserve Bank according to the instructions on the reverse of a preinscribed Federal Tax Deposit Form 508 which must accompany each deposit.

Figure Federal unemployment tax on a quarterly basis. Deposit any amount due by the last day of the first month following the close of the quarter. (If you do not qualify as an employer until the second or third quarter, your deposit requirements do not begin until then.)

To determine if you must make a deposit for any of the first three quarters in 19 , compute the total tax by multiplying by .007 that part of the first $6,000 of each employee's annual wages you paid during the quarter.

If the amount subject to deposit (plus the undeposited amount for any prior quarter) is more than $100, deposit it during the first month following the quarter. If the amount is $100 or less, you do not have to deposit it, but you must add it to the amount subject to deposit for the next quarter.

If the tax reportable on Form 940 less amounts deposited for the year is more than $100, deposit the entire amount. If the tax for the year less any deposits is $100 or less, either deposit it or pay it with Form 940.

If you deposited the proper amounts, following these rules, the balance due will not exceed $100.

How to Make Deposits.—Follow the instructions on the reverse of the preinscribed Federal Tax Deposit Form 508.

Employer's Name, Address, and Identification Number.—Use the preaddressed Form 940 mailed to you. If you must use a nonpreaddressed form, type or print your name, trade name, address, and employer identification number on it.

Penalties and Interest.—Avoid penalties and interest by filing a correct return and paying the proper amount of tax when due. The law provides a penalty for late filing unless you show reasonable cause for the delay. If you file late, attach an explanation.

There are also penalties for willful failure to pay tax, keep records and make returns, and for filing false or fraudulent returns. Taxpayers who willfully claim credit for deposits not made are subject to fines and other criminal penalties.

Credit for Contributions Paid into State Funds.—You can claim credit for contributions you pay into a certified State unemployment compensation fund by the due date of Form 940.

"Contributions" mean payments required by State law to be made into an unemployment fund by any person on account of having individuals in his or her employ, to the extent that such payments are made without being deducted or deductible from the employees' remuneration.

You may credit contributions against the tax whether or not made with respect to "employment." You may not take credit for voluntary contributions or for penalties or interest payments to a State.

263-038-1

Form **940**
Department of the Treasury
Internal Revenue Service

Employer's Annual Federal Unemployment Tax Return

1979

YOUR COPY

Calendar Year
1979
Employer identification number

A Are you required to pay contributions to only one State? . . . . . ☐ Yes ☐ No
If you check the "Yes" box, enter the name of the State to which you are required to pay contributions . . . ▶
B Have you paid all required contributions to your State unemployment fund by the due date of Form 940? . . . . . ☐ Yes ☐ No
If you check the "Yes" box, enter amount of contributions timely paid to your State unemployment fund . . ▶

Part I Computation of Taxable Wages (To be Completed by All Taxpayers)

1 Total remuneration (including exempt remuneration) paid during the calendar year for services of employees

Exempt Remuneration	Amount paid
2 Exempt remuneration. (Explain each exemption shown, attaching additional sheets if necessary) ▶	
3 Remuneration in excess of $6,000. Enter only the excess over the first $6,000 paid to individual employees exclusive of exempt amounts entered on line 2. Do not use State wage limitation	

4 Total exempt remuneration (add column b, lines 2 and 3) . . . . .
5 Total taxable wages (subtract line 4 from line 1) . . . . . ▶

Part II Complete Only if You Checked the "Yes" Boxes in Items A and B Above

1 FUTA tax. Multiply the wages on line 5, Part I by .007 and enter here . . . . .
2 (Name of State) wages included on line 5, Part I ▶ $ ..... multiplied by .006 . . .
3 Total (add lines 1 and 2) . . . . .
4 Less: Total Federal tax deposited from line 5, Part IV . . . . .
5 **Balance due** (subtract line 4 from line 3—this should not be over $100). Pay to Internal Revenue Service . . ▶
6 **Overpayment** (subtract line 3 from line 4) . . . . . ▶

Part III Complete If You Checked the "No" Box in Item A or Item B Above

1 Gross FUTA tax. Multiply the wages on line 5, Part I by .034 . . . . .
2 Maximum credit. Multiply the wages on line 5, Part I by .027 . . . . .
3 Enter the smaller of the amount on: { line 11, Part V / Line 2, above } . . . . .
4 (Name of State) wages included on line 5, Part I ▶ $ ..... multiplied by .006 .
5 Credit allowable (subtract line 4 from line 3) . . . . .
6 Net FUTA tax (subtract line 5 from line 1) . . . . .
7 Less: Total Federal tax deposited from line 5, Part IV . . . . .
8 **Balance due** (subtract line 7 from line 6—this should not be over $100). Pay to Internal Revenue Service . . ▶
9 **Overpayment** (subtract line 6 from line 7) . . . . . ▶

If no longer in business at end of year, write "Final" here . . . . . ▶

Keep This Copy For Your Records

You must retain this copy, and a copy of each related schedule or statement for a period of 4 years after the date the tax is due or paid, whichever is the later. These copies must be available for inspection by the Internal Revenue Service.

263-038-1

Form 940 (197) Page 4

Part IV Record of Federal Tax Deposits for Unemployment Tax (Form 508)

	a. Quarter	b. Liability by period	c. Date of deposit	d. Amount of deposit
1	First			
2	Second			
3	Third			
4	Fourth			

5 Total Federal tax deposited (add column d, lines 1 through 4) . . . . . ▶

Part V Computation of Tentative Credit— See Instructions

Name of State 1	State reporting number as shown on employer's State contribution returns 2	Taxable payroll (As defined in State act) 3	Experience rate period 4 From—	To—	Experience rate 5	Contributions had rate been 2.7% (col. 3×2.7%) 6	Contributions payable at experience rate (col. 3×col. 5) 7	Additional credit (col. 6 minus col. 7) 8	Contributions actually paid to State 9
10 Totals . . . . . ▶									

11 Total tentative credit (add line 10, columns 8 and 9) . . . . . ▶

Credit for contributions you make after the due date (or extended due date) for filing Form 940 may not exceed 90 percent of the amount that would have been allowable had you paid the contributions by the due date.

Employers who have been granted an experience rate lower than 2.7 percent by a State for the whole or part of the year are entitled to an "additional credit," which is equal to the difference between actual contributions and the amount they would have been required to contribute at (1) the highest rate applied by the State, or (2) 2.7 percent, whichever is lower.

The total credit allowable may not exceed 2.7 percent of taxable wages.

Specific Instructions

Generally, all filers must complete Questions A and B; Part I; and Part IV if they paid total taxable wages of $14,000 or more to 3 or more employees during the year.

If you pay contributions to only one State unemployment fund, made all State payments by the due date of Form 940, and all of the FUTA wages are subject to the State's unemployment fund taxes, use Part II. Otherwise, you must complete Parts III and V.

Part I.—Computation of Taxable Wages

Line 1—Total remuneration.—Show the total remuneration for services you paid employees during the calendar year, even if it is not taxable. Include salaries, wages, commissions, fees, bonuses, vacation allowances, amounts paid to temporary or part-time employees, and the value of goods, lodging, food, and clothing. Show the amount before any deductions.

How you pay the remuneration is not important in determining if it is wages. Thus, you may pay it for piecework or as a percentage of profits, and you may pay it hourly, daily, weekly, monthly, or yearly. You may pay it in cash or some other way, such as goods, lodging, food, or clothing. For items other than cash, use the fair value at time of payment.

Line 2—Exempt remuneration.—"Wages" and "employment" as defined for FUTA purposes do not include every payment of remuneration and every kind of service an employee may perform. In general, remuneration excluded from wages and remuneration for services excepted from employment are not included in wages subject to tax. You may deduct these payments from total remuneration paid only if you identify them on line 2.

Show such items as (1) agricultural labor if you paid cash wages of less than $20,000 for agricultural labor for each calendar quarter in 19 and 19 , and did not employ 10 or more agricultural workers during some portion of a day during any 20 different weeks in 19 or 19 , (2) benefit payments for sickness or injury under a workmen's compensation law, insurance plan, and certain employer plans, (3) domestic service if you paid cash wages of less than $1,000 in each calendar quarter in 19 and 19 , (4) family employment, (5) certain fishing activities, and (6) any other exempt payments or services. For more detailed information, see Circular E, Employer's Tax Guide.

Line 3.—Show the total amount of remuneration you paid each employee in excess of $6,000. For example, you have 10 employees whom you paid $8,000 each during the year. Show $80,000 on line 1 and $20,000 on line 3. The $6,000 wage limitation is for FUTA purposes only. Do not use the State wage limitation for this entry.

Part II

Use if you made payments to only one State by the due date of Form 940, and all your wages shown on line 5 of Part I are subject to the State's unemployment fund taxes.

Line 2—Show the FUTA wages (if any) subject to the unemployment compensation laws of . (If in doubt, ask your local IRS office.) Multiply the wages by .006. This adjustment is required by Internal Revenue Code section 3302(c)(2). If no wages are subject, show "none" on line 2.

Part III

Use if you do not qualify for Part II.

Line 3.—Show the smaller amount of (1) Line 11, Part V—Total tentative credit, or (2) line 2, Part III—2.7% of taxable FUTA wages.

Line 4.—Show the FUTA wages (if any) subject to the unemployment compensation laws of the . (If in doubt, ask your local IRS office.) Multiply the wages by .006. This reduction in allowable credits is required by Internal Revenue Code section 3302(c)(2). If no wages are subject, show "none" on line 4.

Part IV.—Record of Federal Tax Deposits

Complete this schedule if your total tax for the year is over $100. To figure your liability per quarter, multiply by .007 that part of the first $6,000 of each employee's yearly wages you paid during the quarter. Enter the date and the amount of the deposit you made for each quarter in columns c and d. See "Deposit Requirements" on page 2 for details.

Part V.—Computation of Tentative Credit

Complete this schedule if: (1) You made payments to the unemployment fund of more than one State; (2) You did not make your State payments by the due date of Form 940; or (3) Some wages subject to Federal unemployment tax were exempted from State taxes. If you have a State experience rate lower than 2.7% for all or part of the year, use columns 1 through 9. If you have no experience rate, use columns 1, 2, 3, and 9 only. If you have a rate of 2.7% or higher, use columns 1, 2, 3, 4, 5, and 9 only. If you have an experience rate on part of your payroll, show separately in columns 1, 2, 3, and 9, that part to which the rate does not apply. If you were granted an experience rate for only part of the year or the rate was changed during the year, show in the appropriate columns the period to which each separate rate applied, your payroll, rate, and required contributions for each period.

Column 3.—Show the taxable payroll on which you must pay contributions to the unemployment funds of the State in column 1. If the experience rate is zero, show the amount on which you would have had to pay contributions if the rate had not been granted.

Column 8.—Subtract the amount in column 7 from column 6. If zero or less, show zero (0).

Column 9.—Show the amount of contributions actually paid into the State fund.

Line 10.—Add columns 8 and 9. Credit for contributions you make after the due date (or extended due date) for filing Form 940 may not exceed 90 percent of the amount that would have been allowed had you paid the contributions by the due date.

[FR Doc. 78-23765 Filed 8-24-78; 8:45 am]

[4810-25]

Office of the Secretary

TRIGGER PRICE MECHANISM COLD FINISHED BARS REVISION

New Effective Date

I am hereby announcing a change in the effective date for the revised cold finished bar trigger price announced in the Treasury Department Release of July 20, 1978 (43 FR 33993, August 2, 1978). The base trigger prices as shown in footnote [1] below (i.e., the third quarter trigger price for this product prior to the July 20 revisions) will continue to apply to cold finished bars exported through September 30, 1978. The announced fourth quarter revised base trigger prices will apply to carbon cold finished bars shipped on or after October 1.

The new effective date is being established since the revised cold finished bar trigger price represents a change in a previously announced trigger price and many parties have acted in reliance on the previously published trigger price. The Department has concluded that substantial unfairness would result if the revised price were to take effect before October 1. Thus, the revised cold finished bar prices are effective on or after October 1 consistent with the previously announced prices of galvanized sheets, tin plate, double reduced plate, and others noted on page 12 of Treasury's July 20 press release, 43 FR 33993.

Dated: August 22, 1978.

HENRY C. STOCKELL, Jr.,
Acting General Counsel.

[FR Doc. 70-23966 Filed 8-24-78; 8:45 am]

TPM page	Grade	Applicable 3d quarter base price (per M/T)	4th quarter base price applicable to shipments exported on or after Oct. 1, 1978
12-1	Cold finished round bar AISI 1008 to 1029.	381	460
12-2	Cold finished sulphur free cutting round bar AISI 1212 to 1215.	430	521
12-3	Cold finished free cutting lead round bar 12L14 and 12L15.	452	544

[7035-01]

INTERSTATE COMMERCE COMMISSION

[Notice No. 706]

ASSIGNMENT OF HEARINGS

AUGUST 22, 1978.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

MC 107012 (Sub-250), North American Van Lines, Inc., now assigned for continued hearing on October 11, 1978, at Chicago, IL, is advanced to October 10, 1978 (3½ days), at Chicago, IL, in a hearing room to be later designated.

MC 139973 (Sub-29), and MC 139973 (Sub-38), J. H. Ware Trucking, Inc., now being assigned August 31, 1978, at the offices of the Interstate Commerce Commission, Washington, D.C.

MC 141033 (Sub-36F), Continental Contract Carrier Corp., now assigned September 12, 1978, at San Francisco, CA, will be held in Room No. 510, 5th floor, 211 Main Street.

MC 112822 (Sub-437), Bray Lines, Inc., now assigned September 12, 1978, at San Francisco, CA, will be held in Room 510, 5th floor, 211 Main Street.

MC 125996 (Sub-53), Road Runner Trucking, Inc., now assigned September 13, 1978, at San Francisco, CA, will be held in Room 510, 5th floor, 211 Main Street.

MC 124947 (Sub-98), Machinery Transport, Inc., now assigned September 15, 1978, at San Francisco, CA, will be held in Room 510, 5th floor, 211 Main Street.

MC 107012 (Sub-259), North American Van Lines, Inc., now assigned September 18, 1978, at San Francisco, CA, will be held in Room 510, 5th floor, 211 Main Street.

MC 74321 (Sub-140), B. F. Walker, Inc., and MC 125433 (Sub-115), F-B Truck Line Co., now assigned September 25, 1978, at San Francisco, CA, will be held in Room 510, 5th floor, 211 Main Street.

MC 144268, Barney Hirson, d.b.a. B. Hirson Trucking, now assigned September 21, 1978, at San Francisco, CA, will be held in Room 510, 5th floor, 211 Main Street.

MC 143546, Atlantic Marketing Cooperative Association, now assigned September 14, 1978, at San Francisco, CA, will be held in Room 510, 5th floor, 211 Main Street.

MC 115826 (Sub-301F), W. G. Digby, Inc., now being assigned for hearing on November 28, 1978 (1 day), at Denver, CO, in a hearing room to be later designated.

MC 115826 (Sub-295F), W. G. Digby, Inc., now being assigned for hearing on November 28, 1978 (1 day), at Denver, CO, in a hearing room to be later designated.

MC 57697 (Sub-14), Lester Smith Trucking, Inc., now being assigned for hearing on December 4, 1978 (1 week), at Denver, CO, at the Regency Inn, 3900 Elati, Denver, CO.

MC 110817 (Sub-25F), E. L. Farmer & Co., now being assigned for hearing on December 11, 1978 (1 week), at Denver, CO, in a hearing room to be later designated.

MC 113843 (Sub-250F), Refrigerated Food Express, Inc., MC 114273 (Sub-341F), Crst, Inc., and MC 124170 (Sub-80F), Frostways, Inc., now being assigned September 6, 1978 (2 days), at Denver, CO, in Room 3855A, 230 South Dearborn Street.

MC 107012 (Sub-258), North American Van Lines, Inc., now being assigned November 13, 1978 (3 days), at Atlanta, GA, in a hearing room to be later designated.

MC 65941 (Sub-48F), Tower Lines, Inc., now being assigned November 16, 1978 (2 days), at Atlanta, GA, in a hearing room to be later designated.

MC 143364 (Sub-1F), Associated Cab Co., Inc., d.b.a. Gray Line of Atlanta, now being assigned for November 20, 1978 (2 days), at Atlanta, GA, in a hearing room to be later designated.

MC 120181 (Sub-8), Main Line Hauling Co., Inc., now assigned September 12, 1978, at Jefferson City, MO, is postponed indefinitely.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-23980 Filed 8-24-78; 8:45 am]

[7035-01]

[EXPARTE NO. 241; Exemption 90; 49th rev.]

MANDATORY CAR SERVICE RULES

Exemption

To all railroads:

It appearing, That certain of the railroads named below own numerous 50-ft. plain boxcars; that under present conditions, there are substantial surpluses of these cars on their lines; that return of these cars to the owners would result in their being stored idle; that such cars can be used by other carriers for transporting traffic offered for shipments to points remote from the car owners; and that compliance with Car Service Rules 1 and 2 prevents such use of these cars, resulting in unnecessary loss of utilization of such cars; and

It further appearing, That there are substantial shortages of 50-ft. plain boxcars throughout the country; that the carriers identified in this exemption by the symbol (%) have 150% or more of their ownership of these cars on their lines; and that such a dispro-

portionate use of the total supply of such cars causes shippers served by other lines to be deprived of their proper share of such cars.

It is ordered, That, pursuant to the authority vested in me by Car Service Rule 19, 50-ft. plain boxcars described in the Official Railway Equipment Register, ICCC-RER No. 408, issued by W. J. Trezise, or successive issues thereof, as having mechanical designation "XM", and bearing reporting marks assigned to the railroads named below, shall be exempt from provisions of Car Service Rules 1, 2(a), and 2(b).

Aberdeen & Rockfish Railroad Co.
Reporting Marks: AR
Atlanta & Saint Andrews Bay Railway Co.
Reporting Marks: ASAB
%The Baltimore & Ohio Railroad Co.
Reporting Marks: BO
%Bessemer & Lake Erie Railroad Co.
Reporting Marks: BLE
Camino, Placerville & Lake Tahoe Railroad Co.
Reporting Marks: CPLT
%The Chesapeake & Ohio Railway Co.
Reporting Marks: CO-PM
%Chicago & Illinois Midland Railway Co.
Reporting Marks: CIM
%Chicago, Rock Island & Pacific Railroad Co.
Reporting Marks: RI-ROCK
City of Prineville
Reporting Marks: COP
The Clarendon & Pittsford Railroad Co.
Reporting Marks: CLP
%Consolidated Rail Corp.
Reporting Marks: CR-DLW-EL-ERIE-LV-NH-NYC P&E-PAE-PC-PCA-PRR-RDG-TOC *
%Delaware & Hudson Railway Co.
Reporting Marks: DH
Duluth, Missabe & Iron Range Railway Co.
Reporting Marks: DMIR
%Florida East Coast Railway Co.
Reporting Marks: FEC
Genessee & Wyoming Railroad Co.
Reporting Marks: GNWR
%Grand Trunk Western Railroad Co.
Reporting Marks: GTW
Greenville & Northern Railway Co.
Reporting Marks: GRN
* Lake Erie, Franklin & Clarion Railroad Co.
Reporting Marks: LEF
Lenawee County Railroad Co., Inc.
Reporting Marks: LCRC
Louisiana Midland Railway Co.
Reporting Marks: LOAM
Louisville & Wadley Railway Co.
Reporting Marks: LW
Louisville, New Albany & Corydon Railroad Co.
Reporting Marks: LNAC
Middletown & New Jersey Railway Co., Inc.
Reporting Marks: MNJ
Missouri-Kansas-Texas Railroad Co.
Reporting Marks: BKTY-MKT
New Orleans Public Belt Railroad
Reporting Marks: NOPB
%Norfolk & Western Railway Co.
Reporting Marks: ACY-N&W-NKP-WAB
Pearl River Valley Railroad Co.
Reporting Marks: PRV
* Peninsula Terminal Co.
Reporting Marks: PT
Providence & Worcester Co.
Reporting Marks: PW
Raritan River Rail Road Co.
Reporting Marks: RR
Sacramento Northern Railway
Reporting Marks: SN
St. Lawrence Railroad
Reporting Marks: NSL
Sierra Railroad Co.
Reporting Marks: SERA
Terminal Railway, Alabama State Docks
Reporting Marks: TASD
Tidewater Southern Railway Co.
Reporting Marks: TS
Toledo, Peoria & Western Railroad Co.
Reporting Marks: TPW
Vermont Railway, Inc.
Reporting Marks: VTR
WCTU Railway Co.
Reporting Marks: WCTR
%Western Maryland Railway C.
Reporting Marks: WM
%Western Railway of Alabama
Reporting Marks: WA
Youngstown & Southern Railway Co.
Reporting Marks: YS
Yreka Western Railroad Co.
Reporting Marks: YW

Effective August 15, 1978, and continuing in effect until further order of this Commission.

Issued at Washington, D.C., August 11, 1978.

INTERSTATE COMMERCE COMMISSION,
JOEL E. BURNS,
Agent.

% Carriers having 150% or more of ownership on lines.

* Addition.

[FR Doc. 78-23982 Filed 8-24-78; 8:45 am]

[7035-01]

[Notice No. 24]

SPECIAL PROPERTY BROKERS

AUGUST 22, 1978.

The following applicants seek to participate in the property broker special licensing procedure under 49 CFR 1045A authorizing operations as a broker at any location, in arranging for the transportation by motor vehicle, in interstate or foreign commerce, of property (except household goods), between all points in the United States including AK and HI. Any interested person shall file an original and one copy of a verified statement in opposition limited in scope to matters regarding applicant's fitness on or before September 25, 1978. Statements must be mailed to: Broker Entry Staff, Room 2379, Interstate Commerce Commission, Washington, D.C. 20423.

Opposing parties shall serve one copy of the statement in opposition concurrently upon applicant's representative, or applicant if no representative is named.

If an applicant is not otherwise informed by the Commission, it may commence operation 45 days after this notice (Oct. 10, 1978).

NOTICE No. 24

B-78-93, filed August 4, 1978. Applicant: DAVIDSON FORWARDING CO., a corporation, 698 Fairmount Avenue, Baltimore, Md. 21204. Representative: Henry J. Bouchat, P.O. Box 58, Baltimore, Md. 21203.

B-78-94, filed June 15, 1978. Applicant: UNITED EBONY TRANSPORTATION, INC., 57 Hathaway Street, Wallington, N.J. 07057. Representative: Ronald I. Shapss, 450 Seventh Avenue, New York, N.Y. 10001.

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-23981 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (sub-No. 19F)]

ATCHISON, TOPEKA AND SANTA FE RAILWAY CO.

Trackage Rights Over the St. Louis-San Francisco Railway Co., Between Tulsa and Oklahoma City, OK

The Atchison, Topeka and Santa Fe Railway Co. (Santa Fe), 80 East Jackson Boulevard, Chicago, IL 60604, represented by Richard K. Knowlton, vice President—Law, of the same address, gives notice that on the 27th day of July 1978, it filed with the Interstate Commerce Commission at Washington, DC, an application under section 5(2) of the Interstate Commerce Act for a decision approving and authorizing the grant of trackage rights to permit Santa Fe to operate between Tulsa and Oklahoma City, OK, over trackage of the St. Louis-San Francisco Railway Co. (Frisco). The transaction proposed by Santa Fe is subject to the execution of an appropriate agreement between Santa Fe and Frisco. This application is a major market extension and has been accepted and assigned Finance Docket No. 28583 (Sub-No. 19F).

This application has been filed in response to Finance Docket No. 28583 (Sub-No. 1F), Burlington Northern, Inc.—Control and Merger—St. Louis-San Francisco Railway Co. Santa Fe is seeking the imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission, in order to offset projected gross revenue losses. This proceeding will be consolidated with Finance Docket No. 28583 (Sub-No. 1F).

Santa Fe operates approximately 12,531 miles of railroad in the States of AR, CA, CO, IL, IA, KS, LA, MO, NE, NM, OK, and TX. Santa Fe Indus-

tries, Inc., is the sole owner of Santa Fe.

The trackage involved is approximately 112.8 miles in length. Santa Fe will use the line for overhead traffic and seeks to serve only shippers on the line already served by Santa Fe. Santa Fe will reroute one train per day in each direction over this route between Kansas City, MO, and Oklahoma City, OK. This will relieve congestion between Kansas City, MO, and Oklahoma City, OK, via Arkansas City, KS, particularly between Ellinor and Augusta, KS. Santa Fe will route the trains between Kansas City, KS, and Oklahoma City, OK, via its line between Ottawa, KS, and Tulsa, OK, and Frisco's line between Tulsa and Oklahoma City, OK.

Interested persons may participate formally in a proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceeding designation (Finance Docket No. 28583 (Sub-No. 19F)), and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, DC 20423, not later than October 10, 1978. Such written comments shall include the following: the person's position, e.g., party protestant or party in support, regarding the proposed transaction; and specific reasons why approval would or would not be in the public interest.

This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon the applicant, the Secretary of Transportation, the Attorney General, and all parties of record in Finance Docket No. 28583 (Sub-No. 1F).

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24090 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (Sub-8F)]

CHICAGO & NORTH WESTERN TRANSPORTATION CO.

Trackage Rights Over Burlington Northern, Inc., Between BN M.P. 492.7 at Council Bluffs, Iowa and BN M.P. 2.16 at BN Junction, Mo.

Chicago & North Western Transportation Co. (CNW), represented by Anne E. Valle, attorney, Chicago & North Western Transportation Co., 400 West Madison Street, Room 616, Chicago, Ill. 60606, filed an application under section 5(2) of the Interstate Commerce Act on July 27, 1978, with the Interstate Commerce Commission for a decision authorizing and approving the grant of trackage rights to permit CNW to operate its engine and trains over the tracks of Burlington Northern, Inc. (BN) between Council Bluffs, Iowa, and BN Junction, Stillings, Mo., via Pacific Junction, Iowa and St. Joseph, Mo. The transaction proposed by CNW is subject to the execution of an appropriate agreement between CNW and BN. This application has been accepted and assigned Finance Docket No. 28583 (Sub-8F).

This proceeding has been filed in respone to Finance Docket No. 28583 (Sub-1F), Burlington Northern, Inc.-Control and Merger-St. Louis-San Francisco Railway Co. CNW is seeking the imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to offset projected gross revenue losses. This proceeding will be consolidated with Finance Docket No. 28583 (Sub-1F).

CNW operates approximately 10,233 miles of railroad in the States of Illinois, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, South Dakota, Wisconsin and Wyoming.

Under the proposal, CNW would operate between BN milepost 492.70 at Council Bluffs, Iowa and BN milepost 2.2 at BN Junction, Stillings, Mo., a distance of approximately 168 miles, then over Missouri Pacific trackage to KC Junction and into Kansas City. The proposed route which runs alongside the Missouri River would make the distance between Council Bluffs and Kansas City approximately 197 miles. CNW currently operates between Council Bluffs, Iowa and Kansas City, Mo., over its own mainline track, approximately 411 miles, via Missouri Valley, Ames Junction and Des Moines, Iowa, to BN Junction, then over Missouri Pacific trackage to KC Junction and then into Kansas City. This proposal is a major market extension.

Interested persons may participate formally in a proceeding by submitting written comments regarding the application. Such submissions shall indicate the proceeding designation. (F.D. No. 28583 (Sub-8F)), and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: The person's position, *e.g.*, party protestant or party in support, regarding the proposed transaction; and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding, but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon Applicant, the Secretary of Transportation, the Attorney General and all parties of record in Finance Docket No. 28583 (Sub-1F).

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24080 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (Sub-No. 9F)]

CHICAGO & NORTH WESTERN TRANSPORTATION CO.

Trackage Rights Over Burlington Northern, Inc., Between East Minneapolis, Minn. and East Superior, Wis.

Chicago & North Western Transportation Co. (CNW), represented by Anne E. Valle, Attorney, Chicago & North Western Transportation Co., 400 West Madison Street, Room 616, Chicago, Ill. 60606, filed an application under section 5(2) of the Interstate Commerce Act on July 27, 1978, with the Interstate Commerce Commission for a decision authorizing and approving the grant of trackage rights to permit CNW to operate its engines and trains over the tracks of Burlington Northern, Inc. (BN) between East Minneapolis, Minn., and East Superior, Wis. The transaction proposed by CNW is subject to the execution of an appropriate agreement between CNW and BN. This application has been accepted and assigned Finance Docket No. 28583 (Sub-No. 9F).

This proceeding has been filed in response to Finance Docket No. 28583 (Sub-No. 1F), Burlington Northern, Inc.—control and merger—St. Louis-San Francisco Railway Co. CNW is seeking the imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to offset projected revenue losses. This proceeding will be consolidated with Finance Docket No. 28583 (Sub-No. 1F).

CNW operates approximately 10,233 miles of railroad in the States of Illinois, Iowa, Kansas, Mississippi, Michigan, Minnesota, Missouri, Nebraska, North Dakota, South Dakota, Wisconsin, and Wyoming.

Under the proposal, CNW would operate over BN trackage between BN

milepost 9.3 at East Minneapolis, Minn., and BN milepost 10.3 at Saunders, Wis., then over 5.5 miles of BN terminal track to a point of connection with CNW trackage at East Superior, Wis., for a total distance of approximately 143.8 miles. CNW currently operates between these points over its own mainline track, approximately 171.2 miles, via Northline and Spooner, Wis.

Interested persons may participate formally in a proceeding by submitting written comments regarding the application. Such submissions shall indicate the proceeding designation (Finance Docket No. 28583 (Sub. No. 9F)), and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: the person's position, *e.g.*, party protestant or party in support, regarding the proposed transaction, and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding, but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon Applicant, the Secretary of Transportation, the Attorney General, and all parties of record in Finance Docket No. 28583 (Sub-No. 1F).

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24081 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (Sub-No. 10F)]

WILLIAM M. GIBBONS, TRUSTEE OF THE PROPERTY OF THE CHICAGO, ROCK ISLAND & PACIFIC RAILROAD CO., DEBTOR

Trackage Rights Over Burlington Northern, Inc., Between Lincoln and Havelock, Nebr.

William M. Gibbons, trustee of the property of the Chicago, Rock Island & Pacific Railroad Co., Debtor (Rock Island), with general offices at 332 South Michigan Avenue, Chicago, Ill. 60604, represented by Nicholas G. Manos, trustee's counsel and Martin Cassell, general counsel, both of the same address, hereby gives notice that on July 27, 1978, he filed with the Interstate Commerce Commission at Washington, D.C., an application under section 5(2) of the Interstate Commerce Act for a decision approving and authorizing the grant of trackage rights to permit Rock Island to operate between Lincoln and Havelock, Nebr. over trackage of Burlington Northern, Inc. (BN). The transaction proposed by Rock Island is subject to the execution of an appropriate agreement between Rock Island is subject to the execution of an appropriate agreement between Rock Island and BN. This application has been accepted and assigned Finance Docket No. 28583 (Sub-No. 10F).

This application has been filed in response to Finance Docket No. 28583 (Sub-No. 1F), Burlington Northern, Inc.—control and merger—St. Louis-San Francisco Railway Co. Rock Island is seeking the imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to offset projected gross revenue losses. This proceeding will be consolidated with Finance Docket No. 28583 (Sub-No. 1F).

Rock Island operates approximately 7,013 miles of railroad in the States of Arkansas, Colorado, Illinois, Iowa, Kansas, Louisiana, Minnesota, Missouri, Nebraska, New Mexico, Oklahoma, Tennessee, and Texas. Rock Island is under the sole control of the U.S. District Court for the Northern District of Illinois, Eastern Division, Judge Frank J. McGarr, and the trusteeship of William M. Gibbons.

The trackage involved is approximately 5 miles in length and would be used by Rock Island to serve industries local to BN at Havelock, Nebr.

Interested persons may participate formally in a proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceeding designation (F.D. No. 28583 (Sub-No. 10F)), and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: The person's position, e.g., party protestants or party in support, regarding the proposed transaction; and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon Applicants, the Secretary of Transportation, the Attorney General and all parties of record in Finance Docket No. 28583 (Sub-No. 1F).

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24082 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (Sub-No. 11F)]

WILLIAM M. GIBBONS, TRUSTEE OF THE PROPERTY OF THE CHICAGO, ROCK ISLAND & PACIFIC RAILROAD CO., DEBTOR

Trackage Rights Over the Colorado & Southern Railway Co., Between Denver and Golden, Colo.

William M. Gibbons, trustee of the property of the Chicago, Rock Island & Pacific Railroad Co., Debtor (Rock Island), with general offices at 332 South Michigan Avenue, Chicago, Ill. 60604, represented by Nicholas G. Manos, trustee's counsel and Martin Cassell, general counsel, both of the same address, hereby gives notice that on July 27, 1978, he filed with the Interstate Commerce Commission at Washington, D.C. 20423, an application under section 5(2) of the Interstate Commerce Act, for a decision approving and authorizing the grant of trackage rights to permit Rock Island to operate between Denver and Golden, Colo., over the trackage of the Colorado & Southern Railway Co. (C&S). C&S is a subsidiary of Burlington Northern, Inc. The transaction proposed by Rock Island is subject to the execution of an appropriate agreement between Rock Island and C&S. This application is a major market extension and has been accepted and assigned Finance Docket No. 28583 (Sub-No. 11F).

This application has been filed in response to Finance Docket No. 28583 (Sub-No. 1F), Burlington, Northern, Inc.—control and merger—St. Louis-San Francisco Railway Co. Rock Island is seeking the imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to offset projected gross revenue losses. This proceeding will be consolidated with Finance Docket No. 28583 (Sub-No. 1F).

Rock Island operates approximately 7,013 miles of railroad in the States of Arkansas, Colorado, Illinois, Iowa, Kansas, Louisiana, Minnesota, Missouri, Nebraska, New Mexico, Oklahoma, Tennessee, and Texas. Rock Island is under the sole control of the U.S. District Court for the Northern Distrist of Illinois, Eastern Division, Judge Frank J. McGarr, and the trusteeship of William M. Gibbons.

The trackage involved in approximately 13 miles in length and would be used by Rock Island to serve all industries along the line.

Interested persons may participate formally in a proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceeding designation (Finance Docket No. 28583 (Sub-No. 11F)) and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: the person's position, e.g., party protestant or party in support, regarding the proposed transaction; and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon applicant, the Secretary of Transportation, the Attorney General and all parties of record in Finance Docket No. 28583 (Sub-No. 1F).

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24083 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (Sub-No. 12F)]

WILLIAM M. GIBBONS, TRUSTEE OF THE PROPERTY OF THE CHICAGO, ROCK ISLAND & PACIFIC RAILROAD CO., DEBTOR

Trackage Rights Over Burlington Northern, Inc., Between Ottawa and Streator, Ill.

William M. Gibbons, trustee of the property of the Chicago, Rock Island & Pacific Railroad Co., Debtor (Rock Island), with general offices at 332 South Michigan Avenue, Chicago, Ill. 60604, represented by Nicholas G. Manos, Trustee's counsel and Martin Cassell, general counsel, both of the same address, hereby gives notice that on July 27, 1978, he filed with the Interstate Commerce Commission, at Washington, D.C., an application under section 5(2) of the Interstate Commerce Act for a decision approving and authorizing the grant of trackage rights to permit Rock Island operate between Ottawa and Streator, Ill., over trackage of Burlington Northern, Inc. (BN). The transaction proposd by Rock Island is subject to the execution of an appropriate agreement between Rock Island and BN. This application has been accepted and assigned Finance Docket No. 28583 (Sub-No. 12F).

This application has been filed in response to Finance Docket No. 28583 (Sub-No. 1F), Burlington Northern, Inc.—control and merger—St. Louis-San Francisco Railway Co., Rock Island is seeking the imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to offset projected gross revenue losses. This proceeding will be consolidated with Finance Docket No. 28583 (Sub-No. 1F).

Rock Island operates approximately 7,013 miles of railroad in the States of Arkansas, Colorado, Illinois, Iowa, Kansas, Louisiana, Minnesota, Missouri, Nebraska, New Mexico, Oklahoma, Tennessee, and Texas. Rock Island is under the sole control of the U.S. District Court for the Northern District of Illinois,, Eastern Division, Judge Frank J. McGarr, and the trusteeship of Wiliam M. Gibbons.

The trackage involved is approximately 17 miles in length and would be used by Rock Island to serve industries local to BN at Ottawa, Ill. Rock Island would also use the trackage to connect with the Consolidated Rail Corp., at Streator, Ill.

Interested persons may participate formally in a proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceedings designation (F. D. No. 28583 (Sub-No. 12F)), and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: the person's position, e.g., party protestant or party in support, regarding the proposed transaction; and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon applicant, the Secretary of Transportation, the Attorney General and all parties of record in Finance Docket No. 28583 (Sub-No. 1F).

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24084 Filed 8-24-78; 8:45 am

[7035-01]

[Finance Docket No. 28583 (Sub 13F)]

STANLEY E. G. HILLMAN, TRUSTEE OF THE PROPERTY OF CHICAGO, MILWAUKEE, ST. PAUL & PACIFIC RAILROAD CO., DEBTOR

Trackage Rights over Burlington Northern, Inc., Between Terry, Mont., and Spokane, Wash.

Stanley E. G. Hillman, trustee of the property of Chicago, Milwaukee, St. Paul & Pacific Railroad Co., debtor (Milwaukee Road), 516 West Jackson Boulevard, Chicago, Ill. 60606, represented by Thomas H. Ploss, general solicitor, and William C. Sippel, attorney, each of the foregoing address, hereby gives notice that on July 27, 1978, he filed with the Interstate Commerce Commission at Washington, D.C., an application under section 5(2) of the Interstate Commerce Act for an order approving and authorizing a grant of trackage rights to permit the Milwaukee Road to operate its own locomotives, cars and trains with its own crews between Terry, Mont., and Spokane, Wash., over trackage of Burlington Northern, Inc. (BN), a distance of approximately 1,181.07 miles. A grant of trackage rights to BN over Milwaukee Road trackage between Three Forks, Mont., and Silver Bow, Mont., is contemplated. The transaction proposed by Milwaukee Road is subject to the execution of an appropriate agreement between Milwaukee Road and BN. This application is a major market extension and has accepted and assigned Finance Docket No. 28583 (Sub-13F).

This application has been filed in response to Finance Docket No. 28583 (Sub-1F), Burlington Northern, Inc.—control and merger—St. Louis-San Francisco Railway Co. It will be consolidated with Finance Docket No. 28583 (Sub-1F). Milwaukee Road is seeking imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to reduce its operating costs.

Milwaukee Road operates approximately 9,891 miles of railroad in the States of Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Montana, Nebraska, North Dakota, Oregon, South Dakota, Washington, and Wisconsin. Milwaukee Road is under the sole control of the U.S. District Court for the Northern District of Illinois, Eastern Division, Judge Thomas R. McMillen, and the trusteeship of Stanley E. G. Hillman. The Chicago Milwaukee Corp. owns 96 percent of Milwaukee Road's outstanding stock.

Interested persons may participate formally in a proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceeding designation (Fi-

nance Docket No. 28583 (Sub-13F)), and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: The person's position, e.g., party protestant or party in support, regarding the proposed transaction; and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon Applicant, the Secretary of Transportation, the Attorney General, and all parties of record in Finance Docket No. 28583 (Sub-1F).

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24085 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (Sub-No. 14F)

STANLEY E. G. HILLMAN, TRUSTEE OF THE PROPERTY OF CHICAGO, MILWAUKEE, ST. PAUL & PACIFIC RAILROAD CO., DEBTOR

Trackage Rights Over Burlington Northern, Inc., Between Tacoma and Chehalis, Wash.

Stanley E. G. Hillman, trustee of the property of Chicago, Milwaukee, St. Paul & Pacific Railroad Co., debtor (Milwaukee Road), 516 West Jackson Boulevard, Chicago, Ill. 60606, represented by Thomas H. Ploss, general solicitor, and William C. Sippel, attorney, each of the foregoing address, hereby gives notice that on July 27, 1978, he filed with the Interstate Commerce Commission at Washington, D.C., an application under section 5(2) of the Interstate Commerce Act for an order approving and authorizing a grant of trackage rights to permit the Milwakee Road to operate its own locomotives, cars, and trains with its own crews between Tacoma and Chehalis, Wash., over trackage of Burlington Northern, Inc. (BN), a distance of approximately 62.7 miles. The transaction proposed by Milwaukee Road is subject to the execution of an appropriate agreement between Milwaukee Road and BN. This application is a major market extension and has been accepted and assigned Finance Docket No. 28583 (Sub-No. 14F).

This application has been filed in response to Finance Docket No. 28583 (Sub-1F), Burlington Northern, Inc.—Control and Merger—St. Louis-San Francisco Railway Company. It will be consolidated with Finance Docket No. 28583 (Sub-1F). Milwaukee Road is seeking imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to reduce its operating costs and gain additional revenues which would enhance its reorganization on an income basis.

Milwaukee Road operates approximately 9,891 miles of railroad in the States of Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Montana, Nebraska, North Dakota, Oregon, South Dakota, Washington, and Wisconsin.

Milwaukee Road is under the sole control of the U.S. District Court for the Northern District of Illinois, Eastern Division, Judge Thomas R. McMillen, and the trusteeship of Stanley E. G. Hillman. The Chicago Milwaukee Corp. owns 96 percent of the Milwaukee Road's outstanding stock.

Interested persons may participate formally in a proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceeding designation (F.D. No. 28583 (Sub-14F)). and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: the person's position—e.g., party protestant or party in support, regarding the proposed transaction—and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting writteen comments to the Commission shall, at the same time, serve copies of such written comments upon applicant, the Secretary of Transportation, the Attorney General, and all parties of record in Finance Docket No. 28583 (Sub-1F).

By the Commission

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24086 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (Sub-16F)]

STANLEY E. G. HILLMAN, TRUSTEE OF THE PROPERTY OF CHICAGO, MILWAUKEE, ST. PAUL & PACIFIC RAILROAD CO., DEBTOR

Trackage Rights—Over Burlington Northern, Inc., Between Council Bluffs, Iowa, and Kansas City, Mo.

Stanley E. G. Hillman, trustee of the property of Chicago, Milwaukee, St. Paul & Pacific Railroad Co., debtor (Milwaukee Road), 516 West Jackson Boulevard, Chicago, Ill. 60606, represented by Thomas H. Ploss, general solicitor, and William C. Sippel, attorney, each of the foregoing address, hereby gives notice that on July 27, 1978, he filed with the Interstate Commerce Commission at Washington, D.C., an application under section 5(2) of the Interstate Commerce Act for an order approving and authorizing a grant of trackage rights to permit the Milwaukee Road to operate its own engines, trains, and crews between Council Bluffs, Iowa, and Kansas City, Mo., over trackage of Burlington Northern, Inc. (BN), a distance of approximately 186.69 miles, for bridge purposes only. The transaction proposed by Milwaukee Road is subject to the execution of an appropriate agreement between Milwaukee Road and BN. This application is a major market extension and has been accepted and assigned Finance Docket No. 28583 (Sub-16F).

This application has been filed in response to Finance Docket No. 28583 (Sub-1F), Burlington Northern, Inc.—Control and Merger—St. Louis-San Francisco Railway Co. It will be consolidated with Finance Docket No. 28583 (Sub-1F). Milwaukee Road is seeking imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to reduce its operating and maintenance expenses.

Milwaukee Road operates approximately 9,891 miles of railroad in the States of Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Montana, Nebraska, North Dakota, Oregon, South Dakota, Washington, and Wisconsin. Milwaukee Road is under the sole control of the U.S. District Court for the Northern District of Illinois, Eastern Division, Judge Thomas R. McMillen, and the trusteeship of Stanley E. G. Hillman. The Chicago Milwaukee Corp. owns 96 percent of the Milwaukee Road's outstanding stock.

Interested persons may participate formally in a proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceeding designation (Finance Docket No. 28583 (Sub-16F)), and the original and two copies thereof shall be filed with the Secretary, In-

terstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: the person's position—e.g., party protestant or party in support, regarding the proposed transaction—and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon applicant, the Secretary of Transportation, the Attorney General, and all parties of record in Finance Docket No. 28583 (Sub-1F).

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24087 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (Sub-17F)]

STANLEY E. G. HILLMAN, TRUSTEE OF THE PROPERTY OF CHICAGO, MILWAUKEE, ST. PAUL, AND PACIFIC RAILROAD CO., DEBTOR

Trackage Rights—Over Burlington Northern, Inc., Between Bellingham and Cherry Point, Wash.

Stanley E. G. Hillman, Trustee of the Property of Chicago, Milwaukee, St. Paul, and Pacific Railroad Co., Debtor (Milwaukee Road), 516 West Jackson Boulevard, Chicago, Ill. 60606, represented by Thomas H. Ploss, General Solicitor, and William C. Sippel, Attorney, each of the foregoing address, hereby gives notice that on July 27, 1978, he filed with the Interstate Commerce Commission at Washington, D.C., an application under section 5(2) of the Interstate Commerce Act for a decision approving and authorizing a grant of trackage rights to permit the Milwaukee Road to operate its own trains, with its own locomotives and crews between Bellingham and Cherry Point, Wash., over trackage of Burlington Northern, Inc. (BN), a distance of approximately 22 miles. The transaction proposed by Milwaukee Road is subject to the execution of an appropriate agreement between Milwaukee Road and BN. This application has been accepted and assigned Finance Docket No. 28583 (Sub-17F).

This application has been filed in response to Finance Docket No. 28583 (Sub-1F), Burlington Northern, Inc.-Control and Merger-St. Louis-San Francisco Railway Co. It will be consolidated with Finance Docket No. 28583 (Sub-1F). Milwaukee Road is seeking imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to improve its financial viability by reducing operating and maintenance expenses.

Milwaukee Road operates approximately 9,891 miles of railroad in the States of Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Montana, Nebraska, North Dakota, Oregon, South Dakota, Washington, and Wisconsin.

Milwaukee Road is under the sole control of the U.S. District Court for the Northern District of Illinois, Eastern Division, Judge Thomas R. McMillen, and the trusteeship of Stanley E. G. Hillman. The Chicago Milwaukee Corp. owns 96 percent of the Milwaukee Road's outstanding stock.

Interested persons may participate formally in a proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceeding designation (F.D. 28583 (Sub-17F)), and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: The person's position, e.g., party protestant or party in support, regarding the proposed transaction; and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon the applicant, the Secretary of Transportation, the Attorney General and all parties of record in Finance Docket No. 28583 (Sub-1F).

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24088 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (Sub-7F)]

ILLINOIS CENTRAL GULF RAILROAD CO.

Trackage Rights Over the St. Louis-San Francisco Railway Co. Between Memphis, Tenn. and Jasper, Ala.

Illinois Central Gulf Railroad Co. (ICG), 233 North Michigan Avenue, Chicago, Ill. 60601, represented by Howard D. Koontz, Senior General Solicitor, hereby gives notice that on July 27, 1978, ICG filed with the Interstate Commerce Commission an application under section 5(2) of the Interstate Commerce Act for a decision authorizing and approving the grant of trackage rights to permit ICG to operate over the line of the St. Louis-San Francisco Railway Co. (Frisco) between Memphis, Tenn., and Jasper, Ala., as a condition to the proposed merger of the Frisco and Burlington Northern, Inc. (BN). The transaction proposed by ICG is subject to the execution of an appropriate agreement between ICG and BN. This application has been accepted and assigned Finance Docket No. 28583 (Sub-7F).

This proceeding has been filed in response to Finance Docket No. 28583 (Sub-1F), Burlington Northern, Inc.-Control and Merger-St. Louis-San Francisco Railway Co. ICG is seeking the imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to offset projected gross revenue losses. This proceeding will be consolidated with Finance Docket No. 28583 (Sub-1F).

ICG operates approximately 8,948 miles of railroad in the states of Alabama, Illinois, Indiana, Iowa, Kentucky, Louisiana, Minnesota, Mississippi, Missouri, Nebraska, South Dakota, Tennessee, and Wisconsin. IC Industries, Inc., controls ICG through ownership of 100 percent of ICG's outstanding common stock.

ICG seeks trackage rights over the line of the Frisco between Memphis, Tenn. and Jasper, Ala., a distance of approximately 209.9 miles. ICG would not serve any station on the line of the Frisco which is not already served by ICG. Under the trackage rights requested, ICG would have the right to pick up and set out cars at Memphis, Tenn., Tupelo, Miss., Holly Springs, Miss.; New Albany, Miss., Jasper, Ala.; and at any other common point created as a result of future mergers or consolidations involving either the proposed merged company (BN) or ICG. This proposal is a major market extension.

Interested persons may participate formally in a proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceeding designation (F.D. No. 28583 (Sub-7F)), and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: the person's position, e.g., party protestant or party in support, regarding the proposed transaction; and specific reasons why approv-

al would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon Applicant, the Secretary of Transportation, the Attorney General and all parties of record in Finance Docket No. 28583 (Sub-1F).

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24079 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (Sub-No. 3F)]

SOO LINE RAILROAD CO.

Trackage Rights Over Burlington Northern, Inc., Between McGregor, Minn., and Superior, Wis.

Soo Line Railroad Co. (Soo), a Minnesota corporation, with general offices at 804 Soo Line Building, P.O. Box 530, Minneapolis, Minn. 55440. Represented by F. W. Crouch, Vice President and General Counsel, and Robert G. Gehrz, General Solicitor, each of the foregoing address, hereby gives notice that on the 26th day of July 1978, it filed with the Interstate Commerce Commission at Washington, D.C., an application under section 5(2) of the Interstate Commerce Act for a decision approving and authorizing the grant of trackage rights to permit Soo Line to operate its own locomotives, cars and trains with its own crews for "bridge" purposes only between McGregor, Minn., and Superior, Wis., over trackage of Burlington Northern, Inc. (BN), and to construct appropriate connections at McGregor and Superior, Wis. The transaction proposed by Soo Line is subject to the execution of an appropriate agreement between Soo Line and BN. This application has been accepted and assigned Finance Docket No. 28583 (Sub-No. 3F).

This application has been filed in response to Finance Docket No. 28583 (Sub-No. 1F), Burlington Northern, Inc.-Control and Merger-St. Louis-San Francisco Railway Co. Soo Line is seeking the imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to offset projected gross revenue losses. This proceeding will be consolidated with Finance Docket No. 28583 (Sub-No. 1F).

Soo Line operates approximately 4,588 miles of railroad in the States of Illinois, Minnesota, Michigan, Montana, North Dakota, South Dakota, and Wisconsin. Canadian Pacific Limited (CP) controls Soo Line and had the right to vote 56.23 percent of Soo Line's common stock, as of March 10, 1978. Soo Line is operated independently of CP.

The trackage involved is approximately 69 miles in length and would be used by Soo Line only for overhead traffic. Soo Line would not serve any local industries located on the line between McGregor, Minn., and Superior, Wis.

Interested persons may participate formally in this proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceeding designation (F. D. No. 28583 (Sub-No. 3F)), and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: The person's position, e.g., party protestant or party in support, regarding the proposed transaction; and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding, but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon Applicant, the Secretary of Transportation, Attorney General, and all parties of record in Finance Docket No. 28583 (Sub-No. 1F).

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24075 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (Sub-4F)]

SOO LINE RAILROAD CO.

Trackage Rights Over Burlington Northern, Inc., Between Paynesville, Minn., and Superior, Wis.

Soo Line Railroad Co. (Soo Line), a Minnesota corporation, with general offices at 804 Soo Line Building, P.O. Box 530, Minneapolis, Minn. 55440, represented by F. W. Crouch, Vice President and General Counsel, and Robert G. Gehrz, General Solicitor, each of the foregoing address, hereby gives notice that on the 26th day of July 1978, it filed with the Interstate Commerce Commission at Washington, D.C., an application under section 5(2) of the Interstate Commerce Act for a decision approving and authorizing the grant of trackage rights to permit Soo Line to operate its own locomotives, cars and trains with its own crews for "bridge" purposes only between Paynesville, Minn., and Superior, Wis., over trackage of Burlington Northern, Inc. (BN), and to construct an appropriate connection at Superior, Wis. The transaction proposed by Soo Line is subject to the execution of an appropriate agreement between Soo Line and BN. This application has been accepted and assigned Finance Docket No. 28583 (Sub-4F).

This application has been filed in response to Finance Docket No. 28583 (Sub-1F), Burlington Northern, Inc.-Control and Merger-St. Louis-San Francisco Railway Co. Soo Line is seeking the imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to offset projected gross revenue losses. This proceeding will be consolidated with Finance Docket No. 28583 (Sub-1F).

Soo Line operates approximately 4,588 miles of railroad in the States of Illinois, Michigan, Minnesota, Montana, North Dakota, South Dakota, and Wisconsin. Canadian Pacific Limited (CP) controls Soo Line and had the right to vote 56.23 percent of Soo Line's common stock, as of March 10, 1978. Soo Line is operated independently of CP. The trackage involved is approximately 162 miles in length and would be used by Soo Line only for overhead traffic. Soo Line would not serve any local industries located on the line between Paynesville, Minn., and Superior, Wis.

Interested persons may participate formally in this proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceeding designation (F.D. No. 28583 (Sub-4F)), and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: The person's position, e.g., party protestant or party in support, regarding the proposed tranaction; and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of

such written comments upon the applicant, the Secretary of Transportation, the Attorney General and all parties of record in Finance Docket No. 28583 (Sub-1F).

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24076 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (Sub-5F)]

SOO LINE RAILROAD CO.

Trackage Rights Over Burlington Northern, Inc., Between Schley (Soo Junction), Minn. and Superior, Wis.

Soo Line Railroad Co. (Soo Line), a Minnesota corporation, with general offices at 804 Soo Line Building, P.O. Box 530, Minneapolis, Minn. 55440 represented by F. W. Crouch, vice president and general counsel, and Robert G. Gehrz, general solicitor, each of the foregoing address, hereby gives notice that on the 26th day of July 1978, it filed with the Interstate Commerce Commission at Washington, D.C. an application under section 5(2) of the Interstate Commerce Act for a decision approving and authorizing the grant of trackage rights to permit Soo Line to operate its own locomotives, cars and trains with its own crews for "bridge" purposes only between Schley (Soo Junction), Minn., and Superior, Wis., over trackage of Burlington Northern, Inc. (BN), and to construct an appropriate connection at Superior, Wis. The transaction proposed by Soo Line is subject to the execution of an appropriate agreement between Soo Line and BN. This application has been accepted and assigned Finance Docket No. 28583 (Sub-5F).

This application has been filed in response to Finance Docket No. 28583 (Sub-1F), Burlington Northern, Inc.—control and merger—St. Louis-San Francisco Railway Co. Soo Line is seeking the imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to offset projected gross revenue losses. This proceeding will be consolidated with Finance Docket No. 28583 (Sub-1F).

Soo Line operates approximately 4,588 miles of railroad in the States of Illinois, Michigan, Minnesota, Montana, North Dakota, South Dakota, and Wisconsin. Canadian Pacific Limited (CP) controls Soo Line and had the right to vote 56.23 percent of Soo Line's common stock, as of March 10, 1978. Soo Line is operated independently of CP.

The trackage involved is approximately 146.2 miles in length and would be used by Soo Line only for overhead traffic. Soo Line would not serve any local industries located on the line between Schley (Soo Junction), Minn., and Superior, Wis.

Interested persons may participate formally in this proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceeding designation (F.D. No. 28583 (Sub-5F)), and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: the person's position, e.g., party protestant or party in support, regarding the proposed transaction; and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon applicant, the Secretary of Transportation, Attorney General, and all parties of record in Finance Docket No. 28583 (Sub-1F).

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24077 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (Sub-No. 6F)]

SOO LINE RAILROAD CO.

Trackage Rights Over Burlington Northern, Inc., Between Bald Eagle, Minn., and Superior, Wis.

Soo Line Railroad Co. (Soo Line), a Minnesota corporation, with general offices at 804 Soo Line Building, P.O. Box 530, Minneapolis, Minn. 55440. Represented by F. W. Crouch, Vice President and General Counsel, and Robert G. Gehrz, General Solicitor, each of the foregoing address, hereby gives notice that on the 26th day of July 1978, it filed with the Interstate Commerce Commission at Washington, D.C., an application under section 5(2) of the Interstate Commerce Act for a decision approving and authorizing the grant of trackage rights to permit Soo Line to operate its own locomotives, cars and trains with its own crews for "bridge" purposes only between Bald Eagle, Minn., and Superior, Wis., over trackage of Burlington Northern, Inc. (BN), via White Bear Lake, Forest Lake, Rush City, Pine City, Hinckley, and Sandstone. The transaction proposed by Soo Line is subject to the execution of an appropriate agreement between Soo Line and BN. This application has been accepted and assigned Finance Docket No. 28583 (Sub-No. 6F).

This application has been filed in response to Finance Docket No. 28583 (Sub-No. 1F), Burlington Northern, Inc.—control and merger—St. Louis-San Francisco Railway Co. Soo Line is seeking the imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to offset projeted gross revenue losses. This proceeding will be consolidated with Finance Docket No. 28583 (Sub-No. 1F).

Soo Line operates approximately 4,588 miles of railroad in the States of Illinois, Michigan, Minnesota, Montana, North Dakota, South Dakota, and Wisconsin. Canadian Pacific Limited (CP) controls Soo Line and had the right to vote 56.23 percent of Soo Line's common stock, as of March 10, 1978. Soo Line is operated independently of CP.

The trackage involved is approximately 126.4 miles in length and would be used by Soo Line only for overhead traffic. Soo Line would not serve any local industries located on the line between Bald Eagle, Minn., and Superior, Wis.

Interested persons may participate formally in this proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceeding designation (F.D. No. 28583 (Sub.-No. 6F)), and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: The person's position, e.g., party protestant or party in support, regarding the proposed transaction, and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding, but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon the Applicant, the Secretary of Transportation, the Attorney General, and all parties of record in Finance Docket No. 28583 (Sub-No. 1F).

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24078 Filed 8-24-78; 8:45 am]

[7035-01]

[Finance Docket No. 28583 (Sub-No. 18F)]

SOUTHERN PACIFIC TRANSPORTATION CO.

Trackage Rights Over Burlington Northern, Inc., and the Union Pacific Railroad Co. Between the Connection of BN and the Portland Terminal Railroad Co. and (1) Trackage Serving North Rivergate and (2) the Barnes Yard of Union Pacific Railroad Co.

Southern Pacific Transportation Co. (SP), One Market Plaza, San Francisco, Calif. 94105, represented by Charles W. Burkett, general solicitor, of the same address, hereby gives notice that on the 27th day of July 1978, it filed with the Interstate Commerce Commission at Washington, D.C., an application under section 5(2) of the Interstate Commerce Act for a decision approving and authorizing the grant of trackage rights to permit SP to operate over trackage of Burlington Northern, Inc. (BN) and the Union Pacific Railroad Co. (UP) in Portland, Oreg. The transaction proposed by SP is subject to the execution of an appropriate agreement between SP, BN, and UP. This application has been accepted and assigned Finance Docket No. 28583 (Sub-No. 18F).

This application has been filed in response to Finance Docket No. 28583 (Sub-No. 1F), Burlington Northern, Inc.—control and merger—St. Louis-San Francisco Railway Co. SP is seeking the imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to offset projected gross revenue losses. This proceeding will be consolidated with Finance Docket No. 28583 (Sub-No. 1F).

SP and its subsidiaries operate approximately 13,356 miles of railroad in the States of Arizona, Arkansas, California, Illinois, Louisiana, Missouri, Nevada, New Mexico, Oregon, Tennessee, Texas, and Utah. The Southern Pacific Co. owes 100 percent of the stock of SP.

The trackage involved is approximately 16.3 miles in length. SP would use the line to directly serve the Rivergate industrial area. SP would provide the service over the BN double main track from its point of connection with trackage of the Portland Terminal Railway Co. (1) to a connection with North Rivergate trackage at North Portland and (2) to a connection with the tracks of UP near UP Barnes Yard; thence over the UP trackage over which BN has rights through UP's Barnes Yard to the south Rivergate industrial lead tracks. All of this trackage is in the city of Portland, Oreg. Currently, SP serves the Rivergate area through reciprocal switching with BN and UP. SP will use the trackage rights to provide improved service to the shippers and receivers it currently serves through reciprocal switching arrangements.

Interested persons may participate formally in a proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceeding designation (F.D. No. 28583 (Sub-No. 18F)), and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than October 10, 1978. Such written comments shall include the following: the persons position, e.g., party protestant or party in support, regarding the proposed transactions; and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding, but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon Applicant, the Secretary of Transportation, the Attorney General, and all parties of record in Finance Docket No. 28583 (Sub-No. 1F).

By the Commission.

H.G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-24089 Filed 8-24-78; 8:45 am]

sunshine act meetings

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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[6320-01]

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CIVIL AERONAUTICS BOARD.

Notice of addition of item to the August 23, 1978, agenda; M-155, amdt. 1, August 18, 1978.

TIME AND DATE: 1:30 p.m., August 23, 1978.

PLACE: Room 1027, 1825 Connecticut Avenue NW., Washington, D.C. 20428.

SUBJECT: 9a. Dockets 32364, 32577 and 32365, Application of Air New England to amend its certificate to allow it to serve Hartford/Springfield on a subsidy-ineligible basis; Application of Allegheny to amend its certificate for Route 97 to allow nonstop Burlington-Hartford authority; Application of Air New England for exemption authority to serve Hartford/Springfield (BPDA).

STATUS: Open.

PERSON TO CONTACT:

Phyllis T. Kaylor, the Secretary, 202-673-5068.

SUPPLEMENTARY INFORMATION: Consideration of this item will insure that the Board will make its show cause order final before the promised deadline of September 1, 1978. Accordingly, the following members have voted that agency business requires the addition of Item 9a. to the August 23, 1978, agenda and that no earlier announcement of this addition was possible:

Chairman, Alfred E. Kahn
Vice Chairman, G. Joseph Minetti
Member, Richard J. O'Melia
Member, Elizabeth E. Bailey

All amendments to previously announced agendas are publicly posted at the Board's offices, sent to the FEDERAL REGISTER for publication, and mailed to parties to docketed cases affected by the change. We regret any inconvenience that may be caused by these changes or the delayed receipt of our notices.

[S-1698-78 Filed 8-23-78; 8:55 am]

[6320-01]

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CIVIL AERONAUTICS BOARD.

Notice of addition of item to the August 23, 1978, Agenda; M-155, Amdt. 2, August 18, 1978.

TIME AND DATE: 1:30 p.m., August 23, 1978.

PLACE: Room 1027, 1825 Connecticut Avenue NW., Washington, D.C. 20428.

SUBJECT: 16a. Docket 27631, *Foremost International Tours* v. *Qantas Airways, Enforcement Proceeding*—Petitions for review of initial decision holding that Qantas' inclusive tour operation was not unlawful (Memo 8131, OGC).

STATUS: Open.

PERSON TO CONTACT:

Phyllis T. Kaylor, the Secretary, 202-673-5068.

SUPPLEMENTARY INFORMATION: Because of the time consumed in making changes in the draft order in the Office of the General Counsel after submission for supervisory approval, this item did not reach the Secretary in time to place it on the calendar for August 23. In order to meet the announced target date of August 25, 1978, however, Board action is required by August 23. Accordingly, the following Members have voted that agency business requires the addition of Item 16a to the August 23, 1978 agenda and that no earlier announcement of this addition was possible:

Chairman, Alfred E. Kahn
Vice Chairman, G. Joseph Minetti
Member, Richard J. O'Melia
Member, Elizabeth E. Bailey

All amendments to previously announced agendas are publicly posted at the Board's offices, sent to the FEDERAL REGISTER for publication, and mailed to parties to docketed cases affected by the change. We regret any inconvenience that may be caused by these changes or the delayed receipt of our notices.

[S-1699-78 Filed 8-23-78; 8:55 am]

[6320-01]

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[M-156, August 17, 1978]

CIVIL AERONAUTICS BOARD.

TIME AND DATE: 10 a.m., August 24, 1978.

PLACE: Room 1027, 1825 Connecticut Avenue NW., Washington, D.C. 20428.

SUBJECT: Oral Argument—Docket 32786, Philadelphia-Bermuda Nonstop Proceeding.

STATUS: Open.

PERSON TO CONTACT:

Phyllis T. Kaylor, the Secretary, 202-673-5068.

[S-1700-78 Filed 8-23-78; 8:55 am]

[6335-01]

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U.S. COMMISSION ON CIVIL RIGHTS.

DATE AND TIME: Wednesday, August 30, 1978, 9 a.m. to 12 noon; 1:30 p.m. to 4:30 p.m. Thursday, August 31, 1978, 9 a.m. to 12 noon.

PLACE: Room 512, 1121 Vermont Avenue NW., Washington, D.C.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: Wednesday, August 30, 9 a.m. to 12 noon.

I. Approval of agenda.
II. Approval of minutes from last meeting.
III. Staff Director's Report:
  A. Status of funds.
  B. Personnel report.
  C. Correspondence:
    1. Letter from McDonald Fraser re pregnancy disability.
    2. Letter from OMB Director James McIntyre re Commission recommendation on affirmative action in Cleveland.
    3. Letter from Reorganization Task Force Director Jeffrey Miller re Commission comments.
  D. Office Director's reports.
IV. Report on Civil Rights Developments in the Rocky Mountain Region.
V. Approval of Contract for Followup to Battered Women Consultation.
VI. Action on Recommendation re Women in Poverty Report.

VII. Discussion of Advisory Committee for Pacific Trust Territories.

MATTERS TO BE CONSIDERED: Wednesday, August 30, 1978, 1:30 p.m. to 4:30 p.m.

Review of School Desegregation Update.

MATTERS TO BE CONSIDERED: Thursday, August 31, 9 a.m. to 12 noon.

Review of School Desegregation Update (continued).

FOR FURTHER INFORMATION PLEASE CONTACT:

Loretta Ward, Publications Office, 254-6697.

[S-1701-78 Filed 8-23-78; 8:55 am]

[6351-01]

5

COMMODITY FUTURES TRADING COMMISSION.

TIME AND DATE: 10 a.m., August 29, 1978.

PLACE: 2033 K Street NW., Washington, D.C., 5th floor hearing room.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Portions open to the public:

Minimum financial requirements.
Request by the New York Coffee and Sugar Exchange for approval of lower daily price fluctuation limits in sugar.
Final rule imposing a temporary moratorium on the offer and sale of leverage contracts.

Portions closed to the public:

Enforcement matters/institution of administrative proceedings.

CONTACT PERSON FOR MORE INFORMATION:

Jane Stuckey, 254-6314.

[S-1702-78 Filed 8-23-78; 8:55 am]

[6351-01]

6

COMMODITY FUTURES TRADING COMMISSION.

TIME AND DATE: 10 a.m., August 30, 1978.

PLACE: 2033 K Street NW., Washington, D.C., 8th floor conference room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Judicial session.

CONTACT PERSON FOR MORE INFORMATION:

Jane Stuckey, 254-6314.

[S-1703-78 Filed 8-23-78; 8:55 am]

[6351-01]

7

COMMODITY FUTURES TRADING COMMISSION.

TIME AND DATE: 11 a.m., September 1, 1978.

PLACE: 2033 K Street NW., Washington, D.C., 8th floor conference room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Market surveillance matters.

CONTACT PERSON FOR MORE INFORMATION:

Jane Stuckey, 254-6314.

[S-1704-78 Filed 8-23-78; 8:55 am]

[6740-02]

8

FEDERAL ENERGY REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCMENT: 43 FR 37073, published August 21, 1978.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10 a.m., August 23, 1978.

CHANGE IN THE MEETING: The following item was added:

Item No., Docket No., and Company

CAM-3. RM78-19, Delegation of the Commission's Authority to Various Staff Office Directors.

KENNETH F. PLUMB,
Secretary.

[S-1705-78 Filed 8-23-78; 11:50 am]

[6720-02]

9

FEDERAL HOME LOAN MORTGAGE CORPORATION.

TIME AND DATE: 2:30 p.m., August 31, 1978.

PLACE: 1700 G Street NW., sixth floor, Washington, D.C.

STATUS: Open meeting.

CONTACT PERSON FOR MORE INFORMATION:

Mr. Henry Judy, 202-789-4734.

MATTERS TO BE CONSIDERED:

Consideration of Corporation Bylaws.
Consideration of New Building Status Report.
Consideration of Foley Building Lease.
Consideration of Refinance Loans.

No. 175, August 23, 1978.

RONALD A. SNIDER,
Assistant Secretary.

[S-1707-78 Filed 8-23-78; 3:32 pm]

[6210-01]

10

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 43 FR 37332, August 22, 1978.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 11 a.m., Friday, August 25, 1978.

CHANGES IN THE MEETING: Addition of the following closed items to the meeting:

1. Proposals relating to mandatory retirement for Federal Reserve System employees.
2. Appointment of an officer at a Federal Reserve Bank. (This matter was previously announced for a meeting on Friday, August 18, 1978.)
3. Personnel appointments within the Board's staff. (This matter was previously announced for a meeting on Wednesday, August 16, 1978.)

CONTACT PERSON FOR MORE INFORMATION:

Mr. Joseph R. Coyne, Assistant to the Board, 202-452-3204.

Dated: August 23, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[S-1706-78 Filed 8-23-78; 3:32 pm]

federal register

FRIDAY, AUGUST 25, 1978
PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN DRUGS

Proposed Safety, Effective and Labeling Conditions

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 352]

[Docket No. 78N-0038]

SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Establishment of a Monograph; Notice of Proposed Rulemaking

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) sunscreen drug products. The proposed rule, based on the recommendations of the Panel on Review of Topical Analgesic including antirheumatic, otic, burn, and sunburn treatment and prevention drugs is part of the Food and Drug Administration's ongoing review of OTC drug products.

DATES: Comments by November 24, 1978; reply comments by December 26, 1978.

ADDRESSES: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, Department of health, Education, and Welfare, 5600 Fishers lane, Rockville, Md. 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: Pursuant to part 330 (21 CFR Part 330), the Commissioner of Food and Drugs received on December 14, 1977, a report of the Advisory Review Panel on Over-The-Counter (OTC) Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Products. In accordance with § 330.10(a)(6) (21 CFR 330.10(a)(6)), the Commissioner is issuing (1) a proposed regulation containing the monograph recommended by the Panel, which establishes conditions under which OTC sunscreen drugs are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that they would result in the drugs not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that the available data are insufficient to classify such conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel to the Commissioner. The minutes of the Panel meetings are on public display in the office of the hearing Clerk (HFA-305), Food and Drug Administration (address given above).

The purpose of issuing the Panel's unaltered conclusions and recommendations is to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The Commissioner has not yet fully evaluated the report; the Panel's findings are being issued as a formal proposal to obtain public comment before the agency reaches any decision on the Panel's recommendations. The report has been prepared independently of the Food and Drug Administration (FDA). It represents the best scientific judgment of the Panel members but does not necessarily reflect the agency position on any particular matter contained in it.

The Commissioner recognizes that extensive changes will result in the current marketing practices of these products if the Panel recommendations are fully implemented. The Panel's recommendations include many labeling revisions. One of these labeling recommendations is the statement "Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of premature aging of the skin and skin cancer." As with other of the Panel's recommendations, the Commissioner is not at this time making a final decision with regard to this labeling. However, he finds it necessary to comment that the issue is important and requires careful study. Because of the critical nature of the disease conditions involved, the wording of any claim concerning them must be very carefully considered especially because three of the seven panel members oppose the use of the recommended statement. Special attention must be given to assure that consumers are not misled or confused. The Commissioner recognizes the potential for such a statement to mislead the public, and is concerned about its use. However, the issue is open and will receive the fullest attention before any claim with regard to skin cancer or aging of the skin is included in any OTC drug monograph.

After careful review of all comments submitted in response to this proposal, the Commissioner will issue a tentative final regulation in the FEDERAL REGISTER to establish a monograph for OTC sunscreen drug products.

In accordance with § 330.10(a)(2) (21 CFR 330.10(a)(2)), all data and information concerning OTC sunscreen drug products submitted for consideration by the Panel have been handled as confidential by the Panel and FDA. All such data and information will be put on public display at the office of the Hearing Clerk, Food and Drug Administration, after September 25, 1978, except to the extent that the person submitting it demonstrates that it still 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 given above).

Based on the conclusions and recommendations of the Panel, the Commissioner proposes the following:

1. That the conditions included in the monograph, under which the drug products would be generally recognized as safe and effective and not misbranded (category I), be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

2. That the conditions excluded from the monograph because they would cause the drug to be not generally recognized as safe and effective or to be misbranded (category II), be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER, regardless whether further testing is undertaken to justify their future use.

3. That the conditions excluded from the monograph because the available date are insufficient (category III) to classify such conditions either as category I or category II be permitted to remain on the market, or to be introduced into the market after the date of publication of the final monograph in the FEDERAL REGISTER, provided that FDA receives notification of testing in accordance with § 330.10(a)(13) (21 CFR 330.10(a)(13)). The Panel recommended that a period of 2 years be permitted for the completion of studies to support the movement of category III conditions to category I. The Commissioner will review that recommendation as well as all comments on this document, and will determine what time period to permit for category III testing after that review is completed.

In the FEDERAL REGISTER for January 5, 1972 (37 FR 85), the Commissioner of Food and Drugs announced a proposed review of the safety, effectiveness and labeling of all OTC drugs by independent advisory review panels. In the FEDERAL REGISTER of May 11, 1972 (37 FR 9464), the Commissioner published the final regulations providing

for the OTC drug review under § 330.10 which were made effective immediately. Pursuant to these regulations, the Commissioner issued in the FEDERAL REGISTER of December 12, 1972 (37 FR 26456) a request for data and information on all active ingredients utilized in topical analgesic, including antirheumatic, otic, burn, sunburn prevention and treatment drug products.

The Commissioner appointed the following Panel to review the data and information submitted and to prepare a report pursuant to § 330.10(a)(1) on the safety, effectiveness and labeling of those products:

Thomas G. Kantor, M.D., Chairman, John Adriani, M.D., Col. William A. Akers, M.D., Maxine Bennett, M.D., Minerva S. Buerk, M.D., Walter L. Dickison, Ph. D., and Jerry Mark Shuck, M.D.

The Panel was charged to review submitted data and information for OTC topical analgesic ingredients, including antirheumatic, otic, burn, and sunburn prevention and treatment active ingredients. For purposes of this review, the Panel grouped the active ingredients and labeling into four major phamacologic groups, i.e., external analgesics, skin protectants, topical otics, and sunscreens.

The Panel presents its conclusions and recommendations for sunscreen active ingredients in this document. The Panel's conclusions for topical otic active ingredients were published in the FEDERAL REGISTER of December 16, 1977 (42 FR 63556), and its conclusions for skin protectant active ingredients were published in the FEDERAL REGISTER of August 4, 1978 (43 FR 34628). The Panel's conclusions and recommendations for external analgesic ingredients will be presented in a later issue of the FEDERAL REGISTER.

The Panel was first convened on March 6, 1973 in an organizational meeting. Working meetings were held on May 8 and 9, July 12 and 13, September 27 and 28, November 3 and 4, November 26 and 27, 1973; January 30 and 31, March 6 and 7, April 10 and 11, May 8 and 9, June 10 and 11, July 17 and 18, September 24 and 25, October 22 and 23, November 26 and 27, 1974; January 21 and 22, March 13 and 14, April 17 and 18, May 21 and 22, July 15 and 16, September 30 and October 1, November 12 and 13, 1975; March 4 and 5, May 19 and 20, June 22 and 23, September 27 and 28, November 18 and 19, 1976; February 23 and 24, May 25 and 26, August 22, 23, and 24, October 25, and December 13, 14, and 15, 1977.

Seven nonvoting liaison representatives served on the Panel: Mrs Jacqueline Pendleton (at the initial meeting), Mrs. Valerie Howard (from May 8, 1973 to September 28, 1973), Lynn Berry (from November 3, 1973 to April 27, 1976), Kathleen A. Blackburn (from July 6, 1976 to August 24, 1977) and Emily Londos (from October 25, 1977). Each was nominated by an ad hoc group of consumer organizations and served as the consumer liaison; and Joseph L. Kanig, Ph. D., nominated by the Proprietary Association, and Ben Marr Lanman, M.D., nominated by the Cosmetic, Toiletry, and Fragrance Association, served as the industry liaisons.

The following FDA employees served: C. Carnot Evans, M.D., Served as Executive Secretary. Lee Geismar served as Panel Administrator. Lee Quon, R.Ph., served as Drug information Analyst until July 1975, followed by Timothy T. Clark, R.Ph., until July 1973, followed by Thomas H. Gingrich, R.Ph., until July 1976, followed by Victor H. Lindmark, Pharm.D.

The following individuals were given an opportunity to appear before the Panel to express their views either at their own or the Panel's request on the issues before the Panel:

Joseph P. Armellino, M.D., Charles Bluestone, M.D., Stuart Ericksen, Ph. D., Alexander A. Fisher, M.D., Thomas Fitzpatrick, M.D., Ph. D., J. M. Glassman, M.D., Peter Hebborn, Ph. D., George E. Heinze, Kenneth R. Johannes, Albert M. Kligman, M.D., Howard Maiback, M.D., Edward Marlowe, Ph. D., Kenneth L. Milstead, Ph. D., John Parrish, M.D., Madhue Pathak, M.D., Robert Sayre, Ph. D., Joseph P. Soyka, M.D., Garrett Swenson, Esq., Stephen M. Truitt, Esq., and Frederick Urbach, M.D.

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 data and information submitted through December 14, 1977, in arriving at its conclusions and recommendations for OTC sunscreens.

In accordance with the OTC drug review regulations (21 CFR 330.10), the Panel's findings with respect to sunscreen active ingredients are set out in three categories:

Category I. Conditions under which sunscreen products are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which sunscreen 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.

I. SUBMISSION OF DATA AND INFORMATION

Pursuant to the notice published in the FEDERAL REGISTER of December 12, 1972 (37 FR 26156) requesting the submission of data and information on OTC topical sunscreen drugs, the following firms made submissions related to the indicated products:

A. SUBMISSIONS BY FIRMS

Firms and Marketed Products

AVA, Inc., Garland, Tex. 75040, AVA Suntan Lotion.

Bonne Bell, Lakewood, Ohio 44107, Sure Tan Gel and Sure Tan Lotion.

Paul B. Elder Co., Bryan, Ohio 43506, RVP Wide Range Sunscreen, RVP Ultra-Range Sun Protection, RVPlus, RVPaque Ultra-Violet Occlusive Agent, RVPABA Lipstick.

Elizabeth Arden, Inc., New York, N.Y. 10022, Sun Gelee and Suncare.

Greiter Corp., Inc., Weidling, Austria, Piz Buin Exclusiv Suntan Cream, Piz Buin Exclusiv Extrem Suntan Cream, Piz Buin Exclusiv Suntan Liquid Cream.

G. S. Herbert Laboratories, Irvine, Calif. 92664, Eclipse Sunscreen Lotion.

Lanvin-Charles of the Ritz, Inc., Holmdel Township, N.J. 07733, Alexandra de Markoff Lip Emollient, Alexandra de Markoff Allevia Body Treatment, Alexandra de Markoff Allevia Travel Stick, Bain de Soleil Suntan Creme White, Bain de Soleil Suntan Cream, Bain de Soleil Suntan Lotion, Bain de Soleil Leg Make-Up, Bain de Soleil Foam Concentrate, Bain de Soleil Bronzer, Imperial Nutricia Moisture Tint, Revenescence Sun Bronze, Revenescence Protective Cream for the Face, Revenescence Extra Protective Creme for the Face, Revenescence Moisture Glow-Bronze Shade, Revenescence Moisture Glow Liquid-Bronze Shade.

Menley & James Laboratories, Philadelphia, Pa. 19101, Sea & Ski Golden Tan, Sea & Ski Block Out.

Miles Laboratories, Inc., Elkhart, Ind. 46514, Sungard Lotion.

Plough, Inc., Memphis, Tenn. 38101, Coppertone Improved Shade Suntan Lotion, Coppertone Lipkote Lip Balm, Coppertone Noskote Sunscreen, Coppertone Suntan Cream, Coppertone Suntan Foam, Coppertone Suntan Lotion, Coppertone Suntan Oil, Coppertone Suntan Oil Aerosol Spray, Q.T. Foam, Q.T. Lotion, Sudden Tan, Sun Protective Foam, Sun Shielding Lotion.

Rowell Laboratories, Inc., Baudette, Minn. 56623, Duoshield One and Duoshield Two.

Texas Pharmacal Co., San Antonio, Tex. 78296, A-Fil Cream, Sundare Creamy Lotion, Sundare Clear Lotion, SunStick Lip Protectant, SunSwept Cream.

Westwood Pharmaceuticals, Inc., Buffalo, N.Y. 14213, Presun Lotion.

In addition, the following firms made related submissions:

Amerchol, Edison, N.J. 08817, Amerscreen P.

Chattem Laboratories, Chattanooga, Tenn. 37409, Alpaba.

EM Laboratories, Inc., Elmsford, N.Y. 10523, Eusolex 161, Eusolex 232, Eusolex 4360, Eusolex 6300, Eusolex 3573, Eusolex 5563.

Felton International, Inc., Brooklyn, N.Y. 11237, Sunarome.

GAF Corp., New York, N.Y. 10020, Sulisobenzone.

Givaudan Corp., Clifton, N.J. 07104, Giv-Tan-F, Parsol MCX and Parsol Hydro.

Greiter Corp., Tulsa, Okla. 74101, Exclusiv Creme, Exclusiv Milk, Exclusiv Moisture Creme, Exclusiv Oil Lotion, Exclusiv

Stick, Extrem Creme, Extrem Glacier Creme, Extrem Junior Creme, Extrem Milk, Piz Buin.

Haarmann and Reimer Corp., Springfield, N.J. 07081, Neo Heliopan AV.

Hill Top Research, Inc., St. Petersburg, Fla. 33709, Sun Block 253E, Sun Block 256E, Sun Block U-2575.

Ingram Pharmaceutical Co., San Francisco, Calif. 94111, 2-Ethylhexyl 2-cyano-3,3-diphenylacrylate.

Scher Chemicals, Inc., Clifton, N.J. 07012, Dipsal (Dipropylene Glycol Salicylate).

Van Dyk & Co., Inc., Belleville, N.J. 07109, Escalol 106, Escalol 506, Escalol 507.

B. Labeled Ingredients Contained in Marketed Products and Other Ingredients Submitted to the Panel.

Alcohol
Allantoin
Allantoin-*p*-aminobenzoic acid complex
p-Aminobenzoic acid
Amyl dimethyl PABA
Amyl para-dimethylaminobenzoate
Amyl-*p*-dimethylaminobenzoate
Beeswax
Benzophenone-3
Benzyl alcohol
BHA
BHT
2-Bromo-2-nitropropane-1,3-diol
Camphor
Carbomer 934
Carboset
Cellulose gum
Cetyl alcohol
Cetyl palmitate
Cetyl stearyl glycol
Cinoxate
Citric acid
Clove oil
Cocoa butter
Color
Digalloyl trioleate
Dihydroxyacetone
Dimethicone
5-(3,3-Dimethyl-2-norbornyliden)-3-penten-2-one
3,4-Dimethylphenyl-glyoxylic acid sodium salt
Dimethyl polysiloxane
Dioxybenzone
Dipropylene glycol salicylate
Ethyl alcohol
2-Ethylhexyl 2-cyano-3,3-diphenylacrylate
Ethylhexyl-*p*-methoxycinnamate
2-Ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid
2-Ethylhexyl salicylate
FD&C yellow No. 5
FD&C red No. 4
Fragrances
Glycerin
Glyceryl PABA
Glyceryl stearate
Homosalate
Isopropyl myristate
Isopropyl palmitate
Lanolin
Lanolin alcohol
Lanolin derivatives
Lanolin oil
Lawsone (2-hydroxy-1,4-naphthoquinone)
Menthol
Menthyl anthranilate
p-Methoxycinnamic acid diethanolamine
3-(4-Methylbenzyliden)-camphor
Methylparaben
Microcrystalline titanium-coated mica platelets
Microcrystalline wax
Mineral oil
Octyl dimethyl PABA
Oleth-3-phosphate
Oxybenzone
Padimate
Padimate A
Padimate O
Parabens
Paraffin
PEG 2 stearate
Petrolatum
2-Phenylbenzimidazole
Polyoxyl-40-stearate
Polysorbate 60
Propellant 46
Propellant 12/114
Propoxylate of *p*-aminoethylbenzoate
Propylparaben
Propylene glycol
Propylene glycol stearate
Quaternium 15
Red petrolatum
SD alcohol 40
Sesame oil
Silaca
Sodium carbomer
Sorbitan oleate
Sorbitan stearate
Stabilized aloe vera gel
Stearyl alcohol
Sulisobenzone
Synthetic spermaceti
Titanium dioxide
Triethanolamine
Triethanolamine salicylate
Triethanolamine stearate
Water
Wax
Zinc oxide

C. Classification of Ingredients

1. *Active ingredients.*

Allantoin combined with aminobenzoic acid (allantoin *p*-aminobenzoic acid complex)
Aminobenzoic acid (*p*-aminobenzoic acid)Cinoxate
Diethanolamine *p*-methoxycinnamate (*p*-methoxycinnamic acid diethanolamine)
Digalloyl trioleate
5-(3,3-Dimethyl - 2 - norbornyliden)-3-penten-2-one
Dioxybenzone
Dipropylene glycol salicylate
Ethyl 4-[bis(hydroxypropyl)] aminobenzoate (propoxylate of *p*-aminoethylbenzoate)
2-Ethylhexyl 2-cyano-3,3-diphenylacrylate
Ethylhexyl *p*-methoxycinnamate
2-Ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid
2-Ethylhexyl salicylate
Glyceryl aminobenzoate (glyceryl PABA)
Homosalate
Lawsone with dihydroxyacetone [dihydroxyacetone; lawsone (2-hydroxy-1,4-naphthoquinone)]
Menthyl anthranilate
3-(4-Methylbenzylidene)-camphor
Oxybenzone (benzophenone-3)
Padimate A (amyl *p*-dimethylaminobenzoate, amyl para-dimethylaminobenzoate, amyl dimethyl PABA, padimate)
Padimate O (octyl dimethyl PABA)
2-Phenylbenzimidazole - 5 - sulfonic acid (2-phenylbenzimidazole sulfonic acid)
Red petrolatum
Sodium 3,4-dimethylphenyl - glyoxylate (3,4-dimethylphenyl-glyoxylic acid sodium salt)
Sulisobenzone
Titanium dioxide
Triethanolamine salicylate

2. *Inactive ingredients.*

The Panel has classified the following as inactive ingredients or pharmaceutical necessities. In some cases, depending upon dosage and claim, some of the ingredients may be classified as skin protectants, which will be discussed more fully in a later issue of the Federal Register.

Alcohol
Allantion
Beeswax
Benzyl alcohol
BHA
BHT
2-Bromo - 2 - nitropropane-1,3-diol
Camphor
Carbomer 934
Carboset
Cellulose gum
Cetyl alcohol
Cetyl palmitate
Cetyl stearyl glycol
Citric acid
Clove oil
Cocoa butter
Color
Dimethicone
Dimethyl polysiloxane
Ethyl alcohol
FD&C yellow No. 5
FD&C red No. 4
Fragrances
Glycerin
Glyceryl stearate
Isopropyl myristate
Isopropyl palmitate
Lanolin
Lanolin alcohol
Lanolin derivatives
Lanolin oil
Menthol
Methylparaben
Microcrystalline titanium-coated mica platelets
Microcrystalline wax
Mineral oil
Oleth-3-phosphate
Parabens
Paraffin
PEG 2 stearate
Petrolatum
Polyoxyl-40-stearate
Polysorbate 60
Propellant 46
Propellant 12/114
Propylparaben
Propylene glycol
Propylene glycol stearate
Quaternium 15
SD alcohol 40
Sesame oil
Silica
Sodium carbomer
Sorbitan oleate
Sorbitan stearate
Stabilized aloe vera gel
Stearyl alcohol
Synthetic spermaceti
Triethanolamine
Triethanolamine stearate
Water
Wax
Zinc oxide

3. *Ingredients deferred to other OTC advisory review panels or other experts.*

None.

D. REFERENCED OTC VOLUME SUBMISSIONS

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call for data notice published in the FEDERAL REGISTER of December 12, 1972 (37 FR 26456). The volumes will be put on public display after September 25, 1978, in the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

II. General Statements and Recommendations

A. INTRODUCTION

As part of its review, the Panel was charged to evaluate data and information on the safety, effectiveness, and labeling of OTC sunburn prevention active ingredients. In general, the Panel found upon reviewing submissions, the scientific literature, and other evidence that over-exposure to sunlight damages the skin and can lead to various skin lesions. In the long run, suntanning is not good for the skin. The cumulative exposure to sunlight from childhood into adulthood can lead to skin cancer. Persons most at risk to the harmful effects of sunlight are those with light eyes and light skin of northern European descent who now live in sunny climates. Susceptible persons can avoid the sunshine between 10 a.m. to 2 p.m. solar time by covering their skin with clothing, wearing broad brim hats, applying opaque cosmetics, or staying indoors. Avoidance of excessive sun exposure would be best, but it is often impractical because of occupational demands or is often undesirable for leisure pursuits. Another protective measure available to the consumer is to apply sunscreens to prevent sunburn immediately and to prevent further sun damage.

The Panel recognizes that many of these products have been traditionally considered by the Food and Drug Administration as cosmetics with labeling such as "for tanning" and "for fast suntanning". This is due in part to the statutory definition of a cosmetic as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance * * *." (21 U.S.C. 321(i)). The Panel believes that, regardless of claims, products intended to be used for prevention of sunburn or any other such similar condition should be regarded as drugs. The use of sunscreens may mitigate the harmful effects of the ultraviolet (UV) radiation from the sun on the exposed skin of susceptible individuals. The Panel discusses these harmful effects elsewhere in this document. (See part II. paragraph D. below—The Harmful Effects of Sunlight on the Skin.) In fact, the statutory definition of a drug in part states "articles (other than food) intended to affect the structure or any function of the body of man or other animals * * *." (21 U.S.C. 321(g)).

The Panel has evaluated the claimed active ingredients contained in the products submitted for review. The Panel finds that these preparations reduce by varying amounts the solar radiation absorbed by the skin and thereby affect the physiological response and extent of the erythemal reaction (redness) produced. Indeed, these products affect the structure and function of the body by screening, reflecting, or scattering the harmful, burning rays of the sun. This is a desirable alteration to a normal physiological response to solar radiation for individuals with sensitive and extra sensitive skin.

The Panel has classified products intended to be used for preventing sunburn and similar conditions as drugs regardless of claims made for the products and has identified them as sunscreen products. Sunscreens may act either chemically or physically. The majority of sunscreens commonly used in the OTC drug market act chemically to absorb specific portions of the UV spectrum. An example of a chemical sunscreen is aminobenzoic acid (para-aminobenzoic acid). Physical sunscreens act by providing an actual physical barrier to solar radiation. Instead of absorbing UV light, these agents scatter and reflect such light, thereby reducing the likelihood of sunburn. An example is titanium dioxide. Regardless of the mechanism employed, the active ingredients in such products, which either absorb, reflect, or scatter UV light between 290 and 777 nanometers (nm), have been classified as drugs and identified as sunscreen agents which are more fully discussed below.

The Panel further recognizes that ingredients that are not sunscreens may be contained in sunscreen products and may also be classified as drugs. These include skin protectants, and repellants to ward off flying insects.

No perfect topical preparation for preventing sunburn is available, but there are many satisfactory preparations on the market. Interestingly, no "prescription only" products are available to protect the sunsensitive person. All currently marketed sunscreen products are sold OTC. The majority of consumers who purchase sunscreen products have no pathological conditions, but desire to acquire a suntan and to prevent a painful sunburn. Some individuals, however, are particularly susceptible to the immediate and cumulative effects of sunlight exposure and for health reasons should protect themselves from the harmful UV radiation from the sun.

B. TYPES OF SOLAR RADIATION

For practical purposes, the solar spectrum at the earth's surface consists of wavelengths of electromagnetic energy between 295 and 1,800 nanometers (nm) (ref. *1*). The sun's rays associated with diseases are related to the light sensitivity range from 290 to 800 nm. The UV spectrum lies between 290 and 400 nm, visible light between 400 and 770 nm, and the infrared rays beyond 770 nm. Ultraviolet radiation from both sunlight and artificial sources is sometimes subdivided into three bands from the longer to the shorter wavelengths as follows:

1. *UV-A (black light radiation, longwave UV radiation, near UV radiation) wavelength 320 to 400 nm.* UV-A radiation can cause tanning of the skin, but is weak in causing reddening of the skin. About 20 to 50 Joules/cm^2 of UV-A energy is required to produce a minimally perceptible redness reaction (the Minimal Erythema Dose or MED). The Panel has further discussed MED below. (See part II. paragraph D. below—The Harmful Effects of Sunlight on the Skin.) The erythema (redness) reaction is maximal in intensity about 72 hours after exposure.

2. *UV-B (sunburn radiation, middle UV radiation) wavelength 290 to 320 nm.* Radiation causes the sunburn, reaction, which also stimulates pigmentation (tanning) in the skin. Approximately 20 to 50 millijoules/cm^2 of UV-B energy is required to produce one MED (about 1,000 times less than the dose of UV-A). The erythema reaction is maximal in intensity at 6 to 20 hours after exposure.

The action spectrum causing sunburn lies between 290 and 320 nm in the UV-B band, with a maximum effect at 296.7 nm, although the quantity reaching the earth's surface is small. Under optimal environmental conditions for sunburn, only 0.2 percent of the total solar radiation causes erythema of the skin. Ninety-five percent of this burning radiation may be absorbed by the normal white skin. Different amounts of energy reach the earth's surface at various wavelengths from 295 to 320 nm. At 307.4 nm the maximal amount of energy to cause sunburn is delivered by the sun to the skin (ref. *2*).

3. *UV-C (germicidal radiation, short UV radiation, far UV radiation) wavelength 200 to 290 nm.* UV-C radiation from sunlight does not reach the earth's surface, but artificial UV sources can emit this radiation. Although UV-C is not effective in stimu-

lating pigmentation (tanning), it does cause erythema requiring about 5 to 20 millijoules/cm² of UV-C energy to produce one MED.

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C. FACTORS AFFECTING THE AMOUNT OF SUNLIGHT EXPOSURE

At sea level, the UV energy of sunlight is greatest between the hours of 10 a.m. and 2 p.m. in midsummer, when the sun is overhead (ref. *1*). Even within the most intense 4-hour period, the sunlight intensity varies. Exposure at noon results in more UV-B energy falling on the skin than exposure at 10 a.m. or 2 p.m. In the morning and late afternoon, the sun is at a lower angle, sharply reducing the sunlight's intensity by 75 percent, and sunburn is not likely to occur. Atmospheric conditions similarly alter the solar erythemic intensity. Reflection of additional ultraviolet light from snow and white sand may greatly shorten the time to sunburn (ref. *2*). Depending upon the latitude, the average unprotected, untanned, white-skinned person requires approximately the following exposures in June to cause the observed reaction:

GUIDE FOR FAIR-SKINNED PEOPLE (REF. 2)

Reaction from exposure	New Jersey 40 N	Florida Keys 25 N
	(minutes)	*(minutes)*
Minimal redness (erythema) (the minimal erythema dose, MED)	21	10
Vivid redness (erythema), no pain	42	25
Painful sunburn	80	50
Blistering sunburn	165	120

An average white-skinned person would be exposed to an average of 19 MED's during the entire day atop Mauna Loa on the island of Hawaii. To date, this is the highest reading obtained by network of UV recording meters (ref. *3*). About 4 MED's are required to cause a painful sunburn; about 8 MED's will produce blistering.

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D. THE HARMFUL EFFECTS OF SUNLIGHT ON THE SKIN

The UV energy absorbed by the skin can produce an erythemal reaction (redness). The intensity of the reaction is dependent upon the amount of energy absorbed. As discussed above, UV radiation from both sunlight and artificial sources has been divided into three bands (UV-A, UV-B, and UV-C), which emit different quantities of energy and therefore produce an erythemal reaction at different time intervals after exposure. The amount of energy from any source required to produce a minimally perceptible redness reaction of the skin is termed the Minimal Erythema Dose or MED. The length of time required to produce an MED is dependent, as discussed above, on the quantity of energy emitted by the source and the response of the host's skin to sunlight. Sunscreen agents decrease the amount of energy absorbed by the skins by limiting the total amount of available energy that reaches the skin. Besides the UV source and the sunscreen agent, the pigmentation of an individual's skin determines the length of time required to produce an MED. Less time is required to produce an MED in light-skinned individuals than is required to produce an MED in dark-skinned individuals. The source of the UV radiation, the type of sunscreen agent used, and the pigmentation of the individual's skin determine the length of time required to produce an MED.

The tanning ability of an individual is genetically predetermined and is governed by the individual's capacity to produce melanin pigment within the pigment cells (melanocytes) when stimulated by UV-B and UV-A. There is a spectrum of pigmentation in humans, ranging from Negro (black) to Caucasian (white). The extent of any erythemal response is a function of skin color, and the MED for Dark-skinned blacks is about 33 times as high as that for light-complexioned Caucasians (ref. *1*).

The Panel finds that the current labeling of sunscreen products makes no reference to skin color because such products are actually intended for individuals whose skin color falls within the pigmentation spectrum that would have an erythemal response to the UV light of the sun. The Panel emphasizes that despite the fact that deeply pigmented skin has more inherent protection, it is still susceptible to sunburn and the effects of overexposure as discussed below.

Urbach stated, "All of us, even those with dark complexions, can develop skin cancer if we expose ourselves to the sun long enough. But that would take 200 to 300 years in some cases, and we just don't live that long" (ref. *2*).

Some commercial preparations on the OTC drug market today that permit suntanning without painful sunburn fall into four groups, each aimed at a certain consumer group.

MARKETED SUNSCREEN PREPARATIONS (REF. 3)

Indication and Solar Transmission

For quick tanning—Transmit about 15 percent of the sunburning rays.
For normal skin—Transmit from 4 to 8 percent of the sunburning rays.
For sensitive skin—Transmit from 1 to 4 percent of the sunburnig rays.
For extra sentive skin—Transmit under 1 percent of the sunburning rays.

The Panel emphasizes that sunscreen preparations only extend the time it takes the sun to produce a sunburn. Tanning cannot be rushed, taking about 2 weeks in most white people, if painful erythema is to be avoided. The most rapid way to cause tanning is to allow the sun to produce erythema of the skin. Erythema sufficient to induce tanning yet not so severe as to cause pain requires only one-half of the time of exposure that is required to produce a painful sunburn. Suntanning can occur at UV wavelengths from 320 to 400 nm, but develops slowly under natural conditions. Tanning most commonly develops after exposure to the "sunburn" UV wavelengths between 290 and 320 nm, the UV-B band.

As previsously noted, sunscreen preparations contain certain chemicals which absorb UV light at various wavelengths or contain an opaque substance that physically reflects or scatters the UV light rather than absorbing the rays (refs. *4* and *5*).

In our cosmetically conscious society, most persons consider a suntan to be healthy. Certainly, sun exposure forms vitamin D in the skin, and this enhances absorption of calcium from the intestine and prevents rickets. However, dermatologists are well aware that light-eyed and fair-skinned individuals are particularly susceptible to premature aging of the skin and skin cancers caused by sunlight (ref. *3*).

A recent study in the United States reported a high incidence of sun-induced cancer in susceptible people (ref. *6*). In 1973, in the United States alone, 1,409 deaths were due to sun-induced skin cancers (excluding melanomas) in susceptible people (ref. *7*). Annually in the United States with a population of over 210,000,000, an esti-

mated 9,000 individuals develop cutaneous malignant melanoma, 300,000 develop other skin cancers, and 600,000 develop cancers of all other organs exclusive of the skin (ref. *8*). Other specific diseases of congenital, metabolic, toxic, immunologic, allergic, or idiopathic origins are caused or aggravated by sunlight exposure. The pain and blistering of sunburn from overexposure is known to many. The Panel discusses below, in detail, the more common harmful effects that may be induced by the UV radiation from the sun, i.e., skin cancer and premature aging of the skin.

1. *Skin cancer in susceptible individuals.* As described above, one of the risk factors of chronic exposure to the sun is the development of keratoses and skin cancer. Epidemiological evidence shows that the incidence of skin cancer is increased in populations located in the southern latitudes as compared with populations in northern latitudes. Auerbach (ref. *9*) showed a constant rate of increase of skin cancer incidence approaching the equator from north to south; the incidence doubled for every 3° 48' reduction in latitude. This geographical relationship has been accepted as indirect evidence that skin cancer in man is related to the greater exposure of individuals to sunlight in southern latitudes than in northern latitudes. Several epidemiological studies reinforce the conclusion that prolonged sun exposure is a factor in the etiology of skin cancer (refs. *9* through *14*). The damage due to sunlight is insidious and cumulative.

Retrospective studies have been done to identify those characteristics in individuals that may increase their susceptibility to skin cancer if overexposed to sunlight. These contributory factors proved to be age, sex, skin pigmentation, and occupation. The general conclusion drawn from these studies was that they corroborated the evidence for a cumulative influence of sun exposure on tumor development and that they indicated the protective effect of pigmented skin. For example, the incidence of cancer was reported to increase with age among Caucasian adults in a rural county of Tennessee (ref. *12*). The incidence increased from 0.7 per 100 up to the age of 44 years to 13.6 per 100 between age 65 and 74 years for males. For females in these age groups, the incidence of skin cancer increased from 0.4 per 100 to 6.8 per 100. The incidence for males was higher than the incidence for females. Other studies indicated a higher incidence of skin cancer in whites than in nonwhite populations (refs. *14* and *15*), implying that the dark pigmentation of nonwhites protects against the harmful effects of the UV radiation. The higher incidence in males than in females may be explained by the increased exposure of males to the sun from their outdoor occupations. Skin cancer occurs most frequently in those areas of the body that are exposed to the sun, such as the neck, head, arms, and hands. Consequently, the frequency of skin cancer is higher in farmers, sailors, and construction workers (ref. *12*).

The Panel agrees with the concept that sunlight plays an important role in the etiology of skin cancer in man. The Panel recognizes the epidemiological evidence for the carcinogenic properties of UV radiation from the sun and the relationship to human skin cancer, such as premalignant keratoses, and malignant basal cell epitheliomas and squamous cell epitheliomas. The Panel is particularly concerned about recurrent sunburn and overexposure to the sun throughout the years, because the lower wavelength limit of cancer-producing radiation on the skin of mice and rats has been shown to be 325 nm, i.e., the same spectral range that produces sunburn in human skin (ref. *16*). Although the epidemiological evidence favors a casual relationship between sunlight and skin cancer in man, prospective direct evidence to substantiate the relationship will be difficult to obtain for ethical and moral reasons. However, the evidence indicates that there is a lower risk in heavily pigmented individuals; that there is a continued rise in the incidence with increasing age, thus indicating a cumulative effect from sunlight exposure; and that the incidence rate is higher among susceptible populations living in subtropical and tropical latitudes. Physical, genetic, and environmental factors interact, apparently, to alter the causal effect of sunlight on tumor development (ref. *10*).

In addition, factors unrelated to sunlight may operate in the development of basal cell carcinoma in man. This conclusion is based on the observations that one-third of all basal cell carcinomas occur in areas of the skin receiving little or no UV radiation. The ratio of the incidence of basal cell carcinoma to squamous cell carcinoma shows a great north-south difference varying from approximately 10 to 1 in favor of basal cell carcinoma in northern cities, to 4 to 1 in northern and central rural areas, and to 2 or 3 to 1 in southern rural areas (ref. *9*). These observations suggest that increasing exposure to sunlight has a greater effect on the development of squamous cell carcinoma than on that of basal cell carcinoma. nevertheless, some association between basal cell carcinoma and sunlight is indicated from epidemiological studies.

The Panel recognizes the influence of genetic factors on the development of skin cancer, i.e., the protective mechanism of skin pigmentation which is genetically determined. The susceptibility to skin cancer is decreased in individuals with deeply pigmented skin. Epidemiological evidence indicates that susceptible individuals have a fair complexion, light hair, blue or gray eyes, tan less and to a lighter color, and sunburn more easily and more severely than individuals not developing skin cancer. Studies show that skin cancer patients have greater outdoor exposure than those not affected.

The Panel concludes that continuous and prolonged exposure over the years to sunlight increases the risk of skin cancer in susceptible individuals and that the use of sunscreens by such individuals may mitigate the harmful effects of overexposure to the sun. Below, the Panel assesses the overall harmful effects of sunlight exposure and recommends that the labeling of sunscreen products, alert the consumer to these harmful effects.

2. *Premature aging of the skin in susceptible individuals.* Another harmful effect that may result from the cumulative action of chronic prolonged exposure to the UV radiation from the sun is a condition which has been commonly referred to as premature aging of the skin. Premature aging of the skin refers to the thinning, dryness, and fine wrinkling produced by the exposure of the skin to sunlight. Although the external characteristics of this condition, i.e., dry, wrinkled, thin skin with a loss of elasticity, are similar to the characteristics of the aging process, premature aging of the skin due to UV radiation has histological and biochemical characteristics that differ qualitatively and quantitatively from those seen in the aging process. The changes that are associated with premature aging of the skin are seen in the dermis of the skin. In addition to these dermal changes are the effects that UV radiation induces in the epidermal layer of the skin, where the basal and squamous cell epitheliomas (skin cancers) casually related to sunlight exposure occur. The relationship between the changes in the dermal connective tissue of the skin and epidermal carcinogenesis are not understood, although dermal changes associated with premature aging of the skin have often been associated with skin cancer formation (ref. *17*)

The dry, wrinkled, atrophic condition of sunlight-exposed skin was first reported by Unna from observations in sailors. Since that observation, biochemical and histological studies have been done comparing the changes in sunlight-exposed and unexposed skin of white and nonwhite individuals. Prolonged UV radiation from the sun

on the dermal layer of exposed skin ultimately produces elastic degeneration and elastic tissue dissolution. This effect is qualitatively and quantitatively different from the aging unexposed skin of white individuals and, in addition, is less pronounced in both the exposed and unexposed skin of nonwhite (pigmented) individuals (ref. *18*).

The quantity of elastic tissue in the dermis of sunlight-exposed skin increases with age in both white and nonwhite individuals. This elastic tissue hyperplasia is greater than that seen in unexposed skin and is apparently accompanied by a decrease in collagen and eventually culminates in the disintegration of the elastic fibers into an amorphous mass as seen in stained histological tissue sections. The loss of the elasticity of exposed skin is the result of the dissolution of the elastic fibers. Quantitative biochemical changes occur in elastic degeneration of exposed skin that differs from that seen in the aging process in unexposed skin. In contradistinction to aging unexposed skin, it has been shown that in chronically sunlight-exposed skin the concentration of hexosamine is increased and the concentration of hydroxyproline is decreased. Glucosamine is also increased in chronically exposed skin which is thought to correlate with the increased staining for mucopolysaccharides in the skin (refs. *19* and *20*).

Just as in studies on the effect of pigmentation on the incidence of skin cancer in man, it has been reported that biopsies of exposed skin of elderly nonwhite individuals showed little of the elastic degenerative changes seen in biopsy specimens obtained from similar exposed regions of elderly white individuals, and that biopsy specimens of unexposed areas were almost identical in similar age groups of both white and nonwhite individuals. The evidence pointed to a correlation between the degree of pigmentation and the degree of elastosis. The less pigmented individuals showed a greater amount of degeneration. The reports indicate that pigmentation has a protective effect and that the elastotic degenerative effects of UV radiation from the sun are not simply the result of the aging process.

The Panel concludes that because pigmentation of the skin appears to have an influence in preventing the harmful effect of elastotic degeneration in sunlight-exposed skin, the use of sunscreens may mitigate elastotic degenertion in light skinned individuals (susceptible individuals). It appears that elastotic degeneration (premature aging of the skin) is more likely to occur in individuals with the characteristics that make them susceptible to the harmful effects of chronic exposure to UV radiation from the sun, as discussed above.

3. *Conclusions.* The Panel recognizes the epidemiological evidence that skin cancer, and degenerative skin changes (elastotic degeneration) commonly referred to as premature aging of the skin are causally related to chronic exposure to the UV radiation from the sun. The Panel is concerned that because it is difficult to substantiate this evidence by adequate and direct information, susceptible individuals will continue to be subjected to the harmful effects of continuous sun exposure without using whatever protection is presently available. The Panel is fully aware of the limitations of the present sunscreens, i.e., primarily the inability to remain on the skin under diverse conditions, and the apparent irreversibility of UV radiation damage to the skin.

However, the Panel feels that because skin cancer is extremely common in susceptible individuals, amounting to one-third to one-half of all cancers of all anatomical sites as reported in the United States (ref. *10*), the use of sunscreens properly and regularly applied may aid in reducing this high incidence.

The Panel believes that sunscreens would be beneficial for children and adolescents with the susceptible skin coloration, genetic background, and geographical environments making them likely to be subject to repeated sunburns. The damage is cumulative and 20 to 50 years may pass before skin changes including skin cancers appear.

Experimental studies in mice have been reported to show that the topical application of 3-benzoyl-4-hydroxy-6-methoxy-benzenesulfonic acid and aminobenzoic acid decreased the erythematous and carcinogenic effect of UV radiation (ref. *21*). Whether such results derived from animal studies can be extrapolated to chronic sun exposure in man remains, of course, undetermined, but the Panel feels that the topical application of sunscreens by susceptible individuals may mitigate the harmful effects of chronic exposure to the sun.

Dermatologists routinely instruct their patients who have skin cancer of the sun-exposed areas to wear long sleeves and a wide-brim hat, to avoid sun exposure between 10 a.m. to 2 p.m. solar time, and to use a sunscreen liberally every day (women may substitute a heavy opaque makeup) "even just to take out the garbage." Most physicians recommend sunscreens for skin cancer patients, not to heal damage that occurred years earlier, nor to prevent skin cancers due to the lag time of 10 to 30 or more years between the time the damage occurred and the tumor appears, but to prevent skin cancer from today's exposure appearing 10 to 20 years hence.

Therefore, the Panel recommends the following statement in the labeling for all sunscreen products: "Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of these harmful effects." or "Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of premature aging of the skin and skin cancer."

4. *Minority report.* The Panel voted 4 to 3 to support a claim which can be used on labels of all sunscreen products. This claim suggests that skin cancer may be prevented by the use of any of these products. The claim presupposes that the person using the product will use it correctly. It also presupposes that alterations in the skin are not yet present which could result in skin cancer, whether the product is used or not. Because data are not yet conclusive that skin cancers are preventable by these OTC products, the minority suggests that a claim of "may reduce harmful effects of the sun" is acceptable, but the final step of preventing cancer is unwarranted at this time. The consumer representative concurs with the minority report.

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E. SUN PROTECTION FACTORS

The "Sun Protection Factor" (SPF) is used in Europe on sunscreen products. The Sun Protection Factor, which is related to the Protective Index gives the consumer a guide as to how the product will act on his skin. The SPF value may be defined as the ratio of the amount of energy required to produce a minimum erythema dose (MED) or minimal sunburn through a sunscreen product film to the amount of energy to produce the same MED without any treatment. The following equation represents this ratio:

SPF value = MED Protected Skin/MED Unprotected Skin

The European experience over the past 20 years has shown the following protection factors based upon skin types (ref. *1*):

SPF value and skin type

SPF 3—For nonsensitive skin and skin already accustomed to the sun (minimal protection).

SPF 4—For normally sensitive skin (moderate protection).

SPF 6—For sensitive skin (extra protection).

The Panel finds SPF values to be a practical guide and has included them in the labeling to aid the consumer in selecting the most suitable sunscreen for his/her own purposes.

F. SUNSCREEN AGENTS

The Panel has discussed the use of OTC sunscreen drug products in reducing by varying amounts the solar radiation absorbed by the skin. The amount of UV light from the sun that penetrates the skin depends upon the amount of energy selectively screened by the product. Consequently, the physiological effect on the skin, manifested as erythema, is determined in large part by the quantity of radiation of the sunscreen product permits the skin to absorb, or conversely, the quantity of UV energy the product prevents the skin from absorbing. The intensity of the erythemal response correlates with the amount of radiation absorbed by the individual's skin. Therefore, the Panel has classified sunscreen active ingredients into categories based upon their UV screening capacity.

The scientific literature contains definitions of sunscreen types, describing the chemicals and substances used to prevent sunburn. However, information from consumer groups revealed that the terms used, such as "sunscreen," "sunshades," and "sunblock" might not be meaningful to the general population. The Panel considered many terms in an effort to find a noun or adjective that would describe the use of these preparations.

The Panel adopts the following definitions for therapeutic sunscreen types:

1. *Sunscreen sunburn preventive agent.* An active ingredient that absorbs 95 percent or more of the light in the UV range at wavelengths from 290 to 320 nm and thereby removes the sunburning rays.

2. *Sunscreen suntanning agent.* An active ingredient that absorbs at least 85 percent of the light in the UV range at wavelengths from 290 to 320 nm, but transmits UV light at wavelengths longer than 320 nm. Such agents permit tanning in the average individual and also permit some reddening (erythema) without pain.

3. *Sunscreen opaque sunblock agent.* An opaque agent that reflects or scatters all light in the UV and visible range at wavelengths from 290 to 777 nm and thereby prevents or minimizes suntan and sunburn. Transparent sunblock agents are not yet available in the OTC drug marketplace.

The Panel realizes that these definitions are based on the UV-absorbing properties of a single active ingredient of a sunscreen product and not on how an ingredient may perform in a formulation or in a combination product during actual use on the skin. Therefore, the Panel has recommended final product testing of each formulation to assure proper use. (See part III. paragraph D. below—Sunscreen product testing procedures for determination of the sun protection factor (SPF) value and related labeling claims.)

G. CATEGORIES OF SUNSCREEN PRODUCTS

To aid the consumer in selecting the type of sunscreen product best suited to the individual's complexion (pigmentation), response to UV light and the type of outdoor activity, the Panel recommends the following product category designations (PCD's) for the product or formulation to be marketed:

1. *Minimal Sun Protection Product.* Sunscreen products that provide an SPF value of 2 to under 4, and offer the least protection, but permit suntanning.

2. *Moderate Sun Protection Product.* Sunscreen products that provide an SPF value of 4 to under 6 and offer moderate protection from sunburning, but permit some suntanning.

3. *Extra Sun Protection Product.* Sunscreen products that provide an SPF value of 6 to under 8, offer extra protection from sunburning and permit limited suntanning.

4. *Maximal Sun Protection Product.* Sunscreen products that provide an SPF value of 8 to under 15, offer maximal protection from sunburning, and permit little or no suntanning.

5. *Ultra Sun Protection Product.* Sunscreen products that provide an SPF value of 15 or greater, offer the most protection from sunburning and permit no suntanning.

The Panel reviewed the effects of UV light on the skin (ref. *2*). The Panel has summarized the following compilation of skin types, sunscreen Sun Protection Factors, and Product Category Designations discussed in this document:

Skin types and recommended sunscreen products

Skin type	Sunburn and tanning history	Recommended sun protection factor and product category designation
I	Always burns easily; never tans (sensitive).	8 or more (maximal, ultra).
II	Always burns easily; tans minimally (sensitive).	6 to 7 (extra)
III	Burns moderately; tans gradually (light brown) (normal).	4 to 5 (moderate)
IV	Burns minimally; always tans well (moderate brown) (normal).	2 to 3 (minimal)
V	Rarely burns; tans profusely (dark brown) (insensitive).	2 (minimal)
VI	Never burns; deeply pigmented (insensitive).	None indicated.

[1] Based on first 30 to 45 minutes sun exposure after winter season or no sun exposure.

The Panel recommends that the following compilation of skin types and product category designations be appropriately included in labeling as a guide:

RECOMMENDED SUNSCREEN PRODUCT GUIDE

Sunburn and Tanning History and Recommend Sun Protection Product

Always burns easily; never tans.—Maximal, Ultra.
Always burns easily; tans minimally.—Extra.
Burns moderately; tans gradually.—Moderate.
Burns minimally; always tans well.—Minimal.
Rarely burns; tans profusely.—Minimal.

The Panel believes this "Recommended Sunscreen Product Guide" will benefit the consumer. On first using this scale some people may misjudge the reactivity of their skin to sunlight. Elevated heat and humidity, sweating, and swimming may lower the SPF value at any one time for an individual. In practical terms, a person who usually gets red in the sun after 20 minutes should be able to stay in the sun for 120 minutes (2 hours) if he applies a sunscreen of extra protection (SPF 6), i.e., 20 minutes X 6, provided the product is not washed or sweated off.

As noted above, the Panel suggests five PCD categories, i.e., minimal, moderate, extra, maximal, and ultra protection. The maximal protection (SPF 8) category would protect, for 320 minutes, the average person who would be burned in 40 minutes or through the dangerous sunburning hours of 10 a.m. to 2 p.m. Once the skin has become accustomed to the sun, the individual's self-protection period is longer, and in practice this means that gradually a product with a lower PCD can replace a product with a higher PCD because the risk of sunburn has become smaller.

The Panel recommends the use of the guideline outlined above with the inclusion of the ultra protection (SPF 15 or more) category for highly sensitive individuals needing this degree of protection against UV light. The Panel emphasizes that the PCD for the package labeling is determined for the final product or furmulation, not the active ingredient alone.

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(1) Greiter, F., "Sonnenschutzmittel-Typen und Anwendung," *Sonderdruck aus Parfumerie und Kosmetick*, 55:199-202, 1974.

(2) Jimbow, K., M. A. Pathak, G. Szabo and T. B. Fitzpatrick, "Ultrastructural Changes in Human Melanocytes after Ultraviolet Radiation," *in* "Sunlight and Man," Edited by M. A. Pathak, L. C. Harber, M. Seiji and A. Kukita, University of Tokyo Press, Tokyo, pp. 195-215, 1974.

H. LABELING OF SUNSCREEN PRODUCTS

1. *Indications.* The indications for use of a sunscreen are to be simply and clearly stated. Statements of indications for use are to be specific and confined to the conditions for which the product is recommended. The directions for use are to be clear and provide the user a reasonable expectation of the results anticipated from use of the product.

The indications for use may contain any of the following:

a. *For all (minimal, moderate, extra, maximal, and ultra) sunscreen products.* (1) "Sunscreen to help prevent sunburn."

(2) "Filters (or screens) out the sun's burning rays to prevent sunburn."

(3) "Screens out the sun's harsh and often harmful rays to prevent sunburn."

(4) "Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of these harmful effects."

(5) "Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of premature aging of the skin and skin cancer."

b. *Additional indications.* In addition to the indications provided above in item a., the following may be used: (1) *For minimal sunscreen products.* (i) "Affords minimal protection against sunburn."

(ii) "Prolongs exposure time before sunburn occurs."

(iii) "Permits tanning (or suntanning) and reduces chance of (or minimizes) sunburning."

(iv) "Helps prevent sunburn on limited exposure of untanned skin."

(v) "Helps to protect the skin against sunburn while permitting tanning."

(vi) "Allows you to stay in the sun 2 times longer than without sunscreen protection."

(vii) "Provides 2 times your natural protection from sunburn."

(2) *For moderate sunscreen products.* (i) "Affords moderate protection against sunburn."

(ii) "Prolongs exposure time before sunburn occurs."

(iii) "Permits tanning (or suntanning) and reduces chance of (or minimizes) sunburning."

(iv) "Helps prevent sunburn on moderate exposure of untanned skin."

(v) "Allows you to stay in the sun 4 times longer than without sunscreen protection."

(vi) "Provides 4 times your natural protection from sunburn."

(3) *For extra sunscreen products.* (i) "Affords extra protection against sunburn."

(ii) "Prolongs exposure time before sunburn occurs."

(iii) "Permits limited tanning (or suntanning) and reduces chance of (or minimizes) sunburn."

(iv) "Helps prevent sunburn."

(v) "For sun-sensitive skin."

(vi) "Extra protection against sunburn for blondes, redheads and fair-skinned persons."

(vii) "Allows you to stay in the sun 6 times longer than without sunscreen protection."

(viii) "Provides 6 times your natural protection from sunburn."

(4) *For maximal sunscreen products.* (i) "Affords maximal protection against sunburn."

(ii) "Prevents sunburn and limits tanning."

(iii) "For sun-sensitive skin."

(iv) "Maximal protection against sunburn for blondes, redheads and fair-skinned persons."

(v) "Allows you to stay in the sun 8 times longer than without sunscreen protection."

(vi) "Provides 8 times your natural protection from sunburn."

(5) *For ultra sunscreen products.* (i) "Affords the most protection against sunburn."

(ii) "Prevents tanning and sunburn."

(iii) "For highly sun-sensitive skin."

(iv) "Greatest protection against sunburn for blondes, redheads and fair-skinned persons."

(v) "Provides the highest degree of sunburn protection and permits no tanning."

(vi) "Provides the highest degree of sunscreen protection and permits no tanning."

c. *For all (maximal and ultra) sunscreen products that contain sunscreen opaque sunblock ingredients.*

"Reflects the burning rays of the sun."

2. *Statement on product performance*—(a) *Product Category Designation (PCD).* The Panel concludes that improved, more informative labeling should be provided to the consumer to aid in selecting the most appropriate sunscreen product. The Panel recommends that the following labeling statements be prominently placed on the principal display panel of appropriate products:

(1) Products containing active ingredients that provide a SPF value of 2 to under 4: "Minimal Sun Protection Product (SPF 2)—Stay in the sun twice as long as before without sunburning."

(2) Products containing active ingredients that provide a SPF value of 4 to under 6: "Moderate Sun Protection Product (SPF 4)—Stay in the sun 4 times as long as before without sunburning."

(3) Products containing active ingredients that provide a SPF value of 6 to under 8: "Medium Sun Protection Product (SPF 6)—Stay in the sun 6 times as long as before without sunburning."

(4) Products containing active ingredients that provide a SPF value of 8 to under 15: "Maximal Sun Protection Product (SPF 8)—Stay in the sun 8 times as long as before without sunburning."

(5) Products containing active ingredients that provide a SPF value of 15 or greater: "Ultra Sun Protection product (SPF 15)—Stay in the sun 15 times as long as before without sunburning."

(b) *Labeling claims related to the PCD and SPF value.* The Panel recommends any of the following labeling claims for sunscreen products that satisfy the sunscreen product testing procedures described elsewhere in this document. (See part III. paragraph D. below—Sunscreen product testing procedures for determination of the sun protection factor (SPF) value and related labeling claims.)

(1) *For all (minimal, moderate, extra, maximal, and ultra) sunscreen products that satisfy the water resistance testing procedures.* (i) "Water resistant."

(ii) "Retains its sun protection for at least 40 minutes in the water."

(iii) "Resists removal by sweating."

(2) *For all (minimal, moderate, extra, maximal, and ultra) sunscreen products that satisfy the waterproof testing procedures.* (i) "Waterproof."

(ii) "Retains its sun protection for at least 80 minutes in the water."

(iii) "Resists removal by sweating."

(3) *For all (minimal, moderate, extra, maximal, and ultra) sunscreen products that satisfy the sweat resistance testing procedures.* (i) "Retains its sun protection for at least 30 minutes of heavy sweating."

(ii) "Sweat resistant."

3. *Warnings*—(a) *For all (minimal, moderate, extra, maximal, and ultra) sunscreen products.* The labeling of all sunscreen products should contain the following warnings:

(1) "For external use only, not to be swallowed."

(2) "Avoid contact with the eyes."

(3) "Discontinue use if signs of irritation or rash appear."

(b) *Specific warnings*—(1) *For sunscreen products providing an SPF value of 2 to under 4:* "Use on children under 2 years of age only with the advice of a physician."

(2) *For sunscreen products providing an SPF value of 4 or greater.* "Use on children under 6 months of age only with the advice of a physician."

4. *Directions for use.* The Panel believes than many consumers use inadequate amounts of sunscreen. Offering more detailed guidelines would benefit the consumer.

Based on a review of the available data, the Panel recommends that the "Directions for Use" state: "Apply liberally before sun exposure and reapply after swimming or after excessive sweating."

However, for sunscreen products that satisfy the water resistance, waterproof, and sweat resistance testing procedures described elsewhere in this document, the directions for use in the labeling of these products may be modified in accordance with the results of the test. (See part III. paragraph D. below—suncreen product testing procedures for determination of the sun protection factor (SPF) value and related labeling claims.) The Panel recommends that for sunscreen products that satisfy these testing procedures the following labeling modifications replace the directions-for-use labeling indicated above:

(a) *For all (minimal, moderate, extra, maximal, and ultra) sunscreen products that satisfy the water resistant testing procedures.* "Apply liberally before sun exposure and reapply after 40 minutes in the water or after excessive sweating."

(b) *For all (minimal, moderate, extra, maximal, and ultra) sunscreen products that satisfy the waterproof testing procedures.* "Apply liberally before sun exposure and reapply after 80 minutes in the water or after excessive sweating."

(c) *For all (minimal, moderate, extra, maximal, and ultra) sunscreen products that satisfy the sweat resistance testing procedures.* "Apply liberally before sun exposure and reapply after 30 minutes of excessive sweating."

I. SUNSCREEN PRODUCTS CONTAINING DIHYDROXYACETONE

Dihyroxyactone (DHA) is an ingredient included in sunscreen preparations. Based upon the discussion below, the Panel concludes that DHA is a cosmetic in all cases except when used in sequential conjuction with lawsone.

DHA is also know as 1,3-dihydroxy-2-propanone. It is produced from glycerol by Aerobacter species under aerobic conditions. It is a fairly hygroscopic, crystalline powder having a characteristic odor and a sweet and cooling taste. DHA normally occurs as a dimer in which form it is slowly soluble in 1 part water and 15 parts alcohol. When freshly prepared, DHA reverts rapidly to a monomer in solution, in which form it is very soluble in water, alcohol, ether, and acetone. DHA is a three-carbon sugar and is an intermediate in the metabolism of carbohydrates in higher plants, animals, and man (refs. *1* and *2*).

DHA has a unique property of producing a reddish brown color when in direct contact with the keratin of the skin. The mechanism of action for producing this color is not completely understood, but most studies agree that DHA reacts with certain amino acids of the stratum corneum to form the color, the intensity of which is directly related to the skin's thickness (refs. *1*, *3*, and *4*). Because the epidermis containing keratin varies over different areas of the body, different degrees of coloration may result. Areas such as the palms of the hands, warts, and caloused skin react to a greater extent than surfaces where skin is thinner. Scar tissue does not react to the extent of normal skin and may show up as a light-colored contrast. The nails and hair of the body show less affinity for DHA and therefore do not react as readily to coloration. Repeated application will cause an increased progressive darkening, as also will an increase in concentration. Alcohols, change in pH, and surfactants may also increase the rate of reaction. It should be noted that human sweat also contains the amino acids necessary to promote coloration (refs. *1*, *3*, and *4*).

One manufacturer submitted data for a sunscreen product composed of two separate lotions containing DHA and lawsone, respectively. The lotions are to be applied to the skin only in the stated sequence. Labeling for the product includes claims such as "sunscreen lotion," "for protection of sunsensitive skin," and "water-resistant barrier to sun's ultraviolet rays." Therefore, the Panel addressed the product not as a cosmetic, but as a sunscreen. Safety and efficacy of DHA in conjunction with lawsone is discussed below. (See part III. paragraph

B.1.1. below—Lawsone with dihydroxyacetone.)

DHA has not been shown to be effective as a topical sunscreen when used alone. Current scientific evidence shows that DHA, except in conjunction with lawsone, has no appreciable sun-screening activity.

Shaffer et al., using 10 white male volunteers, tested the sunscreening properties of DHA. Each subject had three test areas, each measuring 1 inch by 1 inch, marked on the arm. One of the test areas contained aminobenzoic acid, the second area contained 2 percent DHA in isopropyl alcohol, and the third area was used as a control. The areas were subjected to a 4+ erythema dose of UV light with a fluorescent UV lamp. Observations from the test showed the aminobenzoic acid test area with no erythema; the control area developing a 4+ erythema; and the DHA area showing 6 subjects with 4+ erythema, 2 subjects with 3+ erythema, and 2 subjects with 2+ erythema (ref. *5*).

Studies performed by Fusaro et al. (ref. *6*) and Rice (ref. *4*) demonstrated that test sites treated with single active ingredient preparations of DHA or lawsone were essentially unprotected when compared with those sites treated with both ingredients either in a freshly prepared combination preparation or in separate vehicles.

Mumford (ref. *7*) states that DHA does not diminish the response to UV radiation. Comparative testing showed equal erythema when applied to painted and unpainted skin. Repeated application of DHA to recently excised human mammary skin did not appear to develop melanin type of pigment.

Maibach and Kligman tested sunscreening with 5 percent DHA. The backs of 10 white male subjects, half of the back of which were painted with 5 percent DHA, and the other half serving as a control, were subjected to UV radiation and observed for erythema. Results of this test procedure found that DHA neither increased nor decreased the erythema or tanning response to UV light (ref. *8*).

There were no product submissions made to the Panel using DHA as a single ingredient. However, sunscreen products containing DHA were submitted to the Panel for review in combination with the sunscreen ingredients homosalate and padimate A. These products are not for sequential use. The safety and effectiveness of the sunscreens homosalate and padimate A are reviewed separately below. (See part III. paragraphs B.l.k. and o. below—Homosalate; Padimate A). These submissions label DHA a cosmetic and do not make any claims showing that DHA will afford any additional sun-screening protection.

Studies were performed to determine the protective effectiveness of two sunscreen lotions, each containing 8 percent homosalate with and without 3.5 percent dihydroxyacetone, against erythema induced by UV light exposure on nontanned and dihydroxyacetone-tanned skin (ref. *9*). In the first study, a strip of skin on the lower abdomen of a subject was tanned by six applications of a dihydroxyacetone lotion over a 6-hour period. The next day a template was used to mark off eight comparable areas, four nontanned and four dihydroxyacetone-tanned. Within each set, two areas were used as controls, one area was covered with the homosalate/dihydroxyacetone lotion, and the remaining area was covered with the homosalate lotion. All areas were then exposed to 1 hour of late morning sunlight and were scored 24 and 48 hours afterwards on a scale from 0 (no erythema) to 4+ (deep red and painful blisters). The previously tanned control areas showed slight erythema (1+) at 24 hours and were lighter (0.5+) by 48 hours, whereas the nontanned control areas were scored 3+ (deep red with slight pain) at 24 and 48 hours. Those areas treated with the two sunscreens showed no erythema except for the nontanned areas treated with the homosalate lotion, which were scored 1+ (definite pink or light red) at 24 and 48 hours. Similar results were obtained in another study wherein the undersides of three subjects' forearms were prepared in the above-described manner and exposed to the light of a sunlamp at a distance of 12 inches. In a third study a strip across the back of each of 12 subjects (six male and six female) was tanned with two applications of a dihydroxyacetone preparation, one application in the forenoon and a second later in the afternoon. The next day, templates were used to mark off three 1 inch squares each of nontanned and tanned skin. Within each set, one area served as a control; one was treated with the homosalate/dihydroxyacetone lotion; and the remaining square was treated with the homosalate lotion. Owing to rain conditions, a sunlamp instead of natural sunlight was used as the light source, with the nontanned control areas being irradiated for 4 minutes while all other areas were irradiated for 8 minutes at a distance of 12 to 14 inches. All areas were scored 24 and 48 hours afterwards using the above-described scale. The pretanned control areas (1.67+ average) showed slightly less erythema than the nontanned control area (2+ average), even though the pretanned areas were irradiated twice as long. The protective action of pretanning with dihydroxyacetone was demonstrated by those areas treated with the two sunscreens. In this study, however, the homosalate lotion (average of 0.42+ and 0.96+ for pretanned and nontanned areas, respectively) provided slightly better protection than the homosalate/dihydroxyacetone lotion (average of 0.17+ and 0.62+ for pretanned and nontanned areas, respectively). This difference was explained by the variable thicknesses at which these sunscreen lotions were applied.

The Panel concludes that DHA alone is not a sunscreen, but a cosmetic. The Panel further concludes that DHA is a sunscreen when used sequentially with lawsone.

REFERENCES

(1) OTC Volume 060067.

(2) The Merk Index, 9th Ed., Merk and Co., Inc., Rahway, N.J., p. 598, 1976.

(3) OTC Volume 060066.

(4) OTC Volume 060069.

(5) Shaffer, B., M. M. Cahn and E. J. Levy, "The Use of Dihydroxyacetone for Skin Tanning," *Archives of Dermatology*, 83:437-438, 1961.

(6) Fusaro, R. M., W. J. Runge, F. W. Lynch, and C. J. Watson, "Sunlight Protection in Normal Skin," *Archives of Dermatology*, 93:106-111, 1966.

(7) Mumford, P. B., "Dihydroxyacetone," *British Journal or Dermatology*, 72:279-280, 1960.

(8) Maibach, H. I. and A. M. Kligman, "Dihydroxyacetone—A Suntan Stimulating Agent," *AMA Archives of Dermatology*, 82:505-507, 1960.

(9) Black, A. and R. A. Casini, "Ultraviolet Light Screening Effects of Homomenthyl Salicylate Lotions on Nontanned and DHA Tanned Skin," Draft of unpublished paper in OTC Volume 060067.

J. COMBINATIONS

1. *Combinations of sunscreen active ingredients.* The Panel has reviewed the submitted data and finds that a majority of marketed sunscreen products contain only one or two sunscreen active ingredients. Additional sunscreen active ingredients are included primarily to enhance the performance of the final product formulation. Because each final product formulation intended for OTC use is requred to comply with the testing procedure provided for in the OTC sunscreen monograph described below, the Panel has established no upper limit to the number of sunscreen active ingredients a product may contain. However, the Panel believes it is reasonable to require that additional sunscreen active ingredients must make a contribution to the designated indications for the product and not merely be included for marketing promotion purposes.

The Panel concludes that two or more sunscreen active ingredients may be combined provided that:

a. Each is present in sufficient quantity to act additively or by summation to produce the claimed therapeutic effect when the ingredients are within

the effective concentration range specified for each ingredient in the monograph.

b. The ingredients do not interact with each other and one or more do not reduce the effectiveness of the other or others, by precipitation, change in alkalinity or acidity, or in some other manner that reduces the claimed therapeutic effect.

c. The partition of the active ingredients between the skin and the vehicle in which thay are incorporated is not impeded and the therapeutic effectiveness of each remains as claimed or is not decreased.

2. *Combinations of sunscreen and nonsunscreen active ingredients.* The Panel also concludes that sunscreen active ingredients may be combined with other active ingredients, e.g., skin protectants, provided that the ingredients are generally recognized as safe and effective, i.e., Category I active ingredients.

III. Sunscreens

A. General Comment

A considerable number of OTC sunscreen preparations are now available to the American public for prevention of sunburn. As was mentioned above, other ingredients that are not sunscreens may be included in marketed products. These may also be active ingredients, but not sunscreens, or declared as inactive ingredients used as emollients or moisturizers. Regardless of composition, the final formulation for marketing should be evaluated by the procedures described below. (See part III. paragraph C. below—Data Required For Evaluation.) As background to a survey of the safety and efficacy of such preparations, it is necessary to understand certain aspects of the anatomy and physiology of the skin, as well as give some consideration to the penetration of materials into and through the skin barrier.

1. *The skin.* The anatomy and physiology of the skin was considered by the Panel using standard references and texts. Concerning certain features on which there was little objective data, the following decisions were made:

a. *Age.* The Panel accepted adult human skin to be older than 6 months of age. It is possible that geriatric skin requires special consideration, the parameters of which are poorly understood. Human skin, under the age of 6 months, may well have different absorptive characteristics. The Panel concludes that products providing a mainimal SPF value of 2 to under 4 should not be used on children under 2 years, and products providing a minimal SPF value of 4 should not be used on children under 6 months of age.

To provide an added margin of safety, the ingredients reviewed below are not to be used on children under the age of 6 months. This margin of safety is considered important because of the problems of medicating young children. Biologic systems which metabolize and excrete drugs absorbed through the skin may not be fully developed in children under the age of 6 months.

b. *Sex.* Although obvious differences are known between male and female skin, the Panel believes that these are not likely to affect the safety or efficiacy of the various ingredients considered as sunscreens.

2. *Skin penetration.* The Panel has recommended that sunscreens be discontinued if signs of irritation or rash appear. However, possible penetration of sunscreens through the intact skin was considered by the Panel.

Skin penetration is a complex process that is modified by numerous factors. Three portals of entry are possible through the human skin. They are the epidermal barrier, the hair follicles, and the sweat glands. For practical purposes, all absorption occurs through the epidermal barrier and sweat glands. The epidermal barrier consists of the stratum corneum, which is a keratophospholipid complex up to 1,500 microns thick. Absorption through these barriers depends primarily on the physicochemical structure of the drug and less so on the vehicle is which it is contained. However, the vehicle is important and will be considered later.

Three important conditions of the skin affect drug penetration. The conditions are physiological, physicochemical, and abnormal skin.

a. *Physiological conditions.* (1) Skin age which is discussed above.

(2) Blood flow within the skin may increase or decrease penetration, but this effect is questionable and may not directly affect absorption by the flow rate alone.

(3) Data on penetration based on skin site is conflicting and includes variations of absorption in the same site for reasons that are unclear. Studies in cadaver skin suggest that absorption is directly related to skin thickness and that it is greater in areas where large hair follicles are present.

Various skin sites have considerable difference in dermal thickness, in secondary skin appendages including the number of sweat glands and hair follicles, and in the physical location of the skin. For example, in areas well supplied with sweat glands in close apposition to other skin areas, such as the axilla (armpit) and the groin (crotch), medications applied may be more irritating than in other locations because of the presence of constant moisture and friction. Specialized sweat glands, as found in the ear canal, produce a waxy, protective secretion which may further limit the juxtaposition of medication to the skin surface; mucous membranes in close apposition to the skin as found in the mouth, the inner aspects of the labia, and the inside of the eyelids, commonly absorb medications many times more readily than does the skin.

(4) Human skin appears to be unique, and its characteristics and relation to drug absorption are not mimicked exactly by any other species.

b. *Physicochemical conditions.* (1) The skin can absorb considerable quantities of water. By hydrating the skin, absorption is facilitated. Complete occlusion by physical means can increase absorption 100-fold.

(2) The varying temperatures ranges obtainable in human environments greatly affect absorption.

(3) In general, increasing concentration leads to increased absorption of drugs applied to the skin. However, in almost every instance, a plateau effect occurs because there may be a reduced rate of absorption in high concentration due to the effects of the drug on the skin itself.

(4) The Panel accepts the Meyer-Overton theory that lipid-soluble substances diffuse through the lipid portion of the skin barrier and water soluble substances diffuse through the hydrated component of the proteins found within this barrier (ref. *1*). The partition coefficient is rate-limiting when related to the drug in its vehicle and the stratum corneum.

Substances soluble in both water and lipid readily penetrate the skin barrier.

(5) Generally, smaller molecules penetrate more rapidly than larger molecules; substances up to the size of 1,000 daltons are usually well absorbed, while larger ones have more difficulty. Polar groups show less absorption than nonpolar groups. Although molecular configuration unquestionably affects absorption, the mechanisms involved are not well understood.

(6) Vehicles are important in determining the state of the drug with respect to absorption and will be considered below.

The vehicles in which drugs are contained are secondary in importance to other conditions discussed, but they are important nonetheless. For example, a drug should not bind too strongly to any component of its vehicle so that its partition with respect to the skin barrier favors the vehicle. Low vehicular affinity is desirable.

Although the original charge to the Panel was to review only the active ingredients for safety and effectiveness, the Panel believes that the vehicle in which the ingredient or combination of ingredients resides may have con-

siderable effect on the effectiveness of the ingredient or ingredients involved.

The Panel stresses that continued contact of a film of the active ingredient is essential for efficacy in most cases. Therefore, the medium in which an active ingredient is incorporated must provide not only the necessary solubility and stability, but also maintain contact of the active ingredient with the skin. A medium must not retard the passage of the drug into the skin, thereby decreasing its bioavailability.

The rate of diffusion of a drug within its vehicle bears a direct relationship to its ability to penetrate the skin barrier, as does the rate of release of the drug from the vehicle. The vehicle may have an effect on the hydration of the stratum corneum. In general, vehicles which increase or maintain hydration promote drug absorption, but this is not universally true.

Surface-active agents (surfactants) within the vehicle may change the physical state of the water within the skin and thereby increase absorption of polar compounds. Cationic and nonionic groups are considerably less active than anionic groups. Most vehicles consist of emulsions in which there is at least one immiscible liquid within another consisting of a discontinous, internal, or dispersed phase and a continous, external, or nondispersed phase. At the interface, surface tensions are smaller than the largest value of any of the elements of an emulsion. Within an emulsion, there may be surface-active agents which are compounds strongly absorbed at surfaces which have polar and/or nonpolar groups.

Other ingredients combined with an active ingredient may also affect effectiveness by altering the pH of the medium in which the active ingredient is incorporated, thereby changing its ionization and lipophilic qualities. An active ingredient which is effective in the form of a free base may be less effective or ineffective as a salt.

Other semisolid dermatological vehicles, which may or may not be emulsions, are classified as follows: Ointments; cerates or pastes (stiffer than ointments); oleaginous or hydrocarbon vehicles (generally consisting of fatty acids which may become rancid); absorption bases which specifically absorb water; emulsion bases; vanishing creams which contain approximately 75 percent water; and completely water soluble agents such as low molecular weight carbowaxes or polyethylene glycol. Some of the latter, with molecular weights of 1,500 daltons or more, have approximately the same solid characteristics as petrolatum.

An ideal sunscreen vehicle would be stable, neutral, nongreasy, nondegreasing, nonirritant, nondehydrating, nondrying, odorless, efficient on all kinds of human skin, hold at least 50 percent water, be easily compounded of known chemicals, and have infinite stability during storage. There is no ideal vehicle. Vehicles in common use represent a compromise of advantages against disadvantages, many of which have been noted previously. It is difficult to predict with any degree of accuracy the influence of vehicular formulations on the percutaneous absorption of drugs. Many authorities believe that medicinals are absorbed more readily from animal or vegetable oils than from petrolatum bases.

Vehicles for topical delivery of active ingredients are complex mixtures of substances designed to impart a certain characteristic to the finished product. Although classified as inactive or inert ingredients, many vehicles are involved in physical and chemical interactions with the outer layer of human skin (the stratum corneum). The persistance, penetration, and resistance of the active ingredients to abrasion, sweating, and washing often depends upon the vehicle. Ingredients reviewed by this Panel were categorized on the basis of their currently employed topical vehicles.

The Panel strongly recommends that all inactive ingredients, including those in the vehicle, be listed with or without a statement of their quantity. The consumer, his/her physican, or his/her pharmacist may need to know all the ingredients in a product for a variety of reasons, including possible adverse responses on the part of the user.

Therapeutic claims cannot be made on the basis of inactive ingredients or vehicles alone. Because these substances are intended for topical application where cosmetic elegance and cosmetic acceptance are considerations for the consumer, a fair statement describing the vehicle formulation is reasonable, such as nongreasy, nonstaining, oily, greaseless, velvety, emoilient, moisturizer, nonsticky, etc.

c. *Abnormal skin.* Any skin abnormality tends to increase absorption of chemicals through it, but a few skin abnormalities decrease absorption.

The Panel recognizes that drugs effective on the mucous membrane may not be effective on the intact skin. In some cases, concentrations effective on mucous membranes may be inadequate on the skin. Therefore, trials of drug absorption on mucous membranes are not acceptable indications for use on intact or damaged skin.

3. *Determination of safety and effectiveness*—a. *Safety.* It was decided by the Panel that all materials applied to the human skin should also be tested for toxicity in test animals given the ingredient internally, by either the oral route or by injection. Such animal testing is necessary, whether or not substantivity or absorption has been shown, because individuals, especially children, may accidentally ingest or inhale the agents, or absorb them through the skin.

Clinical use and marketing experience were also used by the Panel in establishing the safety of sunscreen ingredients. The Panel accepted the data on "complaints per unit sold," submitted by the various companies, as one indicator of human safety for final preparations. However, anecdotal descriptions of toxicity were not seriously considered by the Panel unless they were supported by data that included the units of actual use.

When a drug is available for widespread use as in OTC sunscreen products, its safety must be well-documented by data on its toxicology, excretion, and pharmacologic action. The Panel evaluated the submitted toxicological data and classified the ingredients as described below.

A number of patch test methods are applicable to human safety testing of category III ingredients or final products. These tests have proven valuable in predicting skin irritancy and sensitization. The Panel recommends the following methods of patch testing:

(1) The Draize human skin irritancy and sensitization tests and the various modifications utilizing the subject's back or arm may be used (ref. *2*).

(2) The method of Shelanski and Shelanski (ref. *3*) is one in which the active ingredient or formulation is applied regularly to the test site for 3 to 4 weeks. Then, following a rest period of 2 weeks, a single challenge application of the drug or formulation is made (ref. *3*). The early applications are to detect primary skin irritants and initiate sensitization. The challenge dose is to detect skin sensitizers.

(3) The maximization procedure of Kligman or its modifications uses an irritant on the test site, thereby hastening and accentuating the skin sensitizing potential of a substance (ref. *4*).

b. *Effectiveness.* The effectiveness of all category I sunscreens has been demonstrated by appropriate studies. The UV absorbance of the individual sunscreen between 290 and 320 nm was established. In addition, in most instances data were available for human subjects treated either with artificial sunlight or with natural sunlight.

4. *Percutaneous absorption.* As noted above, certain ingredients are efficacious in relation to their percutaneous absorption which may also be related to toxicity. Therefore, the Panel considers certain in vitro studies to be applicable both for safety and efficacy. Penetration studies of drugs in

animals are, unfortunately, not directly applicable to man. Some drugs can be applied to large surface areas of the body, and drug penetration can be determined from blood level and excretion detection. Inferences of safety can then be made based on the drug levels obtained when related to toxicity studies. Methods to detect minute quantities of some substances are not available, and in general, no standard procedure to measure skin penetration in man exists. Animal studies should be performed as a preliminary to human in vivo testing.

5. *Photosensitization.* Photosensitization is a broad term used to describe a rare but abnormal or adverse cutaneous reaction to light energy including both the more common phototoxic and the uncommon photoallergic responses.

a. *Photoallergy.* Photoallergy (ref. 5) is an acquired altered photoreactivity dependent on an antigen-antibody or cell-mediated hypersensitivity state. The reactions may be produced by the sun alone or may depend on the presence of a photosensitizer. The clinical pattern may range from immediate urticarial lesions to delayed papular and eczematous lesions. The Panel knows of no universally acceptable test to detect potential photoallergy in man.

b. *Phototoxicity.* Many dermal preparations fluoresce under UV light stimulation, and the energy produced may cause lesions. This process is called phototoxicity. Tests for phototoxicity are extant in animals and man. Sunlight-induced injury of the skin is generally toxic and independent of allergic mechanisms. It can be likened to a primary irritant reaction. The responses are characterized clinically by erythema and edema which may occur within minutes after irradiation, but are usually delayed. The usual response appears as an exaggerated sunburn.

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B. CATEGORIZATION OF DATA

1. *Category I conditions under which sunscreen active ingredients are generally recognized as safe and effective, and are not misbranded.* The Panel recommends that the category I conditions be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

CATEGORY I ACTIVE INGREDIENTS

The Panel has classified the following sunscreen active ingredients as safe and effective and not misbranded:

Aminobenzoic acid
Cinoxate
Diethanolamine *p*-methoxycinnamate
Digalloyl trioleate
Dioxybenzone.
Ethyl 4-[bis(hydroxypropyl)] aminobenzoate
2-Ethylhexyl 2-cyano-3,3-diphenylacrylate
Ethylhexyl *p*-methoxycinnamate
2-Ethylhexyl salicylate
Glyceryl aminobenozate
Homosalate
Lawsone with dihydroxyacetone
Menthyl anthranilate
Oxybenzone
Padimate A
Padimate O
2-Phenylbenzimidazole-5-sulfonic acid
Red petrolatum
Sulisobenzone
Titanium dioxide
Triethanolamine salicylate

a. *Aminobenzoic acid.* The Panel concludes that aminobenzoic acid is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

There are three isomers of aminobenzoic acid—the ortho, meta, and para. The ortho and meta isomers have little, if any, use in human therapeutics. The Panel recognizes only the para isomer, para-aminobenzoic acid, in its deliberations. Aminobenzoic acid has been the official name for this compound since the publication of the National Formulary (NF XII) in 1965. Prior to that time the official name was PABA (*p*-aminobenzoic acid). This obsolete designation occasionally still appears in the published literature.

Aminobenzoic acid is an aromatic acid. It is widely distributed in plant and animal tissues besides being a structural component of the vitamin folic acid, a member of the vitamin B complex. Aminobenzoic acid consists of white to slightly yellowish crystals or crystalline powder. It discolors on exposure to air and light. One g dissolves in about 170 ml of water, in 8 ml of alcohol, and in 50 ml of ether. It melts at 188° C.

(1) *Safety.* Clinical use and marketing experience have confirmed that aminobenzoic acid is safe in the dosage range used as an OTC sunscreen.

Acute toxicity studies have been done in the mouse and rat with an alcoholic solution of aminobenzoic acid. The oral LD_{50} for the mouse and the rat were 17 g/kg and 6 g/kg, respectively (ref. *1*). The percutaneous (topical) LD_{50} was determined in mice by repeated applications of the alcoholic solution of aminobenzoic acid every 15 minutes to the shaved skin of the animals. The percutaneous LD_{50} was 180 g/kg. Death occurred within 24 to 48 hours and was preceded by ataxia and coma (ref. *1*). The toxicity was attributed to the alcohol in the aminobenzoic acid solution.

In monkeys, a commercial preparation of aminobenzoic acid applied directly to the eyes, produced reversible corneal opacity of short duration, minimal conjunctivitis, and moderate chemosis. At the end of the test on day 7, no toxic effects remained. In a second monkey study, a 5 percent aminobenzoic acid solution in alcohol was instilled in the eyes. Observations were made at 10 minutes, 1 hour, 24 hours, and 2, 3, 4 and 7 days posttreatment. Corneal haze, fluorescein staining, minimal conjuctivitis, minimal chemosis, and corneal epithelial haze were seen in some monkeys. The corneal damage was transient, with no permanent damage. The effects on the conjuctiva were minimal and cleared readily (ref. *1*). In a third eye irritation study in rhesus monkeys, it was concluded that an immediate precipitation of some component in the compound caused the corneal and epithelial damage, possibly the result of an additive effect of the test compound and the vehicle. The opacity that occurred could severely restrict vision in man, but this effect seems to be transient. Possible secondary damage could not be excluded (ref. *1*).

In an oral toxicity study, rats were fed 2 g/kg aminobenzoic acid daily for 1, 2, 3, or 6 months. No significant differences from controls were reported with respect to body weight, rate of growth, organ weights, or reproduction. Histological changes were only seen in the thyroids of the treated rats (ref. *2*).

Prior to the broad spectrum antibiotics, aminobenzoic acid was used to treat rickettsial diseases and typhus. Later it was used in treating diseases such as scleroderma and chronic fibrotic disease as an antifibrotic agent.

Aminobenzoic acid has the ability to cross-sensitize to a limited number of structurally similar analogs. Aminobenzoic acid belongs to a group of aromatic amines and nitro compounds capable of cross-reaction with each other because of similar chemical configuratons. The cross-reacting is dependent on previous sensitization to the other related chemical compounds which include sulfonamides, aniline dyes, paraphenylenediamine, "caine" anesthetics, and others. Theoretically, an individual with contact allergic hypersen-

sitivity to any one of these chemicals might develop an allergic dermatitis upon exposure to aminobenzoic acid. Despite this potential for phototoxicity, contact sensitization and allergic reaction, "a review of the literature to date reveals no case reports of phototoxicity and extremely few case reports of questionable photocontact allergy and contact allergy to aminobenzoic acid and its esters" (ref. *3*). Willis has concluded "that PABA possesses only the weakest potential for sensitization. It is indeed fortunate that we have such a highly effective sunscreening agent which appears not to cause any serious side effects in the majority of users."

In a study with 46 individuals hypersensitive to para-phenylenediamine with which aminobenzoic acid reacts, only 3 individuals cross-reacted following the application of 5 percent aminobenzoic acid (ref. *4*). Although aminobenzoic acid has been determined to be the allergen in some cases of photosensitivity, Kligman (ref. *5*) in a study with 25 subjects reported no sensitization in maximization tests using 20 percent aminobenzoic acid. He observed no sun sensitization over several years of testing.

Ten percent concentration of aminobenzoic acid produced no reactions of a phototoxic nature when occlusive applications were made to cellophane tape-stripped sites of 10 subjects who were irradiated with the photoactivating range of the ultraviolet spectrum. No inflammatory reactions greater than the unirradiated control were induced. Ten percent concentrations in petrolatum also showed no significant potential for inducing photocontact allergy (ref. *6*).

Kilgman (ref. 5) has stated that:

> * * * field experience has documented the claim that 5 percent hydroalcoholic solutions of aminobenzoic acid are substantially superior to any other marketed sunscreen. Evidence is accumulating that such solutions are beneficial in other light-sensitive dermatoses * * *. Though we must now concede that an occasional subject will become sensitized, it is our opinion that the merit of the product outweighs this risk.
>
> The prevention of acute sunburn is perhaps the least important of the benefits provided. Our major interest in developing superior sunscreens has been to prevent the aging changes that underlie cancers and precanceroses in sunlight-sensitive subjects. In this context, we would prefer to have such products regarded as drugs rather than cosmetics. Their important role is to prevent disease and not simply to please.

As a general rule, low molecular weight substances with both lipid and water solubility are most likely to penetrate the horny layer. Aminobenzoic acid is none of these agents. Aminobenzoic acid permeability is about that of water which penetrates the horny layer well. Even for these low molecular weight substances, diffusion does not reach a steady state until 1 to 2 hours after application. Aminobenzoic acid diffuses into the horny layer as a reservoir type of sunscreen. A reservoir type of sunscreen is strongly resistant to sweating and partially resistant to immersion (ref. *6*).

No systemic or dutaneous side effects were noted in the course of an investigation in which 30 ml of a 5 percent alcohol solution of aminobenzoic acid was applied once daily to the face, neck, truck, and upper extremities of 10 healthy adult men for 30 days. No changes occurred in blood cell count, urinalysis, blood protein level, albuminglobulin ratio, blood urea nitrogen, fasting blood glucose, serum glutamic oxaloacetic transaminase and serum creatinine levels.

Ninety ml of aminobenzoic acid lotion were applied to the entire body 3 times at 30 minute intervals in 4 subjects. Blood alcohol levels were determined at 15, 30, 60, 240 minutes and pretreatment controls. All failed to show any detectable amount of alcohol.

Five subjects tested with 5 percent aminobenzoic acid lotion for 21 days failed to show any significant irritation of this particular preparation (ref. *1*).

Aminobenzoic acid has been used on thousands of patients with only a rare individual intolerance. The incidence of adverse reaction is low indeed. Aminobenzoic acid has also been used as a systemic and antifibrotic agen.

The Panel concludes that extensive animal and human toxicological and pharmacological data attest to the safety of aminobenzoic acid as a sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of aminobenzoic acid as an OTC sunscreen.

The effectiveness of aminobenzoic acid as a sunscreen agent is demonstrated by its in vitro UV light absorption characteristics. Qualitative spectrographic methods have demonstrated that aminobenzoic acid totally absorbs radiation between the wavelengths of 260 nm and 313 nm of the mercury spectrum, with a maximum absorption at 288.5 nm (ref. *7*). The curve is broad and such that at the wavelengths effective for erythema, the absorption spectrum is enormous and completely encloses the sunburn action spectrum. In vitro study recognizes aminobenzoic acid as a potential protective against sunburn. It has a cutoff point at 313 nm which allows UV rays with beneficial biologic effects to be transmitte (ref. *8*). Its in vivo efficacy can be affected by variables in formulation and the effects of physiological conditions, such as perspiration and sebum on the skin. The solvent in which the sunscreen is applied also influences effectiveness through dielectric effects, solvent-solute interaction, variations in pH and solvent concentration (ref. *1*). Aminobenzoic acid does not penetrate the human skin in any detectable level. One g of aminobenzoic acid dissolves in 170 ml water and in 8 ml ethanol aminobenzoic acid is currently marketed as a hydroalcoholic solution and foam. It has been employed in 5 to 15 percent concentrations in creams and ointments.

Aminobenzoic acid has been used successfully as an effective sunscreen up to approximately 315 nm and affords protection for the short UV sunburn wavelength range of 290 to 320 nm.

For over 40 years, aminobenzoic acid has been known to be an effective sunscreen. Recent studies show it to be superior to many of the popular sunscreens marketed today for preventing sunburn.

The efficacy of aminobenzoic acid is due to diffusion into the horny layer of skin and acting as a reservoir type of sunscreen. The agent is more efficient when applied 2 hours before sun exposure, to allow for maximal diffusion. This feature results in longer protection and there is continuing sunscreen effectiveness after sweating and to a lesser extent after immersion.

The sunscreening efficacy of aminobenzoic acid in ethanol has been studied in experimental animals following exposure to artifical light sources. (ref. *1*). The results demonstrated that aminobenzoic acid protected the animals against 40 to 50 minimal erythermal doses (MED) in one study and against 30 to 38 MED's in another study. In studies done under simulated swimming and sweating conditions, the protection of aminobenzoic acid as a sunscreen was diminished, but still remained (ref. *1*). Cellophane stripping of the stratum of the skin in hairless dogs showed that aminobenzoic acid does substantially penetrate the horny layer (ref. *9*).

In albino mice, 5 percent aminobenzoic acid applied daily to the ears followed by 20-minute exposure to UV irradiation, over a period of 5 months, indicated that the carcinogenic and erythematous effects of UV light can be reduced by the topical application of aminobenzoic acid. The authors concluded that aminobenzoic acid is a highly effective sunscreen that is capable of providing adequate protection against the damaging effects of sunlight in man (ref. *10*).

In a study comparing an aminobenzoic acid lotion (5 percent aminobenzoic acid in alcohol) and an aminobenzoic acid foam (5 percent in alcohol) in rabbits, the foam preparation was 5 times more effective as a UV blocking agent than the lotion. The lotion had a protective efficacy of 7.9; the foam

38.19. After elution, the lotion had a protective efficiacy of 2.91; the foam 2.96. Apparently the primary blocking was enhanced by the vehicle. (The protective efficacy represents the number of MED's against which the sunscreeen will protect (ref. *11*).)

The sunscreening effectiveness of a 5 percent hydroalcoholic solution of aminobenzoic acid was demonstrated by Pathak, Fitzpatrick, and Frank (ref. *12*) and later confirmed by other investigators. Its effectiveness is such that it is the recognized comparison standard for sun-screening efficacy.

Pathak et al. (ref. *12*) compared the efficacy of 5 percent aminobenzoic acid in 70 to 95 percent ethyl alchohol with 24 commercially available sunscreen preparations and various chemical agents in a 3-year study (1965–1968). The effectiveness of a single application of the 5 percent solution of aminobenzoic acid was greater than that of the other UV-absorbing compounds and brand name preparations tested. It afforded very significant (p is less than 0.05) and effective protection. In vitro tests demonstrated that the prolonged effectiveness of aminobenzoic acid results from adsorption of aminobenzoic acid by the intact epidermis and partial chemical conjugation of aminobenzoic acid with constituents of the horny layer. An alcoholic solution of aminobenzoic acid at pH 4.5 to 4.8 was found to be substantive to the horny layer even after repeated washings with water. In Arizona, where the study was conducted, a single application of aminobenzoic acid provided total, day-long protection for subjects who were not swimming or engaged in activity. During periods of sweat-producing exercise, aminobenzoic acid gave 100 percent protection from erythemogenic solar radiation for 2 hours and over 75 percent protection thereafter. These investigators estimated the amount of protection mainly by visually rating the degrees of redness.

In contrast to the findings by Pathak et al., Willis and Kligman (ref. *6*) reported that after immersion, they found aminobenzoic acid less effective than did the former authors. Willis and Kligman estimated the amount of protection by use of the individually determined MED, which they defined as the least amount of radiation that will just produce a uniform redness with sharp borders. They stated that "Claims of effectiveness after swimming must be strongly qualified."

Amounts of 0.12 ml and 0.3 ml of 5 percent aminobenzoic acid in 70 percent ethanol were applied on the backs of 13 normal subjects over a fixed area of the skin. The area was irradiated at 305 nm with a 1,600 watt xenon arc. The efficacy of aminobenzoic acid was higher than other sunscreens tested and was maintained for 7 hours following applications (ref. *13*). The protective action was reduced upon induced sweating and fell to zero following showering.

A 5 percent solution of aminobenzoic acid in 55 percent alcohol with emollients was evaluated with the xenon arc lamp in 8 subjects. The protection was enhanced by applying greater amounts of solution. An application of 60 $\mu l/cm^2$ afforded protection against 25 to 30 MED's. Protection following immersion was reported to be greatest when 2 hours elapsed following application. Three applications at 2-hour intervals was superior to one (ref. *14*). Aminobenzoic acid was found to be more effective than three brand name sunscreen products.

In a study by Rossman, Knox and Freeman (ref. *15*), aminobenzoic acid was reported to be more effective as a sunscreen than over 100 other sunscreen formulations tested. Ten percent aminobenzoic acid in a vanishing cream base was effective in excess of 12 minutes in 17 patients irradiated with the Hanovia hot quartz mercury vapor lamp, and extended from 20 to 60 minutes in 13 additional patients as compared with an approximate minimal erythemal dose of 15 seconds on unprotected skin.

Rothman and Henningsen (ref *16*) studied the effectiveness of 15 percent aminobenzoic acid in Ruggles' cream in a film thickness of 0.03 mm. They found that these conditions increased the amount of irradiation from a mercury vapor lamp necessary to produce threshold erythema 50 to 100 times the amount of irradiation producing the same effect when the vehicle alone is used in the same film thickness. In the same study, these authors found that in 32 subjects highly sensitive to the erythemal action of UV light, an 0.08 mm aminobenzoic acid film provided complete protection to natural sunlight exposure. The experimental data suggest that the sunburn-protecting action of aminobenzoic acid is intense enough to protect the skin againt sunburn in case of extremely strong UV irradiation such as found on glaciers or on the ocean.

Five subjects received 12 g aminobenzoic acid daily in divided doses for 10 days. The immediate protective index was determined before dosing and again on the last day. The protective index was not increased after oral administration of aminobenzoic acid.

Aminobenzoic acid has been found to be an effective sunscreen in concentrations from 2 percent. Effectiveness increases linearly up to 2.5 percent with a clear-cut tendency to plateau at 5 percent. Doubling the concentration does not afford twice the protection. It was found that for equal amounts of aminobenzoic acid, the protection was the same whether this was achieved by a single or multiple applications. In a formulation, erythemal protection has been found to be maximal in vehicles containing between 50 percent and 60 percent alcohol. However, in some studies, concentrations of 10 percent and 15 percent aminobenzoic acid have been reported to be effective as sunscreen agents in a cream base.

The Panel concludes that aminobenzoic acid is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 5 to 15 percent aminobenzoic acid: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 5 to 15 percent aminobenzoic acid: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

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b. *Cinoxate.* The Panel concludes that cinoxate is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

Cinoxate is also known as 2-ethoxyethyl-*p*-methoxycinnamate. Cinoxate is a practically odorless, slightly yellow, viscous fluid, with a specific gravity of 1.000. It is stable to sunlight for 30 days. The empirical formula is $C_{14}H_{18}O_4$, with a molecular weight of 250.29. The UV absorption at 1 percent concentration is 270 to 328 nm, being total from 280 to 320 nm with a maximum at 310 nm. Cinoxate is miscible in 95 percent ethanol, 99 percent propylene glycol monomuristate, isopropyl myristate, oleyl alcohol and soya vegetable oil. It is slightly soluble in water (0.05 percent), 0.5 percent in glycerol, and 3 percent in mineral oil (ref. *1*). Cinoxate can be formulated as an aerosol, oil, hydroalcoholic lotion, and as an emulsified lotion and cream.

(1) *Safety.* Clinical use and marketing experience have confirmed that cinoxate is safe in the dosage range used as an OTC sunscreen.

Cinoxate has low toxicity on animal testing. Human toxicology tests, clinical trials and wide use attest to its safety for human use.

Acute toxicity studies have been done in rats with full strength cinoxate. The oral LD_{50} for the rat was 3.8 ml/kg (ref. *2*). In a single dose acute oral toxicity study of 2 percent cinoxate in a lotion, a single dose level of 5 g/kg administered to 10 rats caused no fatalities during the 14-day observation period or gross organ abnormalities at autopsy (ref. *3*). The Draize rabbit eye irritancy test revealed no irritation when 3 percent cinoxate in equal parts of mineral oil and corn oil was instilled into the rabbits' eyes (ref. *4*).

The repeated insult patch method of Shelanski and Shelanski in 50 subjects revealed that 2 percent cinoxate in an oil and lotion formulation was not a primary irritant, fatiguing agent, or sensitizer. In this test, the active ingredient and the vehicles were applied on 15 separate occasions under an occlusive patch (ref. *5*).

After applying 2 percent cinoxate in a cream base to both arms of six volunteers, 96 percent of the cinoxate was recovered after 4 hours contact with the skin. A photoreactivity test at 1, 25, and 60 MED in 26 subjects with 4 mg cinoxate/cm^2 applied to the back revealed no photoxicity (ref. *6*). One documented case of photodermatitis to cinoxate has been reported (ref. *7*).

Cinoxate is used as a sunscreen in several commercial preparations. One manufacturer reported receiving no complaints per 400,000 units of a 2 percent cinoxate sunscreen lotion sold, and 8 minor complaints and one allergic contact dermatitis per 2,100,000 units of a 1.7 percent cinoxate solution sold, with a ratio of complaints per 100,000 units sold of 0.41 (refs. *8* and *9*).

The Panel concludes that the animal and human toxicological data and the widespread use of cinoxate since its introduction in the late 1950's with few adverse reports attest to the safety of cinoxate as a sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of cinoxate as an OTC sunscreen.

The UV absorbance of cinoxate at 1 percent concentration in isopropyl myristate is less than 10 percent at 270 and 338 nm, but total between 280 to 320 nm with the maximum at 310 nm. Two percent cinoxate in seven experimental vehicles was applied to the backs of seven volunteers and the treated sites were exposed to 7 MED's from fluorescent sunlamps. On a scale of 0 (best score) to 6 (worst score), protection varied according to the formula, with the highest erythema index being 2.25 and the lowest 0.5 (ref. *8*).

A 2 percent cinoxate lotion was compared with a 1.75 percent cinoxate solution in a controlled study in 10 subjects at a medical school. After exposing the treated sites to fluorescent sunlamps, the lotion afforded 5.1 times greater MED protection than the vehicle, while the solution afforded 3.3 time greater MED protection than its vehicle (ref. *10*).

Two dermatologists independently evaluated a 2 percent cinoxate lotion in 48 patients (27 with photosensitivity) during the summer. There were 33 females and 15 males, with a mean age of 23 (range 3 to 52 years of age). Results of use were rated by the investigators as 31 (of 48) excellent, 12 good, and 5 fair. Thirty-four of 41 patients rated suntanning as good to excellent (ref. *11*). Of 150 patients evaluated clinically by six physicians in a company-sponsored, uncontrolled clinical trial, after using the 1.75 percent cinoxate solution for 10 days to over 1 year, results were rated as 111 (of 150) excellent, 35 good, 1 fair, 1 poor, and 2 not rated (ref. *9*). In an independent clinical trial done overseas, 85 of 86 patients reported adequate protection from sunlight and no important adverse effects (ref. *12*).

Based upon the available data, the Panel concludes that cinoxate is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products containing a minimum SPF value of 2 to under 4 containing 1 to 3 percent cinoxate: Adult and children over 2 years of age topical dosage is liveral application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 1 to 3 percent cinoxate: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

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c. *Diethanolamine p-methoxycinnamate.* The Panel concludes that diethanolamine *p*-methoxycinnamate is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

Diethanolamine *p*-methoxycinnamate is also known as *p*-methoxycinnamic acid diethanolamine salt.

Diethanolamine *p*-methoxycinnamate is a pale tan microcrystalline powder which is readily water soluble. Its molecular weight is 283.33 and its fusion point at 87.0° C minimum. It is stable to light and moderate heat and is not hygroscopic. It is suitable for use in aqueous or alcohol/water formulations, gels, and emulsions (ref. *1*).

(1) *Safety.* Clinical use and marketing experience have confirmed that diethanolamine *p*-methoxycinnamate is safe in the dosage range used as an OTC sunscreen.

Animal and human toxicological data attest to its safety for human topical application. The oral LD_{50} is greater than 5 g/kg in male rats and 3.7 g/kg for female rats (ref. *2*).

Application of a 2.0 percent diethanolamine *p*-methoxycinnamate solution on guinea pig epidermis was found to be nonirritating following a single application, and after repeated applications for 21 consecutive days. Repeated applications of 6 and 20 percent solutions on 21 consecutive days produced very light medicament carrier irritation. Sensitization tests on guinea pigs treated for 3 weeks with 2, 6, and 20 percent concentrations determined that allergic sensitization did not occur. Draize tests measuring the irritation of the rabbit's eye revealed that a 1 percent perfumed solution of the ingredient can be tolerated without reaction following a single and repeated (7 days) applications, whereas 3 and 10 percent concentrations produced weak irritation of the conjunctiva (ref. *2*). A commercial sunscreen lotion containing 10 percent diethanolamine *p*-methoxycinnamate applied twice to rabbits' eyes caused a reddening of the margin of the eyelid and the conjunctiva for the duration of 4 hours, after which any irritation effect disappeared (ref. *2*).

A Draize repeated insult patch test on 53 (42 female and 11 male) subjects was performed to evaluate the irritative and sensitizing potentialities of a 2 percent diethanolamine *p*-methoxycinnamate solution. Each patch contained 0.5 ml of the test material and was secured to the test site by overlying strips of occlusive adhesive tape. The patches were alternately placed on the medial surface of the right and left deltoid area. Because of the two holidays and a weekend which occurred during the study, the period of contact and rest period could not consistently be 48 hours and 3 of the 10 applications were 1, 3, and 4 days. Readings were recorded each time the patches were removed. After a 2-week rest period, challenge patches were applied to both inner deltoid areas and were removed 2 days later, with readings being recorded immediately and 24 hours afterwards. No reactions were observed during any of the above readings following the removal of either the sensitization or challenge patches. It was concluded that the test material did not manifest either primary irritation or sensitizing effects (ref. *3*).

Another Draize repeated insult patch test on 54 subjects (17 males and 37 females) was conducted in the same manner as the above test except that a 7.5 percent diethanolamine *p*-methoxycinnamate in water solution was employed, and the patches were removed every 48 hours, except for three 72-hour weekend periods and a 24-hour period at the outset, to observe whether the full group presented any irritative or sensitization reactions before proceeding further with the test. Except for 16 patients who experienced reactions to the adhesive tape used to secure the patches, no reactions to the test material were noted following the removal of the sensitization and challenge patches, thereby leading to the conclusion that the test material was neither a primary irritant nor an allergic sensitizing agent (ref. *4*).

Based upon the available data, the Panel concludes that diethanolamine *p*-methoxycinnamate is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of diethanolamine *p*-methoxycinnamate as an OTC sunscreen.

Its absorbance is between 280 and 310 nm, with the maximum absorbance at 290 nm. Readily water soluble, it is practically insoluble in nonpolar organic solvents, oil, and fatty materials. It can be incorporated into gel, lipstick emulsion, and aqueous formulations (ref. *5*).

In several studies by Pathak, Fitzpatrick and Parrish (ref. *1*), the same formulation containing diethanolamine *p*-methoxycinnamate gave the following results:

Using a hot quartz mercury arc lamp on 12 subjects and comparing 8 different sunscreen formulations against 5 percent animobenzoic acid in ethanol, diethanolamine *p*-methoxycinnamate was shown to have a protective index range of 4 to 15, with a mean minimum of 7.37 and a mean maximum of 10.3 (8 or more is 100 percent protection). All products were found to give significant protection against erythemogenic radiation.

Eight subjects were used under conditions of passive sunbathing to test four formulations. It was found that all were superior to a commercial preparation containing 5 percent aminobenzoic acid. Eleven subjects, also under conditions of passive sunbathing, were used in testing 12 products. The mean indices for the product containing diethanolamine *p*-methoxycinnamate were 1.5 after 30 minutes of exposure, 3.0 after 60 minutes and 4.2 and 4.6, respectively, after 90 and 120 minutes.

In a forth study using the same formulation the product had a mean protective index of 4.6.

Based upon the available data, the Panel concludes that diethanolamine *p*-methoxycinnamate is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) for products providing a minimum SPF value of 2 to under 4 containing 8 to 10 percent diethanolamine *p*-methoxycinnamate: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 8 to 10 percent diethanolamine *p*-methoxycinnamate: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

REFERENCES

(1) OTC Volume 060083.

(2) "Animal Safety Data," Draft of unpublished paper in OTC Volume 060083.

(3) "Human Safety Data," Draft of unpublished paper in OTC Volume 060083.

(4) OTC Volume 060110.

(5) "Efficacy Data," Draft of unpublished paper in OTC Volume 060083.

d. *Digalloyl trioleate.* The Panel concludes that digalloyl trioleate is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

Digalloyl trioleate is a mixture of several derivatives of tannic acid. It is the triester produced by the reaction of digallic acid and oleic acid and conforms generally to the formula $C_{68}H_{106}O_{12}$. It is a clear, viscous, brown liquid with a slight smell. It is insoluble in water but soluble in vegetable oils, 95 percent alcohol, and mineral oil to which has been added 10 to 15 percent vegetable oils. It is incompatible with alkalies, tannic acid, and triethanolamine. The specific gravity is 1.040 to 1.045, and the refractive index is 1.515 to 1.525 (ref. *1*). Digal-

loyl trioleate can be formulated as an oil, emulsified lotion or cream, ointment, alcoholic solution, and lipstick.

(1) *Safety.* Clinical use and marketing experience have confirmed that digalloyl trioleate is safe in the dosage range used as an OTC sunscreen.

Extensive animal and human toxicological testing attests to its safety for topical application.

Acute toxicity studies have been done in mice and rats with digalloyl trioleate. The oral LD_{50} for both mice and rats was 24.5 g/kg (ref. *1*). In a chronic topical application study, eight groups of three rabbits per group had digalloyl trioleate applied as follows: 0.5 ml/kg of bodyweight neat (straight chemical as applied) for 90 days; 4.0 ml/kg of bodyweight neat for 31 days; in lotion 4.0 ml/kg of bodyweight for 90 days and one group with 2 hours of sunlight exposure daily; in ointment 4.0 ml/kg of bodyweight for 93 days plus one group with sunlight exposure; and in cetyl alcohol-ethanol vehicle 4.0 ml/kg of bodyweight for 93 days; and two groups of vehicles applied alone. No dermal toxicity not effect upon the hemogram occurred. The 4.0 ml/kg dose produced some erythema; and due to its physical nature, some matting of the fur which, when removed, resulted in some depilation. No visible toxicity resulted, and the fur regrew normally. The 0.5 ml/kg application caused some erythema, but no toxicity. The vehicle containing a cetyl alcohol-ethanol combination also caused erythema. All animals remained in good condition, gained weight, and showed no gross pathology on autopsy (ref. *1*). Three almost-albino shoats had a weighed amount of 2.5 percent digalloyl trioleate in a lotion, ointment, and cetyl alcohol-ethanol vehicle applied daily to the back, shoulder, and neck for 82 applications. Three swine and a control boar received 2 hours of sunlight daily. After 93 days, all animals were in good condition, gained weight, showed no severe skin irritation or toxicity, and demonstrated no gross or histological pathology of the skin or visceral organs at autopsy. The cetyl alcohol-ethanol treated animal showed some visible irritation (ref. *1*). A modified Landsteiner technique for skin sensitization was negative in 10 guinea pigs injected intracutaneously with 0.1 ml of 0.1 percent digalloyl trioleate in cottonseed oil on alternate days for 10 injections and a final injection 10 days later (ref. *1*).

An independent study in 200 subjects revealed no primary irritation, while one subject developed a sensitivity reaction to digalloyl trioleate. The closed-patch test consisted of applying a 1-cm blotting paper disc saturated with digalloyl trioleate under a patch for 48 hours on days 1 and 7, and reading the results on days 3, 9, and 11 (ref. *1*). A repeated-insult irritation study in 10 white men revealed no irritation or toxicity to a product containing 3.5 percent digalloyl trioleate as the sole active ingredient. One subject developed some erythema on the 9th day (ref. *2*).

The medical literature contains one verified case report of contact photoallergy (ref. *3*). This case has been mentioned directly or indirectly in 16 other publications (ref. *4*). Another reported case of possible contact photoallergy to digalloyl trioleate in a 5-year-old boy with solar dermatitis had no documentation (ref. *5*).

From 1952 through 1972, nearly 4,000,000 units of a sun-protective lipstick product containing 2.5 percent digalloyl trioleate were distributed. Only one complaint of "irritation" had been received by the company from all sources (ref. *6*). During a 20-year period, almost 2,000,000 units of a sunscreen lotion containing 3.5 percent digalloyl trioleate were distributed. The company received a total of six complaints from consumers, yielding a rate of 0.3 per 100,000 units distributed. Of the six complaints, four were concerned with irritation or sensitization. Only one of the four complaints seemed to be a legitimate contact photosensitization, though this was not proven. One person developed redness, but was also "allergic to weeds," while two reported a "reaction." Correspondence with these complainants requesting more details went unanswered (ref. *4*). The Panel received no submissions from other companies who use digalloyl trioleate in their products.

The Panel concludes that the animal and human toxicological data and the extensive use of the substance with few reported complaints attests to the safety of digalloyl trioleate as a sunscreen agent for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of digalloyl trioleate as an OTC sunscreen.

A 1 percent digalloyl trioleate concentration in ethanol absorbs UV light from 270 to 320 nm, with the maximum at 300nm. It has been in use since the early 1930's. No complete data on controlled clinical trials in man were submitted. The United States Army tested and selected 3 percent digalloyl trioleate as one of the four "approved" sunscreens for acquisition under Military Specifications Sunburn Preventative Preparation Cream Base MIL-S-11262 (Quartermaster Corps) July 10, 1951, and MIL-S-11262A March 10, 1953 (refs. *7* and *8*). The efficacy data were not available to the Panel. Abbreviated results were given of a sunscreen test on the backs of men and women employing 2.5 percent digalloyl trioleate in a lotion and a cetyl alcohol-ethanol vehicle on two treated sites with each site compared to an untreated site. Both preparations offered adequate screening against 5 minutes' irradiation at a distance of 40 inches from a quartz mercury arc sunlamp. The vehicles afforded no protection. Tanning was attractive. Unfortunately, the number of subjects was not given (ref. *1*).

A product containing 3.5 percent digalloyl trioleate in a vanishing cream base had 34 unsolicited mentions in the literature from 25 authors concerning its effectiveness as a sunscreen by 1973 (ref. *4*). For example, it was cited as an effective sunscreen for managing photosensitivity dermatitis (ref. *9*), discoid lupus erythematosus (ref. *10*), hydroa aestivale in children (ref. *11*), and for protection from sunlight (ref. *12*). In vivo, it protected better than glyceryl *p*-aminobenzoate and red petrolatum, but it did not protect as well as several other sunscreens (ref. *13*).

Digalloyl trioleate has been used over 40 years by patients and consumers and has been considered an effective sunscreen by authorities. Based on the available data, the Panel concludes that digalloyl trioleate is an effective sunscreen for OTC use in the dosage range specified below.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 2 to 5 percent digalloyl trioleate: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 2 to 5 percent digalloyl trioleate: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

REFERENCES

(1) Hazelton, J. and E. P. Marsh, "Physical, Pharmacological and Dermatological Studies on a Sunscreen," *Proceedings of the Scientific Section, Toilet Goods Association*, 13:1-8, 1950.

(2) "Human Safety Data," Draft of unpublished paper in OTC Volume 060044.

(3) Sams, W. M., "Contact Photodermatitis," *Archives of Dermatology*, 73:142-148, 1956.

(4) OTC Volume 060044.

(5) Kern, A. B., "Solar Dermatitis in a Child," *Archives of Dermatology*, 73:92-93, 1956.
(6) OTC Volume 060004.
(7) Wells, F. V. and I. I. Lubowe, "Cosmetics and the Skin," Rheinhold Publishers, New York, p. 383, 1964.
(8) "Military Specifications; Sunburn-Preventive-Preparation, Cream Paste," Draft of unpublished paper in OTC Volume 060065.
(9) Fisher, A. A., "Dermatitis Medi-camentosa," *in* "Current Therapy," W. B. Saunders and Co., Philadelphia, p. 464, 1962.
(10) Haserick, J. R., "Lupus Erythematosus, *in* "Current Therapy," W. B. Saunders and Co., Philadelphia, p. 445, 1963.
(11) Perlman, H. H., "Hydroa Aestivale," *in* "Current Pediatric Therapy," 5th Ed., Edited by S. S. Gellis and B. M. Kagan, W. B. Saunders and Co., Philadelphia, 1971.
(12) Perry, H. O., "Discoid Lupus Erythematosus and Photosensitive Eruptions," *Modern Treatment*, pp. 909-915, Sept., 1965.
(13) Kahn, G. and G. Wilcox, "Comparison of In-vitro and In-vivo Sunscreen Testing Methods," *Journal of the Society of Cosmetic Chemists*, 20:807-824, 1968.

e. *Dioxybenzone.* The Panel concludes that dioxybenzone is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

Dioxybenzone is also know as 2,2'-dihydroxy-4-methoxybenzophenone. It is an organic benzophenone derivative designated as benzophenone-8 and exhibits a wider UV absorbance range than does padimate.

(1) *Safety.* Clinical use and marketing experience have confirmed that dioxybenzone is safe in the dosage range used as an OTC topical sunscreen.

Animal and human safety data have been obtained from studies evaluating a sunscreen lotion containing dioxybenzone in combination with another sunscreen agent, padimate A. On the basis of five animal toxicity studies the investigators concluded that: "Neither erythema nor edema was produced in any animal following the challenge dose" and "these results suggest that the sunscreen lotion formulation should not cause either skin sensitization or allergic contact dermatitis in man"; "these findings suggest that this sunscreen formulation should be safe for repeated dermal use in man"; the acute oral toxicity was determined to be 17.5 ml/kg for the rat and 14.7 ml/kg for the rabbit suggesting that accidental ingestion "should present little risk of serious toxicity in man"; and the likelihood of serious ocular damage following accidental ocular instillation would appear to be low but such contact may cause "slight to moderate redness of the conjunctivae" (ref. *1*).

Patch test involving 100 white females were performed to determine whether the ingredients contained in the combination product were capable of producing an immediate or primary irritation of the skin. It was reported that "there was no evidence of any inflammatory reaction on the site of application immediately, 15 minutes, and 24 hours after removal of the 48-hour patch test." From the above-described data it was concluded that the combination product is not a primary irritant (ref. *1*).

Based on the available data, the Panel concludes that dioxybenzone is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of dioxybenzone as an OTC sunscreen.

Human efficacy data were obtained from three clinical studies comparing the effectiveness of a combination product (3 percent dioxybenzone and 2.5 percent padimate A) with one to three other marketed sunscreen preparations (ref. *1*). One product contained 5 percent *p*-aminobenzoate; another contained a 5 percent combination of padimate A and monoglycerol *p*-aminobenzoate; and the third contained 2.55 percent padimate A.

The reference contained the conclusions that:

(i) "It is felt that the total effect of these two sunblocking agents will provide greater effective absorption of ultra-violet rays than the effect of either agent used independently, in the range of 260-380 nm (2600-3800 Angstrom units)";

(ii) A double-blind, randomized study involving a total of 33 subjects and four different tests performed simultaneously (passive sunbathing; sweating and passive sunbathing; swimming and passive sunbathing; and passive sunbathing, sweating, swimming, and walk-around) and comparing the first three preparations listed above provided data indicating that the photoprotective potency of the dioxybenzone-padimate A lotion was equal to and in some respects greater than that for the *p*-aminobenzoate and padimate A-monoglycerol *p*-aminobenzoate products;

(iii) Stress, efficacy and protective index tests comparing the dioxybenzone-padimate A lotion with the padimate A-monoglycerol *p*-aminobenzoate product revealed that "there were no significant differences in stinging or burning sensations noted after application," but "there was an increasing incidence of both as additional stress was carried out." Both gave highly significant protection from erythemas as compared to untreated areas, and there were no significant differences regarding the MED, or the degree of pigmentation, and both increased the MED significantly compared to the untreated area;

(iv) A double-blind, randomized study comparing the four formulations listed above and using a solar simulator as the primary light source in the UV spectrum provided data indicating that the padimate A-monoglycerol *p*-aminobenzoate and *p*-aminobenzoate products were most effective in that order, followed by the dioxybenzone-padimate A lotion and the padimate A product last; and

(v) The dioxybenzone-padimate A lotion "is an effective agent to protect against ultraviolet radiation in the erythemogenic range, and has good substantivity."

Based on the available data, the Panel concludes that dioxybenzone is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products containing a minimum SPF value of 2 to under 4 containing 3 percent dioxybenzone: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 3 percent dioxybenzone: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

REFERENCE

(1) OTC Volume 060116.

f. *Ethyl 4-[bis(hydroxypropyl)] aminobenzoate.* The Panel concludes that ethyl 4-[bis(hydroxypropyl)] aminobenzoate is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

Ethyl 4-[bis(hydroxypropyl)] aminobenzoate is also known as the 2-mole propoxylate of aminoethylbenzoate and ethyldihydroxypropyl PABA.

The absorbance range of ethyl 4-[bis(hydroxypropyl)] aminobenzoate is between 280 and 330 nm, with the absorbance maximum at 308 to 311 nm. It is soluble in ethyl and isopropyl alcohol, propylene glycol, castor oil, and isopropyl myristate; but it is insoluble in water, mineral oil, and glycerin. Ethyl 4-[bis(hydroxypropyl)] aminobenzoate is usually formulated in an emulsion base.

(1) *Safety.* Clinical use and marketing experience have confirmed that ethyl 4-[bis(hydroxypropyl)] aminobenzoate is safe in the dosage range used as an OTC sunscreen.

Animal and human toxicological data attest to its safety for human

topical application. The oral LD_{50} is 20 ml/kg in rats while the intraperitoneal LD_{50} in rats was found to be 5.0 ml/kg (ref. *1*).

Animal safety data indicated that 5 percent ethyl 4-[bis(hydroxypropyl)] aminobenzoate in carbowax ointment, U.S.P. is not a primary irritant to the skin. It is not an ocular irritant, and will not induce comedones (blackheads) (ref. *1*).

Human safety data indicated that studies employing a 5 percent ethyl 4-[bis(hydroxypropyl)] aminobenzoate formulation demonstrated that normal and stripped skin sites on 10 healthy male volunteers showed no evidence of phototoxicity and a very low level of irritancy. Liberal application to the faces of 15 healthy male volunteers showed not instances of stinging or burning or irritation at 5, 10, and 30-minute intervals and 24 hours after application. A maximization test (ref. *2*) performed on 25 healthy male volunteers resulted in no instances of contact sensitization with the conclusion that it was unlikely that the formulation would present a danger of contact sensitization in normal, intended use. Topical application to the entire area of the chests, backs, shoulders and faces of 20 healthy male volunteers once daily for 21 days resulted in a very low level of irritancy with erythema being barely perceptible in some subjects with no repetition on successive days of the slight irritation in most cases (ref. *1*).

Based upon the available data the Panel concludes that ethyl 4-[bis(hydroxypropyl)] aminobenzoate is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of ethyl 4-[bis(hydroxypropyl)] aminobenzoate as an OTC sunscreen.

Human efficacy data has been reported. The protective index of 2 to 5 percent ethyl 4-[bis(hydroxypropyl)] aminobenzoate in various vehicles ranged from 20 (2 percent formulation in alcohol/glycerine/water and 5 percent formulation in oil base) to 70 (5 percent formulation in carbowax base). Fifty mg of 1, 2.5 and 5 percent formulations were applied to 1-square inch patches of skin on six healthy male volunteers, who were then exposed using a xenon lamp to 20, 40 and 60 times the radiation necessary to produce mild erythema on untreated skin, with only barely perceptible erythema being observed at the highest radiation dose and minimal concentration. Fifty mg of 1, 2.5 and 5 percent formulations were applied to 1-square inch patches of skin on the forearms of six healthy male volunteers. Their forearms were then immersed in an agitated water bath thermostatically controlled at 37° C. After 10 minutes immersion, the subjects were exposed to 6 MED's. Barely perceptible erythema was noted on the test areas treated with the 2.5 and 5 percent formulations whereas erythema was easily recognized on test areas treated with the 1 percent formulation. Skin treated with an unspecified commercial lotion showed deep redness and swelling after a waterbath immersion test. It was concluded that the ethyl 4-[bis(hydroxypropyl)] aminobenzoate formulations "showed excellent promise of retaining sunburn protection after bathing."

Based on the available data, the Panel concludes that ethyl 4-[bis(hydroxypropyl)] aminobenzoate is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 1 to 5 percent ethyl 4-[bis(hydroxypropyl)] aminobenzoate: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 1 to 5 percent ethyl 4-[bis(hydroxypropyl)] aminobenzoate: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

REFERENCES

(1) OTC Volume 060084.

(2) Kligman, A. M., "The Identification of Contact Allergens by Human Assay," *Journal of Investigative Dermatology*, 47:393-409, 1966.

g. *2-Ethylhexyl 2-cyano-3,3-diphenylacrylate.* The Panel concludes that 2-ethylhexyl 2-cyano-3,3-diphenylacrylate is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

2-Ethylhexyl 2-cyano-3,3-diphenylacrylate is also known as 2-Ethylhexyl-alpha - cyano - beta - phenylcinnamate and is listed in the CFTA Dictionary as UV Absorber 3. The chemical formula is $C_{24}H_{29}O_2N$. It is a nonstaining pale yellow liquid with a specific gravity of 1.0478 (25° C/25° C), a freezing point of −10° C, and a boiling point of 200° C at 0.1 mm. It is insoluble in water, but miscible in methanol, ethanol, ethyl acetate, methyl ethyl ketone, mineral oil, isopropyl myristate, methyl pyrrolidone, and n-vinyl pyrrolidone. It is incorporated in aerosols, alcohol-type solutions, creams, emulsions, and oil formulations.

(1) *Safety.* Clinical use and marketing experience have confirmed that 2-ethylhexyl 2-cyano-3,3-diphenylacrylate is safe in the dosage range used as an OTC sunscreen.

Animal and human toxicological data attest to its safety for human topical application at a concentration of 7 percent (ref. *1*). The oral LD_{50} in Sherman-Wister strain of rats is greater than 64 ml/kg (ref. *2*). The Draize rabbit eye irritancy test revealed no irritation when 0.1 ml of the undiluted material was instilled into the eyes of rabbits (ref. *1*). A primary skin irritation study in six albino rabbits produced minimal effects when the chemical was applied for 72 hours (ref. *1*).

A modified Draize-Shelanski human repeated insult patch test in 52 men and woment from 18 to 65 years of age revealed 2-ethylhexyl 2-cyano-3,3-diphenylacrylate not to be a strong irritant or photosenitizer. After applying the chemical to the upper back of the subjects, patch strips were applied for 24 hours. The patches were removed and the test sites were read. No patches were in place for 24 hours, then another application was made to the same site and the patches applied. This was repeated until 10 insults had been applied to the same site. A 10- to 14-day rest period followed. At the end of the rest period a challenge dose and patch were applied to the original site and remained in place for 48 hours. No reactions occurred during the entire induction period. There were two reactions (1+, mild erythema) seen during the challenge. On repeated challenge to these two subjects, only one gave a repeated 1+ reaction. The reactions were considered to be nonspecific irritation, disappearing by 72 hours (ref. *1*). Twenty-five of the above subjects also had phototoxicity testing done simultaneously with the skin irritancy and sensitization testing. Patches were applied as before. At induction, patches 1, 4, 7, and 10, and at the first challenge patch, the treated sites were exposed to a Hanovia Kromeyer Lamp filtered through window glass for 30 seconds. All photopatch tests were negative.

Additional skin and eye irritation tests have been carried out but details were not supplied. Various concentrations of 2-ethylhexyl 2-cyano-3,3-diphenylacrylate (4, 8, and 16 percent) were incorporated in dimethylphthalate or petrolatum as vehicles. The Draize skin irritancy test in 6 rabbits, the Draize eye irritancy test in 6 rabbits, and skin patch tests (unspecified) in 14 humans revealed no effects observable in all cases (ref. *2*).

Marketing data involving 15,000 units sold over a 24-month period revealed no complaints of sensitivity or intolerance to 2-ethylhexyl 2-cyano-3,3-diphenylacrylate (ref. *1*). 2-Ethylhexyl 2-cyano-3,3-diphenylacrylate in lower dosage has been used by a least three cosmetic manufacturers for several years to protect ingredients in cosmetics against UV degradation (ref. *3*).

Based upon the available date, the Panel concludes that 2-ethylhexyl 2-cyano-3,3-diphenylacrylate is a safe sunscreen for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of 2-ethylhexyl 2-cyano-3,3-diphenylacrylate as an OTC sunscreen.

2-Ethylhexyl 2-cyano-3,3-diphenylacrylate in a 7 percent gel base was tested on the backs of 10 fair skin volunteers using a xenon lamp-solar simulator (ref. *1*). The subjects' MED was determined the day before the test. The test product and a 3 percent aminobenzoic acid in alcohol control solution were applied to separate circular sites 1.9 cm in diameter at a rate of 5 $\mu l/cm^2$. Irradiated sites were 1.2 cm in diameter. 2-Ethylhexyl 2-cyano-3,3-diphenylacrylate sites were exposed to 3, 4, and 5 MED's while the 3 percent aminobenzoic acid solution was exposed to 4 and 5 MED's. Test sites were read 24 hours later. The mean SPF for the 7 percent 2-ethylhexyl 2-cyano-3,3-diphenylacrylate was 4.2 (standard deviation=0.92). In the same test, 10 percent 2-ethylhexyl 2-cyano-3,3-diphenylacrylate in an oil in water lotion was tested simultaneously. Five $\mu l/cm^2$ of the material was applied. The mean SPF for the 10 subjects was 4.6 (standard deviation=0.85) for the 10 percent formulation.

Rossman, Knox, and Freeman (ref. *4*) compared 100 sunscreen products and formulations on the untanned backs of white men. Different test agents were arranged in six vertical strips extending from the waist to the upper scapular areas. Test sites were 36 one-inch squares arranged in six rows of six each. 2-Ethylhexyl 2-cyano-3,3-diphenylacrylate was tested in 10 and 20 percent concentration while 10 percent 3-benzoyl-4-hydroxy-6 methoxy benzenesulfonic acid in a vanishing cream base and 10 percent aminobenzoic acid in the same vanishing cream base were used as control standard sunscreens. The light source was a hot quartz mercury vapor lamp and the test sites were irradiated at a fixed 75 cm distance. The average MED for the light source was 15 seconds (range 10 to 25 seconds).

In 32 subjects, 20 percent 2-ethylhexyl 2-cyano-3,3-diphenylacrylate in a vanishing cream base protected for 9.1 minutes (36 times the average MED) while 10 percent 2-ethylhexyl 2-cyano-3,3-diphenylacrylate in the same vehicle protected 13 subjects for 2.2 minutes (9 MED's). The 10 percent benzophenone formulations on 34 subjects protected in excess of 12 minutes 48 MED's). The 10 percent aminobenzoic acid formulation protected 17 subjects for more than 12 minutes (48 MED's) and in 13 more subjects from 20 to 60 minutes. In general, the protection offered by commercially available products, available in the early 1960's was limited to 2 minutes or less (mean 1.5 minutes or 6 MED's) (ref. *4*).

The 7 percent 2-ethylhexyl 2-cyano-3,3-diphenylacrylate was field tested in Florida, California, Hawaii, the Indian Himalayas, Panama, the Gulf of Mexico, Mt. McKinley, Guadalupe, Israel, France, and England, but the data were not submitted to the Panel.

Based on the available data, the Panel concludes that 2-ethylhexyl 2-cyano-3,3-diphenylacrylate is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 7 to 10 percent 2-ethylhexyl 2-cyano-3,3-diphenylacrylate: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 7 to 10 percent 2-ethylhexyl 2-cyano-3,3-diphenylacrylate: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

REFERENCES

(1) OTC Volume 060171.

(2) Technical Report GAF Corporation, Draft of unpublished paper in OTC Volume 060150.

(3) Strobel, A. and J. J. Inserra, "The Use of UV- Absorbers in Cosmetic Products," *American Perfumer and Cosmetics*, 83:25-30, 1968.

(4) Rossman, R. E., J. M. Knox and R. G. Freeman, "Acrylonitriles, A New Group of Ultraviolet Absorbing Compounds," *The Journal of Investigative Dermatology*, 39:449-453, 1962.

h. *Ethylhexyl p-methoxycinnamate.* The Panel concludes that ethylhexyl *p*-methoxycinnamate is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

Ethylhexyl *p*-methoxycinnamate is also known as 2-methoxycinnamic acid 2-ethylhexyl ester.

Ethylhexyl *p*-methoxycinnamate is a practically odorless, pale yellow, slightly oily liquid with a molecular weight of 290, a boiling point at 3 mm of 198-200° C, and a specific gravity of 1.01-1.02. The ingredient is miscible in alcohols, propylene glycol monomyristate, and various oils, but insoluble in water. It is "stable to light and remains essentially unchanged on exposure to moderate heat." It is often formulated with other sunscreens. Absorbance in pure ethanol is 84 percent at 2 percent, 94 percent at 3 percent, and 98.8 percent at 5 percent concentrations.

(1) *Safety.* Clinical use and marketing experience have confirmed that ethylhexyl *p*-methoxycinnamate is safe in the dosage range used as an OTC sunscreen.

Extensive animal toxicological testing and widespread use attest to its safety for application to humans.

Animal toxicity data for ethylhexyl *p*-methoxycinnamate indicated that the LD_{50} exceeds 8 g/kg in mice. The Draize rabbit eye irritancy test revealed little irritation when 0.1 ml of the pure chemical was instilled into the rabbit's eyes (ref. *1*). The chemical was considered practically nonirritating to the eye. To determine epicutaneous tolerance and possible sensitization in the guinea pig, four guinea pigs received either 0.05 ml of the undiluted chemical unjected intracutaneously on 5 subsequent days or 0.025 ml of a 50 percent acetone solution applied topically daily for 3 weeks to 2 cm^2 areas on their shaved sides. The amount injected intracutaneously or topically administered was approximately 500 mg/kg. There was no allergic sensitization by either topical or intradermal route (ref. *1*).

Human safety studies have been reported. Tests using a 5 percent concentration and performed on 50 subjects, approximately one-third of whom had extremely sensitive skin, including some with eczema and sensitization, demonstrated that the product is very well tolerated on the skin. Patch tests using an unspecified concentration on 27 men and 22 women, 18 to 60 years of age, produced no positive results after 24 and 48 hours, thereby leading to the conclusion that the product would not act as a primary irritant or would not act, under longer use, as an allergenic substance. Photosensitization tests "showed that the product did not provoke photosensitization" (ref. *1*).

In a line of products where the ingredient was combined with a benzophenone, over 8 million units were sold, 38 complaints of skin irritation were received by the manufacturer,

but not a single case of skin irritation could be clearly related to the use of the products. Over 209 tons of ethylhexyl *p*-methoxycinnamate were sold in 27 countries in 2 years (ref. *1*).

A human Draize test was performed in 54 men and women. Ethylhexyl *p*-methoxycinnamate 7.5 percent in petrolatum was applied to the deltoid area alternately under occlusion for 48 hours for 11 applications. Two weeks later the challege dose was reapplied. No reactions occurred to the ethylhexyl *p*-methoxycinnamate (ref. *2*). No adverse reports were found in the literature to the use of topical ethylhexyl *p*-methoxycinnamate.

Based on the available data, the Panel concludes that ethylhexyl *p*-methoxycinnamate is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of ethylhexyl *p*-methoxycinnamate as an OTC sunscreen.

Efficacy data reviewed by the Panel included in vitro studies of the absorption, solubility, and stability properties of ethylhexyl *p*-methoxycinnamate (ref. *1*). Absorption at 308 nm is 84 to 90 percent for 2.0 to 2.5 percent concentrations.

The ingredient absorbs UV light in the 290 to 320 nm range, with the maxima at 308 to 310 nm. Like many sunscreens, the percent of absorption depends upon the concentration. As noted above, absorption in pure ethanol is 84 percent at 2 percent, 94 percent at 3 percent, and 98.8 percent at 5 percent concentrations. It is often formulated with other sunscreens (ref. *1*).

In a series of five well-designed, controlled, randomized, singleblind laboratory and field trials, ethylhexyl *p*-methoxycinnamate alone and in combination performed well. Each subject had his/her MED and skin reflectance measured. In outdoor tests the solar energy flux was measured. In the laboratory test, 2.5 to 5.0 percent ethylhexyl *p*-methoxycinnamate in combination with other sunscreens was applied to the back of 12 men and women. Each subject had four sites; each site had three rows; and each row had five (2.5 X 2.5 cm) windows. Each site had only one product applied to a row, an untreated control row, and a 5 percent PABA in ethanol control row. A hot-quartz mercury lamp delivered 3, 5, 9, 12, and 15 MED's to each subject. Readings were made about 24 hours later. All formulations containing ethylhexyl *p*-methoxycinnamate performed well (ref. *3*). An experiment in 8 men compared two products, an untreated control, and a 5 percent PABA in ethanol control on the back of each man. Three products containing ethylhexyl *p*-methoxycinnamate were tested. The men sunbathed passively from 11 a.m. to 1 p.m. in the April sun in Arizona. The formulations had as SPF value of 2.8 to 10.1 (ref. *1*). The next outdoor experiment involved testing 12 products, 10 containing 2.5 to 5 percent ethylhexyl *p*-methoxycinnamate on 11 men exposed to 30, 60, 90, and 120 minutes sunlight from 11 a.m. to 1 p.m. Each man had three formulations and an untreated control applied. All formulations performed well. One product containing 4 percent ethylhexyl *p*-methoxycinnamate alone had an SPF value of 2.1 after 120 minutes exposure, while an aerosol product containing 2.5 percent ethylhexyl *p*-methoxycinnamate had an SPF value of 2.9 after 120 minutes exposure. The third field experiment tested three products in six subjects after exercising 0.5 hour then exposed to the noon sun for 30, 60, 90, and 120 minutes. All formulations performed well. The fourth experiment tested three products under conditions simulating normal usage like exercise (30 minutes), walking (30 minutes), sunbathing passively (60 minutes), and two swims. Each product was tested in nine subjects along with the 5 percent PABA control. The mean SPF values were 9.1, 5.9, and 9.3. The last experiment in the series compared the same three formulations in six subjects after a 15-minute swim followed by sun exposure to 90 minutes. Each subject tested two products and had an untreated control site. The mean SPF values were 4.2, 1.04, and 4.4 or greater (ref. *3*). Evaluation of the tanning response to two products containing 4.0 and 2.5 percent ethylhexyl *p*-methoxycinnamate exhibited a pigmentary response on clinical and skin reflectometer evaluation, but it was less than the untreated control sites. Another similar series of outdoor testing was performed in Australia, with similar results (ref. *1*).

Several partially controlled studies of formulations containing ethylhexyl *p*-methoxycinnamate were submitted by the manufacturer (ref. *1*).

Based on the available data, the Panel concludes that ethylhexyl *p*-methoxycinnamate is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 2.0 to 7.5 percent ethylhexyl *p*-methoxycinnamate: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 2.0 to 7.5 percent ethylhexyl *p*-methoxycinnamate: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

REFERENCES

(1) OTC Volume 060083.

(2) OTC Volume 060110.

(3) Pathak, M. A., T. B. Fitzpatrick and J. A. Parrish, "Evaluation of Piz Buin (Greiter, AG) Sunscreen Formulations under Laboratory and Field Conditions," Draft of unpublished paper in OTC Volume 060083.

i. *2-Ethylhexyl salicylate.* The Panel concludes that 2-ethylhexyl salicylate is safe and effective for OTC use as a suncreen as specified in the dosage section discussed below.

2-Ethylhexyl salicylate is also known as octyl salicylate.

Its absorbance is between 280 and 320 nm with a maximum absorbance wide peak at about 300 nm. It is an odorless, clear, white-to-slightly yellowish liquid with a molecular weight of 250.33, a specific gravity of 1.013 to 1.022, and a boiling point of 144° C at 1mm. It is completely soluble in mineral oil and two parts of 95 percent ethanol. It has been used as a sunscreen since 1938 and is incorporated in emulsion, oil, ointment, and paste formulations.

(1) *Safety.* Clinical and marketing experience have confirmed that 2-ethylhexyl salicylate is safe in the dosage range used as an OTC sunscreen.

Animal and human toxicological data and long use attest to its safety for human topical application.

The Draize rabbit eye irritation test revealed it to be a nonirritant when 0.1 ml 2-ethylhexyl salicylate was instilled into the eyes of nine albino rabbits. In three rabbits the eyes were not washed, while the other rabbits and the eyes washed in 2 or 4 seconds with 20 ml of lukewarm water. Evaluations were made at 1 hour, 24 hours, and 7 days. No damage was observed of the cornea or iris, while the conjuctiva had a mild reaction (ref. *1*).

The oral LD_{50} in Sherman strain albino rats was found to be 4.8 ± 0.3 g/kg (ref. *2*). U.S. Army Military Specification MIL-S-11262E lists 2-ethylhexyl salicylate among the approved suncreening agents, with a maximum amount of 5 parts by weight approved for toxicity for use with the basic cream formulation specified therein (ref. *2*).

Patch tests were performed on 10 randomly selected human subjects. A 5 percent 2-ethylhexyl salicylate preparation in mineral oil was applied to the inner surface of the upper right

arm of each subject. The patches were removed after the test material had been in contact with the skin for 24 hours. No reactions were observed at that time or after 72 hours. After a 7-day test period the above-described procedure was repeated, and again no reactions were noted either upon removal of the patches or after 72 hours. It was concluded that the test material did not contain primary and/or secondary skin irritants (ref. *2*).

In a human Draize repeated-insult patch test, no primary irritation, "fatiguing," or sensitization reactions were observed when 0.5 ml of 2-ethylhexy salicylate was applied under occlusion to the intact skin of 25 subjects for 10 applications at 48-hour intervals, with the 11th application 2 weeks later (ref. *1*).

The phototoxicity potential of 5 percent 2-ethylhexyl salicylate in ethanol was tested in 10 subjects. The solution was applied to normal skin sites and to cellophane tape-stripped sites. The sites were irradiated after either a 1-hour contact (stripped sites) or 24-hour contact (normal skin). All subjects had a 3 percent demeclocycline hydrochloride solution positive control. The sites were irradiated from 322 to 410 nm with a xenon arc lamp system. All subjects had a positive phototoxicity response to the demeclocycline, but none responded to the 2-ethylhexyl salicylate (ref. *1*).

Over a 10-year period, about 55,000 pounds of 2-ethylhexyl salicylate were sold each year. Several companies market products containing it, but the only data were supplied to the Panel by the manufacturer of the basic chemical (ref. *2*). One product manufacturer indicated that it had produced over a million units in 6 years and had had no complaints or reports of dermatitis, skin irritation, allergies, or sensitivity to the two products containing 2-ethylhexyl salicylate (ref. *2*). Another product manufacturer wrote that before marketing its product in 1946, it had conducted patch tests on 50 persons, with favorable results (ref. *2*). The Panel found no adverse reports to the topical use of 2-ethylhexyl salicylate in the literature.

Based on the available data, the Panel concludes that 2-ethylhexyl salicylate is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are no controlled studies documenting the effectiveness of 2-ethylhexyl salicylate as a sunscreen. However, it is the Panel's conclusion that clinical use and marketing experience have confirmed effectiveness.

The effectiveness of 2-ethylhexyl salicylate as a sunscreen is demonstrated by its in vitro UV light absorption characteristics. The ingredient absorbs UV radiation between 280 and 320 nm, with maximal absorbance at 305 nm. Changing the concentration and vehicle changes the percentage of absorption. For example (refs. *1* and *3*):

Cream concentration (percent)	Erythema transmission (percent)
	290 to 310 nm
3.0	0.3
4.0	0.4
	290 to 320 nm
9.5	4.0
7.0	8.0
5.2	15.0

To meet the special requirements of a sunscreen, a compound must be able to resonate between alternate ionic forms. This ionization change must require an energy quantum within the UV region. This corresponds to electronic transition (ionization) energies of 91.4 to 99.4 kilocalories per gram mole (kc al/g mol) for compounds with absorption maxima between 290 and 315 nm, the sunburn erythema range. Few classes of compounds satisfy this basic requirement. The salicylates, cinnamates, *p*-aminobenzoates, and *p*-dialkyl aminobenzoates are examples of aromatic compounds meeting this basic requirement, and they have performed as effective sunscreens in use (ref. *4*).

The Quartermaster Corps of the U.S. Army approved 5-percent-by-weight 2-ethylhexyl salicylate as a sunburn preventative (U.S. Specification MIL-S-11 262 E, 15 March 1972). It was first approved for military procurement in 1951 (ref. *1*). The efficacy data from the Army tests were not available to the Panel.

Testimonial letters from six cosmetic manufacturers stated that they found 2-ethylhexyl salicylate to be an effective sunscreen and that it was chosen for use in their products because of its efficacy and desirable characteristics (ref. *3*). No data were given. Being one of the older sunscreens, such record-keeping was not necessary.

Based on the available data, the Panel concludes that 2-ethylhexyl salicylate is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 3 to 5 percent 2-ethylhexyl salicylate: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 3 to 5 percent 2-ethylhexyl salicylate: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

REFERENCES

(1) OTC Volume 060151.
(2) OTC Volume 060088.
(3) OTC Volume 060006.
(4) Kreps, S. I., "The Structure, Function and Formulation of Topical Sunscreens. I. Theoretical Considerations," *Journal of the Society of Cosmetic Chemists*, 14:625-630, 1963.

J. *Glyceryl aminobenzoate.* The Panel concludes that glyceryl aminobenzoate is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

Glyceryl aminobenzoate is also known as glyceryl *p*-aminobenzoate.

Glyceryl aminobenzoate is soluble in ethyl and isopropyl alcohol and glycerine and propylene glycol; but it is insoluble in water, mineral oil, and peanut oil. Glyceryl aminobenzoate can be incorporated into aerosols, emulsions, hydroalcoholic solutions, and lipstick formulations. Its absorbance is between 264 and 315 nm, with maximum absorbance at 295 nm (ref. *1*).

(1) *Safety.* Clinical use and marketing experience have confirmed that glyceryl aminobenzoate is safe in the dosage range used as an OTC sunscreen.

Animal and human toxicological data attest to its safety for human topical application in 3 percent concentration (refs. *2* and *3*). The oral LD_{50} is 17.3 ml/kg in rats (ref. *4*).

A 20-day acute toxicity test of a preparation containing 20 percent glyceryl aminobenzoate in a base solution was performed using New Zealand strain male rabbits with abraded and intact skin. A shaved area of skin approximately 10 percent of the body surface was inuncted daily with 1, 2, and 4 g/kg of body weight, with control animals receiving 4 g/kg of the solvent only. No toxic manifestations were observed in any of the test animals. There were no abnormal, irritative, deteriorative, or coagulative effects on the intact or abraded skin (ref. *1*).

Toxicological studies employing a marketed sunscreen lotion containing 3 percent glyceryl aminobenzoate and 3 percent amyl *p*-dimethyl- aminobenzoate indicated that the product was nontoxic to mice and rats when administered in a single oral dose of 50 ml/kg (ref. *2*). For 32 consecutive days, 0.2 ml of lotion was applied to the shaved intrascapular area of albino rats without any dermal toxicity being noted in

any of the eight animals so treated (ref. *2*).

Using two sunscreen lotions each containing 3.15 percent glyceryl- aminobenzoate and 3.15 percent amyl *p*-dimethylaminobenzoate, acute eye irritation studies were performed on 12 New Zealand albino rabbits. Two drops of one lotion were instilled into the left eye of each rabbit, while the contralateral eyes were treated with an equal amount of the other lotion. Two minutes after administration, both eyes of six rabbits were rinsed with 20 ml of lukewarm water. One hour later the rinsed eyes were stained with one drop of 2 percent fluorescein for observation under UV light. Twenty-four hours after instillation, the unrinsed eyes were treated in the same manner. The eyes were scored for toxicity (ref. *5*). No toxicity was noted in any of the rinsed and unrinsed eyes, although mild to moderate discomfort characterized by repeated blinking was observed to last from 15 to 30 seconds in both the rinsed and unrinsed eyes. Slight conjunctival irritation was observed immediately following instillation in both groups; the condition subsided within 1 hour following rinsing and after 24 hours postinstillation in the unrinsed group (ref. *2*).

An evaluation was made as to the primary irritation potential of the two lotions described in the previous paragraph by applying 0.5 ml of the preparations to abraded and intact (occluded and unoccluded) rabbit skin. Twenty-four hours prior to the onset of the study, the dorsal area of 12 adult female New Zealand albino rabbits was shaved free of hair. The following day the shaved area was divided into 4 quadrants of no less than 4 square inches each. Two of the test sites on each rabbit were abraded by making four epidermal incisions through the stratum corneum with a sterile needle in a "tic-tac-toe" pattern. The abraded and intact sites were diagonally located from one another. Each of the two lotions was applied to six rabbits by using a glass disposable syringe under to gauze patch secured by adhesive tape. The test sites for three rabbits in each group were occluded. After 24 hours contact time the patches were removed and the resulting reactions were graded through 72 hours in accordance with a described method (ref. *5*). Variations in the reactions noted for the two preparations were minimal. Essentially, there was slight erythema (value of 1 or less) noted at 24 hours in the rabbits of the abraded-occluded and intact-occluded groups. Little or no irritation was noted at 48 hours and was absent at 72 hours. Likewise, in rabbits of the abraded-unoccluded and intact-unoccluded groups slight erythema (value of 1 or less) was noted at 24 hours and was reduced to very slight at 48 hours, with none noted at 72 hours. There was no edema formation noted in any of the 12 test animals (ref. *2*).

Another evaluation was made as to the primary irritation potential of two preparations, each containing 3.15 percent glyceryl aminobenzoate and 3.15 percent amyl *p*-dimethyl- aminobenzoate. Twelve adult female New Zealand albino rabbits were prepared in the same manner as described above. In the case, 0.2 ml instead of 0.5 ml of the test preparation was applied to each test site. The results were essentially similar to those noted in the study discussed above (ref. *2*).

Each ingredient in the above-described sunscreen preparation was evaluated for potential dermal irritation by combining the ingredient with a suitable vehicle, i.e., petroleum, methanol, or distilled water and applying it topically to rabbit skin for 7 consecutive days. Twenty-four hours prior to the onset of the study, the dorsal region in each of 15 rabbits was shaved free of hair and divided into 4 quadrants of no less than 25 cm^2 each. Three times daily, 0.2 ml of each test material was placed onto a test quadrant in each of three rabbits by using a glass disposable syringe and then gently inuncted onto the skin with a clean stainless steel spatula. The test sites were observed regularly for irritation, physical appearance, and general behavior, with dermal reactions being graded (ref. *5*). Glyceryl aminobenzoate (3 percent) elicited no untoward dermal reactions, while amyl *p*-dimethylaminobenzoate (3 percent) elicited very slight erythema. Slight to moderate erythema was noted on test sites treated with several other ingredients (ref. *2*).

The above-described sunscreen was tested in the rabbit ear for comedogenicity, along with two other sunscreens, one containing 10 percent sulisobenzone and the other containing 3 percent dioxybenzone and 3 percent oxybenzone. It was reported that the preparation containing 3 percent glyceryl aminobenzoate and 3 percent amyl *p*-dimethylaminobenzoate showed marginal hyperkeratosis and produced small comedones, whereas the other two preparations produced huge comedones. No specifics were given as to the testing procedure (ref. *6*).

Controlled human studies of the ralative irritancy potential of eight preparations were performed using the method outlined by Phillips et al. (ref. *7*). The materials to be tested were applied daily for 21 days to Webril patches and attached to the skin with an occlusive tape. Each day the patches were removed, the sites examined and scored, and fresh patches reapplied. It was reported that none of the test materials were rated as significant irritants, with only a few readings indication erythema over the entire test site. All the remaining responses were equivocal, with erythema present over part, but not the entire, test site.

Fifty human subjects were selected on the basis of their general good health and absence of any skin diseases which might be confused with skin reactions form the test material and were treated with glyceryl aminobenzoate to determine whether this ingredient was capable or irritating human skin under controlled test conditions. Sites on the upper arm of each subject were designated to receive a series of 16 applications, each of 24 hours' duration, of the test material. A lintine pad treated with the test material was placed on its predesignated site, covered, and sealed with overlapping strips of an occlusive tape. At the end of 24 hours the seal was broken and the patch was removed. The test sites were examined, and any gross changes were graded on a scale of from 1 to 4, with the absence of any visible changes being assigned a 0 value. After the removal of the patch, the test sites were rested for 24 hours, except on weekends when the rest period was extended to 48 hours. Prior to reapplication the test sites were examined again to determine whether any changes had occured. The test material was reapplied to the same site if the contact site manifested no changes. If significant irritation (2+ or more) was observed, the investigator could at his option rest the subject or apply the test material to a new site for the next contact period. After the fifteenth application the subjects were rested for 2 weeks before being challenged by applying the test material under occlusion for 24 hours to the previously used sites. Following removal of the patch, the test sites were examined immediately and after 24 and 48 hours. In no instance were visible changes noted signifying reaction to injury. It was concluded by the investigator that "under the test conditions, glyceryl para-aminobenzoate was not capable of eliciting visible skin changes consistent with criteria being characteristic of a primary irritant, fatiguing agent or a sensitizer" (ref. *8*). On the basis of the test results for 50 subjects, the investigator predicted with 95 percent certainty that at least 92.89 percent of the general population will not be sensitized by this material.

Maximization tests (ref. *9*) to determine the contact-sensitizing potential of a sunscreen product containing 3 percent glyceryl aminobenzoate and 3 percent amyl *p*-dimethylaminobenzoate were performed on 25 healthy adults male volunteers. The test mate-

rial was applied under occlusion to the same sites on the volar forearms of all subjects for 5 alternate 48-hour periods. The test sites were pretested for 24 hours with 5 percent aqueous sodium lauryl sulfate under occlusion. After a 10-day rest period, challenge patches were applied under occlusion to new sites for 48 hours, but were preceded by 1-hour applications of 10 percent sodium lauryl sulfate under occlusion. It was indicated that the challenge sites were read immediately upon removal of the patch and 24 hours thereafter. However, individual subject data indicated that the challenge sites were read after 48 and 72 hours. It was reported that there were no instances of contact-sensitization and that it was unlikely that the test material would present a danger of contact-sensitization in normal, intended use (ref. *10*).

The phototoxicity and photocontact allergenicity potential of a sunscreen formulation containing 3 percent glyceryl aminobenzoate and 3 percent amyl *p*-dimethylaminobenzoate were evaluated in 35 healthy adult male volunteers (ref. *11*).

To test for phototoxicity, 0.2 ml of the test materials was applied occlusively to duplicate 2 cm^2 normal and stripped skin sites on the upper backs of the subjects. Each stripped site received 6 MED's of xenon solar simulating radiation filtered through window glass. The normal site was similarly exposed to the same dose of long-UV radiation after 24 hours of occlusion. Observations were made a 1, 3, and 24 hours after irradiation. To test for photocontact allergenicity , 0.2 ml of the test materials was applied to one 2-inch square of stripped skin on the upper backs of the subjects, and the sites were then exposed to 3 MED's of xenon solarsimulating radiation and occluded. This procedure was repeated five times at intervals of 48 hours. Ten days after the final induction exposure, the subjects were challenged by applying 0.2 ml of the test materials to both normal and stripped skin sites, followed by exposure to 3 MED's of xenon solarsimulating radiation filtered through window glass. The sites were occluded, and observations were make at 24, 48, and 72 hours after irradiation. The results of the tests revealed no instances of phototoxicity or photocontact allergenicity among any of the subjects (ref. *11*).

Test were performed using 10 adult subjects for the purpose of discriminating among four formulations reported to be equally effective in providing protection against sunburn in the immediate and post-immersion assays. One formulation contained 3 percent glyceryl aminobenzoate and 3 percent amyl *p*-dimethylaminobenzoate; the formulations for the three remaining products were not provided. One-inch square Webril patches were loaded with 25 percent liquor carbonis detergents (LCD) and occluded to four sites on the forearm skin of each patient for 1 hour, after which the site was cleaned with mineral oil before the application of thin film of the test formulation. Each site then received 6 minutes of long-UV radiation. A control LCD site was irradiated on each subject without the application of any test formulation. The test sites were examined 24 hours later, and any gross changes were graded on a scale of 1 to 4, with the absence of any visible changes being assigned a 0 value. The preparation containing 3 percent glyceryl aminobenzoate and 3 percent amyl *p*-dimethylaminobenzoate was one of two formulations found to almost completely block the phototoxic response. It was concluded that these two formulations provide excellent protection in the phototoxic model, permitting the inference to be made that they efficiently absorb long-UV radiation in the spectral range of 320 to 400 nm and that "these two formulations therefore may be regarded as broad-spectrum sunscreens, providing excellent protection against sunburning radiation as well as longer rays which activate photosensitization reactions" (ref. *12*).

The photosensitivity, irritancy, and allergic sensitization potential of a sunscreen formulation containing 3 percent glyceryl aminobenzoate and 3 percent amyl *p*-dimethylaminobenzoate was evaluated in 15 healthy female and 25 healthy male subjects. The test material was applied daily for 30 days to the face and upper trunk of each subject, after which the subjects were irradiated with 3 MED's from a bank of fluorescent lamps. Individual subject data were not provided, but it was reported that 12 subjects (4 females and 8 males) complained of very mild itching around the eyes but that there were no visible signs of irritation in these subjects. It was further reported that there were no instances of photosensitivity of allergenicity in this test (ref. *13*).

Based on the extensive animal and human toxicological data, the Panel concludes that glyceryl aminobenzoate is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of glyceryl aminobenzoate as an OTC sunscreen.

Doubleblind studies were performed comparing nine formulations for sunscreening efficacy in 10 healthy adult white males. The fomulations were applied in random fashion to 2 cm^2 on the medial forearm skin surface at the rate of 60 ul/cm^2. A 1,600 watt xenon lamp was used to provide solar-simulating radiation. One study evaluated protection immediately after application and involved each site immediately after inunction receiving 10 MED's individually determined beforehand for each subject. The skin was evaluated 24 hours later, with any reactions being graded on a 4-point scale (0—negative, 1—mild response, 2—moderate redness, and 3—sharp redness). In the second study, postimmersion protection was evaluated. Previously irradiated sites were avoided. The subjects' forearms were immersed for 10 minutes in a water bath at room temperature 2 hours after application of the test formulations. Following the immersion, 10 MED's were administered, and the skin reactions were evaluated 24 hours later and graded using the above-described scale. In both studies, it was concluded that a sunscreen formulation containing 3 percent glyceryl aminobenzoate and 3 percent amyl *p*-dimethylamino- benzoate provided excellent protection immediately after application (0.45 average value) and postimmersion (0.55 average value). Moderate protection was provided by a formulation containing unspecified concentrations of glycerly aminobenzoate and amyl *p*-dimethyl- aminobenzoate immediately after application (1.30 average value) and postimmersion (1.55 average value). Poor protection was provided by preparations containing unspecified concentrations of the single active ingredients glycerly aminobenzoate and amyl *p*-dimethylaminobenzoate immediately after application (1.90 and 2.50 average values, respectively) and postimmersion (2.20 and 2.50 average values, respectively) (ref. *14*).

Double-blind studies were performed on a series of single active ingredient and combination sunscreen preparations in a water-resistant emollient cream base using natural sunlight and ocean swimming. For the purposes of the present review, the Panel only considered the results for those formulations containing 3 percent glyceryl aminobenzoate and 3 percent amyl *p*-dimethylaminobenzoate alone and in combination and for a marketed sunscreen containing 5 percent aminobenzoate. Opaque white tape was used to mark out a series of 7.5 cm x 7.5 cm approximately 6 cm below the base of the neck and centered between the shoulder blades on the backs of 30 untanned light-skinned Caucasian volunteers. Using a randomized medication schedule, each test site was treated with 0.05 ml of a test formulation. The subjects were simultaneously exposed to 2 hours of sunlight (10 am. to noon on a clear day in Miami, Fla., in August 1971). Following this exposure, the subjects swam for 10 minutes while totally immersed in the ocean. Immediately thereafter they were

again exposed for 2 more hours until the 2 p.m. conclusion. At this point the tape was removed, the test sites photographed, and instructions were given to the subjects not to apply anything other than water to the test sites. Evaluations were made and photographs were taken of the test sites 24 and 72 hours following exposure. At each point the reactions were graded (0—no change, 1—mild erythema, 2—moderate erythema, 3—marked erythema, and 4—marked erythema with edema). Complete data for only 22 subjects were considered in the statistical evaluation, as 3 subjects failed to return for the final evaluation and 5 subjects had an uneven suntanning response. The results for the formulations under consideration in this review were as follows:

Means and standard deviations of severity gradings

	24-hour evaluation		72-hour evaluation	
	Mean value	Standard deviation	Mean value	Standard deviation
1. 3 pct glyceryl aminobenzoate	2.1727	0.0917	1.6818	0.1169
2. 3 pct amyl *p*-dimethylaminobenzoate	2.3545	.0789	1.8728	.0893
3. 3 pct glyceryl aminobenzoate, 3 pct amyl *p*-dimethylaminobenzoate	2.0227	.0696	1.7818	.1084
4. 3 pct glyceryl aminobenzoate, 3 pct amyl *p*-dimethylaminobenzoate	2.2045	.0710	1.8000	.1509
5. 5 pct aminobenzoate	3.0727	.0838	2.4955	.0862

The two combination formulations listed above differed only in a single base ingredient. Both of these formulations and the preparation containing glyceryl aminobenzoate of the formulations tested were found to provide the maximum absorption in the critical erythema range (290 to 320 nm) and maximum resistance to water wash-off if one excludes a similar formulation which also contained 2.5 percent 2-hydroxy-4-methoxy-benzophenone and which provided the lowest mean values at both the 24- and 72-hour evaluation periods. The latter formulation, however, produced sensitivity reactions traced and attributed to the benzophenone component in followup human irritation studies (ref. *15*).

Based on the extensive data, the Panel concludes that glyceryl aminobenzoate is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 2 to 3 percent glyceryl aminobenzoate: Adult and children over 2 years of age topical dosage is liberal application before sunexposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 2 to 3 percent glyceryl aminobenzoate: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

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(13) "Photosensitivity, Irritancy and Allergic Sensitization Potential of G. S. Herbert Sunscreen Z, GSH-1136," Draft of unpublished paper in OTC Volume 060104.
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k. *Homosalate.* The Panel concludes that homosalate is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

Homosalate is also known as 3,3,5-trimethylcyclohexyl salicylate, and was formerly called homomenthyl salicylate.

Homosalate is an oily, colorless-to-faint-yellow liquid which does not precipitate when cooled at 15° C for 12 hours (ref. *1*).

(1) *Safety.* Clinical use and marketing experience have confirmed that homosalate is safe in the dosage range used as an OTC sunscreen.

Animal and human toxicological data attest to its safety for human topical use.

The acute oral LD_{50} in rats for homosalate has been determined to be greater than 8.0 ml/kg of body weight (ref. *2*). The acute oral LD_{50} in rats for a sunscreen lotion containing 8 percent homosalate was found to be greater than 10,000 μl/kg of body weight (ref. *3*). Two rabbit eye irritation studies of a sunscreen lotion and oil containing 8 and 9 percent homosalate, respectively, demonstrated no deleterious effects when 0.1 ml of the undiluted test material was instilled into the conjunctival sac of the right eye of nine albino rabbits, with the left eye serving as a control (ref. *4*).

Homosalate was applied full-strength to the arms, abdomens, and faces of five subjects without any reported untoward effects. An ointment containing unspecified amounts of the sunscreens homosalate and ethyl aminobenzoate was applied to 22 subjects without any reported cases of sensitivity (ref. *5*).

In 1964, the military approved, on the basis of toxicolgical considerations, a maximum of 8 percent homosalate for sunburn preventative preparations in a cream paste formulation (ref. *6*).

Patch tests of 25 human subjects (9 males and 16 females) treated with a 6 percent homosalate sunscreen oil for 48 hours demonstrated that the test material was not a primary irritant, as no reactions were noted at 30 and 60 minutes and at 24 hours following removal of the patches from the inner aspect of each subject's upper left arm (ref. *4*). Thereafter, these 25 subjects applied the preparation to an area approximately 1 inch in diameter on the skin of the dorsal surface or outer aspect of the left forearm daily for 3 weeks, with subsequent exposure to sunlight. Weekly evaluations of the application site for each patient revealed no evidence of reaction. Following a 2-week rest period after cessation of use, challenge patches saturated with the test material were applied to the upper left arm of each patient.

After 48 hours of skin contact the challenge patches were removed. Readings recorded at 30 and 60 minutes and at 24 hours afterwards showed no evidence of reaction. It was concluded that the test material was not a primary irritant or skin sensitizer (ref. 7).

Two Shelanski Repeated Insult Patch Tests were performed on each of 50 human volunteers. In one test each subject received 15 applications of a sunscreen lotion containing 8 percent homosalate, while in the other test each subject received 15 applications of an aerosol spray preparation containing 4 percent homosalate. In both tests no reactions were observed, and it was concluded that the test materials were not a primary irritant, sensitizing agent, or a fatiguing agent and may be considered safe for contact with human skin (ref. *8*).

The safety of a sunscreen lotion containing 8 percent homosalate was evaluated by the Draize patch test method in a study involving 200 male and female subjects. A patch containing the test material was applied to the skin of the arm or back of each subject. After 24 hours of contact the patch was removed, and any reactions were graded and recorded. Following a 24-hour rest period a second patch application was made. This procedure was repeated until each subject experienced 10 exposures. A challenge dose was applied thereafter following a 14-day rest period. Among the 200 subjects one isolated reaction occurred in one subject at the ninth primary application. This reaction consisted of a well-defined erythema, but did not recur. It was concluded (ref. *9*) that the product was not a primary irritant, a fatiguing agent, or a sensitizing agent.

The safety of a sunscreen cream containing 4 percent homosalate was evaluated by the Draize patch test method in 200 male and female subjects. Six of the 200 subjects experienced slight to moderate erythema on 1 to 3 occasions between the third and ninth primary applications. It was concluded (ref. *10*) that the product possessed a mild fatiguing action, but was neither a primary irritant nor a sensitizing agent.

The safety of a sunscreen oil containing 9 percent homosalate was evaluated by the Draize patch test method in 200 male and female subjects. Two of the 200 subjects experienced slight to moderate erythema on two occasions between the fourth and tenth primary applications. It was (ref. *11*) concluded that the product possesses a mild fatiguing effect, but is neither a primary irritant nor a sensitizing agent.

Salicylate excretion tests were performed in six subjects to determine whether homosalate as contained in a sunscreen lotion is absorbed through the unbroken skin. Five g of the test material (8 percent homosalate) were applied by inunction to each arm, including fingers and forearm to elbow, and rubbed in for a period of 5 minutes. Urinary salicylate excreted by each patient during the following 24 hours ranged from 4.3 to 17.7 mg. The testing laboratory reported, however that experience has shown the "values of less than 20 milligrams salicylate in 24 hours can be obtained with control urines in subjects who are in no manner exposed to salicylate" (ref. *1*). It was concluded that the product is not absorbed through the unbroken skin (ref. *12*).

Marketing experience for seven marketed sunscreen products containing between 4 and 9 percent homosalate indicated the ratio of minor untoward effect complaints to the number of units distributed between 1963 and 1972 ranged from 1:294,814 to 4:919,892. No complaints of serious untoward effects were reported, that is, complaints alleging serious illness or injury, prolonged illness or injury, or hospitalization. Of the 316 total complaints of minor untoward effects three had been confirmed; that is, the complaint had been verified by appropriate medical procedures (ref. *13*).

Based upon the available data, the Panel concludes that homosalate is safe for use as an OTC sunscreen.

(2) *Effectiveness.* There are studies documenting the effectiveness of homosalate as a sunscreen.

Absorbance occurs from 295 to 315 nm, with a maximum at 306 nm (ref. *14*). Depending upon the vehicle, 4 to 15 percent homosalate is effective. An 8 percent (W/V) lotion acts as a permits-suntanning sunscreen agent, while a 15 percent lotion will prevent suntanning and acts as a prevents-sunburn sunscreen agent. Homosalate can be formulated as an aerosol spray, oil, emulsified cream, ointment, and foam.

Homosalate demonstrates very high absorption at 297 nm, the maximum of the erythema action spectrum. The extinction coefficient as determined by the Lambert-Beer Law at 297 nm includes the density readying from the Beckman spectrophotometer, the concentration, and the thickness of the absorbing medium as variables, and was found by Geise to be 6,720 at a concentration of 2.5×10^{-4} mol/liter, whereas that for aminobenzoate was 21,750 at a concentration of 2×10^{-4} mol/liter (ref. *15*).

A sunburn curve was determined and plotted by Kumler and Daniels by multiplying the ordinates of the erythema curve by those of the sunlight distribution curve. Such a curve shows graphically the wavelengths which should be screened out to prevent sunburn. The peak of this sunburn curve is at 308 nm. The greater the extinction coefficient at this wavelength the greater will be the effectiveness of the compound as a sunburn preventive. Aminobenzoate was found to have approximately four times the screening power of homosalate (ref. *16*).

Sunburn and suntan curves were established and plotted by Vicklund by multiplying the intensity of radiation of each wavelength by its effectiveness in producing sunburn and suntan, with the height of the curve at any wavelength indicating the ability of such radiation to cause erythema or tan. The development of a deep, bronze, long-lasting tan requires the formation of melanin pigmentation stimulated by the erythema-producing rays of the energy range 290 to 320 nm and the thickening of the stratum corneum of the skin effected by the erythema-producing shorter wavelengths. Longer wavelengths only darken the preformed melanin, and the thickening of the stratum corneum provides natural protection from sunburn, not tanning. A comparison of the UV sunscreen curve of homosalate with the sunburn and suntan curves indicates that homosalate protects against, but does not provide total absorption of, the erythema-producing rays of the UV spectrum (ref. *17*).

Kreps found that a 2 percent glyceryl aminobenzoate lotion and an 8 percent homosalate lotion transmit 7.0 and 7.5 percent incident E-viton units (unit of erythema flux), respectively, which in both cases will prevent a minimum perceptible erythema (MPE). Exposing skin patches to a standarized UV lamp for 3.5 minutes each hour over a 4-hour period (a total of 14 minutes of radiation which is equivalent to 4 hours of midday midsummer sunlight) produced a vivid erythema without any sensitivity in the case of the skin patch treated with the 2 percent glyceryl aminobenzoate lotion, whereas an extremely painful sunburn resulted in the skin patch treated with the 8 percent homosalate lotion. Kreps concluded that the 2 percent glyceryl aminobenzoate lotion was the more effective of the two, as it did not disappear by absorption into the skin as rapidly as did the 8 percent homosalate lotion. He further concluded that when the rate of percutaneous absorption of the sunscreen compound is marked, the concentration required to provide a desired degree of protection is greater than that indicated by in vitro spectrophotometric measurements (ref. *18*).

Yankell at al. evaluated a 7.7 percent homosalate lotion for sunscreen efficacy using a xenon solar simulator and applying 1 ml of the test material over a 2 X 7 cm area on four sites of male

albino guinea pigs (ref. *19*). Reactions were read 18 hours after irradiating these sites at multiples of the previously determined minimum erythema dose (MED). For the unwashed test sites, the percent protection from erythema was calculated to be 100 percent at 1 MED, 100 percent at 2 MED's and 38 percent at 3 MED's. For the test sites which were washed to simulate swimming and sweating conditions, the percent protection from erythema at 1 MED was 38 percent, with no protection at 2 and 3 MED's.

Willis and Kligman reported that the protective index offered by homosalate was reduced from 4.75 to 1.75 at 4 hours postsweating. They further determined that the penetration of homosalate is limited to the loose, noncoherent upper zone of the stratum corneum, based on their observation that the sun-screening effects of homosalate were almost completely eliminated after 4 strippings with cellophane tape.

Human studies reported by Giese and Wells indicated that "Of some 100 formulations tried, a bentonite clay ointment, a stearate mixture base ointment, a vanishing cream, and an ethocel lotion, nearly all containing homomenthyl salicylate and in some cases also ethyl *p*-aminobenzoate as sunscreens and titanium dioxide as the pigment proved most satisfactory. The value of the ointments in sunburn protection was tested by comparing the ratio of the dosage required in the control patch of skin. Sweating and washing with water decrease the protective value of the ointments but not as much as in the case of commercial ointments tried" (ref. *20*).

Controlled human studies of marketed homosalate preparations demonstrated the significance of the way in which a homosalate preparation is formulated on sunburn protection. Oil formulations produced the thinnest films on the skin and accumulated the least after repeated applications under normal use application. Oil formulations provided approximately one-half the protection of cream formulations of the same concentration. Oil-less lotions and creams were found to produce thicker films and to accumulate to a greater extent, thereby producing a reduction in tanning but facilitating the adjustment of the formulation to a wide range of skin sensitivities. A cream formulation containing 4 percent homosalate provided greater sunburn protection than did a lotion formulation containing 8 percent homosalate based upon protective factor determinations, that is, the ratio of MED of protected skin to that of unprotected skin (ref. *21*).

Based on the available data, the Panel concludes that homosalate is an effective sunscreen for OTC use. It recommends that homosalate be used as an internal control standard for in vivo efficacy testing in man.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 4 to 15 percent homosalate: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 4 to 15 percent homosalate: Adult and children over 6 months af age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

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1. *Lawsone with dihydroxyacetone.* The Panel concludes that lawsone in conjunction with dihydroxyacetone is safe and effective for OTC use as a sun screen as specified in the dosage section discussed below.

Lawsone is also known as 2-hydroxy-1,4-naphthoquinone. Lawsone is the principal dye component of henna, which has been used since antiquity to dye skin and hair (ref. *1*). Lawsone has a low vitamin K activity by means of its chemical relationship to 2-methyl-1,4-naphthoquinone (menadione) (ref. *2*).

Dihydroxyacetone (DHA) is also known as 1,3-dihydroxy-2-propanone. DHA is also a dye used as a skin browning agent. DHA is discussed earlier in this document. (See part II. paragraph I. above—Sunscreen Products Containing Dihydroxyacetone.)

DHA is produced from glycerol by *Aerobacter sp.* under aerobic conditions. It is a fairly hygroscopic, crystalline powder and has a characteristic odor and a sweet and cooling taste. It normally occurs as a dimer, in which form it is slowly soluble in 1 part water and 15 parts alcohol. When freshly prepared, DHA reverts rapidly to a monomer in solution, in which form it is very soluble in water, alcohol, ether, and acetone (ref. *3*).

The Panel received one submission for a marketed product composed of two lotions which are packaged together and labeled to be applied separately and in sequence. The first lotion to be applied contains 3 percent DHA, to be followed by application of a second lotion containing 0.25 percent

lawsone. The manufacturer claims that the product is effective, when applied as directed, in preventing sunburn and photosensitivity reactions caused by sunlight. The dual product is claimed to have an action spectrum that spans both short-UV (290 to 320 nm) and long-UV (320 to 400 nm) wavelengths.

The manufacturer claims "the product is unique in that it gains its effectiveness not from forming a film on the surface of the skin, but rather from its active ingredients fixed to the keratin layer to form a permanent, non-washable barrier. How this occurs is not fully understood. It is postulated that dihydroxyacetone (DHA) reacts with certain amino acids of keratin and frees moieties for further reaction with lawsone. One theory is that DHA splits the disulfide bonds and lawsone then reacts with the free sulfhydryl groups by 1,4 addition."

The Panel has evaluated the submitted data and concludes that when the two ingredients are used separately and sequentially, the combination is classified as Category I. Each ingredient when used alone cannot be classified as a Category I sunscreen. The submitted data indicate that the two solution product provides sunscreen protection which varies considerably among individuals, depending on such factors as susceptibility of the skin to fixing of the active ingredients, thickness of the keratin layer where the sunscreen resides, number of daily applications, degree of the individual photosensitivity, and amount of UV radiation received.

(1) *Safety.* The Panel concluded on the basis of toxicity studies that lawsone in conjunction with DHA is safe in the dosage range used as an OTC sunscreen.

Data were submitted for subacute dermal toxicity and irritation studies in which 20 healthy young adult albino rabbits were divided into 5 groups of 4 rabbits per group, including a control group (lotion base). Four concentrations (0.29, 0.58, 1.16, and 2.32 ml/kg) of a lotion containing 0.125 percent lawsone and 3.0 percent DHA were applied to the shaved abdominal skin area for 6-hour periods, 5 days a week for 13 weeks for a total of 65 applications. The application of 0.29 ml/kg of the lotion was considered to be equal to the normal human single dose. The shaved area in a male and female rabbit of each group was abraded initially and at the beginning of each subsequent week by using a hyperdermic needle to make a series of parallel minor epidermal incisions. The test materials were held in place by an occlusive bandage with an initial layer of plastic film. Twice daily each animal was examined for signs of dermal of systemic toxicity. Each rabbit was weighed weekly. Hematology, urinalysis, and blood chemistries were performed prior to the initial application of the test materials and just prior to the sacrificing of the animals at the end of 13 weeks. Hematology was also performed at 7 weeks. Following sacrifice, gross necropsies and histopathology of all organ systems were performed. The investigators concluded from the data that "No significant differences were noted among the groups with respect to body weight gains, gross appearance and behavior, mortalities, hematological findings, blood chemistry findings, urine findings or gross or microscopic pathological findings. The control animals showed mild to marked spotty erythema and mild to moderate desquamation during the study. The animals in the remaining groups showed occasional mild desquamation only" (ref. *4*).

Hanke and Talaat (ref. *1*) reported a study in which 3 g ground whole henna leaf equivalent to 30 mg of lawsone were orally administered daily to 90 patients with intestinal amoebiasis for periods of from 4 to 6 or 8 weeks. Seven patients, who relapsed during the 6-week followup period, were given a second course of treatment. One patient experienced severe diarrhea, and treatment was discontinued after 3 days. Transient diarrhea was experienced by five other patients whose treatment was continued full course. These were the only observed side effects.

Fusaro, Runge, and Johnson reported their experiences with 77 patients with various forms of recalcitrant sunlight sensitivity, who received topical applications of mixtures of 0.13 percent lawsone and 3.0 percent DHA in vanishing cream and 50 percent isopropyl alcohol/distilled water vehicles. They reported that "During these clinical trials, not a single incident of cutaneous sensitization was observed" (ref. *5*).

The Panel reviewed several other published studies by Fusaro et al., representing 10 years experience in the use of dihydroxyacetone/lawsone preparations in more than 350 patients with various types of photosensitivities. No adverse reactions attributable to these two active components were reported (refs. *6* through *13*).

The primary irritant and sensitization effects of a 0.125 percent lawsone lotion, the lotion base, a 3.0 percent DHA lotion, the lotion base, and a 0.125 percent lawsone and 3.0 percent DHA lotion were evaluated in a controlled study using an adaptation of the repeated-insult patch test procedure of Draize (ref. *14*). Webril patches affixed to the center of elastic adhesive bandages were moistened with 0.5 ml of the respective test material just prior to the application to the arms of each of 103 male and female subjects. The patches were applied on Mondays, Wednesdays, and Fridays for 3 consecutive weeks. Duplicate challenge applications of each test material were made after a 2-week rest period, with one set of patches being placed on the original test sites and the other set being placed on adjacent sites. The patch sites were scored on the second through tenth visits and at 48 and 96 hours following the challenge applications. Very slight irritation was observed following repeated applications of the 0.125 percent lawsone lotion and its lotion base. The 0.125 percent lawsone and 3.0 percent DHA lotion was found to be essentially nonirritating. None of the above-noted test materials showed evidence of sensitization.

A total of 9 patients received complete blood counts, SMA-12 profiles, and urinalyses at baseline and after 3 to 6 months of continuous administration of a sunscreen preparation in a lotion formulation containing 0.25 percent lawsone and 3.0 percent DHA. All of the above values remained in the normal range throughout the studies. One patient experienced what appeared to be acne vulgaris, which coincided with the initiation of oral contraceptive therapy. Another patient experienced transient irritation of the cheek during the initial 2 weeks, but responded to topical steroid therapy and continued in the study (refs. *14* and *15*).

A total of 56 photosensitive patients were treated with a sunscreen preparation in a lotion formulation containing 0.25 percent lawsone and 3.0 percent DHA. Adverse reactions consisted of one case of an aggravation of a previous dermatitis condition and a case of a burning sensation on application which was tolerated upon continued use (refs. *14*, *15*, and *16*).

Based on the available data, the panel concludes that lawsone with DHA are safe sunscreen ingredients for OTC use.

(2) *Effectiveness.* There are controlled studies documenting the effectiveness of lawsone in conjunction with DHA as an OTC sunscreen.

The use of lawsone in conjuction with DHA as a topical sunscreen is reported to be effective against both short-UV (290 to 320 nm) and long-UV (320 to 400 nm) wavelengths, to alter the keratin layer and strengthen its inherent light-screening characteristics, to be permanently affixed to the skin thereby resisting bathing, sweating and swimming, and to be especially recommended for light-sensitive individuals (ref. *17*).

Fusaro et al. evaluated the protective effects of 50 percent isopropanol solutions of 3.0 percent DHA in combi-

nation with 0.035 and 0.13 percent lawsone on normal skin using natural sunlight under controlled conditions (ref. *6*). The DHA and lawsone solutions were not mixed until shortly before application. Six consecutive applications of the test materials were made at 1-hour intervals and then were allowed to remain on the skin from 10 to 12 hours prior to washing the test sites with soap and water. Sunlight exposure was started 2 hours afterwards. From 2½ to 3 MED's protection was provided the 18 subjects treated with the combination of the 3.0 percent DHA and 0.035 percent lawsone preparations. The four subjects treated with the mixture of the 3.0 percent DHA and 0.13 percent lawsone preparations received greater than 5 MED protection, as did the subject who increased the number of applications of the 0.035 percent lawsone preparation. Results obtained for five subjects indicated that neither the 3.0 percent DHA solution nor the 0.13 percent lawsone solution provided significant protection when applied alone as compared with the application of the mixture of these two solutions. The protective barrier provided by the application of DHA and lawsone solutions is resistant to washing with soap and water on the basis of the above-described results.

Fusaro et at. evaluated 77 patients with various forms of recalcitrant sunlight sensitivity, who received topical applications of mixtures of 0.13 percent lawsone and 3.0 percent DHA in vanishing cream and isopropyl alcohol/water vehicles. The degree of protection received by each patient was determined by the change in the patient's tolerance to sunlight exposure during use of the test materials. The median tolerance time prior to the application of the test materials was less than 1 hour, which was increased to 3 hours following use of the sunscreen. Of the 77 subjects, 51 (66 percent) obtained 3 or more hours of protection, 8 (10 percent) received less than 1 hour of protection, and 9 (12 percent) failed to obtain any benefit. Fusaro et al. reported that because DHA and lawsone will react and deteriorate when mixed together, the active ingredients should be given in separate vehicles, with the DHA preparation being applied first (ref. *5*).

Fusaro and Runge reported 9 years experience with a total of 267 mental patients with photosensitivity caused by chlorpromazine therapy, who received topical applications of equal amounts of 6.0 percent DHA and 0.25 percent lawsone both in 50 percent isopropyl alcohol/distilled water vehicles which were not mixed until just prior to application. Approximately 10 percent of the patients received the sunscreen for more than one season. The sunscreen mixture was applied by spraying five times daily for 3 days prior to the first exposure and once or twice daily thereafter, depending on the individual patient's degree of photosensitivity. It was reported that 84 percent of the patients experienced good (unlimited protection) or fair (mild erythema after several hours exposure to sunlight) results. Among the explanations offered for treatment failures were improper application of the sunscreen by the staff and uncooperative patients who refused to be sprayed regularly and/or washed the treated area immediately following spraying (ref. *12*).

Fusaro and Runge reported studies involving seven patients with erythropoietic protoporphyria wherein 3.0 percent DHA and 0.13 percent lawsone preparations in both a vanishing cream base and a 50 percent isopropyl alcohol/distilled water solution were applied after the patients' cutaneous eruption had cleared by means of topical steroid therapy and avoidance of sufficient light exposure to cause symptoms. The topical preparations were applied six to eight times daily for the first 2 days and thereafter three times daily for the next 5 days. At the end of the first week each patient was allowed to be exposed to sunlight for a period of time which was equivalent to the time based upon past experience when there would be an outbreak of cutaneous symptoms or eruption. Following the first exposure, each patient, depending on his/her degree of light sensitivity would apply the preparations one to four times daily. Only two patients applied the preparation in the alcohol/water vehicle, and upon receiving virtually no protection they were restarted on the preparation in the cream base. Fusaro and Runge reported that after protection with the above-described preparation in the cream base, all seven patients "were able to change their daily lives from one of predominantly 'indoors' to that of 'outdoors'" and that the five children among the patients were able for the first time to go swimming and participate in outdoor sports. For the seven patients the time necessary to produce symptoms or lesions from sunlight exposure was from less than 10 minutes to 2 hours at baseline and ranged from more than 3 hours to more than 8 hours after receiving protection from the DHA preparation in the vanishing cream base. Fusaro and Runge pointed out, however, that the total amount of electromagnetic radiation available in Minneapolis, where the study was conducted, is much less than in other areas of the country and that the Minnesota area has fewer sunny days than elsewhere (ref. *18*).

Three fair-skinned female volunteers participated in a controlled study wherein application schedules for 3.0 percent DHA and 0.125 percent lawsone creams and 6.0 percent DHA and 0.25 percent lawsone lotions were compared. Five test sites, including one control, were marked on the midthigh area of each leg, and the light source was a xenon-mercury lamp equipped with a filter which excluded all radiation below 260 nm and whose output between 280 and 320 nm was about 6.5 percent of the total energy. The MED was determined for each subject. One of the two preparations tested consisted of equal amounts of 6 percent DHA and 0.25 percent lawsone mixed just prior to application. The other consisted of two single preparations in which a 3.0 percent DHA cream was applied 15 minutes before the application of a 0.125 percent lawsone cream. One of the two application schedules tested involved making three applications of both preparations at 30-minute intervals on days 1 and 2, while the other consisted of three applications of both preparations at 30 minute intervals on day 2 only. On day 3, the treated and control sites on one leg of each patient were exposed to 3 MED's radiation, while the test sites on the other leg were exposed to 6 MED's. On days 4 and 5, the test sites were scored on a 0 (no perceptible erythema) to 4 (marked erythema and blisters) scale. Minimal protection was afforded by three or six applications of DHA and lawsone when applied as freshly prepared mixtures, as the scores mostly fell into the 2 (moderate erythema) to 4 (marked erythema and blisters) range. Scores ranged generally between 0 (no perceptible erythema) and 2 (moderate erythema) when the DHA cream was applied 15 minutes prior to the lawsone cream, with the application shedule involving three applications on both days 1 and 2 providing significantly more protection than that in which the applications were only made 24 hours prior to exposure. The control sites generally showed marked erythema with and without blisters (ref. *19*).

Fusaro treated 16 patients with severe photosensitivities of varied etiologies. The test preparations consisted of a 3.0 percent DHA lotion and a 0.25 percent lawsone lotion applied during spring, summer, and fall prior to exposure to potentially damaging light. Each application was made in the evening prior to retiring with the treated areas being bathed in the morning and throughout the day as required. The DHA lotion was applied 15 minutes before the application of the lawsone lotion. Initially, two or three applications were made each evening, with 15 minutes elapsing from the time the lawsone lotion was

applied prior to the reapplication of the DHA lotion. Either three applications each night for 2 nights or two applications each night for 3 nights were made. Thereafter, the protection was maintained by making one or two daily applications. The tolerance of the subjects to sunlight prior to the use of the test materials ranged from 5 minutes to 3 hours, with a median time of 10 minutes. Following the above applications, the median time increased to 2 hours, with the tolerance ranging from 25 minutes to more than 8 hours for these subjects considered to have benefited from the use of the sunscreens. In the opinion of the investigator, 13 or 80 percent of the 16 subjects exhibited excellent to good response (ref. *16*).

O'Quinn treated 14 patients of whom 12 had allergic contact photodermatitis, and all but 2 were Blacks. A 3.0 percent DHA lotion and a 0.25 percent lawsone lotion were applied in the same manner as described above except that two or three daily applications were in most cases made following the initial exposure to sunlight to maintain protection. O'Quinn reported that excellent or good protection was achieved in eight patients (57 percent), fair protection in one, poor protection in three, and no protection in two. Four of the eight patients with good to excellent protection had previously used various proprietary sunscreens, including those containing aminobenzoate (PABA). The investigator experienced difficulty clearing the dermatitis in several patients and was of the opinion that increased protection would have been obtained had the treated areas been normal throughout the study (Ref. 14).

Rice treated 26 photosensitive patients. A 3.0 percent DHA lotion and a 0.25 percent lawsone lotion were applied in the same manner as in the preceding two studies, with one application daily following the initial exposure to light. In addition, a part of the test area was treated with 3.0 percent DHA lotion in three cases, with 0.25 percent lawsone lotion in two cases, and with the lotion vehicle in two cases. At baseline, three patients tolerated from 1 to 2 hours. Rice reported that all 26 patients achieved good to excellent protection as 11 patients tolerated 6 to 8 hours of sunlight exposure, 5 tolerated 4 to 6 hours and 10 tolerated 2 to 4 hours. Median tolerance time increased from less than 1 hour prior to treatment to about 5 hours during treatment before the patients experienced eruptions or burning. Before the study, 12 patients had used commercial sunscreens containing aminobenzoate (PABA) without obtaining adequate protection. Rice also reported that those test sites were considered unprotected which were only treated with the single ingredient lotions or the lotion vehicle (Ref. 15).

Based on the available data, the Panel concludes that lawsone with DHA are effective sunscreen ingredients for OTC use.

(3) Dosage. (i) For products composed of two separate formulations (Solution 1: containing 3 percent dihydroxyacetone. Solution 2: containing 0.25 percent lawsone) providing a minimum SPF value of 2 to under 4: Adult and children over 2 years of age topical dosage is liberal application before sun exposure as follows: First application. The evening prior to sun exposure: Apply Solution 1. Wait 15 minutes; then apply Solution 2 to the same areas of skin. Wait until dried. Then repeat application of solutions alternately as before until a total of three applications of both lotions has been applied. Leave on skin without washing. Repeated application. After first day, apply one application of each lotion. Reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products composed of two separate formulations (Solution 1 containing 3 percent dihydroxyacetone. Solution 2: containing 0.25 percent lawsone) providing a minimum SPF value of 4: Adult and children over 6 months of age topical dosage is liberal application before sun exposure as follows: First application. The evening prior to sun exposure: Apply Solution 1. Wait 15 minutes; then apply Solution 2 to the same areas of skin. Wait until dried. Then repeat application of solutions alternately as before until a total of three applications of both lotions has been applied. Leave on skin without washing. Repeated application. After first day, apply one application of each lotion. Reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) Labeling. The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.) In addition, based upon the discussion above, the Panel recommends the following warnings: (i) "This is a two lotion product. Do not mix the contents of the two solutions. Use both solutions, for use of one alone will not provide protection."

(ii) "Use only on skin free of rash and abrasions."

(iii) "May stain clothing when freshly applied."

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m. *Menthyl anthranilate.* The Panel concludes that menthyl anthranilate is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

Menthyl anthranilate is the menthyl ester of anthranilic acid. It belongs to the group of ortho-aminobenzoate compounds which are much weaker sensitizers than are the para-amino-

benzoate compounds. Menthyl anthranilate is insoluble in water, and is soluble in 7 parts of 80 percent ethanol.

(1) *Safety.* Clinical use and marketing experience have confirmed that menthyl anthranilate is safe in the dosage range used as an OTC sunscreen.

Animal and human toxicological data and wide use attest to its safety for human topical application. The oral LD_{50} is 8.39 g/kg in rats (ref. *1*).

An in vivo percutaneous absorption study was performed in which 50 mg of a sunscreen cream containing 5 percent menthyl anthranilate and 4 percent ethylhexyl *p*-methoxycinnamate was applied to the inner surface of each arm of six healthy adult subjects. It was reported that 98 percent of the menthyl anthranilate was recovered after 4 hours' contact with the skin (ref. *2*).

Sams reported a study in which a 1:100 alcoholic solution of a perfume was streaked on the undersurface of the right forearm of a subject and allowed to dry. A 5 percent menthyl anthranilate in alcohol solution was then applied across this streak, and the arm was exposed to the midday sun for 1 hour on a bright day. It had previously been demonstrated that the perfume solution under such exposure would provoke a sensitivity reaction with erythema and mild vesiculation. It was reported that the 5 percent menthyl anthranilate solution adequately blocked the erythema from sun exposure (ref. *3*).

The erythema response with equimolar (3×10^{-4} M) solutions of various topical sunscreens was evaluated in 10 subjects and scored on a scale of 0 to 4 following exposure to UV radiation from an artifical light source. The average value for the preparations was tannic acid—0.25, aminobenzoate—0.95, glyceryl aminobenzoate—1.7, menthyl anthranilate—2.2, phenyl salicylate—2.8, and ethyl alcohol control (common vehicle)—3.5 (ref. *4*).

On the subject of the ortho-aminobenzoates, Fisher reported that "The 'ortho' compounds are essentially the anthranilates—methyl, phenyl, menthyl and benzyl—which are much less commonly sensitizers than are the 'para' compounds" (ref. *5*).

Repeat-insult patch tests were performed on 11 healthy Caucasian males to study the relative irritancy of six topical preparations among which were a marketed sunscreen cream containing 5 percent menthyl anthranilate and 5 percent titanium dioxide and another sunscreen cream containing 5 percent menthyl anthranilate and 4 percent ethylhexyl *p*-methoxycinnamate. Each test material was applied to a 1-inch square nonwoven cloth patch which was then placed in contact with the skin of the back of each patient by means of an occlusive, impermeable plastic tape. The patches were replaced daily for 10 days or until redness appeared, after which no further applications were made at that test site. In the case of the menthyl anthranilate/titanium dioxide cream, all but three subjects completed the study, with the tests being concluded on the fourth, seventh, and ninth days for these subjects. As for the menthyl anthranilate/ethylhexyl *p*-methoxycinnamate cream, all subjects completed the study, except for one patient who was terminated on the seventh day when redness appeared at the test sites for both of the above-named creams. On the basis of a 0 to 4 scale, the average index was 1.3 for the former preparation and 0.4 for the latter. The investigator concluded that these preparations were virtually nonirritating (ref. *6*).

The incidence of complaints for a sunscreen containing 5 percent menthyl anthranilate and 5 percent titanium dioxide was reported to be slightly less than one complaint per 100,000 units distributed. Approximately 13 percent of the complaints involved reports of contact dermatitis and possible photocontact dermatitis, but in the latter case photopatch tests were negative or photosensitivity from systemic medication was suspected (ref. *7*).

Based on the available data, the Panel concludes that menthyl anthranilate is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of menthyl anthranilate as an OTC sunscreen.

Insoluble in water, but soluble in ethanol, menthyl anthranilate can be incorporated into emulsion, oil, and paste formulations. It is often used in combinations with other sunscreens. At higher concentrations it does offer 290 to 320 nm range absorption, with peak UV absorption at approximately 340 nm (ref. 8).

Harber evaluated the protection from light provided by five compounds containing the benzoic acid nucleus with various substituted side chains. Each ingredient was dissolved in 95 percent ethyl alcohol, as this solvent was found to have no significant UV absorption. Fifty volunteers (32 females and 18 males) with no skin lesions on their backs were involved in the study. In the first experiment, the test materials were placed in cylindrical quartz cups and were not in contact with the skin. UV radiation was provided by a D.C. Hanovia lamp at 30 inches for 60 seconds which approximated 1½ times the empirical minimal erythema dose. All test materials at a 3×10^{-2}M concentration were effective in preventing erythema, with no significant differences among them being discernible at 3×10^{-4}M and 3×10^{-5}M concentrations. Tannic acid and aminobenzoate were decidedly superior to the remaining compounds which in decreasing order were glyceryl aminobenzoate, menthyl anthranilate, and phenyl salicylate. In the second aspect of the investigation, 2 drops or approximately 0.4 ml of 5 percent solutions of each test material were placed on the backs of the subjects. The source of irradiation was again the D.C. Hanovia lamp at 30 inches for 60 seconds. The investigator reported that phenyl salicylate and menthyl anthranilate provided protection only minimally different from that of the 95 percent ethyl alcohol control; whereas when compared to the control, both tannic acid and aminobenzoate provided excellent protection, and glyceryl aminobenzoate protection was rated as good. In the third part of the experiment, approximately 0.4 ml of each test material was applied to the test sites on the subjects' backs, which were then exposed to 2 hours of midday natural sunlight. The investigator reported that both tannic acid and aminobenzoate were excellent in preventing erythema. Glyceryl aminobenzoate and phenyl salicylate had fair sun-screening ability, and the protection provided by menthyl anthranilate was poor. Harber stated, however, that "Under rigid statistical analysis, no significant differences could be established in the sunscreening properties of phenyl salicylate, menthyl anthranilate, or glyceryl para-aminobenzoate. It is the author's belief that further studies may demonstrate that menthyl anthranilate is the poorest erythema-protecting agent of all compounds tested in this study" (ref. *9*).

Seven Caucasian males were involved in a study comparing the protection to graded dose of UV irradiation by a sunscreen containing 5 percent menthyl anthranilate and 4 percent ethylhexyl *p*-methoxycinnamate and a 5 percent menthyl anthranilate cream. The radiation provided by a hot quartz UV lamp at 30 inches for 15 seconds was calibrated to be equivalent to 1 MED. The test materials were applied to different sides of the subjects' backs. Three patients who had ingested aspirin both before and after as much as 10 MED's irradiation showed no reaction on either side and were retested at different sites on their backs several days later because of the suppressive effects of aspirin. The final test results showed that the menthyl anthranilate/ethylhexyl *p*-methoxycinnamate cream provided complete protection up to and including 14 MED's, whereas the 5 percent menthyl anthranilate cream provided

protection from erythema up to at least 4 MED's in all cases (ref. *10*).

The protective ability of menthyl anthranilate against long-wave ultraviolet (UV-A) radiation constituting the spectrum between 320 and 400 nm was determined using 8 sensitized albino guinea pigs. Seven hours prior to exposure the abdominal skin was shaved and depilatorized. One hour prior to exposure the test animals were sensitized to UV-A by intraperitoneal injections of 88 mg/kg of 8-methoxypsoralen. The UV-A light source was a Black-Ray UVL-56 which was placed 3½ inches from the animals. A 5 percent menthyl anthranilate in alcohol solution and a placebo solution were applied to test sites on the first animal, and the test sites were irradiated at 5-minute increments from 5 to 20 minutes. A 5 percent menthyl anthranilate preparation in its cream base, but without its other active sunscreen component (titanium dioxide), was applied to test sites on the remaining seven animals and exposed at 3-minute increments from 3 to 15 minutes. The test sites were read at 24 and 72 hours following exposure and were scored on a scale from 0 (no erythema) to 4+ (necrotic erythema). In the case of the first test animal, the readings after 20 minutes' exposure at 24 and 72 hours were 2+ (medium erythema) at the menthyl anthranilate-treated site and 3+ (maximum erythema) and 4+ (necrotic erythema) at the placebo-treated and untreated sites, respectively. After 15 minutes exposure the readings for the menthyl anthranilate-treated site in the seven remaining animals were 0 (no erythema) at 72 hours following exposure, whereas five of these animals demonstrated slight erythema (1+) at 24 hours following exposure. For the placebo-treated test sites the latter seven animals had 3+ (maximum erythema) readings at 24 hours and 4+ (necrotic erythema) readings at 72 hours after exposure. The investigators concluded that "The uniqueness of menthyl anthranilate as an UV absorber has been demonstrated in this study. Although menthyl anthranilate showed some absorption in the mid-UV region, as manifested by reduced erythema compared with placebo and untreated sites, it absorbs preferentially in the near UV as demonstrated by its protective effect on psoralensensitized albino guinea pigs" (ref. *11*).

Based on the available data, the Panel concludes that menthyl anthranilate is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 3.5 to 5 percent menthyl anthranilate: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 3.5 to 5 percent menthyl anthranilate: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

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n. *Oxybenzone.* The Panel concludes that oxybenzone is safe and effective for OTC use a sunscreen as specified in the dosage section discussed below.

Oxybenzone is also known as 2-hydroxy-4-methoxybenzophenone and benzophenone-3.

Its absorbance is between 270 and 350 nm, with the maximum absorbance at 290 nm. It is soluble in ethyl and isopropyl alcohol and in mineral oil and linseed oil, but it is virtually insoluble in water. Oxybenzone is incorporated in emulsion, oil, and lipstick formulations. It is frequently used in combination with other sunscreens.

(1) *Safety.* Clinical use and marketing experience have confirmed that oxybenzone is safe in the dosage range used as an OTC sunscreen.

Extensive animal and human toxicological data and wide use attest to its safety for human topical application. The LD_{50} is over 12.8 g/kg in rats treated orally and in excess of 1.6 g/kg in mice treated intraperitoneally (refs. *1*, *2*, and *3*).

Pads, each 4 cm^2 and containing 0.5 g oxybenzone moistened in distilled water, were applied to shaved areas on the backs and flanks of six New Zealand white rabbits. The test sites in one-half of the rabbits had been previously abraded with a skin scraper. After 24 hours, the pads were removed, and the test sites were rinsed with water to remove residues of the substance. Daily examinations were made the next week for signs of systemic poisoning and skin changes in the test site areas. It was reported that both the intact and abraded sites remained free of irritation throughout the 7-day observation period. The investigators instilled 0.1 g oxybenzone into the conjunctival sac of the left eye of each of three New Zealand white rabbits, with the right eye serving as a control. Daily examinations during the following week revealed that the eyes remained completely free of irritation (refs. *2* and *3*).

The subchronic dermal toxicity of a sunscreen containing 6 percent oxybenzone and 12 percent homosalate was evaluated by applying 0.5 g or 2 g/kg of the test material to the shaved intact or shaved abraded skin of albino rabbits daily, five times weekly, for 3 weeks (15 applications), with 2 g/kg of 0.6 percent methycellulose being applied to the controls. All test animals remained healthy and vigorous throughout the study. Hematology, clinical biochemistry, necropsy reports, histopathology, weight gain, and food consumption of all test animals were within normal limits. During the early stages the intact and abraded skin of all test animals, including the controls, exhibited mild erythema, which appeared to be dose related and disappeared early, thereby suggesting some degree ot dermal hardening. From the second week, the abraded skins of all test animals, including the controls, exhibited drying and scaling of the skin, but this condition was considered to be of no major consequence (ref. *4*).

A sunscreen containing 6 percent oxybenzone and 12 percent homosalate was evaluated by instilling 0.1 ml of the product into the conjunctival sac of one eye of each of six New Zealand white rabbits, with the the opposite eye serving as a control. Following instillation, no erythema or edema was observed, and no subsequent irritation

was detected. Detailed visual and ophthalmoscopic examinations were performed 24, 48, and 72 hours after instillation and did not reveal any positive overt ocular abnormalities (ref. *5*). In a similar study, 0.1 ml of the above-named sunscreen product was instilled into the left eye of each of 12 albino rabbits, with the right eye serving as the control. Six test animals received no further treatment, while the treated eyes of the remaining six rabbits were irrigated with 20 ml of lukewarm tap water approximately 4 seconds after instillation of the test material. One hour after instillation and once daily thereafter until any observed eye irritation subsided completely, or for a maximum of 14 days, the eyes were observed both for irritation and gross signs of systemic toxicity from mucous membrane absorption of the test material. The irritative effects in both the irrigated and nonirrigated eyes were limited to mild conjunctivitis, which was observed at the 1-hour reading only. No evidence of systemic toxicity resulting from mucous membrane absorption was observed, nor was corneal opacity or iritis noted (ref. *6*).

Photosensitization studies were conducted in which the hair of the saddle area of each of nine albino rabbits was removed with electric clippers, and 0.4 ml of a sunscreen containing 6 percent oxybenzone and 12 percent homosalate was applied to 2-inch square test sites on six of the rabbits, with the remaining three rabbits being untreated and serving as controls. These applications were made daily, five times weekly, for 2 weeks (10 applications). Following each application the control and test animals were irradiated with UV light for 15 minutes using a sunlamp at a distance of 12 to 14 inches. Readings were made 24 hours after each application and were graded on a scale from 0 (no erythema) to 3 (erythema and trauma, or marked edema or desquamation). No significant increases in the severity of the reaction during the course of the study were noted between the control and test animals. Mild erythema and edema were generally observed in all test animals throughout the study. Desquamation was noted after the fifth application to the test animals and after the eighth application in the controls. It was reported that the reactions were not considered manifestations of photosensitization, but represented a normal response to repeated dermal insult (ref. *6*).

One ml (approximately 0.5 g) of a sunscreen lotion containing 6 percent oxybenzone and 12 percent homosalate was applied to a 1½ X 3 inch area on the posterior forearm of each of 14 subjects. After 4 hours, the lotion was removed. It was calculated that an average of 95.41 and 96.51 percent of the homosalate and oxybenzone, respectively, was recovered from the skin. Within the technical limits of the above-described percutaneous absorption study, essentially complete recovery of the test material was indicated by the data (ref. *7*).

Patch tests of a sunscreen formulation containing 3 percent oxybenzone, 3 percent padimate A, and 4 percent padimate 0 on 100 female volunteers showed no evidence of any inflammatory reaction at the test sites on the upper back of the subjects immediately, 15 minutes, and 24 hours following the removal of the 48-hour patch tests (ref. *8*). Further patch tests of the above-described preparation on 203 female volunteers, who were subjected to ten 48-hour repeated patch tests and a challenge dose 14 days later, confirmed that the preparation is not a primary irritant and also demonstrated that any "sensitizing potential, if existent at all, is exceedingly low" (ref. *9*). The photosensitization potential of the above-described formulation was evaluated by subjecting 25 female volunteers to repeated-insult patch tests with an UV light source. The light source was used to determine the MED for each subject. Comparison of the light-protected control site and the test site treated with the test material and irradiated with the MED established for the subject revealed no change in skin character 24 and 48 hours later. It was concluded that the photosensitization potential of the formulation, if existent at all, is exceedingly low (ref. *10*).

In another study by Kantor, a product containing 7 percent padimate 0 and 3 percent oxybenzone was tested on 150 subjects according to a modified Draize-Shelanski repeated-insult patch procedure. Several non-specific irritation reactions were observed under occlusive conditions, but none showing signs of being a primary irritant. The same test material was applied to the backs of 26 subjects for photpatch testing. Ultraviolet light, from a Hanovia Tanette Mark I lamp, was directed on the subjects' backs for a period of 1 minute, from a distance of 12 inches. Results following 48 hours from initial testing showed no adverse reactions observed in the 26 subjects tested (ref. *11*).

Jordan evaluated a product containing 7 percent padimate 0 and 3 percent oxybenzone applied to the backs of 150 healthy adult patients. The test material was evaluated according to a modified Draize repeated-insult patch test. The material tested was applied to the scapular back under occlusive patches three times a week for 10 applications. Two consecutive occlusive challenge tests were applied to different areas on the scapular back after a 2-week rest period from initial testing. Results from observations taken immediately after removal of the patches showed mild irritational responses from the challenge tests, but no allergic response (ref. *11*).

Based on the available data, the Panel concludes that oxybenzone is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of oxybenzone as an OTC sunscreen.

By means of a solar simulator, the protective indices (P.I.) of a lotion vehicle, 3 percent oxybenzone in the lotion vehicle, 3 percent padimate A in the lotion vehicle, and 4 percent padimate 0 in the lotion vehicle were determined to be 1.31 ± 0.3, 2.37 ± 0.82, 6.03 ± 1.03, and 7.06 ± 1.25, respectively. The tests were performed by applying 100 ml of the test material to a 5×10 cm^2 area on each subject's back. The number of subjects varied from 9 to 17 for each test material. Fifteen minutes after application, each subject had areas of 1 cm^2 exposed to UV light from a solar simulator with a graded series of exposures being administered to both the test sites and adjacent untreated control sites. Twenty-four hours later, the minimal delayed erythemic responses were evaluated, and the protective indices were then calculated. The above-stated values reflect the mean protective index and standard deviation for the respective test material (ref. *12*). In a similarly conducted solar simulator test of a preparation in which the above-stated three ingredients had been combined in the lotion vehicle in the same concentrations as stated above, the mean protective index was determined to be 20.4 ± 5.8 based on the data for 18 subjects (ref. *13*).

Katz evaluated the relative effectiveness of four sunscreen preparations, i.e., 3 percent oxybenzone and 3 percent dioxybenzone in a cream base, 2.5 percent padimate A in 65 percent ethanol with emollients, 5 percent aminobenzoate in 70 percent ethanol with emollients, and 5 percent aminobenzoate in 70 percent ethanol (ref. *14*). Previously unexposed skin of the buttocks or [illegible] shaven suprapubic areas of [illegible] subjects was divided into six equal 2- or 3-inch square p[illegible] adhesive tape. The four [illegible] were liberally applied to ra[illegible] areas on one side of each su[illegible] allowed to dry for 15 minutes. [illegible] swimming in a fresh water pool for 10 minutes, the previously untreated side of each subject was thoroughly dried and the same test materials were applied to randomized areas. The test sites were then exposed to the maximum possible natural sunlight for 1 hour. Erythema was evaluated by three independent observers 24 hours later and graded on a

scale from 0 (no reaction) to 4 (bright and fiery red). Except for the 2.5 percent padimate A preparation, all sunscreens were considered to have provided good protection from the erythematogenic rays of the sun on the side treated following swimming, as the scores ranged from 0 (no reaction) to 2 (pink) for these three preparations. However, none of the preparations was considered to have provided consistently satisfactory protection when applied to the test sites after swimming, but slightly more protection was provided than when the preparations were applied prior to swimming. In the latter instance, it was thought that the failure of the aminobenzoate preparations to provide satisfactory protection when the subjects swam after application may be due to the short interval between application and swimming (i.e., 15 minutes) which lessened the penetration of the aminobenzoate molecules into the stratum corneum.

Based on the available data, the Panel concludes that oxybenzone is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 2 to 6 percent oxybenzone: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 2 to 6 percent oxybenzone: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

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o. *Padimate A.* The Panel concludes that padimate A is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

Padimate A is also known as amyl *p*-dimethylaminobenzoate, isoamyl *p*-*N,N*-dimethylaminobenzoate, and pentyl 4-(dimethylamino) benzoate.

Padimate A is a yellow, mobile liquid, with a faint aromatic odor. It has a molecular weight of 277. It is soluble in isopropyl alcohol, mineral oil, and ethyl alcohol. It is insoluble in water, glycerin, and propylene glycol (ref. *1*).

(1) *Safety.* Clinical use and marketing experience have confirmed that padimate A is safe in the dosage range used as an OTC sunscreen.

Extensive animal and human toxicological data attest to its safety for topical application to human skin. Acute oral toxicity studies determined that the LD_{50} of padimate A in mice was 4.5 ml/kg, whereas it was 13.0 ml/kg in rats, indicating that the ingredient is approximately three times more toxic in mice than in rats (ref. *2*).

Primary skin irritation and eye irritation tests conducted on six female albino rabbits demonstrated that padimate A produced no erythema or edema 24 and 72 hours after the application of 0.5 g (0.5 cc) on intact and abraded skin and that very slight conjunctival redness was observed 24, 48, and 72 hours following the instillation of 0.1 ml padimate A into the conjunctival sac (ref. *2*).

Similar animal (albino rabbit) studies of sunscreen formulations containing 3 and 5 percent padimate A demonstrated that the preparations are mild skin irritants (generally very slight erythema and edema) and are definitely eye irritants (corneal opacity, conjuntival redness, chemosis, and iritis) probably due to the alcoholic nature of the vehicle (ref. *2*).

Draize eye irritation tests of a sunblocking lotion containing 3 percent padimate A, 4 percent padimate 0 and 3 percent oxybenzone were performed on nine New Zealand white rabbits by instilling 0.1 ml of the test material into the conjunctival sac of one eye of each rabbit, with the remaining eye serving as a control. Three animals received no further treatment. Three animals had their eyes gently flushed with 20 ml of lukewarm physiological saline 2 seconds after treatment, and the remaining 3 animals had their eyes flushed in the above-described manner 4 seconds after instillation. Observations were made at 24, 48, and 72 hours later and at 4 and 7 days later. Except for one test animal in the untreated group, which experienced a very mild erythematous response in the palpebral conjunctiva which cleared prior to the 72 hour observation, none of the test animals showed any evidence of eye irritation. The investigator concluded that the preparation was not an eye irritant (ref. *3*).

Willis and Kligman (ref. *4*). reported on their study of the records of several hundred test subjects and their finding that some subjects have complained of burning and itching of the face during hot weather following applications of 2.5 and 5 percent padimate A in alcohol solutions and that this reaction has been reported by up to 20 percent of the subjects using the 5 percent solution. No eye or skin irritation has been observed by them in patients using 5 percent aminobenzoate in alcohol solutions applied to the face and trunk while fishing or sunbathing.

Wilson et al. (ref. *5*) reported that 3 percent of their patients have complained of a stinging or burning sensation when a 5 percent padimate A preparation was applied to the face, especially around the eyes. It was indicated, however, that this reaction was not observed until the beginning of hot summer weather. In some patients the reaction was noticeable only when the face perspired. Some patients experienced the reaction following each application; others experienced a stinging sensation initially which did not recur upon continued use.

A primary irritation test was performed on 100 white female subjects to determine the degree of irritation to the intact skin of the upper back from a sunscreen lotion containing 2.5 percent padimate A and 3.0 percent dioxybenzone. One-half inch square patches impregnated with the test material were applied to the test sites and held in place with plaster. Following

removal of the patches 48 hours later, the test sites were observed immediately and after 15 minutes and 24 hours. The erythema intensity was scored on a scale from 0 (no erythema) to 3+ (vesiculation with edema). It was concluded by the investigator that the preparation was not a primary irritant, as all readings showed no evidence of erythema (ref. *6*).

An irritation test of a sunblock lotion containing 3 percent padimate A, 3 percent oxybenzone, and 4 percent padimate O was conducted on the upper backs of 100 female subjects following the same procedures as described for the previous study. Based on data which showed no evidence of any inflammatory reaction immediately, 15 minutes, and 24 hours following the removal of the 48-hour patch tests, the investigator concluded that the test material was not a primary irritant (ref. *7*).

Irritation tests have indicated that the irritation effect of padimate A is apparently dose related. Various lotions were applied to areas below the eyes, and after 5 to 10 minutes, determination was made as to whether there was any irritation or burning. Lotions containing 5 percent homosalate in combination with 0.5 or 1.2 percent padimate A produced slight facial irritation in 2 of 57 and 1 of 51 subjects, respectively. A lotion containing 5 percent padimate A when applied to the faces of 31 subjects produced moderate irritation in one case and slight irritation in 9 others, whereas an 8 percent homosalate lotion produced slight facial irritation in 2 of 53 subjects tested (ref. *8*).

Repeated insult patch tests of a gel containing 3 percent padimate A were performed on the upper arms of 55 adult human subjects (ref. *9*). The test material was applied to approximately 0.5 square inch lintine discs, which were then applied to the test sites and held in place with occlusive patches. Each 24-hour period the patches were removed, and the reactions were graded on a scale from 0 (no erythema) to 4+ (marked erythema, edma, with vesicles and oozing). After a 24-hour rest period, repeat applications of the test material were made. This sequence was repeated 10 times, after which there was a 2-week rest period before a challenge dose was applied. Of the 55 subjects tested, three patients exhibited slight erythema (1+ reading) following the tenth application. One of these subjects also experienced slight erythema following the seventh application. Otherwise, all other readings for the repeat insult and challenge dose applications showed no evidence of erythema. It was concluded by the investigator that the test material was neither a primary irritant nor a sensitizing agent and that it can be predicated with 95 percent certainty based on the number of test subjects that at least 94 percent or more of the general population will not be sensitized by the test material.

Repeat insult patch tests of an ointment containing 4 percent padimate A in white petrolatum USP were performed on the upper arms of 50 human volunteers (ref. *10*). The repeat insult and challenge dose applications were made in the sequence described above except that there were 15 repeat insult applications and 48-hour rest periods on weekends. None of the 50 subjects exhibited visible skin changes at any time throughout the study. It was concluded that the test material did not demonstrate characteristics of a primary irritant, fatiguing agent, or sensitizer.

A report indicated that adverse reaction complaints for millions of units of padimate A-containing sunscreens used during the 1967–1972 period averaged less than one complaint per 100,000 units sold (ref. *11*).

Based on the available data, the Panel concludes that padimate A is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of padimate A as an OTC sunscreen.

Padimate A absorbance is between 290 and 315 nm, with the peak absorbance at 310 nm. Soluble in isopropyl and ethyl alcohol, mineral oil, and peanut oil, but insoluble in water, glycerine, and propylene glycol, padimate A is formulated in anhydrous emulsion, hydroalcoholic solutions, oil, and ointment preparations (ref. *12*).

Yankell et al. (ref. *13*) determined by tape stripping, combined with spectrophotometric analysis, the recovery of various sunscreens from the stratum corneum of Mexican hairless dogs. The sunscreens tested consisted of 3 and 5 percent concentrations of padimate A and aminobenzoate in 75 percent ethanol and 75 percent isopropanol vehicles. The solutions were applied on 1.5 cm^2 sites on the animals' flanks. One hour after application the test sites were stripped 13 times by repeatedly applying and removing 2 cm^2 cellulose tape squares. This procedure was repeated on other test sites, except that 1 hour after application the test sites were swabbed with damp absorbent cotton squares prior to being tape stripped in the above-described man- ner. The swabs were assayed along with the tapes as part of the determination of ingredient recovery. In the case of the unwashed test sites, 70 to 90 percent padimate A and 40 to 48 percent aminobenzoate were recovered, whereas 24 to 32 percent padimate A and 2 to 7 percent aminobenzoate were recovered from the tapes for the washed test sites. Recovery from the ethanol and isopropanol vehicles was comparable. Additional test sites were treated with 3 percent aminobenzoate in a hydroalcoholic vehicle and commercial sunscreen creams, i.e., 2.5 percent padimate A in the same hydroalcoholic vehicle, 2.5 percent padimate A, 4.4 percent homosalate, and a 3 percent oxybenzone and 3 percent dioxybenzone combination. One hour after application the treated sites were rinsed for 1 minute with a moderate stream of warm (37° C) water to simulate exercise, swimming, etc. and allowed to air dry before being tape stripped 13 times. In the case of the two ingredients in hydroalcoholic vehicles, 30.8 percent padimate A and 2.9 percent aminobenzoate were recovered. The remaining data indicated that 5.9 percent padimate A in the other formulation, 13.1 percent of homosalate, and less than 1 percent oxybenzone and dioxybenzone were recovered. The investigators reported that the data demonstrated that "sunscreens in alcoholic vehicles provide more protection than many available preparations in lotion or cream vehicles."

Yankell et al. (ref. *14*), using a solar simulator to produce erythema, evaluated eight sunscreens on male albino guinea pigs both with and without washing after application. The minimum erythemal dose (MED) for the shaved and depilated test areas was determined to be 2 seconds of solar simulator exposure time. One-tenth ml (0.1 ml) of each test material was applied over a 2 × 7 cm area on four sites on each side of dorsal surfaces. Two different test materials were tested in at least four guinea pigs. The unwashed sites 1 hour after application of the test materials were exposed to UV irradiation from the solar simulator at 1, 2, and 3 MED levels. Control areas were exposed to 1 MED irradiation. Other test sites 1 hour after application of the test materials were rinsed for 1 minute under a stream of warm (35° C) water, dried with a soft cloth, and then exposed to 1, 2, and 3 MED irradiation with control areas receiving 1 MED irradiation. The test materials consisted of a sunscreen containing 2.5 percent padimate A in a water-repellent cream base with opaque constituents (I), a sunscreen containing 2 percent padimate A in 75 percent ethyl alcohol (II), a sunscreen containing 2.5 percent padimate A in a hydroalcoholic lotion with emollients (III), a sunscreen containing 1.1 percent padimate A in oils (IV), a sunscreen lotion containing 2 percent glyceryl aminobenzoate (V), a sunscreen lotion containing 7.7 percent homosalate (VI), a sunscreen lotion containing 3 percent oxybenzone and 3 percent dioxybenzone (VII), and a sunscreen containing 5 percent aminobenzoate in 75 percent ethyl alcohol

(VIII). For the unwashed sites all test materials provided complete protection at 1 MED, but at 3 MED's only preparation I was fully effective; preparations II (50 percent), III (63 percent), VII (50 percent) and VIII (87 percent) were less effective; preparations V (25 percent) and VI (38 percent) were marginally effective; and preparation IV (0 percent) exhibited no effect. In the case of the washed test sites only preparations II and VIII, the only sunscreens prepared in 75 percent ethyl alcohol vehicles, provided protection above 1 MED. Preparation IV, which contained the lowest concentration of padimate A of the four padimate A-containing test materials and the lowest level of active ingredient among all test materials, provided the least protection to both the washed and unwashed sites.

Pathak et al. (ref. *15*) reported their 3-year study (1965-68) of the protective value of 24 sunscreens of various chemical agents known to absorb UV light. They indicated that 5 percent aminobenzoate in 70 to 90 percent ethyl alcohol and 2.5 percent padimate A in 65 to 95 percent alcohol "are by far the best sunscreen preparations" and that these preparations, after a single application, "can protect fair-skinned persons undergoing long exposure (over 4 hours) under natural sunlight, and are more effective than 24 of the commercially available products tested" and "afford excellent protection when subjects undergo exercise accompanied by profuse sweating, and tend to remain on the skin after bathing or swimming and exert a partial yet very satisfactory protection." Pathak et al. further found that these preparations provided very effective protection against sunburn "under intensely bright sun with hot, dry climatic conditions (in the Arizona desert), under warm and humid conditions (during the months of July and August in the Northern Hemisphere, 40° N. latitude) and on snow-covered mountains at high altitudes that reflect UV radiation causing sunburn of the exposed parts of the skiers." In addition, it was determined by Pathak et al. that these preparations "only partially inhibit tanning and allow immediate pigment darkening, as well as melanogenesis by long-wave UV and visible radiation" and "are cosmetically acceptable, being invisible and without odor or color on the skin."

Armati and Johnson (ref. *16*) evaluated the efficacy of two sunscreen creams containing 2.5 percent padimate A, one in a hydrophilic base and the other in a petrolatum and propylene glycol base, in nine human subjects with varying degrees of skin pigmentation. Fluorescent lights situated 25 cm from the skin surface were used to produce UV light in the 290 to 340 nm wavelength range. The minimum erythemal dose (MED) was determined for each subject. The test materials were applied to 1-inch square test sites on the subjects' backs, which were then exposed to 3 MED's irradiation with the results being assessed 24 hours afterwards. Padimate A in the petrolatum and propylene glycol base provided absolute protection (no erythema), whereas just detectable to moderate erythema was observed in test sites treated with padimate A in a hydrophilic base. It was noted, however, that test areas treated with the hydrophilic base only showed erythema which in the case of four subjects was worse than that for untreated sites exposed to the above-specified light source. A hydroxybenzoate derivative used as a preservative in the hydrophilic base was considered to be a possible source of the above-described phototoxic reaction.

From 9 to 17 human subjects were treated with one of four test materials to determine their protective indices using a solar simulator, i.e., 3 percent padimate A in the lotion vehicle, 4 percent padimate O in the lotion vehicle, 3 percent oxybenzone in the lotion vehicle, and the lotion vehicle. The mean protective indices and their respective standard deviation were 6.03 ± 1.03, 7.06 ± 1.25, 2.37 ± 0.82, and 1.31 ± 0.3, respectively (ref. *17*).

Kreps (ref. *18*) reported that padimate A transmits 10 percent of the incident erythemal flux at a 1 percent concentration and is a total sunblock at a 2 percent concentration. Based on determinations of percent erythemal (290 to 320 nm) and tanning (320 to 375 nm) transmission, a 1.4 percent concentration would provide a protective suntan for sensitive skin. A 1.1 percent concentration would provide a regular suntan for average skin, and a 0.8 percent concentration would be suitable for a minimum-protection quick-tanning preparation.

Based on the available data, the Panel concludes that padimate A is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 1 to 5.0 percent padimate A: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 1.0 to 5.0 percent padimate A: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

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p. *Padimate O.* The Panel concludes that padimate O is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

Padimate O is also known as 2-ethylhexyl *p*-dimethylaminobenzoate, 2-ethylhexyl 4-(dimethylamino)ben-

zoate, octyl dimethyl PABA and 2-ethylhexyl PABA.

Padimate O is a yellow mobile liquid, with a faint aromatic odor. It has a molecular weight of 235. It is soluble in isopropyl alcohol, mineral oil and ethyl alcohol. It is insoluble in water, blycerin and propylene glycol (ref. *1*).

(1) *Safety.* Clinical use and marketing experience have confirmed that padimate O is safe in the dosage range used as an OTC sunscreen.

Animal and human toxicological data attest to its safety at 4 percent concentration for human topical applications.

The oral LD_{50} in rats of a 5 percent concentration in corn oil is over 64 ml/kg (refs. *2*, *3*, and *4*).

A primary irritation and sensitization study of a 5 percent padimate O sunscreen was conducted on the shaved backs of 10 male albino guinea pigs. A 0.1 percent solution of the test material in sterile, pyrogen-free physiological saline was injected intracutaneously three times weekly until a total of 10 injections was reached, after which there was a 12-week rest period before a challenge dose was injected just below the region of the 10 sensitizing injections. Each injection consisted of a 0.1 ml dose except for the initial and challenge doses, which were 0.05 ml each. Distilled water was used as a control. Except for one test animal who exhibited barely perceptible erythema throughout the study following injections of the test material and distilled water, readings made 24 hours following each injection showed no evidence of erythema or edema. It was concluded by the investigator that the test material was neither a primary irritant nor a sensitizer (refs. *2*, *5*, and *6*).

The intact and abraded skin on the clipped backs of three albino rabbits was used for a primary irritation study of 5 percent padimate O in mineral oil (refs. *2*, *7*, and *8*). Double-layered, light gauze patches, 2.5 cm^2, were secured by thin bands of adhesive tape to four areas approximately 10 cm apart on each test animal's back. One-half ml (0.5 ml) of the test material was introduced beneath each patch before wrapping the animals' trunks in clear plastic trunk bands to hold the patches in place and prevent the evaporation of volatile substances during the 24-hour exposure period. Following exposure the patches were removed, and readings were made immediately and 72 hours later. None of the readings showed any evidence of erythema or edema. The investigator concluded that the test material was not a primary irritant.

A Draize eye irritation study of 2.0 percent padimate O in mineral oil was performed on the unwashed eyes of three rabbits. The data indicated that the test material was not a primary irritant to the cornea and iris of the test animals, but was at the upper limit of the mild primary irritant range in regard to its effect on the conjunctivae, as hyperemia was observed (ref. *2*).

Eye irritation studies with 5 percent padimate O in mineral oil were conducted on the unwashed eyes of three rabbits (refs. *9* and *10*). A dose of 0.1 ml was instilled into the conjunctival sacs, and evaluations were made after 1 hour, 24 hours, and daily thereafter until 7 days had elapsed. The test material was determined not to be an irritant to the cornea or iris of the test animals. Slight redness (1 on a scale of 0 to 3) of the palpebral and bulbar conjunctivae of each test animal was noted on the first and second days following treatment, but not during the remaining 5 days of the study.

Repeated insult patch tests of 4 percent padimate O in which petrolatum, U.S.P., were conducted on 50 human volunteers (refs. *11*, and *12*). Lintine pads moistened with the test material were placed on predesignated sites on the upper arm of each subject and were then covered and seated with overlapping strips of tape. After 24 hours the patches were removed. The test sites were evaluated on a scale of 0 (no erythema) to 4+ (marked erythema, edema, with vesicles and oozing). The test material was reapplied to the same sites after a 24-hour rest period if less than marked erythema (less than 2+ value) was observed. The above-described cycle was repeated 15 times, except rest periods lasted 48 hours on weekends. Following the fifteenth application, there was a 2-week rest period before a challenge dose was applied to each of the previous test sites. After 24 hours the challenge doses were removed, and readings were made immediately and 24 and 48 hours afterwards. Throughout the study none of the 50 subjects exhibited any evidence of erythema at the test sites. The investigator concluded that the test material was not a primary irritant, a fatiguing agent, or a sensitizer. Based on the data for the above-described 50 subjects, the investigator predicted with 95 percent certainty that at least 92.89 percent of a general population would not be sensitized by the test material.

In another study by Kantor, a product containing 7 percent padimate O and 3 percent oxybenzone was tested on 150 subjects according to a modified Draize-Shelanski repeated insult patch procedure. Several non-specific irritation reactions were observed under occlusive conditions, but none showed signs of being a primary irritant. The same test material was applied to the backs of 26 subjects for photopatch testing. Ultraviolet light from a Hanovia Tanette Mark I lamp was directed on the subjects' backs for a period of 1 minute, from a distance of 12 inches. Results following 48 hours from initial testing showed no adverse reactions observed in the 26 subjects tested (ref. *13*).

Jordan evaluated a product containing 7 percent padimate O and 3 percent oxybenzone applied to the backs of 150 healthy adult patients. The test material was evaluated according to a modified Draize repeated insult patch test. The material tested was applied to the scapular back under occlusive patches three times a week for 10 applications. Two consecutive occlusive challenge tests were applied to different areas on the scapular back after a 2-week rest period from initial testing. Results from observations taken immediately after removal of the patches showed mild irritational responses from the challenge test, but no allergic response (ref. *13*).

Based on the available data, the Panel concludes that padimate O is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are controlled studies documenting the effectiveness of padimate O as an OTC sunscreen.

Its absorbance is between 290 to 315 nm, with a maximum absorbance at 310 nm. Soluble in ethyl and isopropyl alcohol, mineral oil, and peanut oil, but insoluble in water, glycerine, and propylene glycol, padimate O can be incorporated in emulsions, hydroalcoholic solutions, and anhydrous formulations (refs. *1*, *14*, and *15*).

Cumpelik (ref. *16*) evaluated the relative substantivity or retention by the skin of 2 percent padimate A in isopropanol compared with isopropanol solutions containing 2 percent padimate O, aminobenzoate, homosalate, cinoxate, sulisobenzone, or ethyl 4-[bis- (hydroxypropyl)] aminobenzoate. After the hands and the arms of the five subjects were washed up to the elbows in isopropanol at 30° C, their left arms were dipped into the 2 percent padimate A solution for 1 minute. Each subject's right arm was then dipped for 1 minute into a 2 percent solution of one of the other sunscreen ingredients listed above. The amount of each solution deposited on the subject's arm was determined by weighing the amount of test solution remaining and by spectrophotometric analysis of the residual solution. Following air drying, the subjects' hands were submerged in 2 gallons of tap water at 25° C for 30 minutes, during which time the hands and fingers were moved constantly without touching any surface of the container. After air drying, the hands were exposed to irradiation by a Hanovia UV lamp with a Corex D filter for 7 minutes, which was equivalent to 2 hours of midsummer midday sun expo-

sure. Following the water insult and irradiation, the residual sunscreen on the subjects' hands was extracted by immersing the hands in isopropanol at 50° C for 2 minutes. The volumes of the solutions were then equalized and spectro-analyzed. The percent substantivity was then determined by multiplying the amount of ingredient recovered after exposure by 100 and dividing this figure by the amount of the ingredient initially deposited. The percent substantivity of padimate A compared with that of each of the other test solutions was 42.2 vs. 58.6 for padimate O; 48.3 vs. 0.3 for aminobenzoate; 46.8 vs. 11.4 for homosalate; 40.6 vs. 7.6 for cinoxate; 40.6 vs. 2.3 for sulisobenzone; and 37.3 vs. 0.4 for ethyl 4-[bis- (hydroxypropyl)] aminobenzoate. The data above correlated very well with the relative differences in the degree of reddening on the subjects' hands and lower forearms 24 hours following irradiation. Because sunscreens containing aminobenzoate and homosalate contain concentrations above 2 percent, the above-described test using 5 percent aminobenzoate and a 10 percent homosalate was performed on another subject. The hand treated with aminobenzoate was allowed to air dry 30 minutes and to permit the material to attach itself to the stratum corneum before the 30-minute water insult. As before, these preparations demonstrated poor resistance to washoff. The data above did demonstrate, however, that in terms of percent substantivity or degree of skin retention under conditions involving perspiration and/or swimming, padimate O was superior to padimate A, and both were decidedly superior to aminobenzoate, homosalate, cinoxate, sulisobenzone, and ethyl 4-[bis- (hydroxypropyl)] aminobenzoate.

A comparative substantivity study of six sunscreen lotions was conducted on six untanned human subjects with fair complexions. The lotions were a combination of 4 percent padimate O, 3 percent padimate A, and 3 percent oxybenzone; a combination of 3 percent padimate A and 3 percent glyceryl aminobenzoate, 10 percent sulisobenzone; a combination of 3 percent oxybenzone and 3 percent dixoybenzone; and 5 percent aminobenzoate (ref. *17*). Each test material was applied to two sites on each subject's back at the rate of 2 ul/cm² (20 ul applied to a 10 cm² area) and allowed to dry for 1 hour without sunlight exposure. Following a 10-minute swim in an indoor swimming pool, the treated areas and untreated control areas were delineated with Dermical and masking tape before applying a 5 percent aminobenzoate lotion other than the one being tested and toweling to the remainder of the body. Sunlight exposure measured at 1,200 counts on the Berger-Robertson Meter and equivalent to a total exposure of 4 to 6 MED's was then administered. Twenty-four hours after this exposure the test sites were photographed and graded on a scale from 0 (no burn) to 4 (severe erythema, i.e., bright red, vesiculation, edema, and painful to touch). Both the photographs and scores demonstrate that the padimate O/padimate A/oxybenzone lotion provided the greatest degree of protection among the preparations tested because little if any sunburn resulted under the above-described test conditions (mean protective value of 0.292±0.396). In the order of decreasing protective value, the results for the remaining preparations were 3 percent padimate A and 3 percent glyceryl aminobenzoate (1.250±0.866), 3 percent oxybenzone and 3 percent dixoybenzone (2.833±0.937), 5 percent aminobenzoate (3.500±0.674), 10 percent sulisobenzone (3.583±0.515), and control (3.667±0.651). From the data above, it would appear that the 5 percent aminobenzoate and 10 percent sulisobenzone preparations were almost completely removed during swimming, as the resulting burns in the test sites treated with these preparations were as severe as in the untreated control sites. The investigator concluded that the padimate O/padimate A/oxybenzone preparation showed statistically significant protection and even after swimming should provide at least one-half day of protection without reapplication for most users.

Using a solar simulator, the mean protective indexes and their respective standard deviations were determined for the components of a sunblock lotion consisting of lotion vehicle (1.31±0.3), lotion vehicle plus 3 percent padimate A (6.03±1.03), lotion vehicle plus 4 percent padimate O (7.06±1.25), and lotion vehicle plus oxybenzone (2.37±0.82). Between 9 and 17 human subjects were used to test each component. A 5x10 cm² area on each subject's back was treated with 100 ul of the test material, and after 15 minutes the test areas and adjacent untreated control areas were administered a graded series of 1 cm² UV exposures from a solar simulator. Twenty-four hours after exposure the minimal delayed erythemic responses were evaluated and the protective indexes were then calculated (ref. *18*). In another solar simulator study, the mean protective index for the above-described sunblock lotion was determined to be 20.4±5.8 (ref. *19*).

In another solar simulator study of the above-described preparation (ref. *20*), the test material was applied to the forearm of 14 human volunteers at the rate of 2 ul/cm² (100 mg applied to a 5x10 cm² area) and allowed to dry for 15 minutes. The treated areas were then rinsed in a stream of flowing tepid water for 1 minute and allowed to air dry before administering a graded series of UV exposures from a solar simulator to the treated and adjacent unprotected control areas. Twenty-four hours following this exposure, the minimal delayed erythemic responses were evaluated and the protective indexes were then calculated. A substantive protective index of 13.0±3.6 was determined by dividing the MED for the treated area by that for the control area.

The mean protective index of a sunscreen lotion containing 7 percent padimate O and 3 percent oxybenzone was found by a solar simulator study to be 18.6±4.3 (ref. *19*). For this and the previous study, however, there were no results given for any determination of the mean protective index of the lotion vehicle itself; thus, a determination as to the contribution of the lotion vehicle to the product's protective index was not feasible.

Based on the available data, the Panel concludes that padimate O is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 1.4 to 8 percent padimate O: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 1.4 to 8 percent padimate O: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

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(18) Sayre, R., "Sunscreen Evaluations, Human Testing," Draft of unpublished paper in OTC Volume 060131.

(19) Sayre, R., "PSL Formula—RB 360-272A, PLB 75-238, Protective Index Using Solar Simulator," Draft of unpublished paper in OTC Volume 060131.

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q. *2-Phenylbenzimidazole-5-sulfonic acid.* The Panel concludes that 2-phenylbenzimidazole-5-sulfonic acid is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

2-Phenylbenzimidazole-5-sulfonic acid has a chemical formula of $C_{13}H_{10}N_2O_3S$ and a molecular weight of 274.30. It is a white, finely crystalline powder, almost odorless. It is practically insoluble in benzene, but it is soluble in water, ethanol, ether, and chloroform (ref. *1*).

(1) *Safety.* Clinical use and marketing experience have confirmed that 2-phenylbenzimidazole-5-sulfonic acid is safe in the dosage range used as an OTC sunscreen.

Extensive animal and human toxicological data attest to its safety for human topical application. The oral LD_{50} is more than 5 g/kg in mice (refs. *2* and *3*).

Tolerance tests of the sodium, monothanolamine, and triethanolamine salts of 2-phenylbenzimidazole-5-sulfonic acid and two unidentified preparations of the ingredient were performed on both the skin of the auricle and the mucous membrane of the conjunctiva of rabbits. Concentrations of the test materials ranged from 1 to 5 percent. The test materials were administered twice daily for 5 days by placing three drops on the conjunctiva and 0.5 ml on the auricle. In vitro tissue tolerance tests were also performed on growing chicken heart fibroplastic cultures. The results reportedly demonstrated that the salts and their preparations were well tolerated, with skin tolerance, in particular, being very good. The ingredient itself was found to have no irritating effect on the mucous membrane of the conjunctiva. There was no observable difference in tolerance between the three salts (ref. *2*).

The subacute skin tolerance and sensitizing effect of 5 and 10 percent solutions and a 5 percent cosmetic preparation of the sodium salt of 2-phenylbenzimidazole-5-sulfonic acid were evaluated by applying 4 ml of each test material to the shaved backs of five rabbits for a total of 30 times during a 43-day period. Blood counts were performed at the beginning, midpoint, and end of the test period. In addition, 1.5 ml of each test material was applied to the shaved backs of five guinea pigs for a total of 3 times during a 40-day period. A second group of five guinea pigs received a total of 20 such treatments during a 25-day period. After a 14-day rest period there were concurrent injections of 0.2 ml of the test material intramuscularly into the popliteal fossa and 0.1 ml of the test material intracutaneously into the skin of the neck. It was reported that no irritating effects were observed on the backs of any of the rabbits or guinea pigs and that the sensitization test was absolutely negative. Blood counts remained normal throughout the study, and the animals did not experience any weight loss or behavioral changes (refs. *2* and *3*).

Oil/water emulsions of 3 percent 2-phenylbenzimidazole-5-sulfonic acid were applied daily for a period of 3 weeks to 21 human subjects of different sex and ages, some of whom suffered from skin disorders (refs. *2* and *3*). It was reported that the preparations were well-tolerated and did not give any indication that they might cause undesired skin reactions, particularly toxic acne, or might led to sensitization of the skin.

Eye irritation tests of two sunscreen lotions containing 1.5 and 2 percent 2-phenylbenzimidazole-5-sulfonic acid and 2.5 and 4.5 percent ethylexyl *p*-methoxy cinnamate, respectively, were performed on two rabbits and one human subject (ref. *4*). In the case of the rabbits, a drop of one preparation was instilled in the conjunctival sac of one eye, and a week later a drop of the other preparation was instilled into the conjunctival sac of the previously untreated eye. In each case the untreated eye was used as the control. Evaluations were performed 1, 2, 3, 24, and 48 hours following instillation. Both animals reacted similarly to both preparations; that is, immediately after instillation the rim of the eyelid and the conjunctiva reddened slightly and the cornea showed "slight freckles" for 1 to 2 hours. All these changes disappeared within 24 hours. The investigator rubbed a small quantity of each preparation into a conjunctival sac and reported that he experienced a slight reddening of the conjunctiva and a slight burning sensation, both of which disappeared within 1 hour. It was concluded by the investigator that these sunscreen preparations when used as directed present no danger to the eyes (ref. *4*).

A manufacturer of 2-phenylbenzimidazole-5-sulfonic acid reported that in the preceding 10 years more than 50 tons of the compound were marketed worldwide and that the suppliers have received no reports of adverse reactions from the use of the ingredient in sunscreen preparations (ref. *5*).

Based on the available data, the Panel conludes that 2-phenylbenzimidazole-5-sulfonic acid is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are controlled studies documenting the effectiveness of 2-phenylbenzimidazole-5-sulfonic acid as an OTC sunscreen.

Its absorbance is between 290 and 320 nm, with the maximum absorbance at 302 nm. This ingredient is used in the form of its sodium, monoethanolamine, and triethanolamine salts. Aqueous solutions of these salts are miscible with ethanol and ispropanol in almost any proportion. The ingredient is practically insoluble in alkali solutions, and at a pH below 6.3, the free acid is precipitated as insoluble matter. It is recommended for hydrous formulations, including emulsions and transparent gels, and is frequently used in combination with other sunscreens (ref. *6*).

Twelve subjects (8 females and 4 males) participated in a laboratory study to determine the protective indexes of a sunscreen containing 5 percent aminobenzoate and 7 sunscreen preparations containing 2-phenylbenzimidazole-5-sulfonic acid in combination with ethylhexyl *p*-methoxy cinnamate with and without 2-hydroxy-4-methoxy benzophenone (ref. *7*). The test materials were applied to the subjects' backs 60 minutes prior to UV exposures equivalent to 3, 6, 9, 12, and 15 times the minimal erythemal dose (MED) of the subject. A hot quartz

mercury arc lamp was used as the light source. Twenty-four hours after exposure the test sites were evaluated as to the degree of erythema by visual gradations which were used to determine the protective index of each of the test materials. All test materials were found to provide significant protection against erythemnogenic radiation. Three formulations were considered to have provided excellent protection, as their maximum protective indexes always exceeded 10. They were a cream containing 2.75 percent 2-phenylbenzimidazole-5-sulfonic acid, 4 percent ethylhexyl *p*-methoxycinnamate, and 3 percent 2-hydroxy-4-methoxy benzophenone (preparation 1); a lotion containing 3 percent 2-phenyl-benzimidazole-5-sulfonic acid and 4.5 percent ethylhexyl *p*-methoxy cinnamate (preparation 2); and a cream containing 2.75 percent 2-phenylbenzimidazole-5-sulfonic acid, 5 percent ethylhexyl *p*-methoxy cinnamate, and 4 percent 2-hydroxy-4-methoxy benzophenone (preparation 3). These preparations provided greater protection than a sunscreen containing 5 percent aminobenzoate, but this was explained as resulting from the latter preparation not exerting its maximum photoprotective effect at higher doses of UV radiation (12 and 15 times the MED) because of it being less protective against the erythemogenic effects of 254 nm radiation emitted by the light source. The least protection (mean minimum protective index of 6.7) was provided by a cream preparation containing 1.5 percent 2-phenylbenzimidazole-5-sulfonic acid and 2.5 percent ethylhexyl *p*-methoxycinnamate.

A total of 39 untanned fair-skinned male subjects participated in studies conducted in Arizona in the early spring to determine the photoprotective properties of the above-described and other sunscreen preparations under conditions of passive sunbathing, swimming and/or sweating induced by exercise. The MED for each subject was determined by exposing appropriate sites to 5, 10, 20, 25, and 30 minutes of midday sun on the day of the test (ref. *8*).

In one study, 80 subjects participated in a passive sunbathing study to evaluate the photoprotective properties of the three formulations described above, a sunscreen containing 5 percent aminobenzoate, and a lotion contining 10 percent *p*-methoxy cinnamic acid diethanolamine salt. Sixty minutes prior to exposure, two of the above-described preparations were applied to test sites on the back of each subject. Each test material was then exposed to 1- or 2-hour periods of midday sunlight without the subject engaging in any physical activity. Preparation 3 (cream containing 2.75 percent 2-phenylbenzimidazole-5-sulfonic acid, 5 percent ethylhexyl *p*-methoxy cinnamate, and 4 percent 2-hydroxy-4-methoxy benzophenone) provided the best and most consistent protection. The protection afforded by the sunscreen containing 5 percent aminobenzoate only exceeded that provided by the 10 percent *p*-methoxy cinnamic acid diethanolamine salt preparation, which itself was considered to provide a good degree of protection under the above-described conditions.

Eleven subjects participated in another passive sunbathing study to evaluate the photoprotective properties of the above-described and other sunscreen preparations except that the sunscreen containing 5 percent aminobenzoate was not included. Sixty minutes prior to exposure, three preparations were applied to test sites on the back of each subject and were then exposed to 30-, 60-, 90-, or 120-minute periods of midday sunlight without the subjects engaging in any physical activity. Preparation 3 described above again provided the best and most consistent protection. Substantial protection was also provided by preparation 1 and 2 discussed above. A preparation containing 3 percent 2-phenylbenzimidazole-5-sulfonic acid, even though one of the least protective of the 12 preparations tested, had a mean protective index of 5.0 after 120 minutes of exposure, which compared favorably with protective indexes of 6.6 and 7.0 for preparations 1 and 2, respectively, after similar exposure.

Six patients participated in a study to evaluate the photoprotective properties of preparations 1, 2, and 3 described above under conditions of sweating induced by exercise. Sixty minutes prior to 30 minutes of strenuous calisthenics two preparations were applied to the back of each subject. Following the exercise period the test sites were exposed to 30-, 60-, 90-, or 120-minute periods of midday sunlight. All three preparations were considered to have provided excellent protection, as it was concluded that they could protect normal skin against sunburn reaction for a period of 2 hours.

Nine patients participated in a study to evaluate the photoprotective properties of the five preparations involved in the first study in this series under conditions of normal beach activities. Sixty minutes following the application of two test materials to different sides of each subject's back, the subjects performed 60 minutes of passive sunbathing, 10 minutes of swimming, 30 minutes of passive sunbathing, 15 minutes of exercise to induce sweating, and 30 minutes of walking. Total sun exposure was 150 minutes. Again, preparation 3 described above provided the best protection, whereas the 10 percent *p*-methoxycinnamic acid diethanolamine salt lotion was easily removed from the skin during swimming and sweating and gave only partial protection. In terms of decreasing degree of protection under the above-described conditions as determined by their mean protective indexes, the ranking of the test materials was preparation 3 (9.3), preparation 1 (9.1), a sunscreen containing 5 percent aminobenzoate (6.8), preparation 2 (5.9), and a lotion containing 10 percent *p*-methoxy cinnamic acid diethanolamine salt (4.6).

Six subjects participated in a study to evaluate the photoprotective properties of preparations 1, 2, and 3 described above, wherein 60 minutes after two test materials were applied to test sites on each subject's back there was a 15-minute swimming period followed by the exposure of the test sites to 30-, 45-, 60-, or 90-minute periods of midday sunlight. It was determined that preparations 1 and 3 were not removed by swimming and afforded fairly good protection, as no test sites treated with these preparations showed evidence of erythema even after 90 minutes of midday sunlight exposure. Preparation 2, however, was readily removed as the result of swimming, and the test sites treated with this material showed evidence of a sunburn reaction. The mean protective indexes were as follows: preparation 3 (greater than 4.4), preparation 1 (greater than 4.2), and preparation 2 (1.04).

In the latter two studies described above, the substantivity of preparation 2 was decidedly less than that for either preparation 1 or 3. The formulations for the three preparations are quite similar, except that preparation 2 does not contain 2-hydroxy-4-methoxy benzophenone. In regard to 2-phenylbenzimidazole-5-sulfonic acid, the second study cited above demonstrated that a lotion containing a 3 percent concentration of this compound provided adequate protection after 120 minutes of midday sunlight exposure, but the last two studies would appear to demonstrate that the substantivity of this compound is questionable.

A total of 41 fair-skinned male subjects participated in a series of four studies under conditions similar to those for the five studies described above to evaluate the photoprotective properties of several preparations which were 1.5 percent 2-phenylbenzimidazole-5-sulfonic acid and 3 percent ethylhexyl *p*-methoxycinnamate cream; 2.75 percent 2-phenylbenzimidazole-5-sulfonic acid, 4 percent ethylhexyl *p*-methoxy-cinnamate and 3 percent 2-hydroxy-4-methoxy benzophenone cream; 2.75 percent 2-phenylbenzimidazole-5-sulfonic acid, 5 percent eth-

ylhexyl *p*-methoxycinnamate and 4 percent 2-hydroxy-4-methoxy benzophenone cream; 7 percent ethylhexyl *p*-methoxycinnamate and 3 percent 2-hydroxy-4-methoxy benzophenone oil; 5 percent aminobenzoate in 55 percent ethanol lotion; and 2.55 percent padimate A in 70 percent ethanol lotion (ref. 9). The latter two preparations were commercial sunscreens. The studies were conducted in Australia under bright sunlight and high humidity (over 90 percent) in mid-November. The MED for each subject was determined by exposing the appropriate sites to 5, 10, 15, 20, 25, and 30 minutes of midday sun on the day of the study.

In one study (study 1), 11 male subjects were used to evaluate the photoprotective properties of the above-described preparations against the stress of prolonged sunbathing without seating and swimming. Sixty minutes after applying two test materials and one of the two commercial sunscreen lotions to designated test sites on the back of each subject, each test site received 45, 90, 135, or 180 minutes of midday sunlight exposure. Erythema response was evaluated immediately and 24 hours later; 5 days following exposure an evaluation was made as to pigment response and evidence of any delayed phototoxic or photoallergic reactions. Preparations 1, 2, 3, and 5 (a lotion containing 5 percent aminobenzoate) were found to protect the skin against an immedate erythema reaction and to provide good protection against a sunburn reaction 24 hours following exposure. Preparations 4 (lacking 2-phenylbenzimidazole-5-sulfonic acid found in preparations 1, 2, and 3) and 6 (a lotion containing 2.55 percent padimate A) did not block an immediate erythema reaction and exhibited unsatisfactory protection 24 hours following exposure. All the above-described preparations neither stimulated nor inhibited a tanning reaction. A greater tanning response was obtained with the least protective formulations, namely, preparations 4 and 6 described above. None of the 11 subjects showed evidence of immediate or delayed phototoxicity or evidence of any cell-mediated delayed hypersensitivity reactions.

Nine male subjects (study 2) were involved in a substantivity study to evaluate the photoprotective properties of the above-described formulations under the combined stress of sweating and prolonged sunbathing. Sixty minutes after the application of two test materials and one of the two commercial lotions to designated test sites on the back of each subject, the subjects performed 30 minutes of calisthenics, running, and walking before the test sites were exposed to 90 or 180 minutes of midday sunlight exposure. Evaluations of the pigment darkening and erythema reactions were made immediately and 24 hours after exposure. Preparations 1, 2, 3, and 5 (commercial lotion containing 5 percent aminobenzoate) were again found to protect the skin against the immediate erythema reaction and to provide good protection against a sunburn reaction 24 hours after exposure. Preparation 2 was found to be especially substantive. Test sites treated with preparations 4 and 6 showed evidence of immediate vasodilation following sun exposure. These latter two preparations did not prevent an immediate erythema reaction and demonstrated unsatisfactory protection 24 hours following exposure. Evaluations performed 5 days after exposure found no evidence that any of the formulations caused phototoxic or photoallergic reactions or that they stimulated or inhibited the tanning response.

Eleven male subjects (study 3) participated in a substantivity study to evaluate the photoprotective properties of the six formulations under the combined stress of swimming and prolonged sunbathing. Sixty minutes following the application of two test materials and one of the two lotions to designated test sites on the back of each subject, the subjects swam in a chlorinated pool for 15 minutes prior to exposing the test sites to 60 or 120 minutes of midday sun. In terms of the immediate response, preparations 4, 5, and 6 showed definite presence of erythema, whereas the remaining three formulations rarely showed any immediate sunburn response. Erythema response 24 hours following exposure indicated that preparations 1, 2, and 3 were significantly more protective than preparation 4 and the two sunscreen lotions. Most of the test sites treated with the least protective formulation (the commercial lotion containing 5 percent aminobenzoate) showed a fair degree of sunburn reaction 24 hours after exposure. The protection provided by preparations 1, 2, and 3 was rated as good to excellent for a 120-minute sun exposure period. None of the formulations tested were found to be phototoxic or photosensitizing.

Ten male subjects (study 4) participated in a substantivity study to evaluate the photoprotective properties of the six formulations under the combined stress of sweating, swimming, and prolonged sunbathing. Sixty minutes after aplying three test materials and one of the two sunscreen lotions to designated test sites on the back of each subject, the volunteers engaged in 75 minutes of passive sunbathing before swimming in a chlorinated pool for 15 minutes. This was followed by 60 minutes of passive sunbathing, 10 minutes of calisthenics, 10 minutes of jogging and running, 10 minutes of walking, and 30 minutes of sunbathing while walking or in the sitting position. Total sun exposure for each subject was 195 minutes. The results were identical to those described above for the previous study.

The four studies described above revealed that preparations 1, 2, and 3 are significantly more protective and substantive than preparation 4. Preparation 4 differed from preparations 1, 2, and 3 in that it lacked 2-phenylbenzimidazole-5-sulfonic acid and was formulated with an oil rather than a cream base.

Based on the available data, the Panel concludes that 2-phenylbenzimidazole-5-sulfonic acid is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 1 to 4 percent 2-phenylbenzimidazole-5-sulfonic acid: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 1 to 4 percent 2-phenylbenzimidazole-5-sulfonic acid: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

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(7) "Efficacy Data," Part IV.C.1.a., Draft of unpublished paper in OTC volume 060083.

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(9) OTC volume 060130.

r. *Red petrolatum.* The Panel concludes that red petrolatum is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

Red petrolatum is also known as red veterinary petrolatum. Red petrola-

tum is a product of oil refineries, as are the other petrolatums. It is the product of minimal filtration, which accounts for its red color. Specifications, other than color, are similar to those of the liquid, white or yellow petrolatum.

(1) *Safety.* Clinical use and marketing experience have confirmed that red petrolatum is safe in the dosage range used as an OTC sunscreen.

Long use by millions of people attest to the safety of petrolatum. The petrolatums (liquid petrolatum, white petrolatum, yellow petrolatum, and red patrolatum) are products of oil refineries. A parafinic base crude oil is subjected to distillation at the refinery to remove the lighter hydrocarbons like gasoline and home fuel oil. The residue is a complex mixture containing heavy lubricating oil and petrolatum. This residue is mixed with a solvent (usually methyl ethyl ketone) and chilled to precipitate the petrolatum. The petrolatum is removed by special canvas filters. The petrolatum remains on the canvas, is distilled to remove the solvent, and is filtered through fuller's earth to the desired color. The red color passes through the filter as part of the petrolatum and is not an additive. Red petrolatum is the product of minimal filtration of the petrolatums (ref. *1*).

The physical properties of the petrolatums are vague in the "United States Pharmacopeia XV," where white and yellow petrolatum are mentioned, but red petrolatum is not. Penetrometer tests for consistency for both white and yellow petrolatum can vary from 100 to 275. Melting points vary from 38° to 60° C. Red petrolatum conforms to these tests. Red petrolatum contains the intrinsic red pigment from crude oil and some paraffin wax. Because it is the heaviest of the petrolatums (industrial petrolatum number zero), it contains more wax than the other petrolatums; but red petrolatum spreads to a smooth, almost invisible film on the skin, and leaves no visible greasy film that can be felt, as do the other petrolatums (ref. *1*).

The petrolatums are considered to be inert when applied to the skin. They serve as vehicles for many drugs and cosmetics for topical application. The product manufacturer reports one complaint per 120,000 units sold (ref. *2*).

The Panel concludes that the long and extensive use of the substance with no adverse effects being reported in the medical literature attests to the safety of red petrolatum as a sunscreen for OTC use.

(2) *Effectiveness.* There are well-controlled studies documenting the effectiveness of red petrolatum as an OTC sunscreen.

A 0.03 mm film of red petrolatum absorbs UV-light below 320 nm. About 16 percent is transmitted at 334 nm and 58 percent at 365 nm (ref. *3*). Why red petrolatum is also called red veterinary petrolatum is not clear because veterinarians do not use it. Currently, the red pigment is thought to be the single ingredient responsible for its sun-protective effect. Red petrolatum fluoresces brilliantly under Wood's light (365 nm).

In December 1942, the Army Air Corps requested the most effective protective substance against sunburn for men marooned on life rafts or in the desert following airplane crashes. The substance was required to have maximum protection per unit weight and volume so as to fit into life rafts and emergency equipment, maximum skin coverage per unit weight and volume, stability and freedom from rancidity, and should not burst on freezing. Red petrolatum was found to be the most effective (ref. *3*). Red petrolatum completely protected a subject against erythema at a dose of 20 minutes' exposure from an S-1 type of sunlamp, the equivalent to 20 hours of the strongest sunlight in Cleveland, Ohio.

A controlled clinical trial performed in Houston, Tex., on 30 light-complexion white subjects compared red petrolatum, a benzophenone, amyl *p*-dimethylaminobenzoic acid and 7 percent para-aminobenzoic acid, simultaneously, for protection against exposure to the summer sun. Testing began at noon and continued for periods of 5 to 60 minutes. Red petrolatum gave the following cumulative percent protection for duration of exposure in minutes: 100 percent for 20 minutes, 92 percent for 30 minutes, 92 percent for 40 minutes, 84 percent for 50 minutes, and 65 percent for 60 minutes. The end point was the minimal time necessary to produce erythema. In this test, red petrolatum performed second best (ref. *4*).

Jillson and Baughman (ref. *5*) recommended red petrolatum as an effective sunscreen following their study of eight patients with photo-allergic dermatitis to bithionol, an antiseptic. They found it more effective than para-aminobenzoic acid for these patients (ref. *5*). Other dermatologists have recommended red petrolatum for patients and other consumers (refs. *6* and *7*).

Based on the available data, the Panel concludes that red petrolatum is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) for products providing a minimum SPF value of 2 to under 4 containing 30 to 100 percent red petrolatum: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 30 to 100 percent red petrolatum: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

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s. *Sulisobenzone.* The Panel concludes that sulisobenzone is safe and effective for OTC use as a sunscreen as specified in the dosage sectin discussed below.

Sulisobenzone is also known as 2-hydroxy-4-methoxybenzophenone-5-sulfonic acid and is a sulfonic acid derivative of oxybenzone (ref. *1*). It has an approximate melting point of 145° C and is soluble in water, methanol, and ethanol (ref. *2*).

(1) *Safety.* Clinical use and marketing experience have confirmed that sulisobenzone is safe in the dosage range used as an OTC sunscreen.

The oral LD_{50} of sulisobenzone in rats is greater than 6.4 g/kg (ref. *3*). In a rabbit eye irritation study patterned after the Draize method, 0.1 ml of a 5 percent aqueous solution of sulisobenzone was instilled in the conjunctival sac of the right eye of each of nine albino rabbits. Four seconds after instillation the treated eye of three test animals was washed with 20 ml of lukewarm water. The left eye of each rabbit served as a control. Every 24 hours for the following 7 days, the cornea, iris, and conjunctiva of each rabbit were examined for signs of irritation and were graded according to

the standard Draize scoring system. It was reported that none of the washed or unwashed eyes treated with the test material showed any involvement of the cornea, iris, or conjunctiva fat any time during the 7-day period following instillation. It was thus concluded that the test material was not an ocular irritant (ref. *3*).

A repeated insult patch study was performed by applying 1-square inch gauze pads wetted with 0.5 ml of a 5 percent aqueous solution of sulisobenzone to the skin of 50 human subjects for 24 hours. Following the removal of the patches the test sites were evaluated. After a 24-hour rest the patches were reapplied. This process was repeated until there had been 15 applications of the treated patches after which there was a 2-week rest period before challenge doses were applied for 24 hours to the previous test sites. It was reported that the above-described test material was determined not to be a primary irritant, a fatiguing agent, or a sensitizer in any of the 50 subjects tested (ref. *3*).

Based on the available data, the Panel concludes that sulisobenzone is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of sulisobenzone as an OTC sunscreen.

Sulisobenzone is soluble in water, ethanol, and methanol. It absorbs throughout the UV range, with its maximum absorbance at 285 nm (ref. *2*).

Using a solar simulator with a filter to eliminate wavelengths below 295 nm, 10 human subjects (8 females and 2 males) participated in a study to determine the protective factors of 1 and 3 percent aqueous solutions of sulisobenzone and similar concentrations of aminobenzoate preparations (ref. *4*). Once the MED for each subject was determined, 3.6 ul of each test material was applied to each cm^2 of test site area. Each sulisobenzone-treated area was exposed to 1.5, 2, 2.5, and 3 times MED. The 1 percent aminobenzoate-treated areas were exposed to 2.5, 3, 3.5, and 4 times MED. Twenty-four hours after exposure, the test areas were graded for erythemal response on a scale from 0 (no perceptible erythema) to 4 (severe erythema with blistering). The protection factor was determined by dividing a test material's MED for protected skin by its MED for unprotected skin. the mean protection factors were 1.9 for 1 percent sulisobenzone, 2.5 for 3 percent sulisobenzone, 3.35 for 1 percent aminobenzoate, and 4.6 for 3 percent aminobenzoate.

A substantivity study of five sunscreens, including one containing 10 percent sulisobenzone, found that the mean protective value exhibited by the 10 percent sulisobenzone preparation was only slightly less than that for the untreated control sites when the subjects, 1 hour after applying the test materials, swam in an indoor pool for 10 minutes before the test sites were exposed to 4 to 6 MED's of sunlight. This study was discussed elsewhere in this document. (See part III. paragraph B.1.p. above—Padimate O.) The data would indicate that sulisobenzone was for all practical purposes completely removed during the swimming period (ref. *5*).

Knox et al. (ref. *6*) evaluated the comparative ability of sulisobenzone and aminobenzoate to prevent the development of ultraviolate-induced skin cancers in albino mice. In a series of studies, 5 and 10 percent solutions of sulisobenzone in alcohol and a 5 percent solution of aminobenzoate in alcohol were employed. Both ingredients were reported to decrease markedly the erythematous and carcinogenic effect of UV light, with sulisobenzone being superior to aminobenzoate under certain conditions because of its wider absorption spectrum.

Based on the available data, the Panel concludes that sulisobenzone is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 5 to 10 percent sulisobenzone: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 5 to 10 percent sulisobenzone: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

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t. *Titanium dioxide.* The Panel concludes that titanium dioxide is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

Titanium dioxide is employed as a physical sunscreen. It reflects and scatters UV and visible light rays providing a barrier for sun-sensitive individuals, against the effects of the sun. It is used to prevent sunburn and suntan.

Titanium dioxide is found in nature as the minerals rutile, ilmenite, perovskite, anatase or octahedrite and brookite. It is a white powder, with a melting point of 1,855° C, insoluble in water, hydrochloric acid, nitric acid, and diluted sulfuric acid. It is used as a mordant in dyeing, as a pigment in the rubber industry, and in the manufacture of synthetic resins and oil cloth. It is also used in preparations of face powders and beauty creams (ref. *1*).

Titanium dioxide scatters both UV and visible light radiation (290 to 700 nm) rather than absorbing the rays. It may occasionally be so occlusive as to produce miliaria (ref. *2*).

(1) *Safety.* Clinical use and marketing experience have confirmed that titanium dioxide is safe in the dosage range used as an OTC sunscreen.

Because titanium dioxide is chemically inert, no meaningful oral LD_{50} can be obtained in animals. For all practical purposes, titanium dioxide is inert, devoid of toxicity, and is not a sensitizer or primary irritant. Being a brilliant white powder, it is formulated with cosmetic pigments for consumer acceptance. Often other sunscreens are incorporated with titanium dioxide in emulsion bases, lipsticks, and ointments.

In a single dose, acute oral toxicity study in which a cream containing 5 percent titanium dioxide in combination with 5 percent menthyl anthranilate was given in a dose of 5 g/kg to 10 Sherman albino rats, no fatalities were reported during a 14-day observation period. Histopathological examination revealed no gross organ abnormalities (ref. *3*).

No reports of irritation have been attributed to titanium dioxide (ref. *4*). The probable lethal dose in humans is reported to be above 15 g/kg, or more than 1 qt for a 70 kg man. A pound (16 oz) has been ingested without apparent harm or distress. It was eliminated in about 24 hours (ref. *5*).

Fisher proposed the inclusion of titanium dioxide, "an effective non-sensitizing sun-screen for all wavelengths of UV light," with other effective sunscreens to possibly prevent photosensi-

tizing reactions caused by the latter (ref. *2*).

Between 1949 and 1972 almost 3.5 million units of a sunscreen containing 5 percent menthyl anthranilate and 5 percent titanium dioxide were distributed with less than one complaint received per 100,000 units marketed. None of the complaints could be attributed to the inclusion of titanium dioxide in the formulation (ref. *6*).

Based on the available data, the Panel concludes that titanium dioxide is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of titanium dioxide as an OTC sunscreen.

Titanium dioxide is a white, amorphous, odorless powder which is insoluble in water. It is used in ointments and lotions at a concentration of 15 to 25 percent as a protective against sunburn. It is also used in other protective preparations and in dusting powders and face powders (ref. *12*). It is physiologically and pharmacologically an inert substance (ref. *7*).

Titanium dioxide was found to be an effective mechanical screen in humans exposed to artificial UV light (ref. *8*). It is effective in preventing or reducing the passage of UV radiation to the skin. Titanium dioxide is "perhaps the most suitable and widely used" light-scattering ingredient in sunburn preventives (ref. *9*).

Titanium dioxide is recognized as an effective opaque chemical for use as a physical sunscreen because it scatters UV rays, thereby preventing sunburn.

Giese and Wells investigated the use of various pigments such as titanium dioxide, zinc oxide, magnesium oxide, magnesium carbonate, magnesium stearate, etc. as fillers in vehicles for sunscreen preparations. Titanium dioxide was found to surpass the other ingredients tested in terms of overcoming the after-sticky or greasy feel and improving the water resistance, covering power and screening power in a mechanical way (ref. *10*). They further concluded that "As a pigment, titanium dioxide was found more satisfactory than magnesium oxide. The pigment gives covering power and mechanical screening."

Schwartz and Peck reported that "Heavily pigmented preparations (liquids, creams or powders) will prevent or reduce the passage of the UV radiation" but, "while preventing sunburn, such preparations will prevent also suntan. Zinc oxide, calamine, and titanium dioxide are most effective in this regard" (ref. *11*).

Based on the available data, the Panel concludes that titanium dioxide is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 2 to 25 percent titanium dioxide: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 2 to 25 percent titanium dioxide: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

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u. *Triethanolamine salicylate.* The Panel concludes that triethanolamine salicylate is safe and effective for OTC use as a sunscreen as specified in the dosage section discussed below.

Triethanolamine salicylate is miscible in all proportions in water, glycerin, propylene glycol, ethyl and isopropyl alcohol but it is insoluble in mineral or vegetable oil.

(1) *Safety.* Clinical use and marketing experience have confirmed that triethanolamine salicylate is safe in the dosage range used as an OTC sunscreen.

Animal and human toxicological data attest to its safety for human topical application. The oral LD_{50} is 2.8 g/kg in rats (ref. *1*).

Triethanolamine salicylate was applied to the intact and abraded skin of six albino rabbits. The intact skin sites showed no evidence of erythema or edema 24 and 72 hours following treatment except for two rabbits where very mild erythema was present after 24 hours, but disappeared by the time of the 72-hour evaluation. The abraded skin sites generally showed moderate erythema and mild edema 24 and 72 hours after application. A primary irritation index of 1.5 was obtained, but the compound was not considered to be a primary irritant to the skin (ref. *2*).

A rabbit eye irritation study patterned after the Draize method was conducted in which 0.1 ml of triethanolamine salicylate as instilled into the conjunctival sac of the right eye of each of nine albino rabbits, with the left eye serving as a control. Following the instillation of the test material, the animals were divided into three groups with three rabbits having their treated eyes washed 2 seconds later, three rabbits having their treated eyes washed 4 seconds later, and three rabbits having their treated eyes remain unwashed. No corneal, iridial, or conjunctival irritation was observed after 1, 2, and 3 days in the treated eyes which were washed 2 and 4 seconds following instillation of the test material. The unwashed treated eyes of two rabbits showed very mild, transient conjunctival irritation which cleared by the second day. From the data above the investigator concluded that the test material was not a severe ocular irritant as defined by the Draize procedure (ref. *3*).

Repetitive intracutaneous injections of a 0.1 percent suspension of triethanolamine salicylate in physiological saline into the closely clipped back and flanks of 10 white male guinea pigs (Hartley strain) were performed every other day or three times weekly until each animal had received a total of 10 injections. Initially, 0.05 ml of the test material was injected, with 0.1 ml being administered during each of the nine remaining injections. After a 2-week rest period, a 0.05 ml challenge dose was administered. Twenty-four hours following each injection, readings of the diameter, height, and color of any reactions were made. As none of the animals showed evidence of any response to any of the repetitive or challenge intracutaneous injections, the investigator concluded that the test material was not a sensitizing agent as defined by the Draize procedure (ref. *4*).

The acute oral LD_{50} for a sunscreen gel containing 8.625 percent triethanolamine salicylate was greater than 21.5 ml/kg of body weight in albino rats.

The acute dermal LD_{50} of this preparation in albino rabbits was determined to be greater than 10.0 ml/kg of body weight (ref. *5*). A primary skin irritation study of this preparation involving the intact and abraded skin of six albino rabbits found that the irritative effects were confined to very slight erythema to two intact and three abraded skin sites at the 24-hour reading and had disappeared by the 72-hour reading. The primary irritation index was found to be 0.21 (ref. *5*). When 0.1 ml of this preparation was instilled into one eye of each of six albino rabbits, no irritative effects involving the cornea, iris, and conjuctiva were noted in any of the test animals 24, 48, and 72 hours following instillation (ref. *5*).

A double-blind skin irritation study comparing a 10 percent methyl salicylate cream, 10 and 20 percent triethanolamine creams, and a placebo control or vehicle were performed on seven female and three male human subjects wherein patches of each test material were applied to four different areas of each individual's back (ref. *6*). The patches were evaluated at 0 hour (preapplication) and at 4, 8, and 24 hours postapplication for evidence of skin reactions such as erythema, scaling, itching, dryness, and texture. None of the formulations produced dermographia, ulceration, hair loss, eruption, or burning. It was concluded by the investigator that both the 10 and 20 percent triethanolamine salicylate creams were well-tolerated by all 10 subjects and that the degree and frequency of erythema resulting from these two preparations were very similar and did not differ significantly from the degree and frequency resulting from the placebo. Significantly more erythema was caused by the 10 percent methyl salicylate cream, and there was a statistically significant increase in the erythema caused by this preparation from 4 to 24 hours postapplication, whereas the degree of any erythema caused by the other preparations generally remained constant throughout the evaluation period.

Repeated insult patch tests of a sunscreen gel containing 8.625 percent triethanolamine salicylate were performed on the upper arms of 11 human subjects using an adaptation of the Draize method (ref. *7*). For each application, five drops of the test material were placed on a patch which was then affixed to the designated test site and left in place for 24 hours. Applications were made every other day or three times weekly until each patient received a total of nine applications. Evaluations of any skin reactions were made just prior to reapplication of the test material. After an approximately 3-week rest period, challenge doses were applied and evaluations were made 24 and 72 hours after removal of the patches. None of the 11 subjects showed evidence that the test material was a sensitizing agent, and the test material was nonirritating to all but one subject. This subject experienced erythema and papules at the time of the seventh repeat application which did not reappear when subsequent applications were made to adjacent test sites. Because this subject reacted similarly to two of seven other test materials that were applied concurrently during this study, the investigator concluded that "the pattern of reactions observed indicates that these were probably due to cumulative irritation (skin fatigue)" (ref. *7*).

Similar repeated insult patch tests of a sunscreen lotion containing 8.5 percent triethanolamine salicylate were performed on the upper arms of 57 human subjects in which 0.2 to 0.3 ml of the test material was placed on a patch at the time of each application. Eight subjects showed evidence of slight erythema on one or more occasions during the repeated insult tests. Except for one subject who showed evidence of slight erythema from the first through the seventh application, this reaction was normally observed once but no more than three times during the series for the other seven patients. Another subject showed evidence of slight erythema following removal of the challenge dose. The investigator concluded that the above-described test material was only slightly more irritating than two other compounds tested concurrently in the same population which were considered essentially not irritating throughout the study (ref. *8*).

A percutaneous absorption study of a cream containing 10 percent triethanolamine salicylate was performed on 12 healthy male volunteers by applying the contents of a 0.5 oz tube (equivalent to 750 mg salicylic acid) to a 25 cm x 30 cm area on the back of each subject and determining the amount of salicylic acid and its metabolites excreted in in the urine during the next 24 hours (ref. *9*). In one group of six individuals the test material was layered on the test site with a wood applicator. In the second group of six individuals the test material was applied to the test site and massaged with gloved hands for 5 minutes. The empty tubes of the test material and the application materials were then reweighed to determine the amount of test material actually applied to each test site. The test sites were protected with a polyethylene sheet covering. The sheets were removed after 24 hours, and the test sites were observed then and 2 days later for any sign of irritation. Only one individual experienced any skin reaction, which consisted of very mild transient pruritis with blanching of the skin after slight pressure which cleared by the second day of the study. Total salicylate recovery, including metabolites, in terms of free salicylic acid, ranged from 4.3 to 26.8 (mean of 12.2) percent in those individuals on whom the test material was applied by a wood applicator. Total salicylate recovery for those subjects on whom the test material was massaged for 5 minutes ranged from 0.8 to 32.5 (mean of 14.8) percent. Mean salicylate recovery for all 12 individuals was 13.5 percent. No explanation was given for the little or no recovery (0.8 percent) of salicylate from one individual, but it is possible that additional salicylate would have been recovered from all individuals if urine collection had extended beyond 24 hours.

Percutaneous absorption studies of various salicylates in rabbits demonstrated that 15.6 percent of the salicylic acid contained in a triethanolamine salicylate preparation having a base of glyclo stearate, paraffin oil, and water was excreted in the urine over a 48-hour period (ref. *10*).

Based on available data, the Panel concludes that triethanolamine salicylate is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of triethanolamine salicylate as an OTC sunscreen:

Its absorbance is between 260 and 320 nm, with its maximum absorbance at 298 nm. Miscible in all proportions in water, glycerine, propylene glycol, ethyl and isopropyl alcohol, but insoluble in mineral or vegetable oil, it has been incorporated into aqueous lotions and gels (ref. *11*).

The efficacy of a sunscreen lotion containing 8.5 percent triethanolamine salicylate was evaluated in 16 human subjects at a St. Petersburg, Fla. beach (ref. *12*). Except for a few patients who participated in the study on a mid-November day when the temperature was 67° F and the sky was partly cloudy, the tests were performed on sunny days at a temperature of 73° F. Approximately 0.1 ml of the test material was applied to four 1 x 1½ inch areas on the back of each subject, and each site received 45, 75, 120, or 180 minutes of sun exposure. The erythema response was graded on a scale from 1 (no perceptible erythema throughout the study except in some instances when evaluations of erythema response were made 1 day after sun exposure: The instances of erythema were just perceptible erythema in two cases with 45 minutes' exposure. Two subjects showed just perceptible erythema, and one subject showed moderate erythema with 75 minutes of sun exposure. One subject had just perceptible erythema, and two subjects had moderate erythema

with 120 minutes of exposure. Moderate erythema was seen in four cases with 180 minutes exposure. The percent protection based upon the erythema scores for treated sites and untreated control sites was determined to be 82, 75, and 76 percent after 75, 120, and 180 minutes of sun exposure, respectively. Based on a scale from 00 (no tanning) to 02 (marked tanning), it was determined that treated sites showed a slight tan (score of 01) or greater from the second to fifth day after 120 and 180 minutes of sun exposure and generally showed more of a tan than the untreated control sites during the same period following similar sun exposure.

Based on available data, the Panel concludes that triethanolamine salicylate is an effective sunscreen ingredient for OTC use.

(3) *Dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 5 to 12 percent triethanolamine salicylate: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 5 to 12 percent triethanolamine salicylate: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. below—category I labeling.)

REFERENCES

(1) "Acute Oral LD_{50}—Triethanolamine Salicylate," Draft of unpublished paper in OTC Volume 060091.

(2) "Primary Skin Irritation—Triethanolamine Salicylate," Draft of unpublished paper in OTC Volume 060091.

(3) "Eye Irritation—Triethanolamine Salicylate," Draft of unpublished paper in OTC Volume 060091.

(4) "Intracutaneous Sensitization—Triethanolamine Salicylate," Draft of unpublished paper in OTC Volume 060091.

(5) "Acute Toxicity and Irritation Studies of Suretan Gel," Draft of unpublished paper in OTC Volume 060091.

(6) "Evaluation for Potential Skin Irritation of Mobisyl Cream," Draft of unpublished paper in OTC Volume 060156.

(7) "Pilot Repeated Insult Patch Test of Eight Samples," Draft of unpublished paper in OTC Volume 060091.

(8) "Repeated Insult Patch Test," Draft of unpublished paper in OTC Volume 060091.

(9) OTC Volume 060144.

(10) "Animal Safety Data," Part III.A.2.e., Draft of unpublished paper in OTC Volume 060024.

(11) OTC Volume 060091.

(12) "Sunscreening and Tanning Efficacy Study," Draft of unpublished paper in OTC Volume 060091.

CATEGORY I LABELING

The Panel recommends the following category I labeling for sunscreen active ingredients 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 indications should be limited to one or more of the following phrases:

(1) *For all (minimal, moderate, extra, maximal and ultra) sunscreen products.* (i) "Sunscreen to help prevent sunburn."

(ii) "Filters (or screens) out the sun's burning rays to prevent sunburn."

(iii) "Screens out the sun's harsh and often harmful rays to prevent sunburn."

(iv) "Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of these harmful effects."

(v) "Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of premature aging of the skin and skin cancer."

(2) *Additional indications.* In addition to the indications provided above in item (1), the following may be used:

(i) *For minimal sunscreen products.* (*a*) "Affords minimal protection against sunburn."

(*b*) "Prolongs exposure time before sunburn occurs."

(*c*) "Permits tanning (or suntanning) and reduces chance of (or minimizes) sunburning."

(*d*) "Helps prevent sunburn on limited exposure of untanned skin."

(*e*) "Helps to protect the skin against sunburn while permitting tanning."

(*f*) "Allows you to stay in the sun 2 times longer than without sunscreen protection."

(*g*) "Provides 2 times your natural protection from sunburn."

(ii) *For moderate sunscreen products.* (*a*) "Affords moderate protection against sunburn."

(*b*) "Prolongs exposure time before sunburn occurs."

(*c*) "Permits tanning (or suntanning) and reduces chance of (or minimizes) sunburning."

(*d*) "Helps prevent sunburn on moderate exposure of untanned skin."

(*e*) "Allows you to stay in the sun 4 times longer than without sunscreen protection."

(*f*) "Provides 4 times your natural protection from sunburn."

(iii) *For extra sunscreen products.* (*a*) "Affords extra protection against sunburn."

(*b*) "Prolongs exposure time before sunburn occurs."

(*c*) "Permits limited tanning (or suntanning) and reduces chance of (or minimizes) sunburn."

(*d*) "Helps prevent sunburn."

(*e*) "For sun-sensitive skin."

(*f*) "Extra protection against sunburn for blondes, redheads and fair-skinned persons."

(*g*) "Allows you to stay in the sun 6 times longer than without sunscreen protection."

(*h*) "Provides 6 times your natural protection from sunburn."

(iv) *For maximal sunscreen products.* (*a*) "Affords maximal protection against suburn."

(*b*) "Prevents sunburn and limits tanning."

(*c*) "For sun-sensitive skin."

(*d*) "Maximal protection against sunburn for blondes, redheads, and fair-skined persons."

(*e*) "Allows you to stay in the sun 8 times longer than without sunscreen protection."

(*f*) "Provides 8 times your natural protection from sunburn."

(v) *For ultra sunscreen products.* (*a*) "Affords the most protection against sunburn."

(*b*) "Prevents tanning and sunburning."

(*c*) "For highly sun-sensitive skin."

(*d*) "Greatest protection against sunburn for blondes, readheads and fair-skinned persons."

(*e*) "Provides the highest degree of sunburn protection and permits no tanning."

(*f*) "Provides the highest degree of sunscreen protection and permits no tanning."

(3) *For all (maximal and ultra) sunscreen products that contain sunscreen opaque sunblock ingredients.* "Reflects the burning rays of the sun."

b. *Statement on product performance*—(1) *Product category designation (PCD).* The Panel concludes that improved, more informative labeling should be provided to the consumer to aid in selecting the most approriate sunscreen product. The Panel recommends that the following appropriate labeling statement(s) be prominently placed on the principal display panel of the products:

(i) Products containing active ingredient(s) that provide an SPF value of 2 to under 4: "Minimal sun protection product (SPF 2)—Stay in the sun twice as long as before without sunburning."

(ii) Products containing active ingredient(s) that provide an SPF

value of 4 to under 6: "Moderate sun protection product (SPF 4)—Stay in the sun 4 times as long as before without sunburning."

(iii) Products containing active ingredient(s) that provide an SPF value of 6 to under 8: "Extra sun protection product (SPF 6)—Stay in the sun 6 times as long as before without sunburning."

(iv) Products containing active ingredient(s) that provide an SPF value of 8 to under 15: "Maximal sun protection product (SPF 8)— Stay in the sun 8 times as long as before without sunburning."

(v) Products containing active ingredient(s) that provide an SPF value of 15 or greater: "Ultra sun protection product (SPF 15)—Stay in the sun 15 times as long as before without sunburning."

(2) *Labeling claims related to the PCD and SPF value.* The Panel recommends any of the following labeling claims for sunscreen products that satisfy the sunscreen product testing procedures described elsewhere in this document. (See part III. Paragraph D. below—Sunscreen products testing procedures for determination of the sun protection factor (SPF) value and related labeling claims.)

(i) *For all (minimal, moderate, extra, maximal, and ultra) sunscreen products—(a) That satisfy the water resistance testing procedures. (1)* "Water resistant."

(2) "Retains its sun protection for at least 40 minutes in the water."

(3) "Resists removal by sweating."

(b) That satisfy the waterproof testing procedures. (1) "Waterproof."

(2) "Retains its sun protection for at least 80 minutes in the water."

(3) "Resists removal by sweating."

(c) That satisfy the sweat resistance testing procedures. (1) "Retains its sun protection for at least 30 minutes of heavy sweating."

(2 "Sweat resistant.")

(3) *Labeling guide for recommended sunscreen product use.* The Panel recommends the following compilation of skin types and PCD's be appropriately included in labeling as a guide:

RECOMMENDED SUNSCREEN PRODUCT GUIDE

Sunburn and Tanning History and Recommended Sun Protection Product

Always burns easily; never tans: Maximal, ultra.
Always burns easily; tans minimally: Extra.
Burns moderately; tans gradually: Moderate.
Burns minimally; always tans well: Minimal.
Rarely burns; tans profusely: Minimal.

c. *Warnings—For all (minimal, moderate, extra maximal, and ultra) sunscreen products.* The labeling of all sunscreen products should contain the following warnings:

(i) "For external use only, not to be swallowed."

(ii) "Avoid contact with the eyes."

(iii) "Discontinue use if signs of irritation or rash appear."

(2) *Specific warnings—(i) For sunscreen products providing an SPF value of 2 to under 4.* "Use on children under 2 years of age only with the advice of a physician."

(ii) *For sunscreen products providing an SPF value of 4 or greater.* "Use on children under 6 months of age only with the advice of a physician."

d. *Directions for use.* The Panel believes that many consumers use inadequate amounts of sunscreen. Offering more detailed guidelines would benefit the consumer.

Based upon a review of the available data, the Panel recommends that the directions for use state: "Apply liberally before sun exposure and reapply after swimming or after excessive sweating."

However, for sunscreen products that satisfy the water resistance, waterproof and sweat resistance testing procedures described elsewhere in this document, the directions for use in the labeling of these products may be modified in accordance with the results of the test. (See part III. paragraph D. below—Sunscreen product testing procedures for determination of the sun protection factor (SPF) value and related labeling claims.) The Panel recommends that for sunscreen products that satisfy these testing procedures the following modifications replace the directions-for-use labeling indicated above:

For all (minimal, moderate, extra, maximal and ultra) sunscreen products—(1) That satisfy the water resistant testing procedures. "Apply liberally before sun exposure and reapply after 40 minutes in the water or after excessive sweating."

(2) *That satisfy the waterproof testing procedures.* "Apply liberally before sun exposure and reapply after 80 minutes in the water or after excessive sweating."

(3) *That satisfy the sweat resistance testing procedures.* "Apply liberally before sun exposure and reapply after 30 minutes of excessive sweating."

2. *Category II conditions under which sunscreen ingredients are not generally recognized as safe and effective or are misbranded.* The Panel recommends that the category II conditions be eliminated from OTC sunscreen drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER.

CATEGORY II ACTIVE INGREDIENTS

The Panel has classified the following sunscreen ingredients not generally recognized as safe and effective or as misbranded:

2-Ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid,
3-(4-Methylbenzylidene)-camphor,
Sodium 3,4-dimethylphenyl-glyoxylate.

a. *2-Ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid.* The Panel concludes that 2-ethylhexyl 4-phenylbenzophenone-2'carboxylic acid is not safe and not effective for OTC use as a sunscreen.

The ingredient 2-ethylhexyl 4-phenylbenzophenone-2'carboxylic acid is a clear, faintly brownish-yellow, highly viscous oil with a faint characteristic odor. It is miscible in all proportions with methanol, ethanol, ether, chloroform and benzene, but is immiscible with water. It has a molecular weight of approximately 414 (ref *1*).

(1) *Safety.* Clinical use and marketing experience are insufficient to confirm that 2-ethylhexyl 4-phenylbenzophenone-2'carboxylic acid is safe for use as an OTC sunscreen.

2-Ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid was tested for acute toxicity using 40 rats of the Wistar strain. A dosage ranging from 8,000 mg/kg to 16,000 mg/kg was given to the rats in the form of a 20 percent solution of 2-ethylhexyl 4-phenylbenzophenone-2'carboxylic acid in peanut oil. The test material was administered by means of a gastric tube. Readings on days 1, 7, and 14 showed an approximate LD_{50} in excess of 16,000 mg/kg (ref. *2*).

In another test the approximate LD_{50} of 2-ethylhexyl 4-phenylbenzophenone-2'carboxylic acid was determined by means of topical application. One hour before the start of the test, 10 rats, with an average weight of 152 g, had the hair of the back and stomach removed with an electric clipper. 2-Ethylhexyl 4-phenylbenzophenone-2-carboxylic acid was then applied undiluted onto the shorn skin area. The test material was left on the skin area for 24 hours and then rinsed with water. Observations of the area tested gave an approximate LD_{50} reading in excess of 10,000 mg/kg (ref. *2*).

Skin irritation was studied using six white New Zealand rabbits. Twenty-four hours prior to the test, the backs and flanks of the animals were shorn with an electric clipper. In three of the animals the skin was scarified with razor blade cuts. 2-Ethylhexyl 4-phenyl - benzophenone - 2' - carboxylic acid, undiluted and in the amount of 0.5 ml, was applied to the left side of the test animals. An equal amount of peanut oil was applied to the right side. The 2-ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid was rinsed away 24 hours after initial testing. All the rabbits were observed daily for any skin changes or toxicity. In all rabbits tested, none showed any sign

of behavioral changes, altered general condition, or any sign of skin irritation in either 2-ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid or in peanut oil (ref. *2*).

2-Ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid was also tested for primary mucosal irritation in rabbit's eyes. Three male white New Zealand rabbits with an average weight of 2 kg were used in the test. All animals were preexamined to ensure no pathological states existed in the eye before actual testing. A 0.1 ml volume of 2-ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid was then instilled into the conjunctival sac of the left eye. The untreated right eye served as a control. There was no rinsing of the eye after instillation of the test substance. The eyes were examined for 6 days by evaluation methods proposed by Draize. No eye irritation was observed in any of the rabbits tested (ref. *2*).

Based on the lack of human clinical and marketing data, the Panel concludes that 2-ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid is not a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are no studies documenting the effectiveness of 2-ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid as an OTC sunscreen.

One manufacturer submitted a booklet suggesting the ingredient as a UV filter for cosmetics. It was recommended that a 2 to 4 percent concentration be used in the sunscreen products.

2-Ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid absorbs UV light mainly in the range of 290 to 340 nm. Testing has shown that the UV permeability of 2-ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid dissolved in methanol at a concentration of 0.001 g/100 ml and at a thickness layer of 1 cm, ranges from 98 percent at 340 nm to 27 percent at 290 nm (ref. *1*).

Based on the lack of sufficient data, the Panel concludes that 2-ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid is not an effective sunscreen ingredient for OTC use.

(3) *Evaluation.* Based on the lack of clinical and marketing data, the Panel concludes that 2-ethylhexyl 4-phenylbenzophenone-2'-carboxylic acid is not safe and effective for OTC use.

REFERENCES

(1) OTC Volume 060090.
(2) OTC Volume 060093.

b. *3-(4-Methylbenzylidene)-camphor.* The Panel concludes that 3-(4-methylbenzylidene)-camphor is not safe and not effective for OTC use as a sunscreen.

3-(4-Methylbenzylidene)-camphor is a white crystalline powder, having a faint characteristic odor not resembling camphor. It is soluble in ethanol, chloroform, and vegetable oils, though practically insoluble in water. It has a melting point of 65° to 67° C. It absorbs UV radiation primarily at 280 to 315 nm (ref. *1*).

(1) *Safety.* Clinical use and marketing experience are insufficient to confirm that 3-(4-methylbenzylidene)-camphor is safe for use as an OTC sunscreen.

3 - (4 - Methylbenzylidene) - camphor was studied in 30 rats of the Wistar strain. An aqueous suspension of 3-(4-methylbenzylidene)-camphor was administered orally by means of an esophageal tube to the rats, in dosages ranging from 10,000 mg/kg to 16,000 mg/kg. Observations recorded on days 1, 7, and 14 of the study showed the approximate LD_{50} to be in excess of 16,000 mg/kg (ref. *1*).

In another study, the approximate LD_{50} of 3-(4-methylbenzylidene)-camphor was determined by means of topical applications. Ten Wistar rats had the hair of the back and stomach removed with an electric clipper. The 3-(4-methylbenzylidene)-camphor was moistened with an equal amount of desalinated water and applied to the shorn skin area. The dosage applied to the skin was 10 g/kg. Twenty-four hours following initial application the test area was rinsed with water and observed for 2 weeks. any changes in the test area were recorded according to the method of Draize. Readings on days 1, 7, and 14 of the study showed an approximate LD_{50} in excess of 10,000 mg/kg. Rats autopsied at the end of the 14 days showed no evidence of abnormality (ref. *1*).

Skin irritation was studied in six white New Zealand rabbits. The rabbits were prepared 24 hours prior to the start of the study by shaving the back and upper flanks with an electric clipper. Three of the six rabbits had the test area scarified by means of a skin scraper consisting of 10 razor blades spaced 1 mm apart. Each blade had an exposed blade area of 0.5 mm. All of the rabbits received, on the left half of the test area, 5 g of 3-(4-methylbenzylidene)-camphor moistened with water and spread on pads 4 centimeters square. The right half of the back received an equal amount of talcum powder applied by the same method. An occlusive bandage was then applied to the area. After 24 hours of skin contact, the test material was removed and rinsed with water. The rabbits were then observed daily for 6 days. No sign of any skin irritation was found in any of the animals tested (ref. *1*).

Another test studied 3-(4-methylbenzylidene)-camphor for primary mucosal irritation on the rabbit eye. Six white New Zealand rabbits, preexamined to exclude any eye abnormalities, were used for the test. The left eye of three of the rabbits was subjected to 0.1 g of 3-(4-methylbenzylidene)-camphor suspended in 0.1 ml peanut oil. the right eye, untreated, served as a control. The other three rabbits had 0.1 ml peanut oil placed in the conjunctival sac of the left eye. The right eye again was left untreated. The rabbits were examined daily for 6 days, and changes were recorded according to the Draize test evaluation. Observations showed no eye reaction or irritation in any of the rabbits tested (ref. *1*).

Based on the lack of human clinical and marketing data, the Panel concludes that 3-(4-methylbenzylidene)-camphor is not a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are no studies documenting the effectiveness of 3-(4-methylbenzylidene)-camphor as an OTC sunscreen.

One manufacturer submitted a booklet suggesting use of the ingredient as a UV filter for cosmetics. The booklet contained in vitro absorption data indicating an absorption maximum at 300 nm. It was recommended that a 1 to 2.5 percent concentration be used in sunscreen products.

3 - (4 - Methylbenzylidene) - camphor absorbs UV light mainly in the range of 280 to 315 nm. Testing has shown that the UV permeability of 3-(4-methylbenzylidene)-camphor dissolved in chloroform at a concentration of .0005 g/100 ml and at a thickness layer of 1 cm, ranges from 53 percent at 280 nm to 39 percent at 310 nm (ref. *2*).

Based on the lack of sufficient data, the Panel concludes that 3-(4-methylbenzylidene)-camphor is not an effective sunscreen ingredient for OTC use.

(3) *Evaluation.* Based on the lack of clinical and marketing experience, the Panel concludes that 3-(4-methylbenzylidene)-camphor is not safe and not effective for OTC use.

REFERENCES

(1) OTC Volume 060090.
(2) OTC Volume 060083.

c. *Sodium 3,4-dimethylphenyl-glyoxylate.* The Panel concludes that sodium 3,4-dimethylphenyl-glyoxylate is not safe and not effective for OTC use as a sunscreen.

Sodium 3,4-dimethylphenly-glyoxylate is also known as 3,4-dimethylphenyl-glyoxylic acid sodium salt.

It is a white powder with no discernible odor. It is very soluble in water but practically insoluble in ethanol, ether, chloroform and benzene. It has a molecular weight of approximately 232 with no sharp melting point (ref. *1*).

(1) *Safety.* Clinical use and marketing experience are insufficient to confirm that sodium 3,4-dimethylphenylglyoxylate is safe for use as an OTC sunscreen.

Safety data included a study in mice which showed the oral toxic dose to be 8.0 g/kg (tachypnea) and the intravenous toxic dose to be 2.0 to 4.0 g/kg (giddiness, dyspnea, etc.). It was reported that 0.3 ml of a 10 percent aqueous solution was tolerated without any adverse reaction.

Based on the lack of sufficient animal data and lack of human clinical and marketing data, the Panel concludes that sodium 3,4-dimethylphenyl-glyoxylate is not a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are no studies documenting the effectiveness of sodium 3,4-dimethylphenyl-glyoxylate as an OTC sunscreen.

Based on the lack of any data, the Panel concludes that sodium 3,4-dimethylphenyl-glyoxylate is not an effective sunscreen ingredient for OTC use.

(3) *Evaluation.* Based on the lack of clinical and marketing experience, the Panel concludes that sodium 3,4-dimethylphenyl-glyoxylate is not safe and not effective for OTC use.

REFERENCE

(1) OTC Volume 060086.

CATEGORY II LABELING

The Panel has examined the submitted labeling claims for sunscreens and for combination products with nonsunscreen ingredients and has placed certain claims into category II.

The Panel found no evidence for labeling claims for sunscreen products such as "promote suntanning," "accelerate suntanning," "fast tanning," "rapid tanning," "give a deeper suntan," "give a longer lasting suntan," "give a deeper, darker suntan," "permits even tanning," "increases your ability to achieve a rich satisfying tan." The Panel concludes that a prudent person can obtain natural tanning without the use of these substances. Suntanning results from sun exposure, but these substances lessen the likelihood of painful sunburn from a consumer's carelessness or ignorance of sun exposure. Therefore, claims such as the above are classified as category II.

3. *Category III conditions for which available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of category III conditions to category I.

CATEGORY III ACTIVE INGREDIENTS

The Panel concludes that the available data are insufficient to permit final classification of the following claimed sunscreen active ingredients:

Allantoin combined with aminobenzoic acid.

5-(3,3-Dimethyl-2-norbornyliden-3-penten-2-one.

Dipropylene glycol salicylate.

a. *Allantoin combined with aminobenzoic acid.* The Panel concludes that allantoin combined with aminobenzoic acid is safe, but there are insufficient data to determine effectiveness as an OTC sunscreen. Other names used for allantoin-aminobenzoic acid are allantoin-*p*-aminobenzoic acid and ALPABA.

Allantoin-aminobenzoic acid is a tannish-white powder having a 1 percent solubility in water.

Information sumbitted to the Panel refers to allantoin-aminobenzoic acid as a complex (refs. *1* and *2*). No data were supplied by the manufacturer to show that there was complexation involved between allantoin and aminobenzoic acid, or that any modification had resulted which would alter in any way the individual characteristics of the two parent compounds. The panel recognizes that allantoin-aminobenzoic acid in combination has shown sun-screening activity equivalent to aminobenzoic acid. However, studies do not show that addition of allantoin to aminobenzoic acid, forming a combination, in any way contributes to the activity of the molecule, insomuch as to influence sunscreen potential or skin protection. It is to be noted that allantoin, used as a single entity and not in the combination form, has been shown to have protectant properties. The Panel has reviewed the data submitted and concludes that further testing is required to show the rationale of combining allantoin with aminobenzoic acid.

(1) *Safety.* Clinical use and marketing experience have confirmed that allantoin combined with aminobenzoic acid is safe in the dosage range used as an OTC sunscreen.

Studies demonstrating the safety of aminobenzoic acid as a single ingredient are discussed elsewhere. (See part III. paragraph B.1.a. above—Aminobenzoic acid.)

A toxicity test using allantoin combined with aminobenzoic acid was performed on five mature rats of the Casworth strain. The weights of the rats ranged from 200 to 240 g. The allantoin-aminobenzoic acid was ground and suspended in a physiological saline solution to form a concentration of 10 mg/0.5 ml. Subcutaneous doses of the test material were injected once daily for 5 days under the loose skin of the back, and observations were made for any signs of toxic symptoms. The rats were autopsied on the 7th day from the start of the testing. No deaths or any signs of toxic symptoms or reactions were observed in any of the rats tested (refs. *1* and *2*).

In another study, a patch test using a 5 percent solution of allantoin-aminobenzoic acid was applied to the backs of 200 white females, and observed for any irritation. The allantoin-aminobenzoic acid solution was placed on a 0.5 inch square of white blotting paper, applied to the back and then covered. An equal square using dry, white blotting paper served as a control. The patches remained on the skin for 48 hours. Observations were recorded immediately and 20 minutes after removal of the patch. Readings were based on a scale ranging from no reaction to vesiculation with edema. Results from both time observations showed that all 200 subjects in the irritation test showed no reaction to allantoin-aminobenzoic acid (refs. *1* and *2*).

Based on the available data, the Panel concludes that allantoin combined with aminobenzoic acid is safe for OTC sunscreen use.

(2) *Effectiveness.* There are no well-controlled studies docmenting the effectiveness of allantoin combined with aminobenzoic acid as an OTC sunscreen.

One study using three females tested allanatoin-aminobenzoic acid for its sun-screening ability. Allantoin-aminobenzoic acid was applied by inunction into a 3 inch by 4 inch area and exposed to UV light by means of a Hanovia sun lamp. An equal skin area served as a control. Both areas were exposed to the UV light daily until slight hypermia was induced in the untreated area. After 5 continuous days of treatment, none of the subjects tested showed any signs of edema in the areas treated with allantoin-aminobenzoic acid. Two of the three untreated patients tested showed evidence of hypermia (refs. *1* and *2*).

Another study compared the effectiveness of aminobenzoic acid with allantoin-aminobenzoic acid. Ten subjects, eight women and two men, were exposed to the midday sun for a period of 2 hours. Each subject was prepared by taping to the back a template consisting of three rows of four 1-inch square holes. Four of the holes were covered with a thin film of 5 percent allantoin-aminobenzoic acid cream. A second group of four holes was covered by a thin film of 5 percent aminobenzoic acid in 60 percent alcohol. The last four holes were used to determine the minimum erythema dose. The holes containing aminobenzoic acid and allantoin-aminobenzoic acid were closed at 30-minute intervals after initial exposure, and the holes testing minimum erythema dosage were closed at 5-minute intervals. Two hours following start of exposure, the test area was dried and checked for tape burns and allergies. Subjects took a warm shower 6 hours later, following which the results were recorded. A subsequent observation was made 24

hours after initial exposure for any further untoward effects.

Readings from the test were varied, mainly due to difficulty in matching erythema produced with tanning observed in both products tested. Both the allantoin-aminobenzoic acid and the aminobenzoic acid showed equivalent sun screening protection (refs. *1* and *2*).

Based on the available data, the Panel concludes that there are insufficient data to determine the effectiveness of allantoin combined with aminobenzoic acid as a sunscreen for OTC use.

(3) *Proposed dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 2 to 5 percent allantoin-aminobenzoic acid: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 2 to 5 percent allantoin-aminobenzoic acid: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. above—category I labeling.)

(5) *Evaluation.* Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for sunscreen active ingredients. (See part III. paragraph C. below—Data required for evaluation.)

REFERENCES

(1) OTC Volume 060117.
(2) OTC Volume 060147.

b. *5-(3,3-Dimethyl-2-norbornyliden)-3-penten-2-one.* The Panel concludes that 5-(3,3-dimethyl-2-norbornyliden)-3-penten-2-one is safe, but there are insufficient data available to permit final classification of its effectiveness for use as an OTC sunscreen as specified in the dosage section discussed below.

(1) *Safety.* Clinical use and marketing experience have confirmed that 5-(3,3-dimethyl-2-norbornyliden)-3-penten-2-one is safe in the dosage range used as an OTC sunscreen.

Eye irritation was studied using the Draize method. The investigator applied 0.1 ml of a 3 percent solution of 5-(3,3-dimethyl-2-norbornyliden)-3-penten-2-one in isopropyl myristate to the conjuctival sacks of nine albino rabbits. The rabbits tested had an average weight of 2 kg. The conjuctivae of three of the rabbits were washed with 20 ml water, 2 seconds after application. In three other rabbits the conjunctivae were washed with 20 ml, but after 4 seconds; and the last three rabbits' conjunctivae were not washed following application. Observations recorded after 24 hours showed that the three rabbits with no conjunctival washing and one rabbit in the 2 second washing developed a slight reddening of the conjuctivae and a slight swelling of the eye lids. At 48 hours no clearly defined eye irritation could be observed in any of the nine test animals (ref. *1*).

A sensitivity dermatological patch test using 5-(3,3-dimethyl-2-norbornyliden)-3-penten-2-one was applied to 50 healthy personnel and 50 skin disease patients of the University Dermatological Hospital, Goettingen, Germany. Testing of both groups was accomplished using 100 percent 5-(3,3-dimethyl-2-norbornyliden)-3-penten-2-one and a 5 percent concentration in Eucerin anhydricum base. The test material was applied to the upper arm or back using small disks of test adhesive for a period of 24 hours. Readings were taken at 24 and 48 hours, and observations were recorded on an evaluation ranging from no reaction to blistering type of reddening. The first reading (24 hours) showed two test subjects with slight reddening, one of them showing the slight reddening from both the 5 and 100 percent concentration. The other of the two subjects was affected by the 5 percent concentration only. A 48-hour observation showed no reaction.

The second group consisting of the 50 skin-diseased patients showed reactions in 7 of those tested. The 100 percent concentration gave six readings of slight reddening after 24 hours. Five of these patients showed no reaction at the second reading at 48 hours; the other showed a slight increase in reddening. Another patient showed no reaction at 24 hours, but a slight reddening at 48 hours. The 5 percent concentration showed three patient reactions, all three of which had also reacted to the 100 percent concentration. Two test subjects showed slight reddening at 24 hours, but only one showed no reaction at 48 hours. The third subject showed increased reddening at both 24 and 48 hour readings (ref. *1*).

In another test, 1 and 2 percent 5-(3,3-dimethyl-2-norbornyliden)-3-penten-2-one was placed on the upper back of 20 test subjects. Six preparations in oil, oil in water, and water in oil emulsions were used. Irradiation was by means of four Ostran Ultravitalux bulbs placed 16 inches from the skin surface for a maximum time of 11.2 minutes. Readings were taken after 24 hours. No reactions (irritation or reddening) occurred (ref. *1*).

Based on the available data, the Panel concludes that 5-(3,3-dimethyl-2-norbornyliden)-3-penten-2-one is a safe sunscreen ingredient for OTC use.

(2) *Effectiveness.* There are no studies documenting the effectiveness of 5-(3,3-dimethyl-2-norbornyliden)-3-penten-2-one as an OTC sunscreen.

The Panel received one submission for the ingredient. The manufacturer indicated the ingredient had been marketed as a sunscreen since 1973 in concentrations varying from 0.5 to 2.5 percent. No effectiveness data were submitted. However, the manufacturer stated that "we are in the process of performing the efficacy tests recommended by your panel." In a more recent communication, the same manufacturer indicated that other sunscreens have replaced 5-(3,3-dimethyl-2-norbornyliden)-3-penten-2-one in marketed products (ref. *1*).

Based on the available data, the Panel concludes that there are insufficient data to determine the effectiveness of 5-(3,3-dimethyl-2-norbornyliden)-3-penten-2-one as a sunscreen ingredient for OTC use.

(3) *Proposed dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 0.5 to 2.5 percent 5-(3,3-dimethyl-2-norbornyliden)-3-penten-2-one: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 0.5 to 2.5 percent 5-(3,3-dimethyl-2-norbornyliden)-3-penten-2-one: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. above—category I Labeling.)

(5) *Evaluation.* Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for sunscreen active ingredients. (See part III. paragraph C. below—data required for evaluation.)

REFERENCE

(1) OTC Volume 060120.

c. *Dipropylene glycol salicylate.* The Panel concludes that there are insufficient data available to permit final classification of the safety and effec-

tiveness of dipropylene glycol salicylate for use as an OTC sunscreen as specified in the dosage section discussed below.

Dipropylene glycol salicylate is a clear viscous liquid with a specific gravity of 1.16 and a faint yellow color. It is soluble in alcohols, blycolesters, ketones, and glycols. It is insoluble in water and mineral oil.

(1) *Safety.* Clinical use has not confirmed that dipropylene glycol salicylate is safe in the dosage range used as an OTC sunscreen.

Toxicity testing was performed using normal, healthy CFW mice of the Carworth strain. Weights ranged from 18 to 21 g. The mice received dipropylene glycol salicylate by means of a rigid stomach pump in groups of 10, in doses of 2.5, 3.75, 5 and 10 ml per kg. The mice were observed for a period of 7 days. Six deaths were observed in the 3.75 ml/kg dose, 7 deaths in the 5 ml/kg dose, and all 10 mice died at the 10 ml/kg dose. There were no mice deaths at the 2.5 ml/kg dose (ref. *1*).

In another test, three normal, healthy albino rabbits had a 0.1 ml solution of a 7 percent dipropylene glycol salicylate instilled into the right eye. There was no rinsing of the eye or any other treatment given to the eye. The left eye served as a control. Observations were recorded every 24 hours for 4 days and again on the 7th day. The findings of this test showed that cornea, conjunctival, and iris irritation was not observed in any of the rabbits tested (ref. *1*).

A skin sensitivity test using a 7 percent concentration of dipropylene glycol salicylate was applied to the clipped intact and abraded skin of three healthy normal albino rabbits. The abraded area was chafed with minor abrasions penetrating the stratum corneum, but not influencing the derma. The dipropylene glycol salicylate was applied in a 0.5 ml volume and then covered with surgical tape. Evaluation of the skin for edema, erythema, and escher formation were recorded at 24 and 72 hours after application. Observations showed no irritation at these times on both abraded and intact skin (ref. *1*).

No human safety data or marketing data were submited or were available. Based on the lack of available human safety data, the Panel concludes that there are insufficient data to permit final classification of the safe use of dipropylene glycol salicylate as an OTC sunscreen.

(2) *Effectiveness.* There are no studies documenting the effectiveness of dipropylene glycol salicylate as an OTC sunscreen.

A manufacturer of the chemical ingredient submitted data not related to a marketed product.

A technical bulletin was submitted describing the physical and chemical properties of dipropylene glycol salicylate. The spectral absorption of a 0.1 percent solution showing different values depending upon the thickness of the film was included. The ingredient appears to absorb UV radiation between 290 and 320 nm. The submission also included military specifications for a sunburn-preventive preparation (cream-base) which was dated January 30, 1967. The composition of the preparation is described as containing light amber petrolatum, stearyl alcohol, mineral oil, sesame oil, calcium stearate, kaolin, and a sunscreen agent. There are six sunscreen agents listed as approved for use in the above formulation. One of these sunscreens listed is dipropylene glycol stearate. No other information is given.

Based on the lack of available data, the Panel concludes that there are insufficient data to permit final classification of the effective use of dipropylene glycol salicylate as an OTC sunscreen.

(3) *Proposed dosage.* (i) For products providing a minimum SPF value of 2 to under 4 containing 3 to 7 percent dipropylene glycol salicylate: Adult and children over 2 years of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For products providing a minimum SPF value of 4 containing 3 to 7 percent dipropylene glycol salicylate: Adult and children over 6 months of age topical dosage is liberal application before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the category I labeling for sunscreen active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(5) *Evaluation.* Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for sunscreen active ingredients. (See part III. paragraph C. below—Data Required for Evaluation.)

REFERENCE

(1) OTC Volume 060134.

CATEGORY III LABELING

The Panel was unable to identify any category III labeling. Suitable labeling claims for the five product categories have been discussed elsewhere in this document. (See part III. paragraph B.1. above—Category I Labeling.)

C. DATA REQUIRED FOR EVALUATION

The Panel considers the protocols recommended in this document for the studies required to bring a category III ingredient into category I to be in agreement with the present state of the art, and does not intend to preclude the use of any advances or improved methodology in the future.

1. *General comments.* Because the first sunburn preventive drugs were introduced in 1928, when a general knowledge of photobiology already existed, testing in the field has been based on sound scientific methodology. Because of the increased medical, regulatory, scientific and social sophistication, the Panel is of the opinion that certain standards of evaluation are now appropriate to increase efficacy and to increase consumer satisfaction. When an ingredient is available for widespread use in OTC products, its safety and efficacy must be well-documented by data regarding its toxicology, absorption, excretion, and pharmacologic action. The drug must meet certain standards of efficacy.

The Panel concludes that it is reasonable to allow 2 years for the development and review of evidence that will permit final classification of the effectiveness of the category III ingredients. The ingredients pose no safety problems for the consumer. Marketing need not cease during this time if adequate testing is undertaken. If data regarding adequate effectiveness and safety are not obtained within 2 years, the ingredients should no longer be marketed in OTC products.

2. *Methods of study*—a. *Toxicological data.* A variety of toxicological data can be obtained to demonstrate that a sunburn preventive is safe. The Panel recommends that the following data be obtained in appropriate studies on the final formulation to be marketed for topical application:

(1) *Patch tests.* A number of patch test methods are applicable to human safety testing of products. These tests have proven valuable for predicting skin irritancy and sensitization. The Panel recommends one of the following methods of patch testing:

(i) The Draize human skin irritancy and sensitization tests and its various modifications in which the subject's back or arm may be used (refs. *1* through *4*);

(ii) The method of Shelanski and Shelanski (ref. *5*); or

(iii) The maximization procedure of Kligman (ref. *6*).

In the first two tests, the formulation is applied many times to the test site for 3 to 4 weeks. A 2-week rest period follows, and then a single challenge application of the drug or formulation is made. The early applications are to detect primary skin irritants, and the last dose is to detect al-

lergic skin sensitizers. The Kligman test uses sodium lauryl sulfate to irritate the test site, thereby hastening and accentuating the allergic skin sensitizing potential of a substance.

b. *Effectiveness data.* For proof of effectiveness of sunscreen active ingredients and formulations, the Panel recommends sunscreen product testing procedures for determining the Sun Protection Factor (SPF) value and related labeling claims. (See part III, paragraph D, below—Sunscreen Product Testing Procedures for Determination of the Sun Protection Factor (SPF) Value and Related Labeling Claims.)

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(3) Lanman, B. M., W. B. Elvers, and C. S. Howard, "The Role of Human Patch Testing in a Product Development Program," *in* "Proceedings, Joint Conference on Cosmetic Sciences," The Toilet Goods Association, Inc., Washington, D.C., pp. 135–145, 1968.

(4) Philips, L., II, M. Steinberg, H. I. Maibach, and W. A. Akers, "a Comparison of Rabbit and Human Skin Response to Certain Irritants," *Toxicology and Applied Pharmacology*, 21:369–382, 1972.

(5) Shelanski, H. A., and M. V. Shelanski, "A New Technique of Human Patch Tests," *Proceedings Scientific Section, Toilet Goods Association*, 19:46–4, 1953.

(6) Kligman, A. M., "The Identification of Contact Allergens by Human Assay," *Journal of Investigative Dermatology*, 47:369–374, 1966.

D. SUNSCREEN PRODUCT TESTING PROCEDURES FOR DETERMINATION OF THE SUN PROTECTION FACTOR (SPF) VALUE AND RELATED LABELING CLAIMS

1. *Sunscreen active ingredients contained in sunscreen products.* The active sunscreen ingredients of the product consist of one or more of the ingredients classified as Category I within any established, maximum daily dosage limit and the finished product provides an SPF value of not less than 2.

2. *Sun protection factor (SPF) value.* An SPF value is defined as the UV energy required to produce a minimal erythema dose (MED) on protected skin divided by the UV energy required to produce an MED on unprotected skin. In effect, the SPF value is the reciprocal of the effective transmission of the product viewed as a light filter. The UV light (UVL) energy is measured by various photodetectors as described below.

The SPF value may also be defined by the following ratio:

$$\text{SPF value} = \frac{\text{MED (protected Skin (PS))}}{\text{MED (unprotected skin (US))}}$$

where, MED (PS) is the minimal erythema dose for protected skin after application of 2 mg/cm^2 or 2 μl/cm^2 of the final formulation of the sunscreen product, and MED (US) is the minimal erythema dose for unprotected skin, i.e., skin to which no sunscreen product has been applied.

The SPF value is the value that can be directly compared between individuals and between products.

3. *Standard sunscreen.*—a. *Laboratory validation.* The use of standard sunscreens for testing purposes permits the direct comparison of results between laboratories to assure uniform evaluation of sunscreen products. Comparing the mean SPF values between laboratories assures that the proper SPF value categorization of a product is maintained. By comparing the standard deviations of the mean SPF values between laboratories, the relative precision of sunscreen testing can be monitored.

A sunscreen preparation containing homosalate was tested by five laboratories in a cooperative trial using solar simulators (ref. *1*). The information accumulated from these studies makes this preparation a suitable standard for use in monitoring the tests for SPF value of sunscreen products. This preparation gave a mean SPF value of 4.24 (standard deviation=1.14). The Panel, therefore, recommends this sunscreen preparation as a standard sunscreen.

b. *Preparation of the standard homosalate sunscreen.* The standard homosalate sunscreen is prepared from two different preparations (part A and part B) with the following compositions:

PREPARATION OF PART A AND PART B OF THE STANDARD SUNSCREEN

PART A

Ingredients	Percent by weight
Homosalate	8.00
White petrolatum	2.00
Stearic acid	3.00
Stearyl alcohol	2.00
Propylparaben	0.015

PART B

Methylparaben	0.025
Sequestrene Na$_2$ (EDTA disodium)	0.05
Sodium lauryl sulfate	0.50
Propylene glycol	12.00
Purified water U.S.P.	72.41

Part A and part B are heated separately to 77 to 82° C with constant stirring until the contents of each part are solubilized. Add part A slowly to part B while stirring. Continue stirring until the emulsion formed is cooled down to room temperature (15 to 30 C). Add sufficient purified water t obtain 100 g of standard sunscreer preparation.

c. *Assay of the standard homosalat sunscreen.* Assay the standard homo salate sunscreen preparation by th following method to ensure prope concentration:

(1) *Preparation of the assay solvent* The solvent consists of 1 percent gla cial acetic acid (V/V) in denature ethanol. The denatured ethano should not contain a UV-absorbing de naturant.

(2) *Preparation of a 1 percent solu tion of the standard homosalate sun screen preparation.* Accurately weigl 1 g of the standard homosalate sun screen preparation into a 100 ml volu metric flask. Add 50 ml of the assa solvent. Heat on a steam bath and mi well. Cool the solution to room tem perature (15 to 30° C). Then dilute th solution to volume with the assay sol vent and mix well to make a 1 percen solution.

(3) *Preparation of the test solution (1:50 dilution of the 1 percent solu tion).* Filter a portion of the 1 percen solution through number 1 filte paper. Discard the first 10 to 15 ml o the filtrate. Collect the next 20 ml o the filtrate (second collection).

Add 1 ml of the second collection o the filtrate to a 50 ml volumetric flask Dilute this solution to volume wit assay solvent and mix well. This is th test solution (1:50 dilution of the 1 percent solution).

(4) *Spectrophotometric determina tion.* The absorbance of the test solu tion is measured in a suitable doubl beam spectrophotometer with th assay solvent and reference beam at a wavelength near 306 nm.

(5) *Calculation of the concentration of homosalate.* The concentration o homosalate is determined by the fol lowing formula which takes into con sideration the absorbance of th sample of the test solution, the dilu tion of the 1 percent solution to pre pare the test solution (1:50), th weight of the sample of the standar homosalate sunscreen preparation (1 g), and the standard absorbance valu (172) of homosalate as determined by averaging the absorbance of a large number of batches of raw homosalate

Concentration of homosalate=absorbanc ×50×100/1×172=percent concentration by weight.

4. *Light source and light monitor ing.*—a. *Artificial light source (sola simulator) and monitoring.* A sola simulator for sunscreen testing shall be defined as a light source having:

(1) A continuous emission spectrum in the UV-B (290 to 320 nm);

(2) Less than 1 percent of its total energy contributed by nonsolar wave-

lengths (wavelengths shorter than 290 nm); and

(3) Not more than 5 percent of its erythemically effective energy contributed by nonsolar wavelengths.

The instrument must be monitored periodically to assure that it delivers the appropriate spectrum described above. The monitoring procedure is described below.

The xenon arc solar simulator is the preferred artificial light source. Test data using other artifical light sources to establish the degree of efficacy at UV-B wavelengths of sunscreens must have corroborating natural sunlight testing for acceptance.

Xenon solar simulators presently utilize xenon arcs from 150 to more than 6,000 watts. For example, to produce 1 MED with a 150-watt lamp requires 120±30 seconds at the exit port of the instrument when the irradiated site is 1 cm in diameter. Depending upon instrumental design, other irradiation sizes and times can be utilized. Solar simulators of 150 watts usually produce 10 or 12 solar constants. A solar constant is the total amount of energy at all wavelengths per square meter, available from the sun, at the Earth's surface. For example, if the MED for a normal subject is 20 minutes of sunlight exposure, then the solar simulator would produce an MED of 2 minutes at 10 solar constants in the same subjects. The more powerful solar simulators can produce up to 40 solar constants. Irradiated sites more than 4 mm in diameter present no difficulty in determining skin erythema.

A solar simulator uses filters to absorb (cut off) the shorter UV wavelengths which do not reach the earth's surface from the sun. The primary filter is a suitable filter of colorless glass, sharp cut in the UV range, with a $^{0}/_{H}$ (50 percent transmittance point) cut location approximately at 310 nm±6. Dichroic or heat-absorbing filters are used to reduce unnecessary visible and infrared radiation.

Regardles of the light source employed, some uncertainties in interpreting results of in vivo testing, using sunlight or artificial sources, include:

(i) Between individual investigators reading the minimal erythema dose response (MED) (the minimal perceptible erythema) on skin, the readings vary ±20 percent. However, each individual investigator is remarkably consistent after some experience. To partially overcome the variation between observers, the investigator indoors should use a constant light source like an incandescent or a warm white fluorescent lamp at a fixed distance and read the results on the subject in a room with white or light grey walls. No instrument has proven so reliable and consistent as the human eye, but the investigator may use a color gauge, a reflectometer, or a series of color-correcting red filters of increasing red intensity. The filters are placed over the irradiated site where the correct filter will eliminate the erythema and produce a uniform color. The reliability of reproducing results obtained from such a system of filters would have to be verified. In addition, it would be difficult to translate such data into SPF values unless there could be shown to be a 1:1 correlation between a color filter and a known standard sunscreen.

(ii) The same dose of UV light produces different intensities of erythema in different people. This is why the MED must be determined for each subject whatever the light source.

(iii) Inherent differences in the erythemic exposure-color relationship occur between individuals because the same dose of UV light causes different degrees of erythema depending on the time or reading after exposure.

The advantages of a xenon lamp solar simulator for in vivo testing include the following: The continuous spectrum mimics the sun in the UV range with comparable output over the 290 to 400 nm range; a constant spectrum at a constant angle with high output is obtained; and the lamp produces a stable spectrum over long use.

The disadvantages of using the xenon lamp for in vivo testing include the following: The full solar spectrum output is low in the visible and infrared wavelengths; using the xenon lamp is time consuming if only one test site can be irradiated at a time; and it is difficult to measure the output, but instrumentation is available for this purpose.

The xenon arc solar simulator can be monitored. Calibrated thermopiles (instruments that measure the xenon UV total output by converting it to heat energy) can be used to successfully measure the output of solar simulators. The total energy output (solar and nonsolar) of the xenon lamp solar simulator can be measured by a thermopile which should be accurate to 1 percent. If the thermopile has a window, it should be constructed of quartz. Such devices are accurate to at least 1 percent when properly used. Other devices have been used to measure solar simulators, including photocells, photodiodes, photomultipliers, with and without filters. The basic requirements for a suitable monitoring device are that they be stable for several hours, be sensitive to UV-B radiation, and provide values reproducible daily.

The output of a solar simulator is measured in units of Joules. A Joule (J) is an absolute unit of work or energy equal to 1 million ergs. One Joule (J)=1×10^{7} ergs=1 watt.second =10^{6} microwatt.second=2.4×10^{-4} kilocalories. The UVL intensity of a solar simulator will be reported in J/m^2.

b. *Natural light source (sunlight) and monitoring.* Testing sunscreen products in sunlight offers several advantages. The test situation more closely approximates the actual ways the sunscreen product will be used by the consumer. The test subject is exposed simultaneously to the full solar spectrum, the heat, and the humidity. Testing of several sunscreen products simultaneously can be done. An estimation of tanning efficacy can be made. Uncontrollable variables in outdoor testing include vagaries of the weather, changing cloud cover, changing radiation intensity with time, changing sun angle to the body surface with time, and variable heat-induced sweating. Monitoring the amount of exposure to natural sunlight is more difficult than for solar simulators. The vagaries of each environment together with the changes in solar altitude with time make timing solar exposure inexact for determing total erythemic exposure. If solar exposures based on time are utilized, the results of 1 day's testing probably cannot be duplicated on another day.

Recently, the Robertson-Berger meter (R-B meter) (ref. *2*) has proved successful in monitoring and reproducing solar erythemic exposures (ref. *3*). An instrument of this type is recommended for monitoring all outdoor studies. Other recording radiometers are in use which permit continuous measurement of the sun's intensity in J/m^2 (ref. *4*).

The R-B meter records a measure of the cumulative amount of UV radiation that passes through its filters and photosensors after each 30-minute interval. Such 30-minute recordings may range from 0 to slightly over 1,000 depending on the geographical location and the meteorological conditions prevailing at the test location. A count of approximately 400 is estimated to produce one MED on the "typical" Caucasian skin.

5. *General guidelines for all testing procedures.*—a. *Selection of test subjects (male and female).* Only fair-skin volunteers with skin types I, II, and III, using the following guidelines, should be selected:

SELECTION OF FAIR-SKIN SUBJECTS

Skin Type and Sunburn and Tanning History [1]

I—Always burns easily; never tans (sensitive).
II—Always burns easily; tans minimally (sensitive).
III—Burns moderately; tans gradually (light brown) (normal).

[1] Based on first 30 to 45 minutes sun exposure after a winter season of no sun exposure.

IV—Burns minimally; always tans well (moderate brown) (normal).
V—Rarely burns; tans profusely (dark brown) (insensitive).
VI—Never burns; deeply pigmented (insensitive).

A medical history will be obtained from each volunteer with emphasis on the effects of sunlight on his/her skin. To be ascertained are the general health of the individual, the individual's skin type (I, II, or III), whether the individual is taking medication, topical or systemic, that is known to produce abnormal sunlight responses, e.g., declomycin or chlorpromazine, and whether the individual is subject to any abnormal responses to sunlight, such as a phototoxic or photoallergic response.

b. *Test site inspection.* The physical examination should determine the presence of sunburn, suntan, scars, active dermal lesions, and uneven skin tones on the areas of the back to be tested. The presence of nevi, blemishes, or moles will be acceptable if in the physician's judgment they will not interfere with the study results. Excess hair on the back is acceptable if the hair is clipped or shaved.

Some investigators have found a reflectometer useful to ensure uniformity of skin tone to the average skin reflectance in the test areas. Reflectance readings should not vary by more than 5 percent (refs. *4* and *5*).

c. *Informed consent.* Legally effective written informed consent must be obtained from each individual.

d. *Test site delineation.*—(1) *Test site area.* A test site area serves as an area for determining the subject's MED after application of either the sunscreen standard or the test sunscreen product, or for determining the subject's MED when the skin is unprotected (control site). The area to be tested is the back between the beltline and the shoulder blade (scapulae) and lateral to the midline. The test site areas may be horizontal or vertical, and rectangular or square. Depending upon the test scheme, each test site area for applying a product or standard control should be a minimum of 50 cm^2, e.g., 5×10 cm. The test sites are outlined with ink. If the person is to be tested in an upright position, the lines should be drawn on the skin with the subject upright. If the subject is to be tested while prone, the markings should be made with the subject prone. Change of position between marking and testing can change the test area as much as 40 percent.

(2) *Test subsite area.* Each test site area is divided into at least three test subsite areas that are at least 1 cm^2. Usually four or five subsites are employed. Each test subsite area within a test site area is subjected for a time interval, in a series of time intervals, in which the test site area is exposed for the determination of the MED as described below.

e. *Application of test materials.* To insure standardized reporting and to define a product's SPF value, the application of the product will be expressed on a weight basis per unit area which establishes a standard film. The Panel recommends that the test sunscreen product and the sunscreen standard application be 2 mg/cm^2 or 2 ul/cm^2. For some products, lesser amounts may be justified based on intended usage.

The specific gravity of the product is determined according to standard techniques. In testing situations, it is easier to accurately measure volumes for applications. Most sunscreen products have a specific gravity near unity. The 50 cm^2 test site area previously recommended above would require 100 mg of a product or 100 ul (assuming a specifc gravity of 1 to obtain a standard 2 mg/cm^2 test application.

For oils and most lotions, the viscosity is such that the material can be applied with a volumetric syringe. For creams, heavy gels, and butters, the product is warmed slightly so that it can be applied volumetrically. On heating, care must be taken so as not to alter the product's physical characteristics, especially separation of the formulations. Pastes and ointments should be weighed, then applied by spreading on the test site. Numerous investigators have obtained more reproducible results by spreading a product using a finger cot than by spreading with a glass or plastic rod.

f. *Waiting period.* Before exposing the test site areas after applying a product, a waiting period is employed. This waiting period will be at least 15 minutes, or depending upon the product's labeling to the consumer, the waiting period before testing will be the amount of time specified on the labeling.

g. *Number of subjects.* The Panel recommends that groups of at least 20 subjects be used for each test panel. One reason for the panel's decision is that the MED testing is done in 25 percent increments of exposure. The 25 percent exposure increments are reasonably close to the standard deviations observed in test results (ref. *5*). The standard error for a 20-subject test panel would be 25 percent divided by the square root of 20, i.e.,

$$\text{Standard error} = (25 \text{ percent})/\sqrt{20}$$

The Panel agreed that a sunscreen product categorizes itself if the mean of the SPF test values fall within the limits of a PCD as described elsewhere in this doecument (see part II, paragraph A.7. above—Categories of sunscreen products.) The standard error should not exceed ± 5 percent of the mean. An appropriate number of additional subjects should be used to determine the PCD, if a PCD does not fall within the limits of the standard error.

6. *Specific guidelines for all testing procedures.* The Panel has provided the following table of specific testing procedures which are discussed more fully below.

Summary of Sunscreen Testing Procedures for Determining Product labeling

Type of test	Light[1] source	Total test time (min)
SPF Value	A	(2)
SPF Value	N	(2)
Sweat Resistance	A	30
Water Resistance	A	40
Waterproof	A	80

[1] A=artificial light source, N=natural light source.
[2] Variable.

The Panel has not proposed tests to determine if a sunscreen product is water resistant, sweat resistant or waterproof, using a natural light source (sunlight), for several reasons.

There are three major difficulties with testing sunscreen products outdoors for water resistance, sweat resistance, and waterproof claims. These are the lack of protection of the subject's untreated skin against sunburn during the long exposures, the determination of the quantity of sunlight striking the skin when immersed and penetrating the wet stratum corneum, and the maintenance of the protective template on the test site during water immersion. The exposed skin outside the test sites can be protected by applying sunscreens between water immersions. Wet clothing usually transmits significant amounts of UVL.

The Panel believes the testing of sunscreen products for water resistance, sweat resistance, and waterproof claims is easier and more reproducible in an indoor pool. The Panel believes that water immersion is a more severe test of a sunscreen product than is sweating. It, therefore, recommends that the claim "Resists removal by sweating" is appropriate if the product proves water resistant or waterproof in the tests described below.

Because of the difficulties inherent in sunlight water resistance, waterproof and sweat resistance testing for substantivity discussed above, the Panel does not recommend that this method of testing be required. It does recommend that ways to test for substantivity of sunscreen products against water immersion and during copious sweating in natural sunlight be developed.

a. *Determination of SPF value using artificial light source.* This test determines the SPF value of a sunscreen

product after UV-A and UV-B irradiation of the skin.

A series of UV light exposures (units of time) are administered to the subsites on each volunteer with the solar simulator. One series of exposures is administered to the untreated, unprotected skin to determine the volunteer's inherent MED. The time intervals selected are a geometric series represented by $(1.25)^n$, where in each exposure time interval is 25 percent greater than the previous time. The reason for using the geometric sequence of UV exposure is to maintain the same relative uncertainity (expressed as a constant percentage), independent of the volunteer' sensitivity to UV light, regardless of whether the subject has a high or low MED. One example is the time intervals of 1, 1.25, 1.56, 1.96, and 2.44 minutes. This series would be suitable for a normal person exposed to the 150-watt xenon lamp solar simulator. Usually, the MED of a person's unprotected skin is determined the day prior to testing a product.

The protected test sites (standard and/or test sunscreen product) usually are exposed to UV light the next day. The exact series of exposures to be given is determined by the MED of the unprotected skin. For example, for the 8 percent homosalate standard sunscreen with an SPF of 4, the time intervals to be selected are 4, 5, 6.24, 7.84, and 9.76 minutes for a person with an MED of 1.56 minutes on the unprotected skin.

Specifically, what is needed is a series of exposures of the sites in which the lower exposure times produce no effect on the skin. Also, at 16 to 24 hours later, the longer exposure times should produce light and moderately red exposure sites. The MED is the time of exposure that produces the minimally perceptible erythema at 16 to 24 hours postexposure. The SPF of the test sunscreen is then calculated from the exposure time interval required to produce the MED of the protected skin, and from the exposure time interval required to produce the MED of the unprotected skin (control site), i.e.,

SPF value=Exposure time interval (MED (PS))/Exposure time interval (MED (US).)

b. *Determination of SPF value using natural light source (sunlight).* This test determines the SPF value of a suncreen product in sunlight.

Applications will dry in at least 15 minutes or longer as specified on the labeling. Common practice utilizes an opaque template or grid of opaque materials to cover the test sites to control the time exposures of the subsites to the sun after the product has dried. The remainder of the back is covered with heavy toweling or other opaque materials when a suncreen is applied to the exposed parts of the subject's skin during the test. The subject will lie in the prone position in direct sunlight for a predetermined period of time. The day of sun exposure may not be the same for all subjects. However, sun exposure of individual subjects will be completed during one continuous exposure period. Sun exposure of all subjects must be completed within 2 weeks for any one test and must be conducted at the same geographical location for any one test. During each exposure, the sun intensity will be measured continuously by a recording radiometer or a recording R-B meter. Empirically, approximately 6×10^6 Joules/m^2, as measured by a recording radiometer, will evoke 1 MED in skin types I and II subjects when read 16 to 24 hours later. Using the recording R-B meter, 400 counts are equivalent to 1 MED in skin type III subjects (ref. *3*), and MED's as low as 200 counts may be expected of skin type I. Duration of sun exposure will be documented in Joules/m^2 or in R-B counts. Temperature and humidity will be measured in R-B meter counts. Temperature and humidity will be measured at the beginning, the end, and at the maximal sun intensity for the exposure period. Descriptive comments about wind and cloud conditions will be made at times, but the primary measure of variations in cloud cover during exposure will be the continuous radiometer or R-B meter record.

At preestablished exposure times as determined by the meter reading, the subsite areas of the test site area will be exposed so that graded exposures will be obtained. Identical sequence of exposures will be administered to all test sites.

The Panel has reviewed several suggested test protocols of varying design that effectively determine the SPF of a sunscreen product. One example test protocol follows. It assumes a subject of skin type I with an MED of 15 minutes, 4.5×10^6 Joules/m^2, or 300 R-B meter counts (ref. *3*). The study is a controlled test of a sunscreen product, a standard sunscreen product, and an untreated control.

With the protective template in place, the approximate dose of sun exposure of individual subsites within the treated and unprotected test sites were as follows:

Robertson-Berger Meter Counts (exposure Count Intervals) (Ref. 3). 160, 213, 283, 376, 501, 666, and 886.

The R-B meter count intervals selected are a geometric series represented by $(1.33)^n$, wherein each exposure count interval is 33 percent greater than the previous exposure count interval. For the unprotected subsite, usually a mixmum of 800 R-B meter counts assures 3 MED's in skin types I and II, and 2 MED's in normal skin type III subjects. Greater exposures increase the risk of severe sunburn, but provide little additional useful data.

For test and standard sunscreen products with different SPF values, the dose of exposure will vary accordingly. Often a pilot study is performed in three to six subjects to obtain the approximate SPF of a new product.

The SPF value of the test sunscreen using the R-B meter is calculated as follows:

SPF value=exposure count interval (MED (PS))/exposure count interval (MED (US)).

c. *Determination of sweat resistance using artifical light source.* This test determines the sweat resistance and substantivity of a sunscreen product after 30 minutes of copious sweating to substantiate the claim of sweat resistance. The claim as appropriate will be allowed if the sunscreen product retains the same PCD, as described elsewhere in this document, after the sweat test as before the sweat test. (See part II. paragraph A.7. above—Categories of sunscreen products.)

The Panel concludes that a 30-minute period of copious sweating induced under controlled environmental conditions is an appropriate test for determinng sweat resistance and substantivity claims of a sunscreen product. If a subject fails to sweat profusely, he will be dropped from the study and another subject selected. The MED of the unprotected test site area on each subject is determined using the solar simulator. Usually the next day, the SPF of the test sunscreen product is determined for each subject using the solar simulator. The same day or the next day the test sunscreen product is applied. The subjects sit quietly in a controlled environment at a temperature of 35 to 38° C (95 to 100° F) and a relative humidity of 70 to 80 percent. To prevent evaporative cooling of the skin with resulting decreased sweating, there should be little air movement. A few subjects may require an air temperature of 105° F, with a relative humidity of 60 percent. For safety purposes, older persons should not be used. All subjects exposed to heat stress should have their pulse and temperature taken every 15 minutes. If a subject's pulse exceeds 160 counts per minute, and oral temperature of 38.9° C (102° F) or a rectal temperature of 39.2° C (102.5° F), the subject's participation must stop.

The 30-minute test period begins when the subject starts to sweat profusely, drops or rivulets of sweat running down the test site. Most subjects will sweat profusely within 10 minutes, but a few may take up to 20 minutes to develop copious sweating. After the

30-minute period of heavy sweating, the subject leaves the controlled environment, permits the test site area to air dry, and then the postsweating SPF of the sunscreen product is determined. The test sunscreen product must permit delivery of sweat through the film. No standard sweat resistant product is available as yet.

If the test sunscreen product retains the same PCD after the sweat test as before the sweat test, the claim of "sweat resistant" will be allowed.

d. *Determinating if a sunscreen is water resistant or waterproof using artifical light source.* This test determines the water resistance of a sunscreen product after 40 minutes of moderate activity (swim and play activity) in water (swimming pool) to substantiate the claim of water resistance, and after 80 minutes of moderate activity to substantiate the claim of waterproof. The claims as appropriate will be allowed if the sunscreen product retains the same PCD, as described elsewhere in this document, after the test as before the test. (See part II., paragraph A.7. above—Categories of sunscreen products.) Because it is impossible to produce even, controlled sweating among individuals, the Panel recommends that the claim "resists removal by perspiration" is appropriate if the product proves water resistant or waterproof in the water test. The Panel believes that water immersion is a more severe test of a sunscreen product than is sweating.

No water resistant or waterproof standard sunscreen product is available; so a standard sunscreen product is not used in the test.

The Panel concludes that a 20-minute period of moderate activity in the water in a swimming pool after the application of the test sunscreen product, followed by a 20-minute rest period, then a second 20-minute period of moderate activity is an appropriate test for determining water resistance and substantivity claims of a sunscreen product. The test site areas are then exposed to the solar simulator. The pool and air temperature and the relative humidity should be recorded. A sample schedule of a water test for a water-resistant sunscreen product is as follows:

9:30—Apply sunscreen product (followed by the waiting period after application of the sunscreen product indicated on the product labeling).
10:00—20 minutes moderate activity.
10:20—Rest period
10:40—20 minutes moderate activity
11:00—Conclude water test (air dry test sites without toweling).
11:10—Begin solar simulator exposure to test site area in the manner described above.

A sample schedule of a water test for a waterproof sunscreen product is as follows:

9:30—Apply sunscreen product (followed by the waiting period after application of the sunscreen product indicated on the product labeling).
10:00—20 minutes moderate activity.
10:20—Rest period.
10:40—20 minutes moderate activity.
11:00—Rest period.
11:20—20 minutes moderate activity.
11:40—Rest period.
12:00—20 minutes moderate activity.
12:20—Conclude water test (air dry test sites without toweling).
12:30—Begin solar simulator exposure to test sites in the manner described above.

Sunscreen active ingredients dissolve much more slowly in seawater than in freshwater because seawater contains about 3 percent salts. Therefore, a freshwater pool (21 to 32° C) should be used. The Panel recommends that this substantivity test should be conducted in an indoor pool to diminish the risk of exposure to natural sunlight during the conduct of the test, especially in skin types I and II.

The solar simulator-exposed test site areas are read at 16 to 24 hours after exposure determine the SPF for the subjects as described above. The Panel believes that a sunscreen product that can withstand 80 minutes of water immersion can reasonably claim to be waterproof. The Panel chose the 20-minute water periods because some unpublished marketing data revealed that the average person goes into the water 3.6 times for an average duration of 21 minutes per immersion at the beach or pool (Ref. 4).

7. *Response criteria.* After UVL exposure to natural or artificial sources is completed, all immediate responses are recorded. These include several types of typical responses such as the following:

a. An immediate darkening or tanning, typically grayish or purplish in color, fading in 30 to 60 minutes, and attributed to photo-oxidation of existing melanin granules;

b. Immediate reddening, fading rapidly, and viewed as a normal response of capillaries and venules to heat, visible and infrared radiation; and

c. An immediate generalized heat response, resembling prickly heat rash, fading in 30 to 60 minutes, and apparently caused by heat and moisture generally irritating to the skin's surface.

After the immediate responses are noted, each subject shields the exposed area from further UV radiation for the remainder of the test day. The MED is determined 16 to 24 hours after exposure.

Specifically, these tests depend upon determining the light energy corresponding to a minimally perceptible erythema of a subject's skin at 16 to 24 hours postexposure for each series of exposures. To determine the MED, somewhat more intense erythemas usually must also be produced. The goal is to have some exposures that produce absolutely no effect, while of those exposures that produce an effect, the maximal exposure should be no more than twice the total energy of the minimal exposure. The maximum exposure anticipated in these tests corresponds to what most individuals would describe as a light to moderate sunburn.

8. *Rejection of test data.* These tests occasionally fail, and must be discarded. There are only the following two technical reasons for rejection of test data:

a. Sometimes the exposure series fails to elicit an MED response on either the treated or unprotected skin sites. In either event, that test is a technical failure and must be discarded. If the subject reacts to one or more exposure on the unprotected control site, but not on the treated site, then a minimal estimate of the SPF can be obtained.

b. The responses on the treated sites are randomly absent, which indicates the product was not spread evenly. Therefore, no assessment of protection is possible.

9. *Treatment of data.* The SPF value will be calculated for each test of a sunscreen product as follows:

a. *Calculation of the SPF value from data obtained in tests using a solar simulator.* The measurement units in tests using a solar simulator to obtain MED's for calculation of the SPF value are time units, usually seconds. The following is an example of the calculation of the SPF value from MED's obtained using a solar simulator:

SPF value=Exposure time interval (MED(PS))/Exposure time interval (MED(US))

SPF value=180 seconds (MED(PS))/60 seconds (MED(US))

Therefore, the SPF value=3.

The PCD for a sunscreen product with an SPF value of 3 would be categorized as a minimal sun protection products because the SPF value of 3 is more than a value of 2 and less than an SPF value of 4.

b. *Calculation of the SPF value from data obtained in tests using a recording radiometer or a Robertson-Berger meter*—(1) *Recording radiometer.* The measurement units in tests using a recording radiometer are energy units, Joules/m^2. The following is an example of the calculation of the SPF value from MED's obtained using a recording radiometer:

SPF value=Joules/m^2 (MED(PS))/Joules/m^2(MED(US))

SPF value=28×10^6 Joules/m^2 (MED(PS))/6×10^6 Joules/m^2(MED(US))

Therefore, the SPF value=4.6.

The PCD for a sunscreen product with an SPF value of 4.6 would be categorized as a moderate sun protection product because the SPF value of 4.6 is more than a value of 4 and less than an SPF value of 6.

(2) *Robertson-Berger meter (R-B meter).* The measurement units in tests using a Robertson-Berger meter are counts. The following is an example of the calculation of the SPF value from MED's obtained using a Robertson-Berger meter:

SPF value = Exposure count interval (MED(PS))/Exposure count interval (MED(US))

SPF value = 2,600 counts (MED(PS))/400 counts (MED(US))

Therefore, the SPF value = 6.5.

The PCD for a sunscreen product with an SPF value of 6.5 would be categorized as an extra sun protection product because the SPF value of 6.5 is more than a value of 6 and less than an SPF value of 8.

REFERENCES

(1) OTC Volume 060169.

(2) Proceedings of the Third Conference on Climatic Impact Assessment Program, February 26-March 1, 1974, DOT, TSC-OST 74-15.

(3) Measurement of Ultraviolet Radiation in the United States and Comparisons with Skin Cancer Data, U.S. Department of Health, Education, and Welfare, National Institutes of Health (DHEW No. 76-1029), November 1975.

(4) OTC Volume 060158.

(5) OTC Volume 060166.

The Food and Drug Administration has determined that this document does not contain an agency action covered by 21 CFR 25.1(b) and consideration by the agency of the need for preparing an environmental impact statement is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371) and the Administrative Procedure Acts (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704) and under authority delegated to him (21 CFR 5.1)), the Commissioner proposes that subchapter D of chapter I of title 21 of the Code of Federal Regulations be amended by adding new part 352, to read as follows:

PART 352—SUNSCREEN PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

352.1 Scope.
352.3 Definitions.

Subpart B—Active Ingredients

352.10 Sunscreen active ingredients.
352.20 Combinations of sunscreen active ingredients.

Subpart C—Testing Procedures

352.40 Standard sunscreen.
352.41 Light source and light monitoring.
352.42 General testing procedures.
352.43 Determination of SPF value using artificial light source.
352.44 Determination of SPF value using natural light source (sunlight).
352.45 Determination of sweat resistance using artifical light source.
352.46 Determination if a sunscreen is water resistant or waterproof using artificial light source.

Subpart D—Labeling

352.50 Labeling of sunscreen products.

AUTHORITY: Secs. 201, 502, 505, 701, 52 Stat. 1040-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371) (5 U.S.C. 553, 554, 702, 703, 704).

Subpart A—General Provisions

§ 352.1 Scope.

An over-the-counter sunscreen product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the following conditions and each of the general conditions established in § 330.1 of this chapter.

§ 352.3 Definitions.

(a) *Product category designation (PCD).* A labeling designation for sunscreen products to aid in selecting the type of product best suited to the individual's complexion (pigmentation) and desired response to ultraviolet (UV) light.

(1) *Mineral sun protection product.* Sunscreen products that provide an SPF value of 2 to under 4, and offer the least protection, but permit suntanning.

(2) *Moderate sun protection product.* Sunscreen products that provide an SPF value of 4 to under 6, and offer moderate protection from sunburning, but permit some suntanning.

(3) *Extra sun protection product.* Sunscreen products that provide an SPF value of 6 to under 8, offer extra protection from sunburning, and permit limited suntanning.

(4) *Maximal sun protection product.* Sunscreen products that provide an SPF value of 8 to under 15, offer maximal protection from sunburning, and permit little or no suntanning.

(5) *Ultra sun protection product.* Sunscreen products that provide an SPF value of 15 or greater, offer the most protection from sunburning, and permit no suntanning.

(b) *Sunscreen active ingredient.* An active ingredient that absorbs at least 85 percent of the light in the UV range at wavelengths from 290 to 320 nanometers, but transmits UV light at wavelengths longer than 320 nanometers. Such agents permit tanning in the average individual and also permit some reddening (erythema) without pain.

(c) *Sunscreen opaque sunblock.* An opaque sunscreen active ingredient that reflects or scatters all light in the UV and visible range at wavelengths from 290 to 777 nanometers and thereby prevents or minimizes suntan and sunburn.

(d) *Sun protection factor (SPF) value.* An SPF value is defined as the UV energy required to produce a minimal erythema dose (MED) on protected skin divided by the UV energy required to produce a MED on unprotected skin. In effect, the SPF value is the reciprocal of the effective transmission of the product viewed as a light filter. The SPF value may also be defined by the following ratio:

SPF value = MED (protected skin (PS)/MED (unprotected skin (US)).

Where MED (PS) is the minimal erythema dose for protected skin after application of 2 milligrams per square centimeter or 2 microliters per square centimeter of the final formulation of the sunscreen product, and MED (US) is the minimal erythema dose for unprotected skin, i.e., skin to which no sunscreen product has been applied.

Subpart B—Active Ingredients

§ 352.10 Sunscreen active ingredients.

The active ingredients of the product consist of the following when used within the topical dosage limits established and the finished product provides a minimum SPF value of not less than 2 as measured by the testing procedure in subpart C of this part:

Aminobenzoic acid 5 to 15 percent.

Cinoxate 1 to 3 percent.

Diethanolamine *p*-methoxycinnamate 8 to 10 percent.

Digalloyl trioleate 2 to 5 percent.

Dioxybenzone 3 percent.

Ethyl 4-[bis(hydroxypropyl)] aminobenzoate 1 to 5 percent.

2-Ethylhexyl 2-cyano-3, 3-diphenylacrylate 7 to 10 percent.

Ethylhexyl *p*-methoxycinnamate 2.0 to 7.5 percent.

2-Ethylhexyl salicylate 3 to 5 percent.

Glyceryl aminobenzoate 2 to 3 percent.

Homosalate 4 to 15 percent.

Lawsone 0.25 percent with dihydroxyacetone 3 percent.

Menthyl anthranilate 3.5 to 5 percent.

Oxybenzone 2 to 6 percent.

Padimate A 1 to 5 percent.

Padimate O 1.4 to 8.0 percent.

2-Phenylbenzimidazole-5-sulfonic acid 1 to 4 percent.

Red petrolatum 30 to 100 percent.

Sulisobenzone 5 to 10 percent.

Titanium dioxide 2 to 25 percent.

Triethanolamine salicylate 5 to 12 percent.

§ 352.20 Combinations of sunscreen active ingredients.

Two or more sunscreen active ingredients identified in § 352.10 may be combined within the topical dosage limits established: *Provided,* The finished product provides a minimum SPF value of not less than 2 as measured by the testing procedures in subpart C of this part.

Subpart C—Testing Procedures

§ 352.40 Standard sunscreen.

(a) *Laboratory validation.* A standard sunscreen shall be used concomitantly in the testing procedures for determining the SPF value of a sunscreen product to assure the uniform evaluation of sunscreen products. The standard sunscreen shall be an 8 percent homosalate preparation with a mean SPF value of 4.24 (standard deviation=1.14).

(b) *Preparation of the standard homosalate sunscreen.* The standard homosalate sunscreen is prepared from two different preparations (preparation A and preparation B) with the following compositions:

COMPOSITION OF PREPARATION A AND PREPARATION B OF THE STANDARD SUNSCREEN

PREPARATION A

Ingredients	Percent by weight
Homosalate	8.00
White petrolatum	2.00
Stearic acid	3.00
Stearyl alcohol	2.00
Propylparaben	0.015

PREPARATION B

Methylparaben	0.025
Sequestrene Na, (EDTA disodium)	0.05
Sodium lauryl sulfate	0.50
Propylene glycol	12.00
Purified water U.S.P.	72.41

Preparation A and preparation B are heated separately to 77 to 82° C with constant stirring until the contents of each part are solubilized. Add preparation A slowly to preparation B while stirring. Continue stirring until the emulsion formed is cooled down to room temperature (15 to 30° C). Add sufficient purified water to obtain 100 grams of standard sunscreen preparation.

(c) *Assay of the standard homosalate sunscreen.* Assay the standard homosalate sunscreen preparation by the following method to ensure proper concentration:

(1) *Preparation of the assay solvent.* The solvent consists of 1 percent glacial acetic acid (V/V) in denatured ethanol. The denatured ethanol should not contain a UV absorbing denaturant.

(2) *Preparation of a 1 percent solution of the standard homosalate sunscreen preparation.* Accurately weight 1 gram of the standard homosalate sunscreen preparation into a 100 milliliter volumetric flask. Add 50 milliliter of the assay solvent. Heat on a steam bath and mix well. Cool the solution to room temperature (15 to 30° FC). Then dilute the solution to volume with the assay solvent and mix well to make a 1 percent solution.

(3) *Preparation of the test solution (1:50 dilution of the 1 percent solution).* Filter a portion of the 1 percent solution through number 1 filter paper. Discard the first 10 to 15 milliliters of the filtrate. Collect the next 20 milliliters of the filtrate (second collection). Add 1 milliliter of the second collection of the filtrate to a 50 milliliter volumetric flask. Dilute this solution to volume with assay solvent and mix well. This is the test solution (1:50 dilution of the 1 percent solution).

(4) *Spectrophotometric determination.* The absorbance of the test solution is measured in a suitable double beam spectrophotometer with the assay solvent and reference beam at a wavelength near 306 nanometers.

(5) *Calculation of the concentration of homosalate.* The concentration of homosalate is determined by the following formula which takes into consideration the absorbance of the sample of the test solution, the dilution of the 1 percent solution to prepare the test solution (1:50), the weight of the sample of the standard homosalate sunscreen preparation (1 gram), and the standard absorbance value (172) of homosalate as determined by averaging the absorbance of a large number of batches of raw homosalate:

Concentration of homosalate=absorbance × 50 × 100/1 × 172=percent concentration by weight.

§ 352.41 Light source and light monitoring.

(a) *Artificial light source (solar simulator).* A solar simulator for sunscreen testing shall be defined as a light source having continuous emission spectrum in the UV-B (290 to 320 nanometers) with less than 1 percent of its total energy contributed by nonsolar wavelengths (wavelengths shorter than 290 nanometers) and not more than 5 percent of its erythemically effective energy contributed by nonsolar wavelengths. The instrument must be monitored periodically to assure that it delivers the appropriate spectrum.

(b) *Natural light source (sunlight).* Sunlight more closely approximates the actual ways the sunscreen product will be used by the consumer. The test subject is exposed simultaneously to the full solar spectrum. However, uncontrollable variables in outdoor testing include vagaries of the weather, changing cloud cover, changing radiation intensity with time, changing sun angle to the body surface with time, and variable heat-induced sweating. A suitable meter should be used for monitoring all outdoor studies.

§ 352.42 General testing procedures.

(a) *Selection of test subjects (male and female).* Only fair-skin volunteers with skin types I, II, and III using the following guidelines shall be selected:

SELECTION OF FAIR SKIN SUBJECTS

Skin Type and Sunburn and Tanning History[1]

I—Always burns easily; never tans (sensitive).
II—Always burns easily; tans minimally (sensitive).
III—Burns moderately; tans gradually (light brown) (normal).
IV—Burns minimally; always tans well (moderate brown) (normal).
V—Rarely burns; tans profusely (dark brown) (insensitive).
VI—Never burns; deeply pigmented (insensitive).

A medical history shall be obtained from each volunteer with emphasis on the effects of sunlight on their skin. To be ascertained are the general health of the individual, the individual's skin type (I, II, or III), whether the individual is taking medication, topical or systemic, that is known to produce abnormal sunlight responses, and whether the individual is subject to any abnormal responses to sunlight, such as a phototoxic or photoallergic response.

(b) *Test site inspection.* The physical examination shall determine the presence of sunburn, suntan, scars, active dermal lesions, and uneven skin tones on the areas of the back to be tested. The presence of nevi, blemishes, or moles will be acceptable if in the physician's judgment they will not interfere with the study results. Excess hair on the back is acceptable if the hair is clipped or shaved.

(c) *Informed consent.* Legally effective written informed consent must be obtained from each individual.

(d) *Test site delineation.*— (1) *Test site area.* A test site area serves as an area for determining the subject's MED after application of either the sunscreen standard or the test sunscreen product, or for determining the subject's MED when the skin is unprotected (control site). The area to be tested shall be the back between the beltline and the shoulder blade (scapulae) and lateral to the midline. Each test site area for applying a product or the standard sunscreen shall be a minimum of 50 square centimeter, e.g.,

[1] Based on first 30 to 45 minutes sun exposure after a winter season of no sun exposure.

5×10 centimeter. The test site areas are outlined with ink. If the person is to be tested in an upright position, the lines shall be drawn on the skin with the subject upright. If the subject is to be tested while prone, the markings shall be made with the subject prone.

(2) *Test subsite area.* Each test site area shall be divided into at least 3 test subsite areas that are at least 1 square centimeter. Usually 4 or 5 subsites are employed. Each test subsite are within a test site area is subjected for a time interval, in a series of time intervals, in which the test site area is exposed for the determination of the MED.

(e) *Application of test materials.* To insure standardized reporting and to define a product's SPF value, the application of the product shall be expressed on a weight basis per unit area which establishes a standard film. Both the test sunscreen product and the standard sunscreen application shall be 2 milligrams per square centimeter or 2 microliters per square centimeter. For oils and most lotions, the viscosity is such that the material can be applied with a volumetric syringe. For creams, heavy gels, and butters, the product shall be warmed slightly so that it can be applied volumetrically. On heating, care shall be taken so as not to alter the product's physical characteristics, especially separation of the formulations. Pastes and ointments shall be weighed, then applied by spreading on the test site area. A product shall be spread by using a finger cot.

(f) *Waiting period.* Before exposing the test site areas after applying a product, a waiting period of at least 15 minutes is required.

(g) *Number of subjects.* Groups of at least 20 subjects shall be used for each test panel. A sunscreen product categorizes itself if the mean of the SPF test values falls within the limits of a PCD. The standard error shall not exceed ± 5 percent of the mean. An appropriate number of additional subjects shall be used to determine the PCD, if a PCD does not fall within the limits of the standard error.

(h) *Response criteria.* After UVL exposure to natural or artificial sources is completed, all immediate responses shall be recorded. These include several types of typical responses such as the following: An immediate darkening or tanning, typically greyish or purplish in color, fading in 30 to 60 minutes, and attributed to photo-oxidation of existing melanin granules; immediate reddening, fading rapidly, and viewed as a normal response of capillaries and venules to heat, visible and infrared radiation; and an immediate generalized heat response, resembling prickly heat rash, fading in 30 to 60 minutes, and apparently caused by heat and moisture generally irritating to the skin's surface. After the immediate responses are noted, each subject shall shield the exposed area from further UV radiation for the remainder of the test day. The MED is determined 16 to 24 hours after exposure. Testing depends upon determining the light energy corresponding to a minimally perceptible erythema of a subject's skin at 16 to 24 hours postexposure for each series of exposures. To determine the MED, somewhat more intense erythemas must also be produced. The goal is to have some exposures that produce absolutely no effect, while of those exposures that produce an effect, the maximal exposure should be no more than twice the total energy of the minimal exposure.

(i) *Rejection of test data.* Test data shall be rejected if the exposure series fails to elicit an MED response on either the treated or unprotected skin sites or if the responses on the treated sites are randomly absent, which indicates the product was not spread evenly.

§ 352.43 Determination of SPF value using artificial light source.

A series of UV light exposures (units of time) are administered to the subsite areas on each volunteer with a solar simulator. One series of exposures shall be administered to the untreated, unprotected skin to determine the volunteer's inherent MED. The time intervals selected shall be a geometric series represented by $(1.25)^n$, wherein each exposure time interval is 25 percent greater than the previous time to maintain the same relative uncertainty (expressed as a constant percentage), independent of the volunteer's sensitivity to UV light, regardless of whether the subject has high or low MED. One example is the time intervals of 1, 1.25, 1.56, 1.96, and 2.44 minutes. This series would be suitable for a normal person exposed to the 150-watt xenon lamp solar simulator. Usually, the MED of a person's unprotected skin is determined the day prior to testing a product. The protected test sites (standard sunscreen and/or test sunscreen product) usually are exposed to UV light the next day. The exact series of exposures to be given shall be determined by the MED of the unprotected skin. For example, for the 8 percent homosalate standard sunscreen with an SPF value of 4.24, the time intervals to be selected are 4, 5, 6.24, 7.84, and 9.76 minutes for a person with an MED of 1.56 minutes on the unprotected skin. A series of exposures of the sites in which the lower exposure times produce no effect on the skin is required. Also, at 16 to 24 hours later, the longer exposure times should produce light and moderately red exposure sites. The MED is the time of exposure that produces the minimally perceptible erythema at 16 to 24 hours postexposure. The SPF value of the test sunscreen is then calculated from the exposure time interval required to produce the MED of the protected skin, and from the exposure time interval required to produce the MED of the unprotected skin (control site) as follows:

SPF value=Exposure time interval (MED (PS))/exposure time interval (MED (US))

§ 352.44 Determination of SPF value using natural light source (sunlight).

An opaque template or grid of opaque materials shall be used to cover the test sites in order to control the time exposures of the subsite areas to the sun after the product has dried. The remainder of the back shall be covered with heavy toweling or other opaque materials when a sunscreen is applied to the exposed parts of the subject's skin during the test. The subject shall lie in the prone position in direct sunlight for a predetermined period of time. The day of sun exposure may not be the same for all subjects. However, sun exposure of individual subjects shall be completed during one continuous exposure period. Sun exposure of all subjects shall be completed within 2 weeks for any one test and shall be conducted at the same geographical location for any one test. During each exposure, the sun intensity shall be measured continuously by a recording radiometer or a recording Robertson-Berger meter. Duration of sun exposure shall be documented in Joules per square meter or in Robertson-Berger meter counts. Temperature and humidity shall be measured at the beginning, the end, and at the maximal sun intensity for the exposure period. Descriptive comments about wind and cloud conditions shall be made at times, but the primary measure of variations in cloud cover during exposure will be the continuous radiometer or Robertson-Berger meter record. At preestablished exposure times as determined by the meter reading, the subsite areas of the test site area shall be exposed so that graded exposures will be obtained. Identical sequence of exposures shall be administered to all test sites. The SPF value of the test sunscreen product using the Robertson-Berger meter is calculated as follows:

SPF value=Exposure count interval (MED(PS))/Exposure count interval (MED(US))

§ 352.45 Determination of sweat resistance using artificial light source.

A 30-minute period of copious sweating induced under controlled environmental conditions shall determine sweat resistance and substantivity claims of a sunscreen product. A subject that fails to sweat profusely shall

be dropped from the study and another subject selected. The MED of the unprotected test site area on each subject shall be determined using the solar simulator. Usually the next day, the SPF of the test sunscreen product is determined for each subject using the solar simulator. The standard sunscreen is not used in this test. The same day or the next day the test sunscreen product is applied. The subjects sit quietly in a controlled environment at a temperature of 35 to 38° C (95 to 100° F) and a relative humidity of 70 to 80 percent. To prevent evaporative cooling of the skin with resulting decreased sweating, there should be little air movement. A few subjects may require an air temperature of 41° C (105° F) with a relative humidity of 60 percent. For safety purposes, older people should not be used. All subjects exposed to heat stress should have their pulse and temperature taken every 15 minutes. If a subject's pulse exceeds 160 counts per minute, an oral temperature of 38.9° C (102° F), or a rectal temperature of 39.2° C (102.5° F), his/her participation shall stop. The 30-minute test period begins when the subject starts to sweat profusely, drops or rivulets of sweat running down the test site. Most subjects will sweat profusely within 10 minutes, but a few may take up to 20 minutes to develop copious sweating. After the 30-minute period of heavy sweating, the subject leaves the controlled environment, permits the test site area to air dry, and then the postsweating SPF of the test sunscreen product is determined. The test sunscreen product must permit delivery of sweat through the film. If the test sunscreen product retains the same PCD after the sweat test as before the sweat test, the claim of "sweat resistant" will be allowed.

§§ 352.46 Determining if a sunscreen is water resistant or waterproof using artificial light source.

The standard sunscreen is not used in the tests. An indoor fresh water pool (23 to 32° C) shall be used in these testing procedures.

(a) *Procedure for testing the water resistance of a sunscreen product.* A 20-minute period of moderate activity in the water in a swimming pool after the application of the test sunscreen product followed by a 20-minute rest period, then a second 20-minute period of moderate activity shall be used to determine the water resistance and substantivity claims of a sunscreen product. The test site areas are then exposed to the solar simulator. The pool and air temperature and the relative humidity shall be recorded.

The following procedure shall be used for the water resistance test:

(1) Apply sunscreen product (followed by the waiting period after application of the sunscreen product indicated on the product labeling).

(2) 20 minutes moderate activity in water.

(3) 20 minute rest period.

(4) 20-minutes moderate activity in water.

(5) Conclude water test (air dry test sites without toweling).

(6) Begin solar simulator exposure to test site areas in the manner described above.

A sunscreen product that can withstand 40 minutes of water immersion may claim to be water resistant.

(b) *Procedure for testing the waterproof claim of a sunscreen product.* The following procedure shall be used for the waterproof test:

(1) Apply sunscreen product (followed by the waiting period after application of the sunscreen product indicated on the product labeling).

(2) 20 minutes moderate activity in water.

(3) 20-minute rest period.

(4) 20 minutes moderate activity in water.

(5) 20-minutes rest period.

(6) 20 minutes moderate activity in water.

(7) 20-minutes rest period.

(8) 20 minutes moderate activity in water.

(9) Conclude water test (air dry test sites without toweling).

(10) Begin solar simulator exposure to test site areas in the manner described above.

The solar simulator-exposed test site areas shall be read at 16 to 24 hours later to determine the SPF for the subjects as described above. A sunscreen product that can withstand 80 minutes of water immersion may claim to be waterproof.

Subpart D—Labeling

§ 352.50 Labeling of sunscreen products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug(s) identified under § 352.10 and identifies the product as a "sunscreen."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indication(s)" and is limited to one or more of the following phrases:

(1) *For all (minimal, moderate, extra, maximal, and ultra) sunscreen products.* (i) "Sunscreen to help prevent sunburn."

(ii) "Filters (or screen) out the sun's burning rays to prevent sunburn."

(iii) "Screens out the sun's harsh and often harmful rays to prevent sunburn."

(iv) "Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of these harmful effects."

(v) "Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of premature aging of the skin and skin cancer."

(2) *Additional indications.* In addition to the indications provided above in § 352.50(b)(1), the following may be used:

(i) *For minimal sunscreen products:* (*a*) "Affords minimal protection against sunburn."

(*b*) "Prolongs exposure time before sunburn occurs."

(*c*) "Permits tanning (or suntanning) and reduces chance of (or minimizes) sunburning."

(*d*) "Helps prevent sunburn on limited exposure of untanned skin."

(*e*) "Helps to protect the skin against sunburn while permitting tanning."

(*f*) "Allows you to stay in the sun two times longer than without sunscreen protection."

(g) "Provides two times your natural protection from sunburn."

(ii) *For moderate sunscreen products.* (*a*) "Affords moderate protection against sunburn."

(*b*) "Prolongs exposure time before sunburn occurs."

(*c*) "Permits tanning (or suntanning) and reduces chance of (or minimizes) sunburning."

(*d*) "Helps prevent sunburn on moderate exposure of untanned skin."

(*e*) "Allows you to stay in the sun four times longer than without sunscreen protection."

(*f*) "Provides four times your natural protection from sunburn."

(iii) *For extra sunscreen products.* (*a*) "Affords extra protection against sunburn."

(*b*) "Prolongs exposure time before sunburn occurs."

(*c*) "Permits limited tanning (or suntanning) and reduces chance of (or minimizes) sunburn."

(*d*) "Helps prevent sunburn."

(*e*) "For sun-sensitive skin."

(*f*) "Extra protection against sunburn for blondes, redheads and fair-skinned persons."

(*g*) "Allows you to stay in the sun six times longer than without sunscreen protection."

(*h*) "Provides six times your natural protection from sunburn."

(iv) *For maximal sunscreen products.* (*a*) "Affords maximal protection against sunburn."

(*b*) "Prevents sunburn and limits tanning."

(*c*) "For sun-sensitive skin."

(*d*) "Maximal protection against sunburn for blondes, redheads and fair-skinned persons."

(e) "Allows you to stay in the sun eight times longer than without sunscreen protection."

(f) "Provides eight times your natural protection from sunburn."

(v) *For ultra sunscreen products.* (a) "Affords the most protection against sunburn."

(b) "Prevents tanning and sunburn."

(c) "For highly sun-sensitive skin."

(d) "Greatest protection against sunburn for blondes, redheads, and fair-skinned persons."

(e) "Provides the highest degree of sunburn protection and permits no tanning."

(f) "Provides the highest degree of sunscreen protection and permits no tanning."

(3) *For all (maximal and ultra) sunscreen products that contain sunscreen opaque sunblock ingredients.* "Reflects the burning rays of the sun."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings:"

(1) *For all (minimal, moderate, extra, maximal, and ultra) sunscreen products.* The labeling of all sunscreen products contains the following warnings:

(i) "For external use only, not to be swallowed."

(ii) "Avoid contact with the eyes."

(iii) "Discontinue use if signs of irritation or rash appear."

(2) *Specific warnings.*—(i) *For sunscreen products providing an SPF value of 2 to under 4:* "Use on children under 2 years of age only with the advice of a physician."

(ii) *For sunscreen products providing an SPF value of 4 or greater:* "Use on children under 6 months of age only with the advice of a physician."

(iii) *For sunscreen products containing lawsone 0.25 percent with dihydroxyacetone 3 percent.* (a) "This is a two lotion product. Do not mix the contents of the two solutions. Use both solutions, for use of one alone will not provide protection."

(b) "Use only on skin free of rash and abrasions."

(c) "May stain clothing when freshly applied."

(d) *Directions for use.* The labeling of the product shall contain the following statement under the heading "Directions:"

(1) (i) For sunscreen products providing a minimum SPF value of 2 to under 4 for adults and children over 2 years of age: Apply liberally before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) For sunscreen products providing a minimum SPF value of 4 for adults and children over 6 months of age: Apply liberally before sun exposure and reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(2) *For all (minimal, moderate, extra, maximal, and ultra) sunscreen products*—(i) *That satisfy the water resistant testing procedures.* "Apply liberally before sun exposure and reapply after 40 minutes in the water or after excessive sweating."

(ii) *That satisfy the waterproof testing procedures.* "Apply liberally before sun exposure and reapply after 80 minutes in the water or after excessive sweating."

(iii) *That satisfy the sweat resistance testing procedures.* "Apply liberally before sun exposure and reapply after 30 minutes of excessive sweating."

(3) *For sunscreen products containing lawsone 0.25 percent with dihydroxyacetone 3 percent.* Products are composed of two separate formulations. Solution 1 contains 3 percent dihydroxyacetone and Solution 2 contains 0.25 percent lawsone.

(i) Products providing a minimum SPF value of 2 to under 4 for adults and children over 2 years of age: Apply liberally before sun exposure as follows: *First application.* The evening prior to sun exposure: Apply Solution 1. Wait 15 minutes then apply Solution 2 to the same areas of skin. Wait until dried. Then repeat application of solutions alternately as before until a total of three applications of both lotions have been applied. Leave on skin without washing. *Repeated application.* After first day, apply one application of each lotion. Reapply after swimming or after excessive sweating. There is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician.

(ii) Products providing a minimum SPF value of 4 for adults and children over 6 months of age: Apply liberally before sun exposure as follows: *First application.* The evening prior to sun exposure: Apply Solution 1. Wait 15 minutes then apply Solution 2 to the same areas of skin. Wait until dried. Then repeat application of solutions alternately as before until a total of three applications of both lotions have been applied. Leave on skin without washing. *Repeated application.* After first day, apply one application of each lotion. Reapply after swimming or after excessive sweating. There is no recommended dosage for children under 6 months of age except under the advice and supervision of a physician.

(e) *Statement on product performance*—(1) *Labeling claims for Product Category Designation (PCD).* The following appropriate labeling statement shall be prominently placed on the principal display panel of the products:

(i) Products containing active ingredient(s) that provide an SPF value of 2 to under 4: "Minimal Sun Protection Product (SPF 2)—Stay in the sun twice as long as before without sunburning."

(ii) Products containing active ingredient(s) that provide an SPF value of 4 to under 6: "Moderate Sun Protection Product (SPF 4)—Stay in the sun 4 times as long as before without sunburning."

(iii) Products containing active ingredient(s) that provide an SPF value of 6 to under 8: "Extra Sun Protection Product (SPF 6)—Stay in the sun 6 times as long as before without sunburning."

(iv) Products containing active ingredient(s) that provide an SPF value of 8 to under 15: "Maximal Sun Protection Product (SPF 8)—Stay in the sun 8 times as long as before without sunburning."

(v) Products containing active ingredient(s) that provide an SPF value of 15 or greater: "Ultra Sun Protection Product (SPF 15)—Stay in the sun 15 times as long as before without sunburning."

(2) *Labeling claims related to the product performance.* One or more of the following labeling claims for sunscreen products that satisfy the sunscreen product testing procedures identified in § 352.40 may be used.

(i) *For all (minimal, moderate, extra, maximal, and ultra) sunscreen products*—(a) *That satisfy the water resistance testing procedures.*

(*1*) "Water resistant."

(*2*) "Retains its sun protection for at least 40 minutes in the water."

(*3*) "Resists removal by sweating."

(b) *That satisfy the waterproof testing procedures.*

(*1*) "Waterproof."

(*2*) "Retains its sun protection for at least 80 minutes in the water."

(*3*) "Resists removal by sweating."

(c) *That satisfy the sweat resistance testing procedures.*

(*1*) "Retains its sun protection for at least 30 minutes of heavy sweating."

(*2*) "Sweat resistant."

(3) *Labeling guide for recommended sunscreen product use.* The Panel recommends that the following compilation of skin types and PCD's be appropriately included in labeling as a guide:

RECOMMENDED SUNSCREEN PRODUCT GUIDE

Sunburn and tanning history	Recommended sun protection product
Always burns easily; never tans	Maximal, Ultra.
Always burns easily; tans minimally	Extra.
Burns moderately; tans gradually	Moderate.
Burns minimally; always tans well	Minimal.
Rarely burns; tans profusely	Minimal.

Interested persons are invited to submit their comments in writing (preferably in quadruplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal on or before November 24, 1978. Such comments should be addressed to the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, and may be accompanied by a supporting memorandum or brief. Comments replying to comments may also be submitted on or before December 26, 1978. Comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: August 8, 1978.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc. 78-22963 Filed 8-24-78; 8:45 am]

federal register

FRIDAY, AUGUST 25, 1978
PART III

DEPARTMENT OF LABOR

Employment Standards Administration

■

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

[4510-27]

DEPARTMENT OF LABOR

Employment Standards Administration

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed in construction activity of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following 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, Office of Special Wage Standards, Division of 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 wage 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:	
AZ78-5115; AZ78-5116	July 28, 1978.
California:	
CA78-5106; CA78-5107	July 7, 1978.
Connecticut:	
CT78-3055; CT78-3056	July 28, 1978.
Delaware:	
DE77-3134	Sept. 30, 1977.
Lousiana:	
LA78-4072	July 14, 1978.
LA78-4077	Aug. 11, 1978.
Minnesota:	
MN77-2046	May 6, 1977.
New Jersey:	
NJ78-3009	Apr. 21, 1978.
Texas:	
TX78-4032	Apr. 14, 1978.
TX78-4073	July 21, 1978.
TX78-4078; TX78-4080	Aug. 11, 1978.
TX78-4081	Aug. 18, 1978.

SUPERSEDEAS DECISIONS 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.

Supersedeas decision numbers are in parentheses following the numbers of the decisions being superseded.

Florida:	
FL78-1062 (FL78-1070)	July 14,1978.
Texas:	
TX78-4028 (TX78-4087); TX78-4033 (TX78-4082); TX78-4036 (TX78-4083); TX78-4037 (TX78-4084); TX78-4043 (TX78-4085);	
TX78-4044 (TX78-4088)	Apr. 14, 1978.
TX77-4264 (TX78-4086)	Sept. 30, 1977.

CANCELLATION OF GENERAL WAGE DETERMINATION DECISIONS

None.

NOTICE

This is to advise all interested parties that the Department of Labor intends to withdraw 30 days from the date of this notice, Fresno County, Calif., from general wage determination No. CA78-5106 dated July 7, 1978, in 43 FR 29431, applicable to residential construction consisting of single family homes and garden type apartments up to and including four stories.

Signed at Washington, D.C., this 18th day of August 1978.

XAVIER M. VELA,
Administrator, Wage and Hour Division.

DECISION #AZ78-5115 - Mod. #1
(43 FR 33018 - July 28, 1978)
Maricopa County, Arizona

Change:
Supersedeas Decision No. AZ77-5025 dated June 17, 1977, in 42 FR 31065 to read: Supersedeas Decision No. AZ77-5059 dated June 17, 1977, in 42 FR 31065.

Basic Hourly Rates	Fringe Benefits Payments			
	H & W	Pensions	Vacation	Education and/or Appr. Tr.

DECISION #AZ78-5116 - Mod. #1
(43 FR 33014 - July 28, 1978)
Pima County, Arizona

Change:
Supersedeas Decision No. AZ77-2026 dated June 17, 1977, in 42 FR 31070 to read: Supersedeas Decision No. AZ77-5060 dated June 17, 1977, in 42 FR 31070.

Basic Hourly Rates	Fringe Benefits Payments			
	H & W	Pensions	Vacation	Education and/or Appr. Tr.

DECISION NO. CA78-5106 - Mod. #1
(43 FR 29431 - July 7, 1978)
Alameda, Alpine, Amador, Calaveras, Contra Costa, Del Norte, El Dorado, Fresno, Humboldt, Marin, Mariposa, Merced, Monterey, Napa, Nevada, Placer, Sacramento, San Benito, San Francisco, San Joaquin, San Mateo, Santa Clara, Santa Cruz, Solano, Sonoma, Sutter, Tehama, Tuolumne, Yolo and Yuba Counties, California

Change:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Roofers:					
Alameda and Contra Costa Cos.					
Roofers	$12.04	$1.27	$1.60	$1.00	.09
Mastic workers; Kettlemen (2 kettles w/o pumps)	12.29	1.27	1.60	1.00	.09
Bitumastic; Enamelers; Pipewrappers; Coal tar built up	14.04	1.27	1.60	1.00	.09
Marin, Napa, Solano and Sonoma Counties					
Roofers	11.68	1.10	1.20	1.93	.09
Mastic workers; Kettlemen (2 kettles w/o pumps)	11.93	1.10	1.20	1.93	.09
Bitumastic; Enamelers; Pipewrappers; Coal Tar Pitch	13.68	1.10	1.20	1.93	.09
San Francisco and San Mateo					
Roofers	12.21	.60	1.45	1.65	.09
Mastic workers and Kettlemen (2 kettles w/o pumps)	12.46	.60	1.45	1.65	.09
Bitumastic; Enamelers; Pipewrappers; Coal tar	13.21	.60	1.45	1.65	.09
Alameda County (Rehabilitation on residential structures defined to include all work, including demolition, repair and alteration, on any existing structure which is intended for residential use only)					
Roofers	9.63	1.27	1.60	1.00	.09

DECISION NO. CA78-5107 - Mod. #2 (43 FR 29444 - July 7, 1978) Alameda, Alpine, Amador, Butte, Calaveras, Colusa, Contra Costa, Del Norte, Eldorado, Fresno, Glenn, Humboldt, Kings, Lake, Lassen, Madera, Marin, Mariposa, Mendocino, Merced, Modoc, Monterey, Napa, Nevada, Placer, Plumas, Sacramento, San Benito, San Francisco, San Joaquin, San Mateo, Santa Clara, Santa Cruz, Shasta, Sierra, Siskiyou, Sutter, Tehama, Trinity, Tulare, Tuolumne, Yolo and Yuba Counties, California	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Roofers:					
Alameda and Contra Costa Cos.					
Roofers	$12.04	$1.27	$1.60	$1.00	.09
Mastic Workers; Kettlemen (2 kettles w/o pumps)	12.29	1.27	1.60	.95	.09
Bitumastic; Enamelers; Pipewrappers; Coal Tar Built Up	14.04	1.27	1.60	.95	.09
Lake, Marin, Mendocino, Napa, Solano and Sonoma Cos.					
Roofers	11.68	1.10	1.20	1.93	.09
Mastic Workers; Kettlemen (2 kettles w/o pumps)	11.93	1.10	1.20	1.93	.09
Bitumastic; Enamelers; Pipewrappers; Coal Tar Pitch	13.68	1.10	1.20	1.93	.09
San Francisco and San Mateo Counties					
Roofers	12.21	.60	1.45	1.65	.09
Mastic Workers and Kettlemen (2 kettles) w/o pumps	12.46	.60	1.45	1.65	.09
Bitumastic; Enamelers; Pipewrappers; Coal Tar	13.21	.60	1.45	1.65	.09

DECISION #CT78-3055 - MOD. #4 (43 FR 33023 - July 28, 1978) Fairfield, Litchfield and Windham Counties, Connecticut	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
Carpenters (Heavy & Highway Construction)					
Fairfield Co.: Greenwich	$10.05	.90	.65	f	.10
ADD:					
Power Equipment Operators:					
Survey Crews:					
Chief of Party	9.88	.90	.85	a	.10
Ass't Chief of Party	9.18	.90	.85	a	.10
Instrument Man	8.48	.90	.85	a	.10
Rodman & Chainman	6.37	.90	.85	a	.10
DECISION #CT78-3056 - MOD. #2 (43 FR 33030 - July 28, 1978) Hartford, Middlesex, New Haven, New London, and Tolland Counties, Connecticut					
ADD:					
Power Equipment Operators:					
Survey Crew:					
Chief of Party	$ 9.88	.90	.85	a	.10
Ass't Chief of Party	9.18	.90	.85	a	.10
Instrument Man	8.48	.90	.85	a	.10
Rodman & Chainman	6.37	.90	.85	a	.10
DECISION #DE77-3134 - Mod. #10 (42 FR 52990 - September 30, 1977) State of Delaware					
Change:					
Carpenters - Building & Heavy: New Castle & Kent Counties	$10.70	1.29	1.00		.02
Carpenters - Highway Construction New Castle & Kent Counties	9.20	1.29	1.00		.02
Soft Floor Layers: New Castle & Kent Counties	10.46	1.29	1.00		.02

DECISION #LA78-4072 - Mod. #4 (43 FR 30456 - July 14, 1978) Bossier, Caddo & Calcasieu Parishes, Louisiana	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Glaziers - Calcasieu Parish	$10.15				.02
Roofers:					
Bossier & Caddo Parishes:					
Roofers	9.35		.20		.04
Kettlemen	6.48		.20		.04
Calcasieu Parish:					
Roofers	10.03		.20		
DECISION #LA78-4077 - Mod. #2 (43 FR 35841 - August 11, 1978) Statewide Louisiana					
Change:					
Glaziers - Zone 1	$10.15				.02
Roofers:					
Zone 1 - Roofers	10.03		.20		
Zone 5 - Roofers	9.35		.20		.04
Kettlemen	6.48		.20		.04
DECISION #MN77-2046 - Mod. #5 (42 FR 23404 - May 6, 1977) Benton, Shereburne & Stearns Counties, Minnesota					
CHANGE:					
Bricklayers & Stonemasons	$10.40		.25	1.00	
Modification #3 - Vol. 43- 3/16/78 Federal Register to read Modification #4					

DECISION #NJ78-3009 - Mod. #3 (42 FR 17223 - April 21, 1978) Bergen, Essex, Hudson, Hunterdon, Middlesex, Morris, Passaic, Somerset, Sussex, Union, and Warren Counties, New Jersey	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Omit:					
Electricians & Cable Splicers: Zone 9 and Zone 10					
Change:					
Area Covered by Electricians & Cable Splicers Zones					
Zone 8: Hunterdon & Somerset Counties					
Air Conditioning and Refrigeration Mechanic	$ 9.10	.065	.31	m	.04
Bricklayers, Stone Masons, Cement Masons, & Plasterers:					
Zone 1	11.75	.92	.90		.05
Zone 5	11.50	1.00	.65		
Zone 9	11.98	.65	.60		.04
Carpenters, Insulators, & Millwrights:					
Zone 5					
Carpenters & Insulators	11.70	8%	7%	5%	.002
Millwrights	11.95	8%	7%	5%	.002
Electricians & Cable Splicers:					
Zone 3	13.645	7%	3%+.90		.015
Zone 5	13.29	10%	9%+.58		1.5%
Zone 6					
Wiremen	13.70	7%	9%		
Cable Splicers	14.77	7%	9%		
Zone 8	13.335	7%	3%+.90		.015
Zone 12	13.77	7%	3%+.90		.015
Zone 13	13.37	13%	7%		.02
Laborers - Asphalt Construction					
Zone 1					
Street:					
Head Raker	8.55	.81	.79	e	.03
Rakers & Screed Men	8.40	.81	.79	e	.03
Tampers, Smoother, Kettlemen, Painters, Top Shovelers, & Roller Boys	8.15	.81	.79	e	.03
Plant:					
Scale mixer & Burner Men	8.40	.81	.79	e	.03

MODIFICATIONS P. 7

DECISION #NJ78-3009 - Mod. #3

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Laborers - Asphalt Construction					
Zone 1 (cont'd)					
Plant:					
Feeders & Dust Men	$ 8.15	.81	.79	e	.03
Lathers	11.40	.15	.40		.02
Line Construction:					
Zone 3					
Linemen, Cable Splicers, Equipment Operators & Groundmen	13.29	10%	9%+.58		3/4 of 1%
Zone 8					
Linemen & Equipment Operator	13.335	7%	3%+.90		3/4 of 1%
Groundmen	11.475	7%	3%+.90		3/4 Of 1%

MODIFICATIONS P. 8

DECISION #TX78-4032 - Mod. #4 (43 FR 16119 - April 14, 1978) Bowie County, Texas	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Line Construction:					
Linemen	$11.15		3%		1/2%
Cable splicers	11.48		3%		1/2%
Hole digger op.; heavy equipment ops. (or pole cat equivalent); powderman	10.15		3%		1/2%
Line truck driver (winch op.)	9.14		3%		1/2%
Jackhammerman	8.36		3%		1/2%
Groundmen	7.47		3%		1/2%
Groundmen, 1st year	5.58		3%		1/2%
Truck driver (flat bed, ton & half & under)	7.92		3%		1/2%
DECISION #TX78-4073 - Mod. #1 (43 FR 31569 - July 21, 1978) Bell, Bosque, Coryell, Falls, Hill & McLennan Cos., Texas					
Change:					
Building Construction:					
Plasterers	9.99	.45	.55		.01
Power Equipment Ops.-Group 1	10.44		.40		
Group 2	9.37		.40		
Group 3	8.15		.40		
Group 4	8.04		.40		
DECISION #TX78-4078 - Mod. #1 (43 FR 35881 - August 11, 1978) Collin, Dallas, Denton, Ellis, Grayson, Hood, Hunt, Johnson, Kaufman, Palo Pinto, Rockwall, Tarrant & Wise Cos., Texas					
Change:					
Carpenters:					
Zone 1 - Carpenters	10.23	.50	.40		.005
Millwrights	10.63	.50	.40		.005
Piledrivermen	10.73	.50	.40		.005
Ironworkers:					
Zone 1 - Collin, Dallas, Denton, Ellis, Grayson, Hood, Hunt, Johnson, Kaufman, Palo Pinto (excluding northwest corner), Rockwall, Tarrant & Wise (excluding northwest 1/2)	9.25	.55	1.00		.07
ZONE 2 - Palo Pinto (northwest corner) & Wise (northwest 1/2)	9.255	.55	1.00		.10

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION #TX78-4081 - Mod. #1 (43 FR - August 18, 1978) Bexar County, Texas					
Change:					
Electricians - Electricians	$10.94	.60	5%		1%
Cable splicers	11.19	.60	5%		1%
DECISION #TX78-4080 - Mod. #1 (43 FR 35886 - August 11, 1978) Jefferson & Orange Cos., Texas					
Change:					
Cement masons	11.02				
Truck drivers:					
Group 1 - under 1½ tons & wash, grease, tiremen, fuel pump operators when used on construction jobs	8.66	.53			
Group 2 - 1½ tons thru 2½ tons, dump trucks less than 7 yds.	9.09	.53			
Group 3 - over 2½ tons, farm tractors (when used to transport personnel or material), fork lifts (when used in warehouses, storage yards & to transport material), floats, hydraulic tail gate lifts, buses, and/or personnel conveyance, trucks pulling trailers	9.28	.53			
Group 4 - Euclids(not self-loading)	9.38	.53			
Group 5 - Town driver; warehousemen-material checker	9.42	.53			
Power Equipment Ops.-Group 1	11.835		.25		
Group 2	9.92		.25		
Group 3	9.20		.25		
Group 4	8.99		.25		

POWER EQUIPMENT OPERATORS

Group 1 - Heavy Duty Mechanic; Blade Grader, Self-Propelled; Bull Clam; Back Filler; Derrick-Power Operated, all types; Draglines; Push Cat Op.; Bulldozer & all types of Cat Tractors; Cableway; Backhoe; Shovel; Crane-Power Operated, all types; Elevating Grader, Self-Propelled; Hoist-Motor Driven, 2 druns or more; Mix Mobile; Winch Truck; Locomotive Crane; Mixer, 14 cu. ft. or more; Paving Mixer, all sizes; Pile-driver; Scraper-Heavy type, over 3 cu. yds.; Trench Machine, all sizes; Gradall; High-Lift; Foundation Boring Machines; Gasoline or Diesel driven welding machines-7 to 12 machines and/or pumps less than 2"; Pumpcrete Machine; Drill Op.-Water Well; DW-10 Euclid; Tournapulls; Asphalt Plants; Crushing Machine & Batch Plants; Scoop-mobiles; Fingerlift Op; Elevators when used to haul men or material on Construction Work; Well Points Systems & operation of similar dewatering devices; Tug Boat Ops.; Work Boat Op. (Inboard)

Group 2 - Air Compressor; Blade Grader-Towed; Flex Plane; Form Grader; Mixer-less than 14 cu. ft.; Pump; Pulsometer; Truck Crane Driver; Gasoline or Diesel Driven Welding Machine-3 to 6 Machines and/or pumps less than 2"; Hoist-Single Drum; Scraper-3 cu. yds. or less; Conveyors-power operated; Work Boat Op. (Outboard)

Group 3 - Fireman

Group 4 - Oiler

SUPERSEDEAS DECISION

STATE: Florida COUNTY: Pinellas

DECISION NO.: FL78-1070 DATE: Date of Publication

Supersedeas Decision No.; FL78-1062 dated July 14, 1978 in 43 FR 30456

DESCRIPTION OF WORK: Building Construction (does not include single family homes and garden apartments of four stories or less).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
AIR CONDITIONING & HEATING MECHANICS	$10.73	.60	1.00		.08
BRICKLAYERS/BLOCKLAYERS	9.20	.45	.50		.10
CARPENTERS	6.56				
CEMENT MASONS	6.50				
ELECTRICIANS	8.20	5%	7% + 3%		1%
ELEVATOR CONSTRUCTORS	9.785				
GLAZIERS	6.13				
IRONWORKERS	6.39				
LABORERS	4.36				
LATHERS	7.36				
PAINTERS	5.27				
PLASTERERS	7.39				
PLUMBERS: PIPEFITTERS	10.73	.60	1.00		.08
ROOFERS	5.81				
SHEET METAL WORKERS:					
Commercial	8.10	.85	.55		.11
Industrial	9.41	.85	.55		.11
SOFT FLOOR LAYERS	5.25				
SPRINKLER FITTERS	10.16	.65	.95		.10
TILE SETTERS	6.86				
POWER EQUIPMENT OPERATORS:					
BACKHOE	5.00				
BULLDOZER	5.25				
COMPACTOR	9.185	.625	.60		
CRANE	10.89	.65	.60		.05
GRADER	4.76				
PILEDRIVER	7.00				

SUPERSEDEAS DECISION

STATE: Texas COUNTY: Brazos
DECISION NO.: TX78-4082 DATE: Date of Publication
Supersedes Decision No. TX78-4033, dated April 14, 1978, in 43 FR 16120.
DESCRIPTION OF WORK: Building Construction (does not include single family homes & garden type apartments up to & including 4 stories). (See current heavy & Highway general wage determination for Paving & Utilities Incidental to Building Construction).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$11.75	.90	.90		.05
BOILERMAKERS	10.55	.80	1.00		.02
BRICKLAYERS	11.36	.63	.60		.06
CARPENTERS	9.75				
CEMENT MASONS	10.60	.52	.58		.08
ELECTRICIANS	11.65	.55	10%		.06
ELEVATOR CONSTRUCTORS:					
Mechanics	10.35	.745	.35	4%+a+b	.02
Helpers	70%JR	.745	.35	4%+a+b	.02
Helpers (probationary)	50%JR				
GLAZIERS	11.17	.60	.425		.01
IRONWORKERS	10.96	.55	1.15		.10
LABORERS:					
GROUP 1	5.03	.38	.27		.02
GROUP 2	5.13	.38	.27		.02
GROUP 3	5.23	.38	.27		.02
GROUP 4	5.18	.38	.27		.02
GROUP 5	5.28	.38	.27		.02
GROUP 6	5.43	.38	.27		.02

LABORERS CLASSIFICATION DEFINITIONS

GROUP 1 - Construction labor, including excavation, concrete work, reinforcing, mason handler and wheeler (stock pile), asphalt ironer and raker, water proofing tender, pipe layer (non-metallic), pump crete pipe (handling and laying) and all building construction labor excepting that hereinafter classified; window washer, carpenters tender, cement mason tender, vibrator operator, other mechanic tender (except as otherwise classified); Dumper & spotter
GROUP 2 - Air tool operator
GROUP 3 - Well driller
GROUP 4 - Cutting torch man; mason tender; mason handler & wheelers handling material from first stock pile; concrete pipe (handling and laying); Sand blaster; Power buggy operator; plasterer tender & hod carrier; lather tender; well driller tender
GROUP 5 - Tool room tender; mortar mixer (hoe and otherwise); Blaster, powder man; gunnite worker
GROUP 6 - Gunnite nozzleman

DECISION NO. TX78-4082

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
LINE CONSTRUCTION:					
Lineman & cable splicer	$11.87	.50	3%		1/2%
Groundman (1st 6 months)	4.15	.50	3%		1/2%
Groundman (2nd 6 months)	4.99	.50	3%		1/2%
Groundman	6.88	.50	3%		1/2%
MARBLE MASONS	10.46				
PAINTERS:					
GROUP 1 - All brush painting, hand roller, steam cleaning, all pneumatic tools	9.795	.565	.45	.40	.04
GROUP 2 - All spray painting, sandblasting, waterblasting	10.17	.565	.45	.40	.04
GROUP 3 - Tape, float & drywall	9.92	.565	.45	.40	.04
GROUP 4 - Steeple jack work, hot materials	10.42	.565	.45	.40	.04
PIPEFITTERS	11.60	.50	.65		.045
PLASTERERS	11.30	.87	.30		.02
PLUMBERS	11.67	.65	.70		.12
SHEET METAL WORKERS	11.23	.325	.695	.42	.06
SOFT LFOOR LAYERS	10.53	.50	.45		.14
TERRAZZO WORKERS	10.46				
TILE SETTERS	10.46				
WELDERS - receive rate prescribed for craft performing operation to which welding in incidental.					

FOOTNOTES FOR ELEVATOR CONSTRUCTORS:
a - 1st 6 months - none; 6 months to 5 years - 2%; over 5 years - 4% of basic hourly rate
b - Paid Holidays A thru G

PAID HOLIDAYS FOR ELEVATOR CONSTRUCTORS
A-New Years' Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-the Friday after Thanksgiving Day; G-Christmas Day

DECISION NO. TX78-4082

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS					
GROUP 1	$10.94	.70	.85		.07
GROUP 2	9.24	.70	.85		.07
GROUP 3	8.66	.70	.85		.07
GROUP 4	8.47	.70	.85		.07

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

GROUP 1 - Heavy Duty Mechanic; Blade Grader, Self-propelled; Bull Clam; Back Filler; Derrick-power operated (all types); Clam shell; Draglines; Push Cat Operator; Bull Dozer & all types Cat Tractors; Cable-Way; Backhoe; Shovel, power operated; Crane, power operated (all types); Elevating Grader, Self-propelled; Hoist, Motor-Driven, Two Drums or more; Mix Mobile; Water Well Drilling Machines, used on construction; Building Elevator, used on construction; Tug Boat Operator, assigned to construction; Winch Truck; Locomotive Crane; Concrete Mixer, 14 cubic feet or more; Paving Mixer (all types); Pile Driver; Scraper, heavy type, over 3 cubic yards; Trenching Machine (all sizes); Gradall; High-Lift; Foundation Boring Machine; Gasoline or Diesel-Driven Welding Machines, 7 or more; Pumpcrete Machine Operator; Turnapulls; DW-10 Caterpillar, S-18 Euclid and similar tractors; Asphalt Plant Mixer Operator on job; Crusher Operator on job; Scoopmobiles; Forklift used on construction (not including warehousing); Well Point Pump; Concrete Batch Plant Operator; Pneumatic Rollers, self-propelled; All other equipment of similar nature coming under the Heavy Equipment Class, when power operated

GROUP 2 - Air Compressors; Blade Grader, Towed; Flex Plane; Form Grader; Concrete Mixer, less than 14 cubic feet; Pumps; Pulsometer; Truck Crane Driver; Gasoline or diesel driven welding machines (on 3 or more, up to 6 machines); Hoist, Single Drum; Scraper, 3 cubic yards or less; Wagon Drill Operator; Conveyor; Generator, Gasoline or diesel driven, over 1500 watts; Rubber Tired Farm Tractor with attachments; A light equipment operator may run 1 or 2 105 cfm compressors; All other equipment of similar nature coming under the Light Equipment Class, when power operated

GROUP 3 - Fireman

GROUP 4 - Oiler

SUPERSEDEAS DECISION

STATE: Texas COUNTY: El Paso

DECISION NO.: TX78-4083 DATE: Date of Publication

Supersedes Decision No. TX78-4036, dated April 14, 1978, in 43 FR 16125

DESCRIPTION OF WORK: Building Construction (does not include single family homes and garden type apartments up to & including 4 stories). (See current heavy general wage determination for Paving Incidental to Building Construction

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$ 8.36	.57	1.20		.03
BOILERMAKERS	10.55	.80	1.00		.02
BRICKLAYERS; BLOCKLAYERS; ROCK MASONS; STONEMASONS	7.70	.67	.20		.05
CARPENTERS:					
Carpenters	8.17	.67			.02
Millwrights	8.68	.67			.02
Stationary radial arm power saw operator	8.34	.67			.02
Floor layers	8.17	.67			.02
CEMENT MASONS	7.12	.67			.03
DRYWALL:					
GROUP 1 - Tapers	7.70	.38			.02
GROUP 2 - Ames tools	7.92	.38			.02
GROUP 3 - Texture spray	8.40	.38			.02
ELECTRICIANS:					
Electricians	9.60	.30	3%		1/10%
Cable splicers	9.85	.30	3%		1/10%
ELEVATOR CONSTRUCTORS:					
Mechanics	8.57	.745	.35	4%+a+b	.02
Mechanic Helpers	70%JR	.745	.35	4%+a+b	.02
Mechanic Helpers (Probationary)	50%JR				
GLAZIERS	7.29	.30	.10		.02
IRONWORKERS	8.90	.55	1.00		.15
LABORERS:					
GROUP 1 - Powderman or blasterer	6.31	.53	.45		
GROUP 2 - Outside wagon drill; wagon drill tenders; miner	6.06	.53	.45		
GROUP 3 - Cement gun or gunite; mason tender; mortar mixer; machine man; track man; chuck tender	5.81	.53	.45		
GROUP 4 - Pipelayer, main sewer and drainage	5.69	.53	.45		
GROUP 5 - Jackhammer operator, asphalt raker; kettlemen; asphalt or pot man	5.56	.53	.45		
GROUP 6 - Common, flag man	5.41	.53	.45		
LATHERS	8.98				.01

DECISION NO. TX78-4083

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
LINE CONSTRUCTION:					
Lineman-Technician; Equipment operators	$ 9.60	.30	3%		1/10%
Cable splicers	9.85	.30	3%		1/10%
Groundman	75%JR	.30	3%		1/10%
Groundman (less than 6 months)	50%JR	.30	3%		1/10%
MARBLE MASONS	6.98		.20		.04
PAINTERS:					
GROUP 1 - Brush & roller, paperhanger; tapers	7.70	.38			.02
GROUP 2 - Steel after erection, steam cleaning, power driven tools	8.11	.38			.02
GROUP 3 - Spray, sandblasting, waterblasting & swing stage, stripping machine	8.415	.38			.02
GROUP 4 - Ames tools	7.92	.38			.02
GROUP 5 - Water tanks, smoke stacks, tower from 70 - 100 ft	9.06	.38			.02
PLASTERERS	8.25	.67			.01
PLUMBERS & STEAMPITTERS	8.54	.59	.44		.05
ROOFERS:					
Roofers; Waterproofers; Pipewrappers	7.00				
SHEET METAL WORKERS	9.82	3%+.51	.385		.04
SOFT FLOOR LAYERS	7.45	.38	.10		.02
SPRINKLER FITTERS	11.60	.75	1.05		.08
TERRAZZO WORKERS	6.98		.20		.04
TERRAZZO WORKERS' FINISHERS	4.40		.20		
TILE SETTERS	6.98		.20		.04
TILE SETTERS' FINISHERS	4.40		.20		
TRUCK DRIVERS:					
GROUP 1 - Up to and including 2 tons	3.50	.26			
GROUP 2 - Flat bed dump trucks, mechanically	3.60	.26			
GROUP 3 - Tank trucks, up to 2500 gallons	3.50	.26			

DECISION NO. TX78-4083

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
TRUCK DRIVERS (CONT'D):					
GROUP 4 - Standard dump trucks, up to and including 4 cu. yds.	$ 3.60	.26			
GROUP 5 - Dump trucks, over 4 cu. yds.; trucks over 4 tons including transit mix, all semitruck, etc.; Lowboy	3.75	.26			
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

FOOTNOTES FOR ELEVATOR CONSTRUCTORS:

a - 1st 6 months - none; 6 months to 5 years - 2%; over 5 years - 4% of basic hourly rate

b - Paid Holidays - A thru G

PAID HOLIDAYS FOR ELEVATOR CONSTRUCTORS:

A-New Years' Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-the Friday after Thanksgiving Day; G-Christmas Day

DECISION NO. TX78-4083

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS					
GROUP 1	$ 7.29	.60	.60		.15
GROUP 2	7.87	.60	.60		.15
GROUP 3	7.96	.60	.60		.15
GROUP 4	8.16	.60	.60		.15
GROUP 5	8.24	.60	.60		.15
GROUP 6	8.58	.60	.60		.15
GROUP 7	8.74	.60	.60		.15
GROUP 8	8.21	.60	.60		.15
GROUP 9	8.44	.60	.60		.15
GROUP 10	8.74	.60	.60		.15

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

GROUP 1 - Fireman, Oiler; Mechanic, Grease truck and welder's helpers; screedman, pneumatic roller towed by farm type tractor or truck; scale operator and such as bin-a-batch; rubber-tired farm type tractors and tractors under 35 HP without attachments

GROUP 2 - Air compressors, power plants, pumps and welding machines; concrete mixers, under 1 yd. & concrete batch plants, under 1 yd., gunnite & pumpcrete machine, mechanical bull floats, spreading & finishing machines. Screening plants. Drilling machines, diamond, torary, core & cable drilling; well under 6". Hoists scoopmobiles, A-frame air tugger; hydrolift, hydrocranes, winch truck. Loaders: elevating, belt type loader, front end loader (under 2 yds.) & over head loaders; forklift & lumber staker on construction job site. Motor man & Industrial locomotive. Tractors under 35 HP with attachments.

GROUP 3 - Concrete mixers 1 yd. & over and batch plants 1 yd. & over, single drum paving machines, crushing plant, drilling machine, 6" & over; front end loaders, 2 yds. & over; Paving: Asphalt plants, boiler or retort heater, distributor, lay down machine, pug mill, breakdown & tandem rollers. Steam Engineer. Trenching machines. Patrol, rough, not required to blue top or finish.

GROUP 4 - Tractor Equipment: Athey & Barber Green Loader, Bulldozer, DW10, DW20, DW21, Dumor, Elevating Grader; Euclid, Highlander, Scraper, Traxcavator, Turnapull, Turnarocker & Tractors 35 HP & up & farm type tractors with backhoe & shovel type attachments

GROUP 5 - Concrete paving machines, double drum. Catcranes, Hysters, Cherry Pickers, Attachments cranes, side & swing boom tractors; Mechanic, welder, patrol, finish; grease truck operator (head oiler). Building hoist, 1 drum. Concrete Pump (Snorkle Type Trailer Mounted)

GROUP 6 - Shovel, Backhoe, clam & dragline 3/4 yds. & under; Cranes 25 tons & under; Building Hoist, 2 drums & up. Concrete pump (Snorkle Type Truck Mounted)

GROUP 7 - Guy & stiff leg derrick, Piledrivers; Crawler or skid rig, shovel, backhoe, clam & dragline over 3/4 yds.; crane over 25 tons. Pecco type cranes

GROUP 8 - Refrigeration, slusher, Jumbo form operators

GROUP 9 - Mucking machines

GROUP 10 - Mine hoists

SUPERSEDEAS DECISION

STATE: Texas COUNTIES: Galveston & Harris
DECISION NO.: TX78-4084 DATE: Date of Publication
Supersedes Decision No. TX78-4037, dated April 14, 1978, in 43 FR 16127
DESCRIPTION OF WORK: Building Construction (does not include single family homes & garden type apartments up to & including 4 stories). (See current heavy general wage determination for Paving & Utilities Incidental to Building Construction.)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$11.75	.90	.90		.05
BOILERMAKERS	10.55	.80	1.00		.02
BRICKLAYERS & STONEMASONS	11.36	.63	.60		.06
CARPENTERS:					
Carpenters & piledrivermen	10.60	.85	.80		.07
Millwrights	10.985	.85	.80		.07
CEMENT MASONS:					
Galveston County	10.60	.52	.58		
Harris County	10.60	.52	.58		.08
ELECTRICIANS:					
Galveston County	12.29	.50	3%+.40		.06
Harris County	11.65	.55	10%		.06
ELEVATOR CONSTRUCTORS:					
Mechanics	10.35	.745	.35	4%+a+b	.02
Helpers	70%JR	.745	.35	4%+a+b	.02
Helpers (Probationary)	50%JR				
GLAZIERS	11.17	.60	.425		.01
IRONWORKERS	10.96	.55	1.15		.10
LABORERS:					
GROUP 1 - Common	7.84	.45	.60		.02
GROUP 2 - Air tool operator (jackhammer-vibrator); Mason tenders; Pipelayers (concrete & clay); Sandblasters; Power buggy operator	8.025	.45	.60		.02
GROUP 3 - Lather tender; Mortar mixers; Plaster tenders & hod carriers	8.135	.45	.60		.02
GROUP 4 - Well driller	8.43	.45	.60		.02
GROUP 5 - Well driller tender	7.975	.45	.60		.02
GROUP 6 - Blaster, powderman	8.295	.45	.60		.02
LATHERS (Harris County only)	11.42	.70	.35		.02
LINE CONSTRUCTION:					
Lineman & cable splicer	11.87	.50	3%		1/2%
Groundmen (1st 6 mos.)	4.15	.50	3%		1/2%
Groundmen (2nd 6 mos.)	4.99	.50	3%		1/2%
Groundmen	6.88	.50	3%		1/2%
MARBLE MASONS:					
Galveston County	10.21				
Harris County	10.46				
MARBLE MASONS' FINISHERS	7.90				

DECISION NO. TX78-4084

	Basic Hourly Rates	Fringe Benefits Payments: H & W	Pensions	Vacation	Education and/or Appr. Tr.
PAINTERS:					
East Harris County:					
GROUP 1 - All brush painting, hand rolling and all other work other than that below	$11.31				
GROUP 2 - All pneumatic and electric tools & steam cleaning	11.665				
GROUP 3 - All tape and float on drywall	11.435				
GROUP 4 - All paper & vinyl hanging	11.56				
GROUP 5 - All spray painting, sandblasting & waterblasting	11.705				
GROUP 6 - Steeple jack work, hot materials	11.97				
Remainder of Harris County:					
GROUP 1 - All brush painting, hand roller, steam cleaning, all pneumatic tools	9.795	.565	.45	.40	.04
GROUP 2 - All spray painting, sandblasting, waterblasting	10.17	.565	.45	.40	.04
GROUP 3 - Tape, float & drywall	9.92	.565	.45	.40	.04
GROUP 4 - Steeple jack work, hot materials	10.42	.565	.45	.40	.04
Galveston County:					
GROUP 1 - Painters on new work	10.31	.60	.50	.85	.035
GROUP 2 - Painters on swinging stage work or using materials injurious to the skin	10.56	.60	.50	.85	.035
GROUP 3 - Painters on rework & repaint	9.555	.60	.50	.85	.035
PIPEFITTERS:					
That part of Galveston County east of the Trinity River	11.845	.545	.60		.10
That part of Galveston County west of the Trinity River & all of Harris County	11.60	.50	.65		.045
PLASTERERS	11.30	.87	.30		.02
PLUMBERS:					
Galveston County	11.845	.545	.60		.10
Harris County	11.67	.65	.70		.12
ROOFERS	9.61	.42	.35	.25	.06
SHEET METAL WORKERS:					
Galveston County	10.82	.80	.50	.50	.10
Harris County	11.23	.325	.695	.42	.06
SOFT FLOOR LAYERS	10.53	.50	.45		.14
SPRINKLER FITTERS	11.60	.75	1.05		.08
TERRAZZO WORKERS:					
Galveston County	10.21				
Harris County	10.46				
TERRAZZO WORKERS' FINISHERS:					
Terrazzo workers' finishers	7.90				
Terrazzo floor machinemen	8.05				
Terrazzo base machinemen	8.20				

DECISION NO. TX78-4084

	Basic Hourly Rates	Fringe Benefits Payments: H & W	Pensions	Vacation	Education and/or Appr. Tr.
TILE SETTERS:					
Galveston County	$10.21				
Harris County	10.46				
TILE SETTERS' FINISHERS	7.90				
TRUCK DRIVERS:					
GROUP 1 - Under 1½ tons; wash, grease, fireman, fuel pump operator when used on construction jobs	7.84				
GROUP 2 - 1½ thru 2½ tons; dump truck less than 7 yds.	8.23				
GROUP 3 - Over 2½ tons; farm tractors; fork lifts, floats	8.45				
GROUP 4 - Euclids (not self-loading)	8.61				
GROUP 5 - Warehousemen	8.10				
GROUP 6 - Material checkers; pick-up drivers	9.14				
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

FOOTNOTES FOR ELEVATOR CONSTRUCTORS:
a - 1st 6 mos. - none; 6 mos. to 5 yrs. - 2%; over 5 yrs. - 4% of basic hourly rates
b - Paid Holidays A thru G

PAID HOLIDAYS FOR ELEVATOR CONSTRUCTORS:
A-New Years' Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; G-the Friday after Thanksgiving Day; F-Christmas Day

DECISION NO. TX78-4084

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS					
GROUP 1	$10.94	.70	.85		.07
GROUP 2	9.24	.70	.85		.07
GROUP 3	8.66	.70	.85		.07
GROUP 4	8.47	.70	.85		.07

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

GROUP 1 - Heavy Duty Mechanic; Blade Grader, Self-propelled; Bull Clam; Back Filler; Derrick - power operated (all types); Clam Shell; Draglines; Push Cat Operator; Bull Dozer & all types Cat Tractors; Cable-Way; Backhoe; Shovel, power operated; Crane, power operated (all types); Elevating Grader, Self-propelled; Hoist, Motor-Driven, Two Drums or more, Mix Mobile; Water Well Drilling Machines, Used on Construction; Building Elevator, used on Construction; Tug Boat Operator, Assigned to Construction; Winch Truck; Locomotive Crane; Concrete Mixer, 14 cu. ft. or more; Paving Mixer (all types); Pile Driver; Scraper, Heavy Type, over 3 cu. yds.; Trenching Machines (all sizes); Gradall; High-Lift; Foundation Boring Machine; Gasoline or Diesel Driven Welding Machines, 7 or more; Pumpcrete Machine Operator; Turnapulls; DW-10 Caterpillar, S-18 Euclid and similar Tractors; Asphalt Plant Mixer Operator on job; Crusher Operator on job; Scoopmobiles; Forklift used on construction (not including warehousing); Well Point Pump; Concrete Batch Plant Operator; Pneumatic Rollers, Self-propelled; All other equipment of similar nature coming under the Heavy Equipment Class, when power operated

GROUP 2 - Air Compressors; Blade Grader, Towed; Flex Plane; Form Grader, Concrete Mixer, less than 14 cu. ft.; Pumps; Pulsometer; Truck Crane Driver; Gasoline or diesel Driven Welding Machines (on 3 or more, up to 6 machines); Hoist, Single Drum; Scraper, 3 cu. yds. or less; Wagon Drill Operator; Conveyor; Generator, Gasoline or Diesel-driven, over 1500 watts; Rubber Tired Farm Tractor with attachments; A Light Equipment Operator may run 1 or 2 105 cfm compressors; All other equipment of similar nature coming under the Light Equipment Class, when power operated

GROUP 3 - Fireman

GROUP 4 - Oiler

SUPERSEDEAS DECISION

STATE: Texas COUNTY: Travis

DECISION NO.: TX78-4085 DATE: Date of Publication

Supersedes Decision No. TX78-4043, dated April 14, 1978, in 43 FR 16134

DESCRIPTION OF WORK: Building Construction (does not include single family homes & garden type apartments up to & including 4 stories). (See current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$11.05	.60	.60		.08
BOILERMAKERS	10.55	.80	1.00		.02
BRICKLAYERS & STONEMASONS	10.32	.50	.40		.05
CARPENTERS:					
Carpenters	10.41	.48	.40		.04
Millwrights	10.66	.48	.40		.04
CEMENT MASONS	9.24	.50	.55		
ELECTRICIANS & CABLE SPLICERS	11.10		8%		.8%
ELEVATOR CONSTRUCTORS:					
Mechanics	9.59	.745	.56	4%+a+b	.025
Helpers	70%JR	.745	.56	4%+a+b	.025
Helpers (Probationary)	50%JR				
GLAZIERS	8.56		.20		.01
IRONWORKERS	10.05	.55	1.00		.12
LABORERS:					
GROUP 1 - General laborer and pier hole men	5.855	.275	.40		.02
GROUP 2 - Mason tender; Pipelayer (concrete & clay); Cement finisher tender; Scaffold builder; Gunnite & cement work mixer & power tool op.	6.005	.275	.40		.02
GROUP 3 - Plaster tender; Hod carrier; Mortar mixers; Lather tender; Water or damp proofers	6.18	.275	.40		.02
GROUP 4 - Gunnite over 1½" thick; Nozzlemen; Machine operator; Powderman & blaster	6.255	.275	.40		.02
LATHERS	10.925				.01
LINE CONSTRUCTION:					
Linemen	11.24	.50	3%		1/2%
Groundmen	6.18	.50	3%		1/2%
Groundmen (1st year)	5.62	.50	3%		1/2%
MARBLE, TILE & TERRAZZO WORKERS	8.46	.45			.04
MARBLE, TILE & TERRAZZO FINISHERS:					
Marble, tile & terrazzo finisher	6.37				
Terrazzo floor machine ops.	6.57				
Terrazzo base machine ops.	6.77				

DECISION NO. TX78-4085

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
PAINTERS:					
GROUP 1 - Brush; Taping & floating of sheetrock	$ 7.95				
GROUP 2 - Paperhangers; Chipper, burner, torch; Skeleton steelwork erected	8.20				
GROUP 3 - Spray; Steam cleaning, sand blast & other powered equipment	8.45				
Swinging stage, bosun chair, window jack or scaffold (above 2nd floor) - 25c per hour above all base rates					
PLASTERERS	9.99	.45	.55		.01
PLUMBERS & PIPEFITTERS	11.05	.45	.40		.05
ROOFERS:					
Roofers	5.23				.01
Kettlemen	5.08				.01
SHEET METAL WORKERS	10.89	3%+.45	.77		.07
SOFT FLOOR LAYERS	10.53	.50	.45		.14
SPRINKLER FITTERS	11.60	.75	1.05		.08
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

FOOTNOTES FOR ELEVATOR CONSTRUCTORS:
a - 1st 6 months - none; 6 months to 5 years - 2%; over 5 years - 4% of basic hourly rate
b - Paid Holidays A thru G

PAID HOLIDAYS FOR ELEVATOR CONSTRUCTORS
A-New Years' Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-the Friday after Thanksgiving Day; G-Christmas Day

DECISION NO. TX78-4085

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS					
GROUP 1	$10.44		.40		
GROUP 2	9.37		.40		
GROUP 3	8.15		.40		
GROUP 4	8.04		.40		

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

GROUP 1 - Heavy Duty Mechanic; Blade Grader - Self-propelled; Bull Clam; Back Filler; Derricks, power operated (all types); Dragline; Push Cat Operator; Euclid Operator; Bull Dozer and all types of Cat Tractors; Cable-Way; Back Hoe; Crane, Power Operated (all types); Elevating Grader, self-propelled; Hoist, Motor Driven, two drums or more; Mix Mobile; High-Lifts & loaders, over 1/3 cu. yd. capacity; Winch Truck; Locomotive; Mixer, 14 cu. ft. or over; Paving Mixer (all sizes); Scraper; Trenching Machine (all sizes); Gradall; Foundation Boring Machine; Scoopmobile; Shovel, Power Operated; Pump Crete Machine; Clam Shell Operator; Rock Crusher, Operated on Job; Welding Machine, 6 to 12, Two 125 cu. ft. Compressors; Well Points, including installations
GROUP 2 - Blade Grader, Towed; Flex Plane; Form Grader; Mixer, less than 14 cu. ft.; Pulsometer; Truck Crane Driver & Oiler, Combination man; Gasoline or Diesel Driven Welding Machine, 3 to 6; Hoist, Single Drum; Pump, 2½ in. or larger; Pneumatic Roller; High-Lifts & Loader, 1/3 cu. yd. or less; Forklift, 1500 lbs. capacity or less; Air Compressors, anytime there are two or more attachments operating on a 125 cu. ft. compressor, a light equipment operator shall be employed. One 125 cu. ft. air compressor and one welding machine requires no operator. One 125 cu. ft. compressor and two welding machines or any 2 air compressors equivalent to a 125 cu. ft. air compressor requires a light equipment operator
GROUP 3 - Firemen
GROUP 4 - Oiler

SUPERSEDEAS DECISION

STATE: Texas COUNTY: Tom Green
DECISION NO.: TX78-4086 DATE: Date of Publication
Supersedes Decision No. TX77-4264, dated September 30, 1977, in 42 FR 53168.
DESCRIPTION OF WORK: Building Construction (does not include single family homes & garden type apartments up to & including 4 stories). (See current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
BOILERMAKERS	$10.55	.80	1.00		.02
BRICKLAYERS	9.50				
CARPENTERS	8.95				.02
CEMENT MASONS	4.75				
ELECTRICIANS:					
Zone 1 - Shall consist of the following cities or towns: Christoval & San Angelo	8.20		3%		1/4%
Zone 2 - Shall consist of all areas outside the five (5) road miles of the city limits of the above named cities and towns	8.55		3%		1/4%
IRONWORKERS:					
Ironworkers	9.13	.55	1.00		.10
On jobs 30 miles or more from the city of San Angelo	9.255	.55	1.00		.10
LABORERS	2.65				
LATHERS	7.65				.01
PAINTERS, BRUSH	4.00				
PLASTERERS	7.25				.01
PLUMBERS & PIPEFITTERS	5.50				
ROOFERS	4.00				
SHEET METAL WORKERS	5.00				
SOFT FLOOR LAYERS	5.00				
TILE SETTERS	5.00				
TRUCK DRIVERS	2.75				
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

SUPERSEDEAS DECISION

STATE: Texas COUNTIES: Armstrong, Carson, Castro, Childress, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler
DECISION NO.: TX78-4087 DATE: Date of Publication
Supersedes Decision No. TX78-4028, dated April 14, 1978, in 43 FR 16112.
DESCRIPTION OF WORK: Building Construction (does not include single family homes & garden type apartments up to & including 4 stories). (See current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$10.30	.75	.85		.07
BOILERMAKERS	10.55	.80	1.00		.02
BRICKLAYERS & STONEMASONS	10.40		.30		
CARPENTERS:					
ZONE 1 - Armstrong, Carson, Castro, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler Counties:					
Carpenters	9.90		.40		.01
Millwrights	10.25		.40		.01
ZONE 2 - Childress County:					
Carpenters	9.87	.48	.50		.07
Millwrights	10.37	.48	.50		.07
CEMENT MASONS	8.30				
ELECTRICIANS:					
ZONE 1 - Armstrong, Carson, Castro, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler Counties:					
Electricians	10.78	.60	3%+.25		1/2%
Cable splicers	11.86	.60	3%+.25		1/2%
ZONE 2 - Childress County:					
Electricians	10.85	.40	3%		1/10%
Cable splicers	11.10	.40	3%		1/10%
GLAZIERS	7.90			a	
IRONWORKERS:					
ZONE 1 - Armstrong, Carson, Castro, Childress (excluding southeastern 1/4), Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler Cos.	9.75	.55	1.00		.10
ZONE 2 - Childress Co. (southeastern 1/4):	9.255	.55	1.00		.10
LABORERS:					
GROUP 1 - Construction laborers, including excavation, pouring concrete, carpenter tenders, reinforcing, shoring, digging, loading & unloading materials, wrecking buildings & all structures & all unskilled laborers	5.16	.53	.27		
GROUP 2 - Air tool operator (jackhammer, tamper, brush hammer, chipping hammer, air or electric), sand blasterer, power buggy man, pipelayer (concrete & clay & all non-metallic pipe) & pipewrappers; mortar mixers, mason tenders, plasterer tenders, cement finisher tenders, lather tenders, asphalt rakers, tampers, well drillers, bell hole men, dumpers, spotters, signal men	5.32	.53	.27		

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
LATHERS	$10.20				.01
LINE CONSTRUCTION:					
ZONE 1 - Childress County:					
Lineman; Operator	10.50		3%		1/2%
Cable splicers	10.75		3%		1/2%
Groundman - 1st 6 months	50%JR		3%		1/2%
Groundman - 2nd 6 months	60%JR		3%		1/2%
Groundman - 1 year & over	70%JR		3%		1/2%
ZONE 2 - Armstrong, Carson, Castro, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler Counties:					
Lineman	10.78	.60	3%+.25		1/2%
Cable splicers	11.86	.60	3%+.25		1/2%
Groundman:					
More than 1 year experience	7.08	.60	3%+.25		1/2%
Less than 1 year experience	6.20	.60	3%+.25		1/2%
Operator-hole digger, line truck	8.23	.60	3%+.25		1/2%
Flat bed truck driver	6.20	.60	3%+.25		1/2%
MARBLE MASONS (EXTERIOR)	10.40		.30		
PAINTERS:					
GROUP 1 - Brush & roller; paper hangers; perfa-tapers	8.80		.40		
GROUP 2 - Structural steel; swinging stage or chair below 50 ft.	8.92		.40		
GROUP 3 - Spray & sandblasters	9.55		.40		
GROUP 4 - Perfa-tape machine op.	9.05		.40		
PLASTERERS	10.20				.01
PLUMBERS & PIPEFITTERS:					
ZONE 1 - shall extend a distance of 25 road miles from the police station in either Amarillo or Borger	9.96	.45	.65	.60	
ZONE 2 - shall extend a distance of 25 to 50 road miles from either Amarillo or Borger	10.21	.45	.65	.60	
ZONE 3 - shall extend a distance of 50 road miles & over from either Amarillo or Borger	10.46	.45	.65	.60	
ROOFERS	4.50				
SHEET METAL WORKERS	10.54	.50	.55		.11
SPRINKLER FITTERS	11.60	.75	1.05		.08
TRUCK DRIVERS:					
1/2 ton to 3 tons; Ready mix concrete to 3 yds.	2.88				
3 to 5 tons; Ready mix concrete over 3 yds.	3.13				
5 tons and over	3.38				
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

FOOTNOTE FOR GLAZIERS:
a - Paid Holidays A thru F

PAID HOLIDAYS FOR GLAZIERS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksviging Day; F-Christmas Day

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS					
GROUP 1	$ 8.75	.40	.50		.10
GROUP 2	8.25	.40	.50		.10
GROUP 3	6.30	.40	.50		.10

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

GROUP 1 - Blade Grader, self-propelled; Clam Shells; Cable Ways; Cranes, power operated (all types); Air Compressors, Pumps, Welding Machines & Light Plants (7 to 12 machines); Derricks, power operated (all types); Draglines; Elevating Graders, self-propelled; Hoist, 2 drum or more; Locomotive; Mixermobiles; Paving Mixers, all types; Pile Drivers; Scrapers; Bulldozers; Side Boom; Cherry Pickers-12½ ton & over; Shovels; Heavy Duty Mechanics; All Welders; All tractors with power attachments; Ditching Machines - crawler type; Farm type Tractor (Loader, 1 yd. & over) with Backhoe; All other equipment of similar nature coming within to Heavy Equipment Classification when power operated

GROUP 2 - Air Compressors, Pumps, Welding Machines, Throttle Valves, Light Plants (3 to 6 machines); Cherry Pickers - under 12½ tons; Ditch Witch - J30 and under; Farm type Tractor (Loader under 1 yd.) with Backhoe; Go-Devil; Mixers, 14 cu. ft. or over; Rollers over 10 tons; Air Compressor and one Tugger; Boilers, 2 or more; Winch Trucks; Front End Scoopmobile, Loader, PayLoader; Blade Grader, towed; Elevators, Building; Fork Lifts; Hoist, single drum or 1 line hoisting (1 tugger); Mixers less than 15 cu. ft.; Rollers; Screening Plants; Crushing Plants; Tractors-Wheel type except when hauling material; All other equipment of similar nature coming within the Light Equipment Classification when power operated

GROUP 3 - Oiler-Fireman-Greaser

STATE: Texas COUNTY: Wichita
DECISION NO.: TX78-4088 DATE: Date of Publication
Supersedeas Decision No. TX78-4044, dated April 14, 1978, in 43 FR 16136.
DESCRIPTION OF WORK: Building Construction (does not include single family homes & garden type apartments up to & including 4 Stories) (See current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$10.43	.40	.76		.03
BOILERMAKERS	10.55	.80	1.00		.02
BRICKLAYERS & STONEMASONS	9.94		.60		.05
CARPENTERS:					
Carpenters	9.87	.48	.50		.07
Millwrights	10.37	.48	.50		.07
CEMENT MASONS	9.12				
ELECTRICIANS:					
ZONE 1 - Work performed within a road mile radius from the Local Union 681 business office up to 30 miles:					
Electricians	10.50	.40	3%		1/10%
Cable splicers	10.75	.40	3%		1/10%
ZONE 2 - All work performed beyond Zone 1:					
Electricians	10.85	.40	3%		1/10%
Cable splicers	11.10	.40	3%		1/10%
ELEVATOR CONSTRUCTORS:					
Mechanics	9.91	.745	.35	4%+a+b	.02
Helpers	70%JR	.745	.35	4%+a+b	.02
Helpers (Probationary)	50%JR				
GLAZIERS	4.97				
IRONWORKERS:					
Structural; Ornamental; Reinforcing	9.13	.55	1.00		.10
Ironworkers on jobs 30 miles or more from the city of Wichita Falls	9.255	.55	1.00		.10
LABORERS:					
GROUP 1 - General Laborers	5.145	.275	.27		
GROUP 2 - Pipelayer (concrete & clay); Power buggy operator; Gunite mixer; Cement work mixer; Power tool operator; Bell hole man(piers)	5.27	.275	.27		
GROUP 3 - Mason tender; Mason mortar mixer; Plasterer tender Hod carrier; Plasterer mortar mixer; Gunite over 1½" thick; Nozzleman & machine operator	5.395	.275	.27		
GROUP 4 - Powerman, blaster	5.645	.275	.27		

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
LATHERS	$ 7.65				.01
LINE CONSTRUCTION:					
Lineman; Lineman operator	10.50		3%		1/2%
Cable splicer	10.75		3%		1/2%
Groundman, 1st 6 months	50%JR		3%		1/2%
Groundman, 2nd 6 months	60%JR		3%		1/2%
Groundman, 1 year & over	70%JR		3%		1/2%
MARBLE SETTERS	8.61				
PAINTERS:					
Brush	7.50				
Spray	8.50				
PLASTERERS	10.50				.01
PLUMBERS & PIPEFITTERS:					
ZONE 1 - Within 25 miles of Wichita Falls City limits	9.55	.35	.55		.02
ZONE 2 - Between 25 & 40 miles of Wichita Falls City limits	10.05	.35	.55		.02
ZONE 3 - Between 40 & 70 miles of Wichita Falls City limits	10.35	.35	.55		.02
ZONE 4 - Between 70 & 100 miles of Wichita Falls City limits	10.65	.35	.55		.02
ZONE 5 - Over 100 miles of Wichita Falls City limits	10.95	.35	.55		.02
ROOFERS	5.42				
SHEET METAL WORKERS	10.58				.07
SOFT FLOOR LAYERS	5.50				
TERRAZZO WORKERS	7.50				
TILE SETTERS	6.50				
TRUCK DRIVERS	2.65				
WELDERS - receive rate perscribed for craft performing operation to which welding is incidental.					

FOOTNOTES FOR ELEVATOR CONSTRUCTORS:
a - 1st 6 months - none; 6 months to 5 years - 2%; over 5 years - 4% of basic hourly rate
b - Paid Holidays A thru G

PAID HOLIDAYS FOR ELEVATOR CONSTRUCTORS
A-New Years' Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-the Friday after Thanksgiving Day; G-Christmas Day

DECISION NO. TX78-4088

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS					
GROUP 1	$ 7.20	.30	.50		.10
GROUP 2	8.10	.30	.50		.10
GROUP 3	8.50	.30	.50		.10

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

GROUP 1 - Oiler-Fireman

GROUP 2 - Air Compressors, Pumps, Welding Machines, Throttle Valves, Light Plants (3 to 6 machines); Conveyor; Wagon Drill; Elevators Building; Form Graders; Hoist, Single Drum; Ford Tractor including blade and mower on rear; Mixers less than 14 cubic feet; Screening Plants; Crushing Plants; Fork Lifts (short, under 25 feet); Concrete Pumps (all types); Bobcat type equipment; Ford tractor or like with any attachments (except blade and mower on rear); All other equipment of similar nature coming under the Light Equipment Class, when power operated

GROUP 3 - Backhoe; Drilling Machines (all types); Scoopmobiles; Hoists, two drums or more; Fork Lifts (over 25 feet); Winch Truck; Six Wheel Truck, when used continuously for 5 days; Mixermobile; Locomotives; Mixers, 14 cubic feet or over; Blade Graders, self-propelled; Cableways; Cranes-power operated (to 100 feet of boom); Derricks, power operated (all types); Gradall; Hy-Ho; Hop-To; Paving Mixer (all types); Pile Drivers; Mobile Concrete Mixers over 14 cu. ft.; Bulldozers, Loaders, Tractovators; Scrapers and Pulls; Welders; Trenching Machines; Roller, ten tons or over; Air Compressors, Pumps, Welding Machines and Light Plants (7 to 12 Machines); Air Compressor & Air Tugger; Boilers, two or more fired by one man; Heavy Duty Mechanic; All other equipment of similar nature coming under the Heavy Equipment Class, when power operated

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federal register

FRIDAY, AUGUST 25, 1978
PART IV

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

CIVIL SERVICE COMMISSION

DEPARTMENT OF LABOR

DEPARTMENT OF JUSTICE

■

ADOPTION BY FOUR AGENCIES OF UNIFORM GUIDELINES ON EMPLOYEE SELECTION PROCEDURES (1978)

[6570-06]

Title 29—Labor

CHAPTER XIV—EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

PART 1607—UNIFORM GUIDELINES ON EMPLOYEE SELECTION PROCEDURES (1978)

Title 5—Administrative Personnel

CHAPTER I—CIVIL SERVICE COMMISSION

PART 300—EMPLOYMENT (GENERAL)

Title 28—Judicial Administration

CHAPTER I—DEPARTMENT OF JUSTICE

PART 50—STATEMENTS OF POLICY

Title 41—Public Contracts and Property Management

CHAPTER 60—OFFICE OF FEDERAL CONTRACT COMPLIANCE PROGRAMS, DEPARTMENT OF LABOR

PART 60-3—UNIFORM GUIDELINES ON EMPLOYEE SELECTION PROCEDURES (1978)

Adoption of Employee Selection Procedures

AGENCIES: Equal Employment Opportunity Commission, Civil Service Commission, Department of Justice and Department of Labor.

ACTION: Adoption of uniform guidelines on employee selection procedures as final rules by four agencies.

SUMMARY: This document sets forth the uniform guidelines on employee selection procedures adopted by the Equal Employment Opportunity Commission, Civil Service Commission, Department of Justice, and the Department of Labor. At present two different sets of guidelines exist. The guidelines are intended to establish a uniform Federal position in the area of prohibiting discrimination in employment practices on grounds of race, color, religion, sex, or national origin. Cross reference documents are published at 5 CFR 300.103(c) (Civil Service Commission), 28 CFR 50.14 (Department of Justice), 29 CFR Part 1607 (Equal Employment Opportunity Commission), and 41 CFR Part 60-3 (Department of Labor) elsewhere in this issue.

EFFECTIVE DATE: September 25, 1978.

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SUPPLEMENTARY INFORMATION:

An Overview of the 1978 Uniform Guidelines on Employee Selection Procedures

I. BACKGROUND

One problem that confronted the Congress which adopted the Civil Rights Act of 1964 involved the effect of written preemployment tests on equal employment opportunity. The use of these test scores frequently denied employment to minorities in many cases without evidence that the tests were related to success on the job. Yet employers wished to continue to use such tests as practical tools to assist in the selection of qualified employees. Congress sought to strike a balance which would proscribe discrimination, but otherwise permit the use of tests in the selection of employees. Thus, in title VII, Congress authorized the use of "any professionally developed ability test provided that such test, its administration or action upon the results is not designed, intended or used to discriminate * * *".[1]

At first, some employers contended that, under this section, they could use any test which had been developed by a professional so long as they did not intend to exclude minorities, even if such exclusion was the consequence of the use of the test. In 1966, the Equal Employment Opportunity Commission (EEOC) adopted guidelines to advise employers and other users what the law and good industrial psychology practice required.[2] The Department of Labor adopted the same approach in 1968 with respect to tests used by Federal contractors under Executive Order 11246 in a more detailed regulation. The Government's view was that the employer's intent was irrelevant. If tests or other practices had an adverse impact on protected groups, they were unlawful unless they could be justified. To justify a test which screened out a higher proportion of minorities, the employer would have to show that it fairly measured or predicted performance on the job. Otherwise, it would not be considered to be "professionally developed."

In succeeding years, the EEOC and the Department of Labor provided more extensive guidance which elaborated upon these principles and expanded the guidelines to emphasize all selection procedures. In 1971 in *Griggs* v. *Duke Power Co.*,[3] the Supreme Court announced the principle that employer practices which had an adverse impact on minorities and were not justified by business necessity constituted illegal discrimination under title VII. Congress confirmed this interpretation in the 1972 amendments to title VII. The elaboration of these principles by courts and agencies continued into the mid-1970's,[4] but differences between the EEOC and the other agencies (Justice, Labor, and Civil Service Commission) produced two different sets of guidelines by the end of 1976.

With the advent of the Carter administration in 1977, efforts were intensified to produce a unified government position. The following document represents the result of that effort. This introduction is intended to assist those not familiar with these matters to understand the basic approach of the uniform guidelines. While the guidelines are complex and technical, they are based upon the principles which have been consistently upheld by the courts, the Congress, and the agencies.

The following discussion will cite the sections of the Guidelines which embody these principles.

II. ADVERSE IMPACT

The fundamental principle underlying the guidelines is that employer policies or practices which have an adverse impact on employment opportunities of any race, sex, or ethnic group are illegal under title VII and the Executive order unless justified by business necessity.[5] A selection procedure

[1] Section 703(h), 42 U.S.C. 2000e(2)(h).

[2] See 35 U.S.L.W. 2137 (1966).

[3] 401 U.S. 424 (1971).

[4] See, *e.g.*, *Albermarle Paper Co.* v. *Moody*, 422 U.S. 405 (1975).

[5] *Griggs*, note 3, supra; uniform guidelines on employee selection procedures (1978), section 3A, (hereinafter cited by section number only).

which has no adverse impact generally does not violate title VII or the Executive order.[6] This means that an employer may usually avoid the application of the guidelines by use of procedures which have no adverse impact.[7] If adverse impact exists, it must be justified on grounds of business necessity. Normally, this means by validation which demonstrates the relation between the selection procedure and performance on the job.

The guidelines adopt a "rule of thumb" as a practical means of determining adverse impact for use in enforcement proceedings. This rule is known as the "⅘ths" or "80 percent" rule.[8] It is not a legal definition of discrimination, rather it is a practical device to keep the attention of enforcement agencies on serious discrepancies in hire or promotion rates or other employment decisions. To determine whether a selection procedure violates the "⅘ths rule", an employer compares its hiring rates for different groups.[9] But this rule of thumb cannot be applied automatically. An employer who has conducted an extensive recruiting campaign may have a larger than normal pool of applicants, and the "⅘ths rule" might unfairly expose it to enforcement proceedings.[10] On the other hand, an employer's reputation may have discouraged or "chilled" applicants of particular groups from applying because they believed application would be futile. The application of the "⅘ths" rule in that situation would allow an employer to evade scrutiny because of its own discrimination.[11]

III. IS ADVERSE IMPACT TO BE MEASURED BY THE OVERALL PROCESS?

In recent years some employers have eliminated the overall adverse impact of a selection procedure and employed sufficient numbers of minorities or women to meet this "⅘th's rule of thumb". However, they might continue use of a component which does have an adverse impact. For example, an employer might insist on a minimum passing score on a written test which is not job related and which has an adverse impact on minorities.[12] However, the employer might compensate for this adverse impact by hiring a sufficient proportion of minorities who do meet its standards, so that its overall hiring is on a par with or higher than the applicant flow. Employers have argued that as long as their "bottom line" shows no overall adverse impact, there is no violation at all, regardless of the operation of a particular component of the process.

Employee representatives have argued that rights under equal employment opportunity laws are individual, and the fact that an employer has hired some minorities does not justify discrimination against other minorities. Therefore, they argue that adverse impact is to be determined by examination of each component of the selection procedure, regardless of the "bottom line." This question has not been answered definitively by the courts. There are decisions pointing in both directions.

These guidelines do not address the underlying question of law. They discuss only the exercise of prosecutorial discretion by the Government agencies themselves.[13] The agencies have decided that, generally, their resources to combat discrimination should be used against those respondents whose practices have restricted or excluded the opportunities of minorities and women. If an employer is appropriately including all groups in the workforce, it is not sensible to spend Government time and effort on such a case, when there are so many employers whose practices do have adverse effects which should be challenged. For this reason, the guidelines provide that, in considering whether to take enforcement action, the Government will take into account the general posture of the employer concerning equal employment opportunity, including its affirmative action plan and results achieved under the plan.[14] There are some circumstances where the government may intervene even though the "bottom line" has been satisfied. They include the case where a component of a selection procedure restricts promotional opportunities of minorities or women who were discriminatorily assigned to jobs, and where a component, such as a height requirement, has been declared unlawful in other situations.[15]

What of the individual who is denied the job because of a particular component in a procedure which otherwise meets the "bottom line" standard? The individual retains the right to proceed through the appropriate agencies, and into Federal court.[16]

IV. WHERE ADVERSE IMPACT EXISTS: THE BASIC OPTIONS

Once an employer has established that there is adverse impact, what steps are required by the guidelines? As previously noted, the employer can modify or eliminate the procedure which produces the adverse impact, thus taking the selection procedure from the coverage of these guidelines. If the employer does not do that, then it must justify the use of the procedure on grounds of "business necessity."[17] This normally means that it must show a clear relation between performance on the selection procedure and performance on the job. In the language of industrial psychology, the employer must validate the selection procedure. Thus the bulk of the guidelines consist of the Government's interpretation of standards for validation.

V. VALIDATION: CONSIDERATION OF ALTERNATIVES

The concept of validation as used in personnel psychology involves the establishment of the relationship between a test instrument or other selection procedure and performance on the job. Federal equal employment opportunity law has added a requirement to the process of validation. In conducting a validation study, the employer should consider available alternatives which will achieve its legitimate business purpose with lesser adverse impact.[18] The employer cannot concentrate solely on establishing the validity of the instrument or procedure which it has been using in the past.

This same principle of using the alternative with lesser adverse impact is applicable to the manner in which an employer uses a valid selection procedure.[19] The guidelines assume that there are at least three ways in which an employer can use scores on a selection procedure: (1) To screen out of consideration those who are not likely to be able to perform the job successfully; (2) to group applicants in accordance with the likelihood of their successful performance on the job, and (3) to rank applicants, selecting those with the highest scores for employment.[20]

The setting of a "cutoff score" to determine who will be screened out may have an adverse impact. If so, an employer is required to justify the initial cutoff score by reference to its need for a trustworthy and efficient work force.[21] Similarly, use of results for

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[6] *Furnco* v. *Waters*, 98 S.Ct. 2943 (1978).

[7] Section 6.

[8] Section 4D.

[9] Section 16R (definition of selection rate).

[10] Section 4D (special recruiting programs).

[11] *Ibid* (user's actions have discouraged applicants).

[12] See, *e.g.*, *Griggs* v. *Duke Power Co.*, 401 U.S. 424 (1971).

[13] Section 4C.

[14] Section 4E.

[15] Section 4C.

[16] The processing of individual cases is excluded from the operation of the bottom line concept by the definition of "enforcement action," section 16I. Under section 4C, where adverse impact has existed, the employer must keep records of the effect of each component for 2 years after the adverse effect has dissipated.

[17] A few practices may be used without validation even if they have adverse impact. See, *e.g.*, *McDonnell Douglas* v. *Green*, 411 U.S. 792 (1973) and section 6B.

[18] *Albermarle Paper Co.* v. *Moody*, 422 U.S. 405 (1975); *Robinson* v. *Lorillard Corp.*, 444 F. 2d 791 (4th Cir. 1971).

[19] Sections 3B; 5G.

[20] *Ibid.*

[21] See sections 3B; 5H. See also sections 14B(6) (criterion-related validity); 14C(9) (content validity); 14D(1) (construct validity).

grouping or for rank ordering is likely to have a greater adverse effect than use of scores solely to screen out unqualified candidates. If the employer chooses to use a rank order method, the evidence of validity must be sufficient to justify that method of use.[22]

VI. TESTING FOR HIGHER LEVEL JOBS

Normally, employers test for the job for which people are hired. However, there are situations where the first job is temporary or transient, and the workers who remain are promoted to work which involves more complex activities. The guidelines restrict testing for higher level jobs to users who promote a majority of the employees who remain with them to the higher level job within a reasonable period of time.[23]

VII. HOW IS VALIDATION TO BE CONDUCTED

Validation has become highly technical and complex, and yet is constantly changing as a set of concepts in industrial psychology. What follows here is a simple introduction to a highly complex field. There are three concepts which can be used to validate a selection procedure. These concepts reflect different approaches to investigating the job relatedness of selection procedures and may be interrelated in practice. They are (1) criterion-related validity,[24] (2) content validity,[25] and (3) construct validity.[26] In criterion-related validity, a selection procedure is justified by a statistical relationship between scores on the test or other selection procedure and measures of job performance. In content validity, a selection procedure is justified by showing that it representatively samples significant parts of the job, such as a typing test for a typist. Construct validity involves identifying the psychological trait (the construct) which underlies successful performance on the job and then devising a selection procedure to measure the presence and degree of the construct. An example would be a test of "leadership ability."

The guidelines contain technical standards and documentation requirements for the application of each of the three approaches.[27] One of the problems which the guidelines attempt to meet is the "borderline" between "content validity" and "construct validity." The extreme cases are easy to understand. A secretary, for example, may have to type. Many jobs require the separation of important matters which must be handled immediately from those which can be handled routinely. For the typing function, a typing test is appropriate. It is justifiable on the basis of content validity because it is a sample of an important or critical part of the job. The second function can be viewed as involving a capability to exercise selective judgment in light of the surrounding circumstances, a mental process which is difficult to sample.

In addressing this situation, the guidelines attempt to make it practical to validate the typing test by a content strategy,[28] but do not allow the validation of a test measuring a construct such as "judgment" by a content validity strategy.

The bulk of the guidelines deals with questions such as those discussed in the above paragraphs. Not all such questions can be answered simply, nor can all problems be addressed in the single document. Once the guidelines are issued, they will have to be interpreted in light of changing factual, legal, and professional circumstances.

VIII. SIMPLIFICATION OF REPORTING AND RECORDKEEPING REQUIREMENTS

The reporting and recordkeeping provisions which appeared in the December 30 draft which was published for comment have been carefully reviewed in light of comments received and President Carter's direction to limit paperwork burdens on those regulated by Government to the minimum necessary for effective regulation. As a result of this review, two major changes have been made in the documentation requirements of the guidelines:

(1) A new section 15A(1) provides a simplified recordkeeping option for employers with fewer than 100 employees;

(2) Determinations of the adverse impact of selection procedures need not be made for groups which constitute less than 2 percent of the relevant labor force.

Also, the draft has been changed to make clear that users can assess adverse impact on an annual basis rather than on a continuing basis.

Analysis of comments. The uniform guidelines published today are based upon the proposition that the Federal Government should speak to the public and to those whom it regulates with one voice on this important subject; and that the Federal Government ought to impose upon itself obligations for equal employment opportunity which are at least as demanding as those it seeks to impose on others. These guidelines state a uniform Federal position on this subject, and are intended to protect the rights created by title VII of the Civil Rights Act of 1964, as amended, Executive Order 11246, as amended, and other provisions of Federal law. The uniform guidelines are also intended to represent "professionally acceptable methods" of the psychological profession for demonstrating whether a selection procedure validly predicts or measures performance for a particular job. *Albemarle Paper Co.* v. *Moody*, 442 U.S. 405, 425. They are also intended to be consistent with the decisions of the Supreme Court and authoritative decisions of other appellate courts.

Although the development of these guidelines preceded the issuance by President Jimmy Carter of Executive Order 12044 designed to improve the regulatory process, the spirit of his Executive order was followed in their development. Initial agreement among the Federal agencies was reached early in the fall of 1977, and the months from October 1977 until today have been spent in extensive consultation with civil rights groups whose clientele are protected by these guidelines; employers, labor unions, and State and local governments whose employment practices are affected by these guidelines; State and local government antidiscrimination agencies who share with the Federal Government enforcement responsibility for discriminatory practices; and appropriate members of the general public. For example, an earlier draft of these guidelines was circulated informally for comment on October 28, 1977, pursuant to OMB Circular A-85. Many comments were received from representatives of State and local governments, psychologists, private employers, and civil rights groups. Those comments were taken into account in the draft of these guidelines which was published for comment December 30, 1977, 42 FR 66542.

More than 200 organizations and individuals submitted written comments on the December 30, 1977, draft. These comments were from representatives of private industry, public employers, labor organizations, civil rights groups, the American Psychological Association and components thereof, and many individual employers, psychologists, and personnel specialists. On March 3, 1978, notice was given of a public hearing and meeting to be held on April 10, 1978, 43 FR 9131. After preliminary review of the comments, the agencies identified four issues of particular interest, and invited testimony particularly on those issues, 43 FR 11812 (March 21, 1978). In the same notice the agencies published questions and answers on four

[22] Sections 5G, 14B(6); 14C(9); 14D(1).
[23] Section 5I.
[24] Sections 5B, (General Standards); 14B (Technical Standards); 15B (Documentation); 16F (Definition).
[25] Sections 5B (General Standards); 14C (Technical Standards); 15C (Documentation); 16D (Definition).
[26] Sections 5B (General Standards); 14D (Technical Standards); 15D (Documentation); 16E (Definition).
[27] Technical standards are in section 14; documentation requirements are in section 15.
[28] Section 14C.

issues of concern to the commenters. The questions and answers were designed to clarify the intent of the December 30, 1977, draft, so as to provide a sharper focus for the testimony at the hearing.

At a full day of testimony on April 10, 1978, representatives of private industry, State and local governments, labor organizations, and civil rights groups, as well as psychologists, personnel specialists, and others testified at the public hearing and meeting. The written comments, testimony, and views expressed in subsequent informal consultations have been carefully considered by the four agencies. We set forth below a summary of the comments, and the major issues raised in the comments and testimony, and attempt to explain how we have resolved those issues.

The statement submitted by the American Psychological Association (A.P.A.) stated that "these guidelines represent a major step forward and with careful interpretation can provide a sound basis for concerned professional work." Most of the A.P.A. comments were directed to clarification and interpretation of the present language of the proposal. However, the A.P.A. recommended substantive change in the construct validity section and in the definition of work behavior.

Similarly, the Division of Industrial and Organizational Psychology (division 14) of the A.P.A. described the technical standards of the guidelines as "superior" in terms of congruence with professional standards to "most previous orders and guidelines but numerous troublesome aspects remain." Division 14 had substantial concerns with a number of the provisions of the general principles of the draft.

Civil rights groups generally found the uniform guidelines far superior to the FEA guidelines, and many urged their adoption, with modifications concerning ranking and documentation. Others raised concerns about the "bottom line" concept and other provisions of the guidelines.

The Ad Hoc Group on Employee Selection Procedures representing many employers in private industry supported the concept of uniform guidelines, but had a number of problems with particular provisions, some of which are described below. The American Society for Personnel Administration (ASPA) and the International Personnel Management Association, which represents State and local governments, generally took the same position as the ad hoc group. Major industrial unions found that the draft guidelines were superior to the FEA guidelines, but they perceived them to be inferior to the EEOC guidelines. They challenged particularly the bottom line concept and the construct validity section.

The building trade unions urged an exclusion of apprenticeship programs from coverage of the guidelines. The American Council on Education found them inappropriate for employment decisions concerning faculty at institutions of higher education. Other particular concerns were articulated by organizations representing the handicapped, licensing and certifying agencies, and college placement offices.

General Principles

1. *Relationship between validation and elimination of adverse impact, and affirmative action.* Federal equal employment opportunity law generally does not require evidence of validity for a selection procedure if there is no adverse impact; e.g., *Griggs* v. *Duke Power Co.*, 401 U.S. 424. Therefore, a user has the choice of complying either by providing evidence of validity (or otherwise justifying use in accord with Federal law), or by eliminating the adverse impact. These options have always been present under Federal law, 29 CFR 1607.3; 41 CFR 60-3.3(a); and the Federal Executive Agency Guidelines, 41 FR 51734 (November 23, 1976). The December 30 draft guidelines, however, clarified the nature of the two options open to users.

Psychologists expressed concern that the December 30 draft of section 6A encouraged the use of invalid procedures as long as there is no adverse impact. Employers added the concern that the section might encourage the use of illegal procedures not having an adverse impact against the groups who have historically suffered discrimination (minorities, women), even if they have an adverse impact on a different group (whites, males).

Section 6A was not so intended, and we have revised it to clarify the fact that illegal acts purporting to be affirmative action are not the goal of the agencies or of the guidelines; and that any employee selection procedure must be lawful and should be as job related as possible. The delineation of examples of alternative procedures was eliminated to avoid the implication that particular procedures are either prescribed or are necessarily appropriate. The basic thrust of section 6A, that elimination of adverse impact is an alternative to validation, is retained.

The inclusion of excerpts from the 1976 Equal Employment Opportunity Coordinating Council Policy Statement on Affirmative Action in section 13B of the December 30 draft was criticized as not belonging in a set of guidelines for the validation of selection procedures. Section 13 has been revised. The general statement of policy in support of voluntary affirmative action, and the reaffirmation of the policy statement have been retained, but this statement itself is now found in the appendix to the guidelines.

2. *The "bottom line" (section 4C).* The guidelines provide that when the overall selection process does not have an adverse impact the Government will usually not examine the individual components of that process for adverse impact or evidence of validity. The concept is based upon the view that the Federal Government should not generally concern itself with individual components of a selection process, if the overall effect of that process is nonexclusionary. Many commenters criticized the ambiguity caused by the word "generally" in the December 30 draft of section 4C which provided, "the Federal enforcement agencies * * * generally will not take enforcement action based upon adverse impact of any component" of a process that does not have an overall adverse impact. Employer groups stated the position that the "bottom line" should be a rule prohibiting enforcement action by Federal agencies with respect to all or any part of a selection process where the bottom line does not show adverse impact. Civil rights and some labor union representatives expressed the opposing concerns that the concept may be too restrictive, that it may be interpreted as a matter of law, and that it might allow certain discriminatory conditions to go unremedied.

The guidelines have been revised to clarify the intent that the bottom line concept is based upon administrative and prosecutorial discretion. The Federal agencies cannot accept the recommendation that they never inquire into or take enforcement action with respect to any component procedure unless the whole process of which it is a part has an adverse impact. The Federal enforcement agencies believe that enforcement action may be warranted in unusual circumstances, such as those involving other discriminatory practices, or particular selection procedures which have no validity and have a clear adverse impact on a national basis. Other unusual circumstances may warrant a high level agency decision to proceed with enforcement actions although the "bottom line" has been satisfied. At the same time the agencies adhere to the bottom line concept of allocating resources primarily to those users whose overall selection processes have an adverse impact. See overview, above, part III.

3. *Investigation of alternative selection procedures and alternative methods of use (section 3B).* The December 30 draft included an obligation on the user, when conducting a validity

study, to investigate alternative procedures and uses, in order to determine whether there are other procedures which are substantially equally valid, but which have less adverse impact. The American Psychological Association stated:

"We would concur with the drafters of the guidelines that it is appropriate in the determination of a selection strategy to consider carefully a variety of possible procedures and to think carefully about the question of adverse impact with respect to each of these procedures. Nevertheless, we feel it appropriate to note that a rigid enforcement of these sections, particularly for smaller employers, would impose a substantial and expensive burden on these employers."

Since a reasonable consideration of alternatives is consistent with the underlying principle of minimizing adverse impact consistent with business needs, the provision is retained.

Private employer representatives challenged earlier drafts of these guidelines as being inconsistent with the decision of the Supreme Court in *Albemarle Paper Co.* v. *Moody*, 422 U.S. 405. No such inconsistency was intended. Accordingly, the first sentence of section 3B was revised to paraphrase the opinion in the *Albemarle* decision, so as to make it clear that section 3B is in accord with the principles of the *Albemarle* decision.

Section 3B was further revised to clarify the intent of the guidelines that the obligation to investigate alternative procedures is a part of conducting a validity study, so that alternative procedures should be evaluated in light of validity studies meeting professional standards, and that section 3B does not impose an obligation to search for alternatives if the user is not required to conduct a validity study.

Just as, under section 3B of the guidelines, a user should investigate alternative selection procedures as a part of choosing and validating a procedure, so should the user investigate alternative uses of the selection device chosen to find the use most appropriate to his needs. The validity study should address the question of what method of use (screening, grouping, or rank ordering) is appropriate for a procedure based on the kind and strength of the validity evidence shown, and the degree of adverse impact of the different uses.

4. *Establishment of cutoff scores and rank ordering.* Some commenters from civil rights groups believed that the December 30 draft guidelines did not provide sufficient guidance as to when it was permissible to use a selection procedure on a ranking basis rather than on a pass-fail basis. They also objected to section 5G in terms of setting cutoff scores. Other comments noted a lack of clarity as to how the determination of a cutoff score or the use of a procedure for ranking candidates relates to adverse impact.

As we have noted, users are not required to validate procedures which do not have an adverse impact. However, if one way of using a procedure (e.g., for ranking) results in greater adverse impact than another way (e.g., pass/fail), the procedure must be validated for that use. Similarly, cutoff scores which result in adverse impact should be justified. If the use of a validated procedure for ranking results in greater adverse impact than its use as a screening device, the evidence of validity and utility must be sufficient to warrant use of the procedures as a ranking device.

A new section 5G has been added to clarify these concepts. Section 5H (formerly section 5G) addresses the choice of a cutoff score when a procedure is to be used for ranking.

5. *Scope: Requests for exemptions for certain classes of users.* Some employer groups and labor organizations (e.g., academic institutions, large public employers, apprenticeship councils) argued that they should be exempted from all or some of the provisions of these guidelines because of their special needs. The intent of Congress as expressed in Federal equal employment opportunity law is to apply the same standards to all users, public and private.

These guidelines apply the same principles and standards to all employers. On the other hand, the nature of the procedures which will actually meet those principles and standards may be different for different employers, and the guidelines recognize that fact. Accordingly, the guidelines are applicable to all employers and other users who are covered by Federal equal employment opportunity law.

Organizations of handicapped persons objected to excluding from the scope of these guidelines the enforcement of laws prohibiting discrimination on the basis of handicap, in particular the Rehabilitation Act of 1973, sections 501, 503, and 504. While this issue has not been addressed in the guidelines, nothing precludes the adoption of the principles set forth in these guidelines for other appropriate situations.

Licensing and certification boards raised the question of the applicability of the guidelines to their licensing and certification functions. The guidelines make it clear that licensing and certification are covered "to the extent" that licensing and certification may be covered by Federal equal employment opportunity law.

Voluntary certification boards, where certification is not required by law, are not users as defined in section 16 with respect to their certifying functions and therefore are not subject to these guidelines. If an employer relies upon such certification in making employment decisions, the employer is the user and must be prepared to justify, under Federal law, that reliance as it would any other selection procedure.

6. *The "Four-Fifths Rule of Thumb" (section 4D).* Some representatives of employers and some professionals suggest that the basic test for adverse impact should be a test of statistical significance, rather than the four-fifths rule. Some civil rights groups, on the other hand, still regard the four-fifths rule as permitting some unlawful discrimination.

The Federal agencies believe that neither of these positions is correct. The great majority of employers do not hire, promote, or assign enough employees for most jobs to warrant primary reliance upon statistical significance. Many decisions in day-to-day life are made on the basis of information which does not have the justification of a test of statistical significance. Courts have found adverse impact without a showing of statistical significance. *Griggs* v. *Duke Power Co.*, supra; *Vulcan Society of New York* v. *CSC of N.Y.*, 490 F. 2d 387, 393 (2d Cir. 1973); *Kirkland* v. *New York St. Dept. of Corr. Serv.*, 520 F. 2d 420, 425 (2d Cir. 1975).

Accordingly, the undersigned believe that while the four-fifths rule does not define discrimination and does not apply in all cases, it is appropriate as a rule of thumb in identifying adverse impact.

Technical Standards

7. *Criterion-related validity (section 14B).* This section of the guidelines found general support among the commenters from the psychological profession and, except for the provisions concerning test fairness (sometimes mistakenly equated with differential prediction or differential validity), generated relatively little comment.

The provisions of the guidelines concerning criterion-related validity studies call for studies of fairness of selection procedures where technically feasible.

Section 14B(8). Some psychologists and employer groups objected that the concept of test fairness or unfairness has been discredited by professionals and pointed out that the term is commonly misused. We recognize that there is serious debate on the question of test fairness; however, it is accepted professionally that fairness should be examined where feasible. The A.P.A. standards for educational and psychological tests, for example, direct users to explore the question of fairness on finding a difference in group performances (section E9, pp. 43-44). Simi-

larly the concept of test fairness is one which is closely related to the basic thrust of Federal equal employment opportunity law; and that concept was endorsed by the Supreme Court in *Albemarle Paper Co.* v. *Moody*, 422 U.S. 405.

Accordingly, we have retained in the guidelines the obligation upon users to investigate test fairness where it is technically feasible to do so.

8. *Content validity.* The Division of Industrial and Organizational Psychology of A.P.A. correctly perceived that the provisions of the draft guidelines concerning content validity, with their emphasis on observable work behaviors or work products, were "greatly concerned with minimizing the inferential leap between test and performance." That division expressed the view that the draft guidelines neglected situations where a knowledge, skill or ability is necessary to an outcome but where the work behavior cannot be replicated in a test. They recommended that the section be revised.

We believe that the emphasis on observable work behaviors or observable work products is appropriate; and that in order to show content validity, the gap between the test and performance on the job should be a small one. We recognize, however, that content validity may be appropriate to support a test which measures a knowledge, skill, or ability which is a necessary prerequisite to the performance of the job, even though the test might not be close enough to the work behavior to be considered a work sample, and the guidelines have been revised appropriately. On the other hand, tests of mental processes which are not directly observable and which may be difficult to determine on the basis of observable work behaviors or work products should not be supported by content validity.

Thus, the Principles for the Validation and Use of Personnel Selection Procedures (Division of Industrial and Organizational Psychology, American Psychological Association, 1975, p. 10), discuss the use of content validity to support tests of "specific items of knowledge, or specific job skills," but call attention to the inappropriateness of attempting to justify tests for traits or constructs on a content validity basis.

9. *Construct validity (section 14D).* Business groups and professionals expressed concern that the construct validity requirements in the December 30 draft were confusing and technically inaccurate. As section 14D indicates, construct validity is a relatively new procedure in the field of personnel selection and there is not yet substantial guidance in the professional literature as to its use in the area of employment practices. The provisions on construct validity have been revised to meet the concerns expressed by the A.P.A. The construct validity section as revised clarifies what is required by the Federal enforcement agencies at this stage in the development of construct validity. The guidelines leave open the possibility that different evidence of construct validity may be accepted in the future, as new methodologies develop and become incorporated in professional standards and other professional literature.

10. *Documentation (section 15).* Commenters stated that the documentation section did not conform to the technical requirements of the guidelines or was otherwise inadequate. Section 15 has been clarified and two significant changes have been made to minimize the recordkeeping burden. (See overview, part VIII.)

11. *Definitions (section 16).* The definition of work behavior in the December 30, 1977 draft was criticized by the A.P.A. and others as being too vague to provide adequate guidance to those using the guidelines who must identify work behavior as a part of any validation technique. Other comments criticized the absence or inadequacies of other definitions, expecially "adverse impact." Substantial revisions of and additions to this section were therefore made.

Uniform Guidelines on Employee Selection Procedures (1978)

NOTE.—These guidelines are issued jointly by four agencies. Separate official adoptions follow the guidelines in this part IV as follows: Civil Service Commission, Department of Justice, Equal Employment Opportunity Commission, Department of Labor.

For official citation see section 18 of these guidelines.

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General Principles

SECTION 1. *Statement of purpose.*—A. *Need for uniformity—Issuing agencies.* The Federal government's need for a uniform set of principles on the question of the use of tests and other selection procedures has long been recognized. The Equal Employment Opportunity Commission, the Civil Service Commission, the Department of Labor, and the Department of Justice jointly have adopted these uniform guidelines to meet that need, and to apply the same principles to the Federal Government as are applied to other employers.

B. *Purpose of guidelines.* These guidelines incorporate a single set of principles which are designed to assist employers, labor organizations, employment agencies, and licensing and certification boards to comply with requirements of Federal law prohibiting employment practices which discriminate on grounds of race, color, religion, sex, and national origin. They are designed to provide a framework for determining the proper use of tests and other selection procedures. These guidelines do not require a user to conduct validity studies of selection procedures where no adverse impact results. However, all users are encouraged to use selection procedures which are valid, especially users operating under merit principles.

C. *Relation to prior guidelines.* These guidelines are based upon and supersede previously issued guidelines on employee selection procedures. These guidelines have been built upon court decisions, the previously issued guidelines of the agencies, and the practical experience of the agencies, as well as the standards of the psychological profession. These guidelines are intended to be consistent with existing law.

SEC. 2. *Scope.*—A. *Application of guidelines.* These guidelines will be applied by the Equal Employment Opportunity Commission in the enforcement of title VII of the Civil Rights Act of 1964, as amended by the Equal Employment Opportunity Act of 1972 (hereinafter "Title VII"); by the Department of Labor, and the contract compliance agencies until the transfer of authority contemplated by the President's Reorganization Plan No. 1 of 1978, in the administration and enforcement of Executive Order 11246, as amended by Executive Order 11375 (hereinafter "Executive Order 11246"); by the Civil Service Commission and other Federal agencies subject to section 717 of Title VII; by the Civil Service Commission in exercising its responsibilities toward State and local governments under section 208(b)(1) of the Intergovernmental-Personnel Act; by the Department of Justice in exercising its responsibilities under Federal law; by the Office of Revenue Sharing of the Department of the Treasury under the State and Local Fiscal Assistance Act of 1972, as amended; and by any other Federal agency which adopts them.

B. *Employment decisions.* These guidelines apply to tests and other selection procedures which are used as a basis for any employment decision. Employment decisions include but are not limited to hiring, promotion, demotion, membership (for example, in a labor organization), referral, retention, and licensing and certification, to the extent that licensing and certification may be covered by Federal equal employment opportunity law. Other selection decisions, such as selection for training or transfer, may also be considered employment decisions if they lead to any of the decisions listed above.

C. *Selection procedures.* These guidelines apply only to selection procedures which are used as a basis for making employment decisions. For example, the use of recruiting procedures designed to attract members of a particular race, sex, or ethnic group, which were previously denied employment opportunities or which are currently underutilized, may be necessary to bring an employer into compliance with Federal law, and is frequently an essential element of any effective af-

firmative action program; but recruitment practices are not considered by these guidelines to be selection procedures. Similarly, these guidelines do not pertain to the question of the lawfulness of a seniority system within the meaning of section 703(h), Executive Order 11246 or other provisions of Federal law or regulation, except to the extent that such systems utilize selection procedures to determine qualifications or abilities to perform the job. Nothing in these guidelines is intended or should be interpreted as discouraging the use of a selection procedure for the purpose of determining qualifications or for the purpose of selection on the basis of relative qualifications, if the selection procedure had been validated in accord with these guidelines for each such purpose for which it is to be used.

D. *Limitations.* These guidelines apply only to persons subject to Title VII, Executive Order 11246, or other equal employment opportunity requirements of Federal law. These guidelines do not apply to responsibilities under the Age Discrimination in Employment Act of 1967, as amended, not to discriminate on the basis of age, or under sections 501, 503, and 504 of the Rehabilitation Act of 1973, not to discriminate on the basis of handicap.

E. *Indian preference not affected.* These guidelines do not restrict any obligation imposed or right granted by Federal law to users to extend a preference in employment to Indians living on or near an Indian reservation in connection with employment opportunities on or near an Indian reservation.

SEC. 3. *Discrimination defined: Relationship between use of selection procedures and discrimination.*—A. *Procedure having adverse impact constitutes discrimination unless justified.* The use of any selection procedure which has an adverse impact on the hiring, promotion, or other employment or membership opportunities of members of any race, sex, or ethnic group will be considered to be discriminatory and inconsistent with these guidelines, unless the procedure has been validated in accordance with these guidelines, or the provisions of section 6 below are satisfied.

B. *Consideration of suitable alternative selection procedures.* Where two or more selection procedures are available which serve the user's legitimate interest in efficient and trustworthy workmanship, and which are substantially equally valid for a given purpose, the user should use the procedure which has been demonstrated to have the lesser adverse impact. Accordingly, whenever a validity study is called for by these guidelines, the user should include, as a part of the validity study, an investigation of suitable alternative selection procedures and suitable alternative methods of using the selection procedure which have as little adverse impact as possible, to determine the appropriateness of using or validating them in accord with these guidelines. If a user has made a reasonable effort to become aware of such alternative procedures and validity has been demonstrated in accord with these guidelines, the use of the test or other selection procedure may continue until such time as it should reasonably be reviewed for currency. Whenever the user is shown an alternative selection procedure with evidence of less adverse impact and substantial evidence of validity for the same job in similar circumstances, the user should investigate it to determine the appropriateness of using or validating it in accord with these guidelines. This subsection is not intended to preclude the combination of procedures into a significantly more valid procedure, if the use of such a combination has been shown to be in compliance with the guidelines.

SEC. 4. *Information on impact.*—A. *Records concerning impact.* Each user should maintain and have available for inspection records or other information which will disclose the impact which its tests and other selection procedures have upon employment opportunities of persons by identifiable race, sex, or ethnic group as set forth in subparagraph B below in order to determine compliance with these guidelines. Where there are large numbers of applicants and procedures are administered frequently, such information may be retained on a sample basis, provided that the sample is appropriate in terms of the applicant population and adequate in size.

B. *Applicable race, sex, and ethnic groups for recordkeeping.* The records called for by this section are to be maintained by sex, and the following races and ethnic groups: Blacks (Negroes), American Indians (including Alaskan Natives), Asians (including Pacific Islanders), Hispanic (including persons of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish origin or culture regardless of race), whites (Caucasians) other than Hispanic, and totals. The race, sex, and ethnic classifications called for by this section are consistent with the Equal Employment Opportunity Standard Form 100, Employer Information Report EEO-1 series of reports. The user should adopt safeguards to insure that the records required by this paragraph are used for appropriate purposes such as determining adverse impact, or (where required) for developing and monitoring affirmative action programs, and that such records are not used improperly. See sections 4E and 17(4), below.

C. *Evaluation of selection rates. The "bottom line."* If the information called for by sections 4A and B above shows that the total selection process for a job has an adverse impact, the individual components of the selection process should be evaluated for adverse impact. If this information shows that the total selection process does not have an adverse impact, the Federal enforcement agencies, in the exercise of their administrative and prosecutorial discretion, in usual circumstances, will not expect a user to evaluate the individual components for adverse impact, or to validate such individual components, and will not take enforcement action based upon adverse impact of any component of that process, including the separate parts of a multipart selection procedure or any separate procedure that is used as an alternative method of selection. However, in the following circumstances the Federal enforcement agencies will expect a user to evaluate the individual components for adverse impact and may, where appropriate, take enforcement action with respect to the individual components: (1) where the selection procedure is a significant factor in the continuation of patterns of assignments of incumbent employees caused by prior discriminatory employment practices, (2) where the weight of court decisions or administrative interpretations hold that a specific procedure (such as height or weight requirements or no-arrest records) is not job related in the same or similar circumstances. In unusual circumstances, other than those listed in (1) and (2) above, the Federal enforcement agencies may request a user to evaluate the individual components for adverse impact and may, where appropriate, take enforcement action with respect to the individual component.

D. *Adverse impact and the "four-fifths rule."* A selection rate for any race, sex, or ethnic group which is less than four-fifths (4/5) (or eighty percent) of the rate for the group with the highest rate will generally be regarded by the Federal enforcement agencies as evidence of adverse impact, while a greater than four-fifths rate will generally not be regarded by Federal enforcement agencies as evidence of adverse impact. Smaller differences in selection rate may nevertheless constitute adverse impact, where they are significant in both statistical and practical terms or where a user's actions have discouraged applicants disproportionately on grounds of race, sex, or ethnic group. Greater differences in selection rate may not constitute adverse impact where the differences are based on small numbers and are not statistically significant, or where special recruiting or other programs cause

the pool of minority or female candidates to be atypical of the normal pool of applicants from that group. Where the user's evidence concerning the impact of a selection procedure indicates adverse impact but is based upon numbers which are too small to be reliable, evidence concerning the impact of the procedure over a longer period of time and/or evidence concerning the impact which the selection procedure had when used in the same manner in similar circumstances elsewhere may be considered in determining adverse impact. Where the user has not maintained data on adverse impact as required by the documentation section of applicable guidelines, the Federal enforcement agencies may draw an inference of adverse impact of the selection process from the failure of the user to maintain such data, if the user has an underutilization of a group in the job category, as compared to the group's representation in the relevant labor market or, in the case of jobs filled from within, the applicable work force.

E. *Consideration of user's equal employment opportunity posture.* In carrying out their obligations, the Federal enforcement agencies will consider the general posture of the user with respect to equal employment opportunity for the job or group of jobs in question. Where a user has adopted an affirmative action program, the Federal enforcement agencies will consider the provisions of that program, including the goals and timetables which the user has adopted and the progress which the user has made in carrying out that program and in meeting the goals and timetables. While such affirmative action programs may in design and execution be race, color, sex, or ethnic conscious, selection procedures under such programs should be based upon the ability or relative ability to do the work.

SEC. 5. *General standards for validity studies.*—A. *Acceptable types of validity studies.* For the purposes of satisfying these guidelines, users may rely upon criterion-related validity studies, content validity studies or construct validity studies, in accordance with the standards set forth in the technical standards of these guidelines, section 14 below. New strategies for showing the validity of selection procedures will be evaluated as they become accepted by the psychological profession.

B. *Criterion-related, content, and construct validity.* Evidence of the validity of a test or other selection procedure by a criterion-related validity study should consist of empirical data demonstrating that the selection procedure is predictive of or significantly correlated with important elements of job performance. See section 14B below. Evidence of the validity of a test or other selection procedure by a content validity study should consist of data showing that the content of the selection procedure is representative of important aspects of performance on the job for which the candidates are to be evaluated. See section 14C below. Evidence of the validity of a test or other selection procedure through a construct validity study should consist of data showing that the procedure measures the degree to which candidates have identifiable characteristics which have been determined to be important in successful performance in the job for which the candidates are to be evaluated. See section 14D below.

C. *Guidelines are consistent with professional standards.* The provisions of these guidelines relating to validation of selection procedures are intended to be consistent with generally accepted professional standards for evaluating standardized tests and other selection procedures, such as those described in the Standards for Educational and Psychological Tests prepared by a joint committee of the American Psychological Association, the American Educational Research Association, and the National Council on Measurement in Education (American Psychological Association, Washington, D.C., 1974) (hereinafter "A.P.A. Standards") and standard textbooks and journals in the field of personnel selection.

D. *Need for documentation of validity.* For any selection procedure which is part of a selection process which has an adverse impact and which selection procedure has an adverse impact, each user should maintain and have available such documentation as is described in section 15 below.

E. *Accuracy and standardization.* Validity studies should be carried out under conditions which assure insofar as possible the adequacy and accuracy of the research and the report. Selection procedures should be administered and scored under standardized conditions.

F. *Caution against selection on basis of knowledges, skills, or ability learned in brief orientation period.* In general, users should avoid making employment decisions on the basis of measures of knowledges, skills, or abilities which are normally learned in a brief orientation period, and which have an adverse impact.

G. *Method of use of selection procedures.* The evidence of both the validity and utility of a selection procedure should support the method the user chooses for operational use of the procedure, if that method of use has a greater adverse impact than another method of use. Evidence which may be sufficient to support the use of a selection procedure on a pass/fail (screening) basis may be insufficient to support the use of the same procedure on a ranking basis under these guidelines. Thus, if a user decides to use a selection procedure on a ranking basis, and that method of use has a greater adverse impact than use on an appropriate pass/fail basis (see section 5H below), the user should have sufficient evidence of validity and utility to support the use on a ranking basis. See sections 3B, 14B (5) and (6), and 14C (8) and (9).

H. *Cutoff scores.* Where cutoff scores are used, they should normally be set so as to be reasonable and consistent with normal expectations of acceptable proficiency within the work force. Where applicants are ranked on the basis of properly validated selection procedures and those applicants scoring below a higher cutoff score than appropriate in light of such expectations have little or no chance of being selected for employment, the higher cutoff score may be appropriate, but the degree of adverse impact should be considered.

I. *Use of selection procedures for higher level jobs.* If job progression structures are so established that employees will probably, within a reasonable period of time and in a majority of cases, progress to a higher level, it may be considered that the applicants are being evaluated for a job or jobs at the higher level. However, where job progression is not so nearly automatic, or the time span is such that higher level jobs or employees' potential may be expected to change in significant ways, it should be considered that applicants are being evaluated for a job at or near the entry level. A "reasonable period of time" will vary for different jobs and employment situations but will seldom be more than 5 years. Use of selection procedures to evaluate applicants for a higher level job would not be appropriate:

(1) If the majority of those remaining employed do not progress to the higher level job;

(2) If there is a reason to doubt that the higher level job will continue to require essentially similar skills during the progression period; or

(3) If the selection procedures measure knowledges, skills, or abilities required for advancement which would be expected to develop principally from the training or experience on the job.

J. *Interim use of selection procedures.* Users may continue the use of a selection procedure which is not at the moment fully supported by the required evidence of validity, provided: (1) The user has available substantial evidence of validity, and (2) the user has in progress, when technically feasible, a study which is designed to pro-

duce the additional evidence required by these guidelines within a reasonable time. If such a study is not technically feasible, see section 6B. If the study does not demonstrate validity, this provision of these guidelines for interim use shall not constitute a defense in any action, nor shall it relieve the user of any obligations arising under Federal law.

K. *Review of validity studies for currency.* Whenever validity has been shown in accord with these guidelines for the use of a particular selection procedure for a job or group of jobs, additional studies need not be performed until such time as the validity study is subject to review as provided in section 3B above. There are no absolutes in the area of determining the currency of a validity study. All circumstances concerning the study, including the validation strategy used, and changes in the relevant labor market and the job should be considered in the determination of when a validity study is outdated.

SEC. 6. *Use of selection procedures which have not been validated.*—A. *Use of alternate selection procedures to eliminate adverse impact.* A user may choose to utilize alternative selection procedures in order to eliminate adverse impact or as part of an affirmative action program. See section 13 below. Such alternative procedures should eliminate the adverse impact in the total selection process, should be lawful and should be as job related as possible.

B. *Where validity studies cannot or need not be performed.* There are circumstances in which a user cannot or need not utilize the validation techniques contemplated by these guidelines. In such circumstances, the user should utilize selection procedures which are as job related as possible and which will minimize or eliminate adverse impact, as set forth below.

(1) *Where informal or unscored procedures are used.* When an informal or unscored selection procedure which has an adverse impact is utilized, the user should eliminate the adverse impact, or modify the procedure to one which is a formal, scored or quantified measure or combination of measures and then validate the procedure in accord with these guidelines, or otherwise justify continued use of the procedure in accord with Federal law.

(2) *Where formal and scored procedures are used.* When a formal and scored selection procedure is used which has an adverse impact, the validation techniques contemplated by these guidelines usually should be followed if technically feasible. Where the user cannot or need not follow the validation techniques anticipated by these guidelines, the user should either modify the procedure to eliminate adverse impact or otherwise justify continued use of the procedure in accord with Federal law.

SEC. 7. *Use of other validity studies.*—A. *Validity studies not conducted by the user.* Users may, under certain circumstances, support the use of selection procedures by validity studies conducted by other users or conducted by test publishers or distributors and described in test manuals. While publishers of selection procedures have a professional obligation to provide evidence of validity which meets generally accepted professional standards (see section 5C above), users are cautioned that they are responsible for compliance with these guidelines. Accordingly, users seeking to obtain selection procedures from publishers and distributors should be careful to determine that, in the event the user becomes subject to the validity requirements of these guidelines, the necessary information to support validity has been determined and will be made available to the user.

B. *Use of criterion-related validity evidence from other sources.* Criterion-related validity studies conducted by one test user, or described in test manuals and the professional literature, will be considered acceptable for use by another user when the following requirements are met:

(1) *Validity evidence.* Evidence from the available studies meeting the standards of section 14B below clearly demonstrates that the selection procedure is valid;

(2) *Job similarity.* The incumbents in the user's job and the incumbents in the job or group of jobs on which the validity study was conducted perform substantially the same major work behaviors, as shown by appropriate job analyses both on the job or group of jobs on which the validity study was performed and on the job for which the selection procedure is to be used; and

(3) *Fairness evidence.* The studies include a study of test fairness for each race, sex, and ethnic group which constitutes a significant factor in the borrowing user's relevant labor market for the job or jobs in question. If the studies under consideration satisfy (1) and (2) above but do not contain an investigation of test fairness, and it is not technically feasible for the borrowing user to conduct an internal study of test fairness, the borrowing user may utilize the study until studies conducted elsewhere meeting the requirements of these guidelines show test unfairness, or until such time as it becomes technically feasible to conduct an internal study of test fairness and the results of that study can be acted upon. Users obtaining selection procedures from publishers should consider, as one factor in the decision to purchase a particular selection procedure, the availability of evidence concerning test fairness.

C. *Validity evidence from multiunit study.* If validity evidence from a study covering more than one unit within an organization statisfies the requirements of section 14B below, evidence of validity specific to each unit will not be required unless there are variables which are likely to affect validity significantly.

D. *Other significant variables.* If there are variables in the other studies which are likely to affect validity significantly, the user may not rely upon such studies, but will be expected either to conduct an internal validity study or to comply with section 6 above.

SEC. 8. *Cooperative studies.*—A. *Encouragement of cooperative studies.* The agencies issuing these guidelines encourage employers, labor organizations, and employment agencies to cooperate in research, development, search for lawful alternatives, and validity studies in order to achieve procedures which are consistent with these guidelines.

B. *Standards for use of cooperative studies.* If validity evidence from a cooperative study satisfies the requirements of section 14 below, evidence of validity specific to each user will not be required unless there are variables in the user's situation which are likely to affect validity significantly.

SEC. 9. *No assumption of validity.*—A. *Unacceptable substitutes for evidence of validity.* Under no circumstances will the general reputation of a test or other selection procedures, its author or its publisher, or casual reports of it's validity be accepted in lieu of evidence of validity. Specifically ruled out are: assumptions of validity based on a procedure's name or descriptive labels; all forms of promotional literature; data bearing on the frequency of a procedure's usage; testimonial statements and credentials of sellers, users, or consultants; and other nonempirical or anecdotal accounts of selection practices or selection outcomes.

B. *Encouragement of professional supervision.* Professional supervision of selection activities is encouraged but is not a substitute for documented evidence of validity. The enforcement agencies will take into account the fact that a thorough job analysis was conducted and that careful development and use of a selection procedure in accordance with professional standards enhance the probability that the selection procedure is valid for the job.

SEC. 10. *Employment agencies and employment services.*—A. *Where selection procedures are devised by agency.* An employment agency, including pri-

vate employment agencies and State employment agencies, which agrees to a request by an employer or labor organization to device and utilize a selection procedure should follow the standards in these guidelines for determining adverse impact. If adverse impact exists the agency should comply with these guidelines. An employment agency is not relieved of its obligation herein because the user did not request such validation or has requested the use of some lesser standard of validation than is provided in these guidelines. The use of an employment agency does not relieve an employer or labor organization or other user of its responsibilities under Federal law to provide equal employment opportunity or its obligations as a user under these guidelines.

B. *Where selection procedures are devised elsewhere.* Where an employment agency or service is requested to administer a selection procedure which has been devised elsewhere and to make referrals pursuant to the results, the employment agency or service should maintain and have available evidence of the impact of the selection and referral procedures which it administers. If adverse impact results the agency or service should comply with these guidelines. If the agency or service seeks to comply with these guidelines by reliance upon validity studies or other data in the possession of the employer, it should obtain and have available such information.

SEC. 11. *Disparate treatment.* The principles of disparate or unequal treatment must be distinguished from the concepts of validation. A selection procedure—even though validated against job performance in accordance with these guidelines—cannot be imposed upon members of a race, sex, or ethnic group where other employees, applicants, or members have not been subjected to that standard. Disparate treatment occurs where members of a race, sex, or ethnic group have been denied the same employment, promotion, membership, or other employment opportunities as have been available to other employees or applicants. Those employees or applicants who have been denied equal treatment, because of prior discriminatory practices or policies, must at least be afforded the same opportunities as had existed for other employees or applicants during the period of discrimination. Thus, the persons who were in the class of persons discriminated against during the period the user followed the discriminatory practices should be allowed the opportunity to qualify under less stringent selection procedures previously followed, unless the user demonstrates that the increased standards are required by business necessity. This section does not prohibit a user who has not previously followed merit standards from adopting merit standards which are in compliance with these guidelines; nor does it preclude a user who has previously used invalid or unvalidated selection procedures from developing and using procedures which are in accord with these guidelines.

SEC. 12. *Retesting of applicants.* Users should provide a reasonable opportunity for retesting and reconsideration. Where examinations are administered periodically with public notice, such reasonable opportunity exists, unless persons who have previously been tested are precluded from retesting. The user may however take reasonable steps to preserve the security of its procedures.

SEC. 13. *Affirmative action.*—A. *Affirmative action obligations.* The use of selection procedures which have been validated pursuant to these guidelines does not relieve users of any obligations they may have to undertake affirmative action to assure equal employment opportunity. Nothing in these guidelines is intended to preclude the use of lawful selection procedures which assist in remedying the effects of prior discriminatory practices, or the achievement of affirmative action objectives.

B. *Encouragement of voluntary affirmative action programs.* These guidelines are also intended to encourage the adoption and implementation of voluntary affirmative action programs by users who have no obligation under Federal law to adopt them; but are not intended to impose any new obligations in that regard. The agencies issuing and endorsing these guidelines endorse for all private employers and reaffirm for all governmental employers the Equal Employment Opportunity Coordinating Council's "Policy Statement on Affirmative Action Programs for State and Local Government Agencies" (41 FR 38814, September 13, 1976). That policy statement is attached hereto as appendix, section 17.

TECHNICAL STANDARDS

SEC. 14. *Technical standards for validity studies.* The following minimum standards, as applicable, should be met in conducting a validity study. Nothing in these guidelines is intended to preclude the development and use of other professionally acceptable techniques with respect to validation of selection procedures. Where it is not technically feasible for a user to conduct a validity study, the user has the obligation otherwise to comply with these guidelines. See sections 6 and 7 above.

A. *Validity studies should be based on review of information about the job.* Any validity study should be based upon a review of information about the job for which the selection procedure is to be used. The review should include a job analysis except as provided in section 14B(3) below with respect to criterion-related validity. Any method of job analysis may be used if it provides the information required for the specific validation strategy used.

B. *Technical standards for criterion-related validity studies.*—(1) *Technical feasibility.* Users choosing to validate a selection procedure by a criterion-related validity strategy should determine whether it is technically feasible (as defined in section 16) to conduct such a study in the particular employment context. The determination of the number of persons necessary to permit the conduct of a meaningful criterion-related study should be made by the user on the basis of all relevant information concerning the selection procedure, the potential sample and the employment situation. Where appropriate, jobs with substantially the same major work behaviors may be grouped together for validity studies, in order to obtain an adequate sample. These guidelines do not require a user to hire or promote persons for the purpose of making it possible to conduct a criterion-related study.

(2) *Analysis of the job.* There should be a review of job information to determine measures of work behavior(s) or performance that are relevant to the job or group of jobs in question. These measures or criteria are relevant to the extent that they represent critical or important job duties, work behaviors or work outcomes as developed from the review of job information. The possibility of bias should be considered both in selection of the criterion measures and their application. In view of the possibility of bias in subjective evaluations, supervisory rating techniques and instructions to raters should be carefully developed. All criterion measures and the methods for gathering data need to be examined for freedom from factors which would unfairly alter scores of members of any group. The relevance of criteria and their freedom from bias are of particular concern when there are significant differences in measures of job performance for different groups.

(3) *Criterion measures.* Proper safeguards should be taken to insure that scores on selection procedures do not enter into any judgments of employee adequacy that are to be used as criterion measures. Whatever criteria are used should represent important or critical work behavior(s) or work outcomes. Certain criteria may be used without a full job analysis if the user can show the importance of the criteria to the particular employment con-

text. These criteria include but are not limited to production rate, error rate, tardiness, absenteeism, and length of service. A standardized rating of overall work performance may be used where a study of the job shows that it is an appropriate criterion. Where performance in training is used as a criterion, success in training should be properly measured and the relevance of the training should be shown either through a comparsion of the content of the training program with the critical or important work behavior(s) of the job(s), or through a demonstration of the relationship between measures of performance in training and measures of job performance. Measures of relative success in training include but are not limited to instructor evaluations, performance samples, or tests. Criterion measures consisting of paper and pencil tests will be closely reviewed for job relevance.

(4) *Representativeness of the sample.* Whether the study is predictive or concurrent, the sample subjects should insofar as feasible be representative of the candidates normally available in the relevant labor market for the job or group of jobs in question, and should insofar as feasible include the races, sexes, and ethnic groups normally available in the relevant job market. In determining the representativeness of the sample in a concurrent validity study, the user should take into account the extent to which the specific knowledges or skills which are the primary focus of the test are those which employees learn on the job.

Where samples are combined or compared, attention should be given to see that such samples are comparable in terms of the actual job they perform, the length of time on the job where time on the job is likely to affect performance, and other relevant factors likely to affect validity differences; or that these factors are included in the design of the study and their effects identified.

(5) *Statistical relationships.* The degree of relationship between selection procedure scores and criterion measures should be examined and computed, using professionally acceptable statistical procedures. Generally, a selection procedure is considered related to the criterion, for the purposes of these guidelines, when the relationship between performance on the procedure and performance on the criterion measure is statistically significant at the 0.05 level of significance, which means that it is sufficiently high as to have a probability of no more than one (1) in twenty (20) to have occurred by chance. Absence of a statistically significant relationship between a selection procedure and job performance should not necessarily discourage other investigations of the validity of that selection procedure.

(6) *Operational use of selection procedures.* Users should evaluate each selection procedure to assure that it is appropriate for operational use, including establishment of cutoff scores or rank ordering. Generally, if other factors reman the same, the greater the magnitude of the relationship (e.g., coorelation coefficent) between performance on a selection procedure and one or more criteria of performance on the job, and the greater the importance and number of aspects of job performance covered by the criteria, the more likely it is that the procedure will be appropriate for use. Reliance upon a selection procedure which is significantly related to a criterion measure, but which is based upon a study involving a large number of subjects and has a low correlation coefficient will be subject to close review if it has a large adverse impact. Sole reliance upon a single selection instrument which is related to only one of many job duties or aspects of job performance will also be subject to close review. The appropriateness of a selection procedure is best evaluated in each particular situation and there are no minimum correlation coefficients applicable to all employment situations. In determining whether a selection procedure is appropriate for operational use the following considerations should also be taken into account: The degree of adverse impact of the procedure, the availability of other selection procedures of greater or substantially equal validity.

(7) *Overstatement of validity findings.* Users should avoid reliance upon techniques which tend to overestimate validity findings as a result of capitalization on chance unless an appropriate safeguard is taken. Reliance upon a few selection procedures or criteria of successful job performance when many selection procedures or criteria of performance have been studied, or the use of optimal statistical weights for selection procedures computed in one sample, are techniques which tend to inflate validity estimates as a result of chance. Use of a large sample is one safeguard: cross-validation is another.

(8) *Fairness.* This section generally calls for studies of unfairness where technically feasible. The concept of fairness or unfairness of selection procedures is a developing concept. In addition, fairness studies generally require substantial numbers of employees in the job or group of jobs being studied. For these reasons, the Federal enforcement agencies recognize that the obligation to conduct studies of fairness imposed by the guidelines generally will be upon users or groups of users with a large number of persons in a a job class, or test developers; and that small users utilizing their own selection procedures will generally not be obligated to conduct such studies because it will be technically infeasible for them to do so.

(a) *Unfairness defined.* When members of one race, sex, or ethnic group characteristically obtain lower scores on a selection procedure than members of another group, and the differences in scores are not reflected in differences in a measure of job performance, use of the selection procedure may unfairly deny opportunities to members of the group that obtains the lower scores.

(b) *Investigation of fairness.* Where a selection procedure results in an adverse impact on a race, sex, or ethnic group identified in accordance with the classifications set forth in section 4 above and that group is a significant factor in the relevant labor market, the user generally should investigate the possible existence of unfairness for that group if it is technically feasible to do so. The greater the severity of the adverse impact on a group, the greater the need to investigate the possible existence of unfairness. Where the weight of evidence from other studies shows that the selection procedure predicts fairly for the group in question and for the same or similar jobs, such evidence may be relied on in connection with the selection procedure at issue.

(c) *General considerations in fairness investigations.* Users conducting a study of fairness should review the A.P.A. Standards regarding investigation of possible bias in testing. An investigation of fairness of a selection procedure depends on both evidence of validity and the manner in which the selection procedure is to be used in a particular employment context. Fairness of a selection procedure cannot necessarily be specified in advance without investigating these factors. Investigation of fairness of a selection procedure in samples where the range of scores on selection procedures or criterion measures is severely restricted for any subgroup sample (as compared to other subgroup samples) may produce misleading evidence of unfairness. That factor should accordingly be taken into account in conducting such studies and before reliance is placed on the results.

(d) *When unfairness is shown.* If unfairness is demonstrated through a showing that members of a particular group perform better or poorer on the job than their scores on the selection procedure would indicate through comparison with how members of other groups perform, the user may either revise or replace the selection instrument in accordance with these guidelines, or may continue to use the selection instrument operationally

with appropriate revisions in its use to assure compatibility between the probability of successful job performance and the probability of being selected.

(e) *Technical feasibility of fairness studies.* In addition to the general conditions needed for technical feasibility for the conduct of a criterion-related study (see section 16, below) an investigation of fairness requires the following:

(i) An adequate sample of persons in each group available for the study to achieve findings of statistical significance. Guidelines do not require a user to hire or promote persons on the basis of group classifications for the purpose of making it possible to conduct a study of fairness; but the user has the obligation otherwise to comply with these guidelines.

(ii) The samples for each group should be comparable in terms of the actual job they perform, length of time on the job where time on the job is likely to affect performance, and other relevant factors likely to affect validity differences; or such factors should be included in the design of the study and their effects identified.

(f) *Continued use of selection procedures when fairness studies not feasible.* If a study of fairness should otherwise be performed, but is not technically feasible, a selection procedure may be used which has otherwise met the validity standards of these guidelines, unless the technical infeasibility resulted from discriminatory employment practices which are demonstrated by facts other than past failure to conform with requirements for validation of selection procedures. However, when it becomes technically feasible for the user to perform a study of fairness and such a study is otherwise called for, the user should conduct the study of fairness.

C. *Technical standards for content validity studies.*—(1) *Appropriateness of content validity studies.* Users choosing to validate a selection procedure by a content validity strategy should determine whether it is appropriate to conduct such a study in the particular employment context. A selection procedure can be supported by a content validity strategy to the extent that it is a representative sample of the content of the job. Selection procedures which purport to measure knowledges, skills, or abilities may in certain circumstances be justified by content validity, although they may not be representative samples, if the knowledge, skill, or ability measured by the selection procedure can be operationally defined as provided in section 14C(4) below, and if that knowledge, skill, or ability is a necessary prerequisite to successful job performance.

A selection procedure based upon inferences about mental processes cannot be supported solely or primarily on the basis of content validity. Thus, a content strategy is not appropriate for demonstrating the validity of selection procedures which purport to measure traits or constructs, such as intelligence, aptitude, personality, commonsense, judgment, leadership, and spatial ability. Content validity is also not an appropriate strategy when the selection procedure involves knowledges, skills, or abilities which an employee will be expected to learn on the job.

(2) *Job analysis for content validity.* There should be a job analysis which includes an analysis of the important work behavior(s) required for successful performance and their relative importance and, if the behavior results in work product(s), an analysis of the work product(s). Any job analysis should focus on the work behavior(s) and the tasks associated with them. If work behavior(s) are not observable, the job analysis should identify and analyze those aspects of the behavior(s) that can be observed and the observed work products. The work behavior(s) selected for measurement should be critical work behavior(s) and/or important work behavior(s) constituting most of the job.

(3) *Development of selection procedures.* A selection procedure designed to measure the work behavior may be developed specifically from the job and job analysis in question, or may have been previously developed by the user, or by other users or by a test publisher.

(4) *Standards for demonstrating content validity.* To demonstrate the content validity of a selection procedure, a user should show that the behavior(s) demonstrated in the selection procedure are a representative sample of the behavior(s) of the job in question or that the selection procedure provides a representative sample of the work product of the job. In the case of a selection procedure measuring a knowledge, skill, or ability, the knowledge, skill, or ability being measured should be operationally defined. In the case of a selection procedure measuring a knowledge, the knowledge being measured should be operationally defined as that body of learned information which is used in and is a necessary prerequisite for observable aspects of work behavior of the job. In the case of skills or abilities, the skill or ability being measured should be operationally defined in terms of observable aspects of work behavior of the job. For any selection procedure measuring a knowledge, skill, or ability the user should show that (a) the selection procedure measures and is a representative sample of that knowledge, skill, or ability; and (b) that knowledge, skill, or ability is used in and is a necessary prerequisite to performance of critical or important work behavior(s). In addition, to be content valid, a selection procedure measuring a skill or ability should either closely approximate an observable work behavior, or its product should closely approximate an observable work product. If a test purports to sample a work behavior or to provide a sample of a work product, the manner and setting of the selection procedure and its level and complexity should closely approximate the work situation. The closer the content and the context of the selection procedure are to work samples or work behaviors, the stronger is the basis for showing content validity. As the content of the selection procedure less resembles a work behavior, or the setting and manner of the administration of the selection procedure less resemble the work situation, or the result less resembles a work product, the less likely the selection procedure is to be content valid, and the greater the need for other evidence of validity.

(5) *Reliability.* The reliability of selection procedures justified on the basis of content validity should be a matter of concern to the user. Whenever it is feasible, appropriate statistical estimates should be made of the reliability of the selection procedure.

(6) *Prior training or experience.* A requirement for or evaluation of specific prior training or experience based on content validity, including a specification of level or amount of training or experience, should be justified on the basis of the relationship between the content of the training or experience and the content of the job for which the training or experience is to be required or evaluated. The critical consideration is the resemblance between the specific behaviors, products, knowledges, skills, or abilities in the experience or training and the specific behaviors, products, knowledges, skills, or abilities required on the job, whether or not there is close resemblance between the experience or training as a whole and the job as a whole.

(7) *Content validity of training success.* Where a measure of success in a training program is used as a selection procedure and the content of a training program is justified on the basis of content validity, the use should be justified on the relationship between the content of the training program and the content of the job.

(8) *Operational use.* A selection procedure which is supported on the basis of content validity may be used for a job if it represents a critical work behavior (i.e., a behavior which is necessary for performance of the job) or

work behaviors which constitute most of the important parts of the job.

(9) *Ranking based on content validity studies.* If a user can show, by a job analysis or otherwise, that a higher score on a content valid selection procedure is likely to result in better job performance, the results may be used to rank persons who score above minimum levels. Where a selection procedure supported solely or primarily by content validity is used to rank job candidates, the selection procedure should measure those aspects of performance which differentiate among levels of job performance.

D. *Technical standards for construct validity studies.*— (1) *Appropriateness of construct validity studies.* Construct validity is a more complex strategy than either criterion-related or content validity. Construct validation is a relatively new and developing procedure in the employment field, and there is at present a lack of substantial literature extending the concept to employment practices. The user should be aware that the effort to obtain sufficient empirical support for construct validity is both an extensive and arduous effort involving a series of research studies, which include criterion related validity studies and which may include content validity studies. Users choosing to justify use of a selection procedure by this strategy should therefore take particular care to assure that the validity study meets the standards set forth below.

(2) *Job analysis for construct validity studies.* There should be a job analysis. This job analysis should show the work behavior(s) required for successful performance of the job, or the groups of jobs being studied, the critical or important work behavior(s) in the job or group of jobs being studied, and an identification of the construct(s) believed to underlie successful performance of these critical or important work behaviors in the job or jobs in question. Each construct should be named and defined, so as to distinguish it from other constructs. If a group of jobs is being studied the jobs should have in common one or more critical or important work behaviors at a comparable level of complexity.

(3) *Relationship to the job.* A selection procedure should then be identified or developed which measures the construct identified in accord with subparagraph (2) above. The user should show by empirical evidence that the selection procedure is validly related to the construct and that the construct is validly related to the performance of critical or important work behavior(s). The relationship between the construct as measured by the selection procedure and the related work behavior(s) should be supported by empirical evidence from one or more criterion-related studies involving the job or jobs in question which satisfy the provisions of section 14B above.

(4) *Use of construct validity study without new criterion-related evidence.*—(a) *Standards for use.* Until such time as professional literature provides more guidance on the use of construct validity in employment situations, the Federal agencies will accept a claim of construct validity without a criterion-related study which satisfies section 14B above only when the selection procedure has been used elsewhere in a situation in which a criterion-related study has been conducted and the use of a criterion-related validity study in this context meets the standards for transportability of criterion-related validity studies as set forth above in section 7. However, if a study pertains to a number of jobs having common critical or important work behaviors at a comparable level of complexity, and the evidence satisfies subparagraphs 14B (2) and (3) above for those jobs with criterion-related validity evidence for those jobs, the selection procedure may be used for all the jobs to which the study pertains. If construct validity is to be generalized to other jobs or groups of jobs not in the group studied, the Federal enforcement agencies will expect at a minimum additional empirical research evidence meeting the standards of subparagraphs section 14B (2) and (3) above for the additional jobs or groups of jobs.

(b) *Determination of common work behaviors.* In determining whether two or more jobs have one or more work behavior(s) in common, the user should compare the observed work behavior(s) in each of the jobs and should compare the observed work product(s) in each of the jobs. If neither the observed work behavior(s) in each of the jobs nor the observed work product(s) in each of the jobs are the same, the Federal enforcement agencies will presume that the work behavior(s) in each job are different. If the work behaviors are not observable, then evidence of similarity of work products and any other relevant research evidence will be considered in determining whether the work behavior(s) in the two jobs are the same.

Documentation of Impact and Validity Evidence

Sec. 15. *Documentation of impact and validity evidence.*—A. *Required information.* Users of selection procedures other than those users complying with section 15A(1) below should maintain and have available for each job information on adverse impact of the selection process for that job and, where it is determined a selection process has an adverse impact, evidence of validity as set forth below.

(1) *Simplified recordkeeping for users with less than 100 employees.* In order to minimize recordkeeping burdens on employers who employ one hundred (100) or fewer employees, and other users not required to file EEO–1, et seq., reports, such users may satisfy the requirements of this section 15 if they maintain and have available records showing, for each year:

(a) The number of persons hired, promoted, and terminated for each job, by sex, and where appropriate by race and national origin;

(b) The number of applicants for hire and promotion by sex and where appropriate by race and national origin; and

(c) The selection procedures utilized (either standardized or not standardized).

These records should be maintained for each race or national origin group (see section 4 above) constituting more than two percent (2%) of the labor force in the relevant labor area. However, it is not necessary to maintain records by race and/or national origin (see § 4 above) if one race or national origin group in the relevant labor area constitutes more than ninety-eight percent (98%) of the labor force in the area. If the user has reason to believe that a selection procedure has an adverse impact, the user should maintain any available evidence of validity for that procedure (see sections 7A and 8).

(2) *Information on impact.*—(a) *Collection of information on impact.* Users of selection procedures other than those complying with section 15A(1) above should maintain and have available for each job records or other information showing whether the total selection process for that job has an adverse impact on any of the groups for which records are called for by sections 4B above. Adverse impact determinations should be made at least annually for each such group which constitutes at least 2 percent of the labor force in the relevant labor area or 2 percent of the applicable workforce. Where a total selection process for a job has an adverse impact, the user should maintain and have available records or other information showing which components have an adverse impact. Where the total selection process for a job does not have an adverse impact, information need not be maintained for individual components except in circumstances set forth in subsection 15A(2)(b) below. If the determination of adverse impact is made using a procedure other than the "four-fifths rule," as defined in the first sentence of section 4D above, a justification, consistent with section 4D above, for

the procedure used to determine adverse impact should be available.

(b) *When adverse impact has been eliminated in the total selection process.* Whenever the total selection process for a particular job has had an adverse impact, as defined in section 4 above, in any year, but no longer has an adverse impact, the user should maintain and have available the information on individual components of the selection process required in the preceding paragraph for the period in which there was adverse impact. In addition, the user should continue to collect such information for at least two (2) years after the adverse impact has been eliminated.

(c) *When data insufficient to determine impact.* Where there has been an insufficient number of selections to determine whether there is an adverse impact of the total selection process for a particular job, the user should continue to collect, maintain and have available the information on individual components of the selection process required in section 15(A)(2)(a) above until the information is sufficient to determine that the overall selection process does not have an adverse impact as defined in section 4 above, or until the job has changed substantially.

(3) *Documentation of validity evidence.*—(a) *Types of evidence.* Where a total selection process has an adverse impact (see section 4 above) the user should maintain and have available for each component of that process which has an adverse impact, one or more of the following types of documentation evidence:

(i) Documentation evidence showing criterion-related validity of the selection procedure (see section 15B, below).

(ii) Documentation evidence showing content validity of the selection procedure (see section 15C, below).

(iii) Documentation evidence showing construct validity of the selection procedure (see section 15D, below).

(iv) Documentation evidence from other studies showing validity of the selection procedure in the user's facility (see section 15E, below).

(v) Documentation evidence showing why a validity study cannot or need not be performed and why continued use of the procedure is consistent with Federal law.

(b) *Form of report.* This evidence should be compiled in a reasonably complete and organized manner to permit direct evaluation of the validity of the selection procedure. Previously written employer or consultant reports of validity, or reports describing validity studies completed before the issuance of these guidelines are acceptable if they are complete in regard to the documentation requirements contained in this section, or if they satisfied requirements of guidelines which were in effect when the validity study was completed. If they are not complete, the required additional documentation should be appended. If necessary information is not available the report of the validity study may still be used as documentation, but its adequacy will be evaluated in terms of compliance with the requirements of these guidelines.

(c) *Completeness.* In the event that evidence of validity is reviewed by an enforcement agency, the validation reports completed after the effective date of these guidelines are expected to contain the information set forth below. Evidence denoted by use of the word "(Essential)" is considered critical. If information denoted essential is not included, the report will be considered incomplete unless the user affirmatively demonstrates either its unavailability due to circumstances beyond the user's control or special circumstances of the user's study which make the information irrelevant. Evidence not so denoted is desirable but its absence will not be a basis for considering a report incomplete. The user should maintain and have available the information called for under the heading "Source Data" in sections 15B(11) and 15D(11). While it is a necessary part of the study, it need not be submitted with the report. All statistical results should be organized and presented in tabular or graphic form to the extent feasible.

B. *Criterion-related validity studies.* Reports of criterion-related validity for a selection procedure should include the following information:

(1) *User(s), location(s), and date(s) of study.* Dates and location(s) of the job analysis or review of job information, the date(s) and location(s) of the administration of the selection procedures and collection of criterion data, and the time between collection of data on selection procedures and criterion measures should be provided (Essential). If the study was conducted at several locations, the address of each location, including city and State, should be shown.

(2) *Problem and setting.* An explicit definition of the purpose(s) of the study and the circumstances in which the study was conducted should be provided. A description of existing selection procedures and cutoff scores, if any, should be provided.

(3) *Job anlysis or review of job information.* A description of the procedure used to analyze the job or group of jobs, or to review the job information should be provided (Essential). Where a review of job information results in criteria which may be used without a full job analysis (see section 14B(3)), the basis for the selection of these criteria should be reported (Essential). Where a job analysis is required a complete description of the work behavior(s) or work outcome(s), and measures of their criticality or importance should be provided (Essential). The report should describe the basis on which the behavior(s) or outcome(s) were determined to be critical or important, such as the proportion of time spent on the respective behaviors, their level of difficulty, their frequency of performance, the consequences of error, or other appropriate factors (Essential). Where two or more jobs are grouped for a validity study, the information called for in this subsection should be provided for each of the jobs, and the justification for the grouping (see section 14B(1)) should be provided (Essential).

(4) *Job titles and codes.* It is desirable to provide the user's job title(s) for the job(s) in question and the corresponding job title(s) and code(s) from U.S. Employment Service's Dictionary of Occupational Titles.

(5) *Criterion measures.* The bases for the selection of the criterion measures should be provided, together with references to the evidence considered in making the selection of criterion measures (essential). A full description of all criteria on which data were collected and means by which they were observed, recorded, evaluated, and quantified, should be provided (essential). If rating techniques are used as criterion measures, the appraisal form(s) and instructions to the rater(s) should be included as part of the validation evidence, or should be explicitly described and available (essential). All steps taken to insure that criterion measures are free from factors which would unfairly alter the scores of members of any group should be described (essential).

(6) *Sample description.* A description of how the research sample was identified and selected should be included (essential). The race, sex, and ethnic composition of the sample, including those groups set forth in section 4A above, should be described (essential). This description should include the size of each subgroup (essential). A description of how the research sample compares with the relevant labor market or work force, the method by which the relevant labor market or work force was defined, and a discussion of the likely effects on validity of differences between the sample and the relevant labor market or work force, are also desirable. Descriptions of educational levels, length of service, and age are also desirable.

(7) *Description of selection procedures.* Any measure, combination of measures, or procedure studied should be completely and explicitly described or attached (essential). If commercial-

ly available selection procedures are studied, they should be described by title, form, and publisher (essential). Reports of reliability estimates and how they were established are desirable.

(8) *Techniques and results.* Methods used in analyzing data should be described (essential). Measures of central tendency (e.g., means) and measures of dispersion (e.g., standard deviations and ranges) for all selection procedures and all criteria should be reported for each race, sex, and ethnic group which constitutes a significant factor in the relevant labor market (essential). The magnitude and direction of all relationships between selection procedures and criterion measures investigated should be reported for each relevant race, sex, and ethnic group and for the total group (essential). Where groups are too small to obtain reliable evidence of the magnitude of the relationship, need not be reported separately. Statements regarding the statistical significance of results should be made (essential). Any statistical adjustments, such as for less then perfect reliability or for restriction of score range in the selection procedure or criterion should be described and explained; and uncorrected correlation coefficients should also be shown (essential). Where the statistical technique categorizes continuous data, such as biserial correlation and the phi coefficient, the categories and the bases on which they were determined should be described and explained (essential). Studies of test fairness should be included where called for by the requirements of section 14B(8) (essential). These studies should include the rationale by which a selection procedure was determined to be fair to the group(s) in question. Where test fairness or unfairness has been demonstrated on the basis of other studies, a bibliography of the relevant studies should be included (essential). If the bibliography includes unpublished studies, copies of these studies, or adequate abstracts or summaries, should be attached (essential). Where revisions have been made in a selection procedure to assure compatability between successful job performance and the probability of being selected, the studies underlying such revisions should be included (essential). All statistical results should be organized and presented by relevant race, sex, and ethnic group (essential).

(9) *Alternative procedures investigated.* The selection procedures investigated and available evidence of their impact should be identified (essential). The scope, method, and findings of the investigation, and the conclusions reached in light of the findings, should be fully described (essential).

(10) *Uses and applications.* The methods considered for use of the selection procedure (e.g., as a screening device with a cutoff score, for grouping or ranking, or combined with other procedures in a battery) and available evidence of their impact should be described (essential). This description should include the rationale for choosing the method for operational use, and the evidence of the validity and utility of the procedure as it is to be used (essential). The purpose for which the procedure is to be used (e.g., hiring, transfer, promotion) should be described (essential). If weights are assigned to different parts of the selection procedure, these weights and the validity of the weighted composite should be reported (essential). If the selection procedure is used with a cutoff score, the user should describe the way in which normal expectations of proficiency within the work force were determined and the way in which the cutoff score was determined (essential).

(11) *Source data.* Each user should maintain records showing all pertinent information about individual sample members and raters where they are used, in studies involving the validation of selection procedures. These records should be made available upon request of a compliance agency. In the case of individual sample members these data should include scores on the selection procedure(s), scores on criterion measures, age, sex, race, or ethnic group status, and experience on the specific job on which the validation study was conducted, and may also include such things as education, training, and prior job experience, but should not include names and social security numbers. Records should be maintained which show the ratings given to each sample member by each rater.

(12) *Contact person.* The name, mailing address, and telephone number of the person who may be contacted for further information about the validity study should be provided (essential).

(13) *Accuracy and completeness.* The report should describe the steps taken to assure the accuracy and completeness of the collection, analysis, and report of data and results.

C. *Content validity studies.* Reports of content validity for a selection procedure should include the following information:

(1) *User(s), location(s) and date(s) of study.* Dates and location(s) of the job analysis should be shown (essential).

(2) *Problem and setting.* An explicit definition of the purpose(s) of the study and the circumstances in which the study was conducted should be provided. A description of existing selection procedures and cutoff scores, if any, should be provided.

(3) *Job analysis—Content of the job.* A description of the method used to analyze the job should be provided (essential). The work behavior(s), the associated tasks, and, if the behavior results in a work product, the work products should be completely described (essential). Measures of criticality and/or importance of the work behavior(s) and the method of determining these measures should be provided (essential). Where the job analysis also identified the knowledges, skills, and abilities used in work behavior(s), an operational definition for each knowledge in terms of a body of learned information and for each skill and ability in terms of observable behaviors and outcomes, and the relationship between each knowledge, skill, or ability and each work behavior, as well as the method used to determine this relationship, should be provided (essential). The work situation should be described, including the setting in which work behavior(s) are performed, and where appropriate, the manner in which knowledges, skills, or abilities are used, and the complexity and difficulty of the knowledge, skill, or ability as used in the work behavior(s).

(4) *Selection procedure and its content.* Selection procedures, including those constructed by or for the user, specific training requirements, composites of selection procedures, and any other procedure supported by content validity, should be completely and explicitly described or attached (essential). If commercially available selection procedures are used, they should be described by title, form, and publisher (essential). The behaviors measured or sampled by the selection procedure should be explicitly described (essential). Where the selection procedure purports to measure a knowledge, skill, or ability, evidence that the selection procedure measures and is a representative sample of the knowledge, skill, or ability should be provided (essential).

(5) *Relationship between the selection procedure and the job.* The evidence demonstrating that the selection procedure is a representative work sample, a representative sample of the work behavior(s), or a representative sample of a knowledge, skill, or ability as used as a part of a work behavior and necessary for that behavior should be provided (essential). The user should identify the work behavior(s) which each item or part of the selection procedure is intended to sample or measure (essential). Where the selection procedure purports to sample a work behavior or to provide a sample of a work product, a comparison should be provided of the manner, setting, and the level of complexity of the selection procedure with those of

the work situation (essential). If any steps were taken to reduce adverse impact on a race, sex, or ethnic group in the content of the procedure or in its administration, these steps should be described. Establishment of time limits, if any, and how these limits are related to the speed with which duties must be performed on the job, should be explained. Measures of central tend- ency (e.g., means) and measures of dispersion (e.g., standard deviations) and estimates of realibility should be reported for all selection procedures if available. Such reports should be made for relevant race, sex, and ethnic subgroups, at least on a statistically reliable sample basis.

(6) *Alternative procedures investigated.* The alternative selection procedures investigated and available evidence of their impact should be identified (essential). The scope, method, and findings of the investigation, and the conclusions reached in light of the findings, should be fully described (essential).

(7) *Uses and applications.* The methods considered for use of the selection procedure (e.g., as a screening device with a cutoff score, for grouping or ranking, or combined with other procedures in a battery) and available evidence of their impact should be described (essential). This description should include the rationale for choosing the method for operational use, and the evidence of the validity and utility of the procedure as it is to be used (essential). The purpose for which the procedure is to be used (e.g., hiring, transfer, promotion) should be described (essential). If the selection procedure is used with a cutoff score, the user should describe the way in which normal expectations of proficiency within the work force were determined and the way in which the cutoff score was determined (essential). In addition, if the selection procedure is to be used for ranking, the user should specify the evidence showing that a higher score on the selection procedure is likely to result in better job performance.

(8) *Contact person.* The name, mailing address, and telephone number of the person who may be contacted for further information about the validity study should be provided (essential).

(9) *Accuracy and completeness.* The report should describe the steps taken to assure the accuracy and completeness of the collection, analysis, and report of data and results.

D. *Construct validity studies.* Reports of construct validity for a selection procedure should include the following information:

(1) *User(s), location(s), and date(s) of study.* Date(s) and location(s) of the job analysis and the gathering of other evidence called for by these guidelines should be provided (essential).

(2) *Problem and setting.* An explicit definition of the purpose(s) of the study and the circumstances in which the study was conducted should be provided. A description of existing selection procedures and cutoff scores, if any, should be provided.

(3) *Construct definition.* A clear definition of the construct(s) which are believed to underlie successful performance of the critical or important work behavior(s) should be provided (essential). This definition should include the levels of construct performance relevant to the job(s) for which the selection procedure is to be used (essential). There should be a summary of the position of the construct in the psychological literature, or in the absence of such a position, a description of the way in which the definition and measurement of the construct was developed and the psychological theory underlying it (essential). Any quantitative data which identify or define the job constructs, such as factor analyses, should be provided (essential).

(4) *Job analysis.* A description of the method used to analyze the job should be provided (essential). A complete description of the work behavior(s) and, to the extent appropriate, work outcomes and measures of their criticality and/or importance should be provided (essential). The report should also describe the basis on which the behavior(s) or outcomes were determined to be important, such as their level of difficulty, their frequency of performance, the consequences of error or other appropriate factors (essential). Where jobs are grouped or compared for the purposes of generalizing validity evidence, the work behavior(s) and work product(s) for each of the jobs should be described, and conclusions concerning the similarity of the jobs in terms of observable work behaviors or work products should be made (essential).

(5) *Job titles and codes.* It is desirable to provide the selection procedure user's job title(s) for the job(s) in question and the corresponding job title(s) and code(s) from the United States Employment Service's dictionary of occupational titles.

(6) *Selection procedure.* The selection procedure used as a measure of the construct should be completely and explicitly described or attached (essential). If commercially available selection procedures are used, they should be identified by title, form and publisher (essential). The research evidence of the relationship between the selection procedure and the construct, such as factor structure, should be included (essential). Measures of central tendency, variability and reliability of the selection procedure should be provided (essential). Whenever feasible, these measures should be provided separately for each relevant race, sex and ethnic group.

(7) *Relationship to job performance.* The criterion-related study(ies) and other empirical evidence of the relationship between the construct measured by the selection procedure and the related work behavior(s) for the job or jobs in question should be provided (essential). Documentation of the criterion-related study(ies) should satisfy the provisions of section 15B above or section 15E(1) below, except for studies conducted prior to the effective date of these guidelines (essential). Where a study pertains to a group of jobs, and, on the basis of the study, validity is asserted for a job in the group, the observed work behaviors and the observed work products for each of the jobs should be described (essential). Any other evidence used in determining whether the work behavior(s) in each of the jobs is the same should be fully described (essential).

(8) *Alternative procedures investigated.* The alternative selection procedures investigated and available evidence of their impact should be identified (essential). The scope, method, and findings of the investigation, and the conclusions reached in light of the findings should be fully described (essential).

(9) *Uses and applications.* The methods considered for use of the selection procedure (e.g., as a screening device with a cutoff score, for grouping or ranking, or combined with other procedures in a battery) and available evidence of their impact should be described (essential). This description should include the rationale for choosing the method for operational use, and the evidence of the validity and utility of the procedure as it is to be used (essential). The purpose for which the procedure is to be used (e.g., hiring, transfer, promotion) should be described (essential). If weights are assigned to different parts of the selection procedure, these weights and the validity of the weighted composite should be reported (essential). If the selection procedure is used with a cutoff score, the user should describe the way in which normal expectations of proficiency within the work force were determined and the way in which the cutoff score was determined (essential).

(10) *Accuracy and completeness.* The report should describe the steps taken to assure the accuracy and completeness of the collection, analysis, and report of data and results.

(11) *Source data.* Each user should maintain records showing all pertinent

information relating to its study of construct validity.

(12) *Contact person.* The name, mailing address, and telephone number of the individual who may be contacted for further information about the validity study should be provided (essential).

E. *Evidence of validity from other studies.* When validity of a selection procedure is supported by studies not done by the user, the evidence from the original study or studies should be compiled in a manner similar to that required in the appropriate section of this section 15 above. In addition, the following evidence should be supplied:

(1) *Evidence from criterion-related validity studies.*—a. *Job information.* A description of the important job behavior(s) of the user's job and the basis on which the behaviors were determined to be important should be provided (essential). A full description of the basis for determining that these important work behaviors are the same as those of the job in the original study (or studies) should be provided (essential).

b. *Relevance of criteria.* A full description of the basis on which the criteria used in the original studies are determined to be relevant for the user should be provided (essential).

c. *Other variables.* The similarity of important applicant pool or sample characteristics reported in the original studies to those of the user should be described (essential). A description of the comparison between the race, sex and ethnic composition of the user's relevant labor market and the sample in the original validity studies should be provided (essential).

d. *Use of the selection procedure.* A full description should be provided showing that the use to be made of the selection procedure is consistent with the findings of the original validity studies (essential).

e. *Bibliography.* A bibliography of reports of validity of the selection procedure for the job or jobs in question should be provided (essential). Where any of the studies included an investigation of test fairness, the results of this investigation should be provided (essential). Copies of reports published in journals that are not commonly available should be described in detail or attached (essential). Where a user is relying upon unpublished studies, a reasonable effort should be made to obtain these studies. If these unpublished studies are the sole source of validity evidence they should be described in detail or attached (essential). If these studies are not available, the name and address of the source, an adequate abstract or summary of the validity study and data, and a contact person in the source organization should be provided (essential).

(2) *Evidence from content validity studies.* See section 14C(3) and section 15C above.

(3) *Evidence from construct validity studies.* See sections 14D(2) and 15D above.

F. *Evidence of validity from cooperative studies.* Where a selection procedure has been validated through a cooperative study, evidence that the study satisfies the requirements of sections 7, 8 and 15E should be provided (essential).

G. *Selection for higher level job.* If a selection procedure is used to evaluate candidates for jobs at a higher level than those for which they will initially be employed, the validity evidence should satisfy the documentation provisions of this section 15 for the higher level job or jobs, and in addition, the user should provide: (1) a description of the job progression structure, formal or informal; (2) the data showing how many employees progress to the higher level job and the length of time needed to make this progression; and (3) an identification of any anticipated changes in the higher level job. In addition, if the test measures a knowledge, skill or ability, the user should provide evidence that the knowledge, skill or ability is required for the higher level job and the basis for the conclusion that the knowledge, skill or ability is not expected to develop from the training or experience on the job.

H. *Interim use of selection procedures.* If a selection procedure is being used on an interim basis because the procedure is not fully supported by the required evidence of validity, the user should maintain and have available (1) substantial evidence of validity for the procedure, and (2) a report showing the date on which the study to gather the additional evidence commenced, the estimated completion date of the study, and a description of the data to be collected (essential).

Definitions

Sec. 16. *Definitions.* The following definitions shall apply throughout these guidelines:

A. *Ability.* A present competence to perform an observable behavior or a behavior which results in an observable product.

B. *Adverse impact.* A substantially different rate of selection in hiring, promotion, or other employment decision which works to the disadvantage of members of a race, sex, or ethnic group. See section 4 of these guidelines.

C. *Compliance with these guidelines.* Use of a selection procedure is in compliance with these guidelines if such use has been validated in accord with these guidelines (as defined below), or if such use does not result in adverse impact on any race, sex, or ethnic group (see section 4, above), or, in unusual circumstances, if use of the procedure is otherwise justified in accord with Federal law. See section 6B, above.

D. *Content validity.* Demonstrated by data showing that the content of a selection procedure is representative of important aspects of performance on the job. See section 5B and section 14C.

E. *Construct validity.* Demonstrated by data showing that the selection procedure measures the degree to which candidates have identifiable characteristics which have been determined to be important for successful job performance. See section 5B and section 14D.

F. *Criterion-related validity.* Demonstrated by empirical data showing that the selection procedure is predictive of or significantly correlated with important elements of work behavior. See sections 5B and 14B.

G. *Employer.* Any employer subject to the provisions of the Civil Rights Act of 1964, as amended, including State or local governments and any Federal agency subject to the provisions of section 717 of the Civil Rights Act of 1964, as amended, and any Federal contractor or subcontractor or federally assisted construction contractor or subcontactor covered by Executive Order 11246, as amended.

H. *Employment agency.* Any employment agency subject to the provisions of the Civil Rights Act of 1964, as amended.

I. *Enforcement action.* For the purposes of section 4 a proceeding by a Federal enforcement agency such as a lawsuit or an administrative proceeding leading to debarment from or withholding, suspension, or termination of Federal Government contracts or the suspension or withholding of Federal Government funds; but not a finding of reasonable cause or a conciliation process or the issuance of right to sue letters under title VII or under Executive Order 11246 where such finding, conciliation, or issuance of notice of right to sue is based upon an individual complaint.

J. *Enforcement agency.* Any agency of the executive branch of the Federal Government which adopts these guidelines for purposes of the enforcement of the equal employment opportunity laws or which has responsibility for securing compliance with them.

K. *Job analysis.* A detailed statement of work behaviors and other information relevant to the job.

L. *Job description.* A general statement of job duties and responsibilities.

M. *Knowledge.* A body of information applied directly to the performance of a function.

N. *Labor organization.* Any labor organization subject to the provisions of the Civil Rights Act of 1964, as amended, and any committee subject thereto controlling apprenticeship or other training.

O. *Observable.* Able to be seen, heard, or otherwise perceived by a person other than the person performing the action.

P. *Race, sex, or ethnic group.* Any group of persons identifiable on the grounds of race, color, religion, sex, or national origin.

Q. *Selection procedure.* Any measure, combination of measures, or procedure used as a basis for any employment decision. Selection procedures include the full range of assessment techniques from traditional paper and pencil tests, performance tests, training programs, or probationary periods and physical, educational, and work experience requirements through informal or casual interviews and unscored application forms.

R. *Selection rate.* The proportion of applicants or candidates who are hired, promoted, or otherwise selected.

S. *Should.* The term "should" as used in these guidelines is intended to connote action which is necessary to achieve compliance with the guidelines, while recognizing that there are circumstances where alternative courses of action are open to users.

T. *Skill.* A present, observable competence to perform a learned psychomoter act.

U. *Technical feasibility.* The existence of conditions permitting the conduct of meaningful criterion-related validity studies. These conditions include: (1) An adequate sample of persons available for the study to achieve findings of statistical significance; (2) having or being able to obtain a sufficient range of scores on the selection procedure and job performance measures to produce validity results which can be expected to be representative of the results if the ranges normally expected were utilized; and (3) having or being able to devise unbiased, reliable and relevant measures of job performance or other criteria of employee adequacy. See section 14B(2). With respect to investigation of possible unfairness, the same considerations are applicable to each group for which the study is made. See section 14B(8).

V. *Unfairness of selection procedure.* A condition in which members of one race, sex, or ethnic group characteristically obtain lower scores on a selection procedure than members of another group, and the differences are not reflected in differences in measures of job performance. See section 14B(7).

W. *User.* Any employer, labor organization, employment agency, or licensing or certification board, to the extent it may be covered by Federal equal employment opportunity law, which uses a selection procedure as a basis for any employment decision. Whenever an employer, labor organization, or employment agency is required by law to restrict recruitment for any occupation to those applicants who have met licensing or certification requirements, the licensing or certifying authority to the extent it may be covered by Federal equal employment opportunity law will be considered the user with respect to those licensing or certification requirements. Whenever a State employment agency or service does no more than administer or monitor a procedure as permitted by Department of Labor regulations, and does so without making referrals or taking any other action on the basis of the results, the State employment agency will not be deemed to be a user.

X. *Validated in accord with these guidelines or properly validated.* A demonstration that one or more validity study or studies meeting the standards of these guidelines has been conducted, including investigation and, where appropriate, use of suitable alternative selection procedures as contemplated by section 3B, and has produced evidence of validity sufficient to warrant use of the procedure for the intended purpose under the standards of these guidelines.

Y. *Work behavior.* An activity performed to achieve the objectives of the job. Work behaviors involve observable (physical) components and unobservable (mental) components. A work behavior consists of the performance of one or more tasks. Knowledges, skills, and abilities are not behaviors, although they may be applied in work behaviors.

APPENDIX

17. *Policy statement on affirmative action* (see section 13B). The Equal Employment Opportunity Coordinating Council was established by act of Congress in 1972, and charged with responsibility for developing and implementing agreements and policies designed, among other things, to eliminate conflict and inconsistency among the agencies of the Federal Government responsible for administering Federal law prohibiting discrimination on grounds of race, color, sex, religion, and national origin. This statement is issued as an initial response to the requests of a number of State and local officials for clarification of the Government's policies concerning the role of affirmative action in the overall equal employment opportunity program. While the Coordinating Council's adoption of this statement expresses only the views of the signatory agencies concerning this important subject, the principles set forth below should serve as policy guidance for other Federal agencies as well.

(1) Equal employment opportunity is the law of the land. In the public sector of our society this means that all persons, regardless of race, color, religion, sex, or national origin shall have equal access to positions in the public service limited only by their ability to do the job. There is ample evidence in all sectors of our society that such equal access frequently has been denied to members of certain groups because of their sex, racial, or ethnic characteristics. The remedy for such past and present discrimination is twofold.

On the one hand, vigorous enforcement of the laws against discrimination is essential. But equally, and perhaps even more important are affirmative, voluntary efforts on the part of public employers to assure that positions in the public service are genuinely and equally accessible to qualified persons, without regard to their sex, racial, or ethnic characteristics. Without such efforts equal employment opportunity is no more than a wish. The importance of voluntary affirmative action on the part of employers is underscored by title VII of the Civil Rights Act of 1964, Executive Order 11246, and related laws and regulations—all of which emphasize voluntary action to achieve equal employment opportunity.

As with most management objectives, a systematic plan based on sound organizational analysis and problem identification is crucial to the accomplishment of affirmative action objectives. For this reason, the Council urges all State and local governments to develop and implement results oriented affirmative action plans which deal with the problems so identified.

The following paragraphs are intended to assist State and local governments by illustrating the kinds of analyses and activities which may be appropriate for a public employer's voluntary affirmative action plan. This statement does not address remedies imposed after a finding of unlawful discrimination.

(2) Voluntary affirmative action to assure equal employment opportunity is appropriate at any stage of the employment process. The first step in the construction of any affirmative action plan should be an analysis of the employer's work force to determine whether precentages of sex, race, or ethnic groups in individual job classifications are substantially similar to the precentages of those groups available in the relevant job market who possess the basic job-related qualifications.

When substantial disparities are found through such analyses, each element of the overall selection process should be examined to determine

which elements operate to exclude persons on the basis of sex, race, or ethnic group. Such elements include, but are not limited to, recruitment, testing, ranking certification, interview, recommendations for selection, hiring, promotion, etc. The examination of each element of the selection process should at a minimum include a determination of its validity in predicting job performance.

(3) When an employer has reason to believe that its selection procedures have the exclusionary effect described in paragraph 2 above, it should initiate affirmative steps to remedy the situation. Such steps, which in design and execution may be race, color, sex, or ethnic "conscious," include, but are not limited to, the following:

(a) The establishment of a long-term goal, and short-range, interim goals and timetables for the specific job classifications, all of which should take into account the availability of basically qualified persons in the relevant job market;

(b) A recruitment program designed to attract qualified members of the group in question;

(c) A systematic effort to organize work and redesign jobs in ways that provide opportunities for persons lacking "journeyman" level knowledge or skills to enter and, with appropriate training, to progress in a career field;

(d) Revamping selection instruments or procedures which have not yet been validated in order to reduce or eliminate exclusionary effects on particular groups in particular job classifications;

(e) The initiation of measures designed to assure that members of the affected group who are qualified to perform the job are included within the pool of persons from which the selecting official makes the selection;

(f) A systematic effort to provide career advancement training, both classroom and on-the-job, to employees locked into dead end jobs; and

(g) The establishment of a system for regularly monitoring the effectiveness of the particular affirmative action program, and procedures for making timely adjustments in this program where effectiveness is not demonstrated.

(4) The goal of any affirmative action plan should be achievement of genuine equal employment opportunity for all qualified persons. Selection under such plans should be based upon the ability of the applicant(s) to do the work. Such plans should not require the selection of the unqualified, or the unneeded, nor should they require the selection of persons on the basis of race, color, sex, religion, or national origin. Moreover, while the Council believes that this statement should serve to assist State and local employers, as well as Federal agencies, it recognizes that affirmative action cannot be viewed as a standardized program which must be accomplished in the same way at all times in all places.

Accordingly, the Council has not attempted to set forth here either the minimum or maximum voluntary steps that employers may take to deal with their respective situations. Rather, the Council recognizes that under applicable authorities, State and local employers have flexibility to formulate affirmative action plans that are best suited to their particular situations. In this manner, the Council believes that affirmative action programs will best serve the goal of equal employment opportunity.

Respectfully submitted,

HAROLD R. TYLER, Jr.,
Deputy Attorney General and Chairman of the Equal Employment Coordinating Council.

MICHAEL H. MOSKOW,
Under Secretary of Labor.

ETHEL BENT WALSH,
Acting Chairman, Equal Employment Opportunity Commission.

ROBERT E. HAMPTON,
Chairman, Civil Service Commission.

ARTHUR E. FLEMMING,
Chairman, Commission on Civil Rights.

Because of its equal employment opportunity responsibilities under the State and Local Government Fiscal Assistance Act of 1972 (the revenue sharing act), the Department of Treasury was invited to participate in the formulation of this policy statement; and it concurs and joins in the adoption of this policy statement.

Done this 26th day of August 1976.

RICHARD ALBRECHT,
General Counsel,
Department of the Treasury.

Section 18. *Citations.* The official title of these guidelines is "Uniform Guidelines on Employee Selection Procedures (1978)". The Uniform Guidelines on Employee Selection Procedures (1978) are intended to establish a uniform Federal position in the area of prohibiting discrimination in employment practices on grounds of race, color, religion, sex, or national origin. These guidelines have been adopted by the Equal Employment Opportunity Commission, the Department of Labor, the Department of Justice, and the Civil Service Commission.

The official citation is:

"Section ——, Uniform Guidelines on Employee Selection Procedure (1978); 43 FR —— (August 25, 1978)."

The short form citation is:

"Section ——, U.G.E.S.P. (1978); 43 FR —— (August 25, 1978)."

When the guidelines are cited in connection with the activities of one of the issuing agencies, a specific citation to the regulations of that agency can be added at the end of the above citation. The specific additional citations are as follows:

Equal Employment Opportunity Commission
29 CFR Part 1607
Department of Labor
Office of Federal Contract Compliance Programs
41 CFR Part 60-3
Department of Justice
28 CFR 50.14
Civil Service Commission
5 CFR 300.103(c)

Normally when citing these guidelines, the section number immediately preceding the title of the guidelines will be from these guidelines series 1-18. If a section number from the codification for an individual agency is needed it can also be added at the end of the agency citation. For example, section 6A of these guidelines could be cited for EEOC as follows: "Section 6A, Uniform Guidelines on Employee Selection Procedures (1978); 43 FR ——, (August 25, 1978); 29 CFR Part 1607, section 6A."

ELEANOR HOLMES NORTON,
Chair, Equal Employment Opportunity Commission.

ALAN K. CAMPBELL,
Chairman,
Civil Service Commission.

RAY MARSHALL,
Secretary of Labor.

GRIFFIN B. BELL,
Attorney General.

[6570-06]

CIVIL SERVICE COMMISSION

Title 5—Administrative Personnel

CHAPTER 1—CIVIL SERVICE COMMISSION

PART 300—EMPLOYMENT (GENERAL)

Uniform Guidelines on Employee Selection Procedures (1978)

The Uniform Guidelines on Employee Selection Procedures (1978) which are printed at the beginning of this part IV in today's FEDERAL REGISTER are adopted by the Civil Service Commission, in conjunction with the Equal Employment Opportunity Commission, Department of Justice, and the Department of Labor to establish uniformity in prohibiting discrimination in employment practices on grounds of race, color, religion, sex, or national origin. Cross reference documents are published at 29 CFR parts 1607 (Equal Employment Opportunity Commission), 28 CFR 50.14 (Department of Justice), and 41 CFR 60-3 (Department of Labor) elsewhere in this issue of the FEDERAL REGISTER.

By virtue of the authority vested in it by sections 3301, 3302, 7151, 7154, and 7301 of title 5 and section 4763(b) of title 42, United States Code, and Executive Order 10577, 3 CFR 1954-58 comp. page 218 and Executive Order 11478, 3 CFR 1959 comp. 133, and section 717 of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000e-16), the Civil Service Commission amends title 5, part 300, subpart A, § 300.103(c) of the Code of Federal Regulations to read as follows:

§ 300.103 Basic requirements.

"(c) Equal employment opportunity. An employment practice shall not discriminate on the basis of race, color, religion, sex, age, national origin, partisan political affiliation, or other nonmerit factor. Employee selection procedures shall meet the standards established by the "Uniform Guidelines on Employee Selection Procedures (1978), 43 FR—— (August 25, 1978)."

The Civil Service Commission rescinds the Guidelines on Employee Selection Procedures, 41 FR 51752, Federal Personnel Manual part 900, subpart F and adopts the Uniform Guidelines on Employee Selection Procedures (1978), to be issued as identical supplement appendices to supplements 271-1, Development of Qualification Standards; 271-2, Tests and Other Applicant Appraisal Procedures; 335-1, Evaluation of Employees for Promotion and Internal Placement; and 990-1 (Book III), part 900, subpart F, Administration of Standards for a Merit System of Personnel Administration of the Federal Personnel Manual in order to insure the examining, testing standards, and employment practices are not affected by discrimination on the basis of race, color, religion, sex or national origin.

Effective date: September 25, 1978.

ALAN K. CAMPBELL,
Chairman,
Civil Service Commission.

[6570-06]

DEPARTMENT OF JUSTICE

Title 28—Judicial Administration

CHAPTER 1—DEPARTMENT OF JUSTICE

PART 50—STATEMENTS OF POLICY

Uniform Guidelines on Employee Selection Procedures (1978)

The Uniform Guidelines on Employee Selection Procedures which are provided at the beginning of this part IV in today's FEDERAL REGISTER are adopted by the Department of Justice, in conjunction with the Civil Service Commission, Equal Employment Opportunity Commission, and the Department of Labor to establish a uniform Federal position in the area of prohibiting discrimination in employment practices on grounds of race, color, religion, sex, or national origin. Cross reference documents are published at 5 CFR 300.103(c), (Civil Service Commission) 29 CFR 1607 (Equal Employment Opportunity Commission), and 41 CFR 60-3 (Department of Labor), elsewhere in this issue of the FEDERAL REGISTER.

By virtue of the authority vested in me by 28 U.S.C. 509 and 5 U.S.C. 301, Sec. 50.14 of part 50 of chapter 1 of title 28 of the Code of Federal Regulations is amended by substituting the Uniform Guidelines on Employee Selection Procedures (1978) for part I through part IV.

Effective date: September 25, 1978.

GRIFFIN B. BELL,
Attorney General.

[6570-06]

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Title 29—Labor

CHAPTER XIV—EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

PART 1607—UNIFORM GUIDELINES ON EMPLOYEE SELECTION PROCEDURES (1978)

The Uniform Guidelines on Employee Selection Procedures which are printed at the beginning of this part IV in today's FEDERAL REGISTER are adopted by the Equal Employment Opportunity Commission, in conjunction with the Civil Service Commission, Department of Justice, and the Department of Labor to establish a uniform Federal position in the area of prohibiting discrimination in employment practices on grounds of race, color, religion, sex, or national origin. Cross reference documents are published at 5 CFR 300.103(c) (Civil Service Commission), 28 CFR 50.14 (Department of Justice) and 41 CFR 60-3 Department of Labor), elsewhere in this issue.

By virtue of the authority vested in it by sections 713 and 709 of title VII of the Civil Rights Act of 1964 (78 Stat. 265), as amended by the Equal Employment Opportunity Act of 1972 (Pub. L. 92-261), (42 U.S.C. 2000e-12 and 2000e-8), the Equal Employment Opportunity Commission hereby revises part 1607 of chapter XIV of title 29 of the Code of Federal Regulations by rescinding the Guidelines on Employee Selection Procedures (see 35 FR 12333, August 1, 1970; and 41 FR 51984, November 24, 1976) and adopting the Uniform Guidelines on Employee Selection Procedures (1978) as a new part 1607.

Effective date: September 25, 1978.

ELEANOR HOLMES NORTON,
Chair.

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[6570-06]

DEPARTMENT OF LABOR

Title 41—Public Contracts and Property Management

CHAPTER 60—OFFICE OF FEDERAL CONTRACT COMPLIANCE PROGRAMS, DEPARTMENT OF LABOR

PART 60-3—UNIFORM GUIDELINES ON EMPLOYEE SELECTION PROCEDURES (1978)

The Uniform Guidelines on Employee Selection Procedures which are printed at the beginning of this part IV of today's FEDERAL REGISTER are adopted by the Department of Labor, in conjunction with the Civil Service Commission, Department of Justice, and the Equal Employment Opportunity Commission to establish a uniform Federal position in the area of prohibiting discrimination in employment practices on grounds of race, color, religion, sex, or national origin. Cross reference documents are published at 5 CFR 300.103(c) (Civil Service Commission), 28 CFR 50.14 (Department of Justice) and 29 CFR 1607 (Equal Employment Opportunity Commission), elsewhere in this issue of the FEDERAL REGISTER.

By virtue of the authority of sections 201, 202, 203, 203(a), 205, 206(a), 301, 303(b), and 403(b) of Executive Order 11246, as amended, 30 FR 12319; 32 FR 14303; section 60-1.2 of part 60-1 of 41 CFR chapter 60, and section 715 of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000e-14), part 60-3 of chapter 60 of title 41 of the Code of Federal Regulations is revised by rescinding the Guidelines on Employee Selection Procedures (see 41 FR 51744, November 23, 1976) and adopting the Uniform Guidelines on Employee Selection Procedures (1978) as a new part 60-3.

Effective date: September 25, 1978.

RAY MARSHALL,
Secretary of Labor.

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[FR Doc. 78-23997 Filed 8-22-78; 4:48 pm]

federal register

FRIDAY, AUGUST 25, 1978
PART V

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Social Security Administration

Office of Human Development Services

Office of Child Support Enforcement

Health Care Financing Administration

■

GRANTS TO STATES FOR FINANCIAL ASSISTANCE PROGRAMS: SOCIAL SERVICES PROGRAMS; CHILD SUPPORT ENFORCEMENT PROGRAMING, AND FOR MEDICAL ASSISTANCE

General Policies and Procedures

[4110-07]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Social Security Administration

[45 CFR Parts 200, 201, 205, and 213]

GENERAL POLICIES AND PROCEDURES ON GRANTS TO STATES FOR FINANCIAL ASSISTANCE PROGRAMS

AGENCY: Social Security Administration, HEW.

ACTION: Notice of proposed rulemaking.

SUMMARY: These proposed regulations clarify, simplify, and reorganize into a single part of the Code of Federal Regulations (CFR) existing procedural rules on administration of grants to States for financial assistance programs. They also fill some gaps in existing policies on appeal procedures for State agencies. Comparable revisions, appearing in part V of this issue, are proposed for programs of child support enforcement, social services, and medical assistance. The revisions reflect the 1977 HEW reorganization, and they separate the financial assistance rules from those for other types of programs.

DATES: Comments must be received by October 24, 1978.

ADDRESSES: Please submit any comments regarding these changes in writing to the Commissioner of Social Security, Department of Health, Education, and Welfare, P.O. Box 1585, Baltimore, Md. 21203. Copies of all comments received in response to this notice will be available for public inspection during regular business hours at the Washington Inquires Section, Office of Information, Social Security Administration, Department of Health, Education, and Welfare, North Building, Room 5131, 330 Independence Avenue, Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT:

Ms. Jacqueline Porter, Office of Policy and Regulations, 6401 Security Boulevard, Baltimore, Md. 21235, telephone 301-594-6639.

SUPPLEMENTARY INFORMATION:

General Program Description

The Social Security Act provides formulas for Federal/State sharing in the costs of financial assistance programs under titles I, IV-A, X, XIV, and XVI (AABD). States and territories are entitled to Federal grants-in-aid for these programs when they are operated under plans approved by HEW. The proposed regulations contain policies and procedures for processing new State plans and plan amendments, for deferring, allowing, and disallowing payment of grants, for program and financial reviews by Federal officials, and for appeal of adverse decisions.

Reasons for Revising Regulations

The HEW reorganization order of March 8, 1977, disbanded the Social and Rehabilitation Service (SRS), which had previously administered the financial assistance grants, and Federal responsibility for the programs was transferred to the Social Security Administration.

On September 12, 1977, the Secretary of Health, Education, and Welfare (HEW) announced two major efforts at improving Departmental regulations. The first, "Operation Common Sense," is a 5-year effort to review and revise existing regulations to make them clearer and more useful. The second effort changed Departmental procedures for developing new regulations.

The Department's reorganization, coupled with the Secretary's directives on improving regulations, prompted this proposal. The amendments reflect the HEW organizational changes and use clearer, simpler, language. Additional content and format changes are outlined below.

Proposed Regulations Format

Under this proposal, general provisions and procedures for administering grants-in-aid are combined into a single part 200 which applies only to financial assistance programs. A similar reorganization is being proposed for regulations, which are presently intermingled with those for financial assistance, on programs of medical assistance, social services, and child support.

Proposed Content Changes

1. *Definitions.* The definitions section has been expanded.

2. *State cost allocation plans.* Responsibility for State cost allocation plans has been assigned to the Assistant Secretary for Management and Budget in HEW. Rules applicable to cost allocation plans appear in part 205 and not in part 200.

3. *Authority to aprove or disapprove a State plan or amendment.* Redelegations of Secretarial authority to approve and disaprove State plans and amendments result in both functions being performed by the Regional Commissioner. He or she will, however, consult with the Associate Commissioner for family assistance before issuing a disapproval notice. Under prior regulations, the Regional Commissioner could approve but disapproval was reserved to the Administrator of SRS after consultation with the Secretary. The proposed regulation makes the Regional Commissioner responsible for both positive and negative actions. By retaining a requirement for consultation at the national level, it also assures uniformity and objectivity in such decisions.

4. *Partial approval of plans and amendments.* A new provision reflects the existing practice of approving certain parts of a new plan or plan amendment even though other parts are disapproved. We believe this procedure can expedite incorporation of approvable provisions into State plans and, in some cases, result in earlier availability of Federal funds.

5. *Decisions on plan amendments not treated as new plans.* These regulations clarify and modify procedures for approval of plan amendments not treated as new plans. A decision to approve or disapprove will be made within 90 days of receipt in the Regional Office just as if the amendment were treated like a new plan. In cases of disapproval, a new provision assures the State of the right to a reconsideration by the Commissioner or his designee. There is now no specific regulatory provision for appeals on disapproved plan amendments of this type although the procedure applicable to disallowances (45 CFR 201.14) has been used. The new reconsideration process for these amendments is simpler and can produce decisions more promptly. It assures the State of a thorough review and a carefully considered decision.

6. *Establishing the submittal date of a plan or amendment.* A new section explains how to determine the submittal date of a proposed State plan or amendment. This is important to States for purposes of claiming Federal funds once the plan or amendment has been approved. Existing regulations are silent on this point.

7. *Authority to allow or disallow a State claim for payment.* These amendments reflect redelegations of Secretarial authority to permit the Regional commissioner to allow and disallow State claims for Federal reimbursement. However, the Regional Commissioner will consult with the Associate Commissioner for family assistance as directed before issuing a disallowance notice. Paralleling the strengthening of the regional role under item 3 above, this gives States a single focus for fiscal decisions. Previously the regional office could allow a claim but disallowances were made by the central office. The Regional Commissioner continues to have the authority to defer payment decisions in certain situations.

8. *Reconsideration of disallowances.* These regulations incorporate by reference new procedures for reconsideration of disallowances of State claims for Federal reimbursement. The new procedures contained in 45 CFR Part

16, Subpart C, and published on March 6, 1978, give final decision authority to the Departmental Grant Appeals Board rather than to the program administrators as provided in earlier regulations. These regulations allow 45 days, rather than the present 30, for a State to request reconsideration of a disallowance. They also give States the option of requesting the Commissioner to review a disallowance before seeking reconsideration by the Appeals Board. Any time devoted to such a review will not count toward the 45-day period for filing a formal reconsideration request.

9. *Format of a State plan.* 45 CFR 204.2 now requires that State plans be submitted in a certain format and within prescribed time limits. This is being incorporated into part 200 as a requirement related to the submission of a plan or amendment.

10. *Effective date for claiming Federal funds.* 45 CFR 205.5(b) now tells when Federal funding becomes available under an amended plan provision. That paragraph is being incorporated into part 200 and revised to distinguish more clearly between the period for which Federal funds can be claimed and the time at which they can be claimed (i.e., not until the new provision has been approved.)

11. *Formal hearing procedures.* The act requires that States be given an opportunity for formal hearings on new plan material which is disapproved and on intended compliance or conformity actions. these formal procedures, now at 45 CFR part 213, are being edited and incorporated into part 200. The result is that the proposed part covers the full sequence of possible processing events.

In addition, the amendments would revise existing regulations to show that a hearing must, as required by law, be set at least 20 (not 30) days from receipt of the hearing notice.

12. *Internal processing requirements.* A number of internal processing requirements do not appear in the proposed regulations. This type of information will be issued in the form of instructions and other issuances rather than in regulations.

Request for Public Comment

On March 29, 1978, several State agencies and special interest groups participated in a meeting to discuss how these regulations should be designed. In addition, internal Departmental discussions have been held to analyze alternatives for format and content of the regulations. To assist further in the decisionmaking process, we invite comments on these regulations, particularly in the following areas:

1. Usefulness of having regulations for a specific program in a single Chapter of the CFR;

2. Usefulness of regulations versus other methods of disseminating procedures; and

3. Effectiveness of concurrent revision of regulations affecting several programs when those rules have previously been intermingled. (See proposals from the Health Care Financing Administration, the Office of Child Support Enforcement, and the Office of Human Development Services.)

The proposed regulations are to be issued under the authority of section 1102 of the Social Security Act; 49 Stat. 647; 42 U.S.C. 1302.

(Catalog of Federal Domestic Assistance Program No. 13.761—Social and Rehabilitation Service programs.)

Dated: July 5, 1978.

DON WORTMAN,
Acting Commissioner of Social Security.

Approved: August 19, 1978.

HALE CHAMPION,
Acting Secretary of Health, Education, and Welfare.

Chapter II of 45 CFR is amended as follows:

1. 45 CFR Parts 201 and 213, and § 205.5(b) of part 205, as they apply to financial assistance programs under titles I, X, XIV, XVI (AABD), and part A of title IV of the Social Security Act, are partially redesignated as part 200 and are revised to read as follows:

PART 200—GENERAL POLICIES AND PROCEDURES ON GRANTS TO STATES FOR FINANCIAL ASSISTANCE PROGRAMS

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AUTHORITY: Sec. 1102, 49 Stat. 647; 42 U.S.C. 1302, unless otherwise indicated.

Subpart A—Introduction

§ 200.0 Scope.

Part 200 contains rules on grants to States under titles I, IV-A, X, XIV, and XVI (AABD) of the Social Security Act. (As used here, "AABD" refers to a program of grants to States for assistance to needy aged, blind, and disabled.) These titles authorize Federal/State sharing of the costs of providing assistance to needy families with dependent children in the 50 States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and the Northern Mariana Islands (90 Stat. 277); and assistance to needy aged, blind, and disabled persons in Guam, Puerto Rico, and the Virgin Islands. This part is divided into 5 subparts as follows:

(a) Subpart A contains descriptions of the financial assistance programs under titles I, X, XIV, XVI (AABD), and part A of title IV of the Act. It includes general definitions related to those programs.

(b) Subpart B describes State plans for financial assistance programs. It tells when a plan must be amended and how a new State plan or plan amendment is submitted, processed, and appealed when it is disapproved.

(c) Subpart C contains rules for computing and authorizing payment of Federal grants. This includes rules on when State claims for Federal funds may be deferred or disallowed and how disallowances may be appealed.

(d) Subpart D describes the types and effects of reviews conducted by Federal officials.

(e) Subpart E describes hearing procedures available to State agencies.

§ 200.1 Definitions.

As used in this part:

"Act" means the Social Security Act and titles referred to are titles of that act.

"AFDC" means a program of aid to families with dependent children under part A of title IV.

"Approvable State plan or plan amendment" means a proposed plan or amendment which meets all applicable Federal requirements.

"Associate Commissioner" means the Associate Commissioner for Family Assistance in the Social Security Administration.

"Central office" means the national headquarters of the Social Security Administration.

"Commissioner" means the Commissioner of Social Security.

"Compliance" means that a State agency is carrying out in practice what is required by Federal statutes, regulations, and pertinent court decisions and contained in the approved State plan.

"Conformity" means that a State plan meets the requirements of Federal statutes, regulations, and pertinent court decisions.

"Department" or "HEW" means the Department of Health, Educaiton, and Welfare.

"FFP" or "Federal financial participation" means the Federal Government's share of expenditures made by a State under a financial assistance program.

"Federal requirements" means Federal statutes, regulations, and instructions.

"Financial assistance program" means a State's program of assistance under title I, IV-A, X, XIV, or XVI (AABD).

"Medicaid" means medical assistance provided under a State plan approved under title XIX.

"Plan" or "State plan" means a comprehensive written commitment by a State agency to administer, or supervise the administration of, a financial assistance program in accordance with all Federal requirements. This does not include a cost allocation plan as described in 45 CFR 205.150.

"Plan amendment" or "amendment" means an amendment to an approved State plan under one of the financial assistance programs.

"Regional Commissioner" means a Regional Commissioner of the Social Security Administration.

"Regional Office" means one of the regional offices of the Social Security Administration.

"Secretary" means the Secretary of Health, Education, and Welfare.

"SSA" means the Social Security Administration.

"State" means a political jurisdiction which is eligible to submit a financial assistance program plan to HEW for approval.

"State agency" means the single State agency administering, or supervising the administration of, a State financial assistance plan.

Subpart B—State Plans and Plan Amendments

STATE PLANS AND AMENDMENTS IN GENERAL

§ 200.100 What a State plan is.

A State plan is a detailed description of the nature and scope of a State's financial assistance program. It commits a State agency to administering the program in accordance with Federal requirements. Only proper program expenditures which are made under an approved plan are eligible for Federal financial participation. The State agency must keep its approved plan current. SSA will not consider material as State plan material unless it is submitted as part of a State plan or amendment and approved by the regional Commissioner.

§ 200.101 When to amend a State plan.

(a) *When a State agency must change its plan.* A State agency must amend its plan whenever:

(1) A new or amended Federal law or regulation requires a new provision or conflicts with an existing plan provision; or

(2) A U.S. Supreme Court decision changes the interpretation of a law or regulation; or

(3) State law, organization, policy, or agency operation undergoes a significant change.

(b) *Automatic nullification of plan provisions.* When a Federal statute or a U.S. Supreme Court decision invalidates a plan provision, it also, on its effective date, automatically nullifies any conflicting provisions of an approved State plan.

SUBMISSION OF PROPOSED STATE PLANS AND PLAN AMENDMENTS

§ 200.110 How to submit a proposed State plan or plan amendment.

(a) *General.* A State agency must submit a proposed State plan or plan amendment to the Regional Commissioner in accordance with SSA instructions concerning format, content, time limits, transmittal forms, and procedures.

(b) *How plan amendments may be treated.* At the time of submittal, a State agency may ask to have a plan amendment treated as a new State plan.

(1) If such a request is made and the amendment is disapproved, the State agency has a right to a hearing under section 1116 of the Act and to judicial review. (See § 200.132.)

(2) If a plan amendment is not treated as a new State plan and the amendment is disapproved, the State agency may appeal as described in § 200.133.

(c) *Review by Governor.* When submitting a proposed State plan or plan amendment to the Regional Commissioner, the State agency shall specify that the Governor or the Governor's designee:

(1) Was given 45 days to review the material and that resulting comments, if any, are included in the submittal; or

(2) Did not wish to review the material. (See § 204.1 for State plan requirements regarding Governor's review.)

§ 200.111 How submittal date is determined.

(a) *General.* The submittal date of a proposed State plan or plan amendment is the date it is mailed to the Regional Office as established by the State agency (for example, in the form of a postmark, registered mail date, or affidavit of mailing). If the material is delivered by hand, the submittal date is that shown by the Regional Office date stamp.

(b) *When submittal date changes.* If a proposed State plan, amendment, or portion of an amendment is not approvable because it does not meet a Federal requirement, the date on which the required change is mailed or delivered to the Regional Office becomes the submittal date.

(c) *When submittal date remains unchanged.* If a new State plan, amendment, or portion of an amendment is approvable but requires clearer wording, the clarifying revision retains the date of the original submittal.

APPROVAL AND DISAPPROVAL OF PROPOSED STATE PLANS AND PLAN AMENDMENTS

§ 200.120 Who can approve or disapprove.

The Regional Commissioner has the authority to approve or disapprove a proposed State plan or plan amendment. Before disapproving, the Regional Commissioner consults with the Associate Commissioner. (See § 200.306 for rules on deciding that a previously approved plan provision no longer meets Federal requirements.)

§ 200.121 Partial or total approval.

(a) *State plan.* SSA approves a State plan only if it meets all Federal requirements. If any required provision is unapprovable or is omitted, SSA will disapprove the entire plan. However, SSA may disapprove sections of a State plan which relate to optional Federal provisions without affecting approval of the rest of the plan.

(b) *Plan amendment.* SSA need not approve or disapprove a proposed plan amendment in its entirety, regardless of whether the State agency asks to have it treated as a new State plan. SSA may approve amendments to specific parts of a State plan and disapprove amendments to other parts.

§ 200.122 What the decision deadline is.

(a) *General.* The Regional Commissioner has 90 days from receipt of a State agency's submittal to issue a decision approving or disapproving a proposed State plan or plan amendment.

(b) *Extension.* The Regional Commissioner and the State agency may agree in writing to an extension of the 90-day period.

§ 200.123 Effective dates and FFP under approved State plans or amendments.

(a) *When a plan or amendment affecting FFP becomes effective.* An approved State plan or plan amendment which affects FFP becomes effective on the later of the following dates:

(1) The first day of the calendar quarter in which an approvable plan or amendment was submitted (see § 200.111 for submittal date); or

(2) The first date on which the plan or amendment is in operation statewide.

(b) *When an amendment not affecting FFP becomes effective.* When an amendment does not affect FFP, it becomes effective on the date set by the State agency.

(c) *When claim for FFP can be submitted.* A State agency shall not submit claims for new or additional expenditures made under a plan or amendment until it has been approved.

§ 200.124 How State is notified

(a) *Approval.* When the Regional Commissioner approves a proposed State plan or plan amendment, he or she notifies the State agency in writing.

(b) *Disapproval.* When the Regional Commissioner, after consulting with the Associate Commissioner, disapproves part or all of a proposed State plan or plan amendment, he or she notifies the State agency in writing. That notice gives the reason for disapproval and informs the State agency that it has 60 days to request reconsideration by the Commissioner (see § 200.130).

RECONSIDERATIONS OF DISAPPROVALS OF STATE PLANS AND PLAN AMENDMENTS

§ 200.130 What reconsideration procedures apply.

(a) *For new plans and plan amendments treated as new plans.* Section 1116 of the Act requires the Secretary to provide a reconsideration to the State of disapproval of a State plan or a plan amendment which is treated as a new State plan. (See § 200.132 for procedures.) For purposes of this subpart, the term "new plan material" includes both categories.

(b) *For plan amendments not treated as new plans.* A State agency also may request reconsideration of disapproval of a plan amendment which is not treated as a new plan. (See § 200.133 for procedures.)

§ 200.131 What happens to FFP pending outcome of reconsideration.

When a State agency requests reconsideration of disapproval of a State plan or plan amendment, FFP in any new or increased expenditures under the disapproved plan or amendment is not available until a final decision is made. If the decision is favorable to the State agency, the Commissioner will certify lump-sum payment of any amount due.

§ 200.132 Procedures for reconsideration of disapproved new plan material.

(a) *How to request.* A State agency has 60 days from receipt of SSA's written notice of disapproval of new plan material to request reconsideration. The State agency shall make the request in writing to the Commissioner with a copy to the Regional Commissioner.

(b) *Acknowledgment of request.* Within 30 days of receiving the reconsideration request, the Commissioner notifies the State agency in writing of the date, time, and place of a hearing and of the issues to be considered. (See subpart E for hearing procedures.)

(c) *Judicial review.* If a State agency is not satisfied with a hearing decision, it may seek judicial review in the U.S. Court of Appeals for the circuit in which the State is located.

(d) *Commissioner determines related issues exist.* If a State agency requests a hearing on the disapproval of a new plan or plan amendment, the commissioner will also determine whether a related compliance issue exists. If it does, that issue will be included in the hearing as described in § 200.407(b).

§ 200.133 Procedures for reconsideration of a disapproved plan amendment not treated as a new plan.

(a) *How to request.* A State agency has 60 days from receipt of SSA's written notice of disapproval to request reconsideration of a plan amendment not treated as a new State plan. The State agency shall make the request in writing to the Commissioner with a copy to the Regional Commissioner.

(b) *Acknowledgment of request.* The Commissioner acknowledges a State agency's request for reconsideration promptly and in writing.

(c) *Submittal of information.* (1) SSA will promptly send the State agency a list of all material that is part of the record. SSA will also make this material available for the State agency's inspection and copying.

(2) The Regional Commissioner and the State agency have 30 days from the transmittal date of SSA's list to submit any additional material to the commissioner and to each other. If the Regional Commissioner or the State agency submits additional material the other party has 20 days from the transmittal date to respond in writing to the Commissioner.

(d) *Right to conference.* (1) At any time during the period allowed under paragraph (c) of this section, the State agency may request a conference with the Commissioner to discuss the issues.

(2) The State agency may have the conference transcribed at its own expense. Upon its request, the transcript becomes part of the record.

(e) *What the record is.* All materials considered in reaching a decision constitute the record of a reconsideration. The record closes on the later of the following dates:

(1) Expiration of the period allowed under paragraph (c) of this section; or

(2) If there is a conference and the transcript becomes part of the record, when the Commissioner receives the transcript; or

(3) If there is a conference and the transcript does not become part of the record, 30 days after the conference.

(f) *How the decision is issued.* Within 60 days after the record is closed, the Commissioner or the person designated to preside at the conference will issue a written decision. He or she will send that decision to the head of the State agency.

(g) *Extension of time limits.* Either the State agency or the Regional Commissioner may, for good cause, request an extension of the time limits in this section.

Subpart C—Awards and Payments to States

Awards and Payments in General

§ 200.200 When FFP can be claimed.

A State agency may claim Federal funds for expenditures for financial assistance, training, and related administration under an approval State plan and other Federal requirements, including prior approval of certain classes of expenditures as required by, and in conformity with, an approved cost allocation plan. (See § 200.123 for the effective date of a new plan or amendment.)

§ 200.201 What the State agency is responsible for.

The State agency is responsible for submitting (or, at the option of SSA, making available) all documentation required by SSA in the format specified to establish the allowability of its claims for FFP. (See §§ 200.230–200.232 on deferrals and § 200.222 on disallowances.)

§ 200.202 Administration of grants.

(a) *General.* Unless otherwise indicated, all grants made to State under this part are subject to the provisions of part 74 of this title, Administration of Grants.

(b) *Exception.* Subpart G, Matching and Cost Sharing, and Subpart I, Financial Reporting Requirements, of part 74 of this title do not apply to these grants.

Submission of Claims

§ 200.210 How grant awards are issued.

(a) *Amount of grant.* Subject to the availability of Federal funds, the Commissioner or the Commissioner's designee issues a grant award for each quarter. The grant award is based on the Regional Commissioner's estimate for that quarter, reduced or increased to the extent of any prior quarter's overpayment or underpayment for which adjustment has not already been made. Examples of adjustments which reduce or increase grant awards include:

(1) The difference between the estimates for a quarter and the amount claimed by the State agency on its statement of expenditures for the quarter;

(2) Amounts (including penalties) which the Regional Commissioner disallows;

(3) Amounts which the Regional Commissioner defers;

(4) Amounts which the Regional Commissioner has deferred and later finds allowable;

(5) Amounts of recoveries, refunds, and collections as determined by the Regional Commissioner;

(6) Amounts which exceed statutory limitations on funds.

(b) *How State is notified.* Each quarter the Commissioner or the Commissioner's designee issues to the State agency a grant award showing the amounts awarded for each program. Accompanying the grant award is a form showing the basis on which the grant was computed. The Commissioner also notifies the State Central Information Reception Agency of the grant award in accordance with section 201 of the Intergovernmental Cooperation Act of 1968.

(c) *How the grant is paid.* The Departmental Federal Assistance Financing System (DFAFS) pays the grant. Subpart K of 45 CFR Part 74, Treasury Circular No. 1075, and the DFAFS Recipient Users Manual govern payment procedures.

200.211 How estimates are made.

(a) *State agency's estimate.* At least 45 days before the beginning of each quarter for which it is estimating funds, the State agency shall submit to the regional office estimates of the total amount, and the Federal share, of expenditures for each program.

(b) *SSA's estimate.* The State agency's quarterly estimate of expenditures and any investigations which the Regional Commissioner may find necessary form the basis for SSA's estimate of expenditures. SSA's estimate is the basis for making a grant award for that quarter.

§ 200.212 How expenditures are claimed.

(a) *What the quarterly statement of expenditures is.* The quarterly statement of expenditures is an accounting by a State agency for expenditures made during a quarter under a financial assistance program and the State agency's claim for Federal reimbursement.

(b) *How to submit the statement.* Within 30 days after the end of each calendar quarter, the State agency shall submit to the regional office a quarterly statement of expenditures for that quarter along with the necessary supporting schedules.

(c) *Rejection of statement.* If the quarterly statement of expenditures is based on estimates, it will be rejected. For this purpose, indirect costs calculated in conformance with approved cost allocation plans are acceptable. (See 45 CFR 205.150 for indirect costs.)

Allowance and Disallowance of Claims

§ 200.220 Who can allow or disallow.

(a) *General.* The Regional Commissioner has the authority to allow or disallow a claim, paid or unpaid, for FFP. Before disallowing, the Regional Commissioner consults with the Associate Commissioner as directed. As used in this subpart, the term "disallowance" does not include implementation of a decision to reduce or withhold FFP for lack of compliance or conformity (see §§ 200.305–200.306).

(b) *Exception.* The Commissioner retains authority to allow FFP in expenditures which have been questioned by the General Accounting Office, the HEW Audit Agency, or SSA officials.

§ 200.221. How a decision is made on a claim.

The Regional Commissioner allows or disallows a State's claim for FFP based on review and analysis of the quarterly statement of expenditures. In determining whether expenditures are allowable, regional or central office officials may conduct onsite reviews involving examination of State agency accounting and operational records and discussions with State officials and third parties. (See Subpart D on Federal Reviews.)

§ 200.222 What happens when a claim is disallowed.

(a) *General.* A disallowance is a finding by the Regional Commissioner, after consulting with the Associate Commissioner, that a State agency's claim for FFP is not properly chargeable to the program. Because of statu-

tory penalties and limitations, the Regional Commissioner may also disallow amounts which are otherwise properly chargeable to the program.

(b) *How State agency is notified.* If any portion of the amount claimed on a quarterly statement of expenditures is disallowed, the Regional Commissioner's notice to the State agency includes pertinent information on amounts, dates, and reasons for the disallowance. The notice also indicates that the State agency may request reconsideration of the disallowance as described in § 200.223.

§ 200.223 How to appeal disallowance of a claim.

(a) *How to request.* A State agency has 45 days from the date of SSA's disallowance notice to request reconsideration under 45 CFR Part 16. The request shall be addressed to the Executive Secretary, Departmental Grant Appeals Board, with copies to the Commissioner and the Regional Commissioner.

(b) *What happens to a claim pending reconsideration decision.* (1) If reconsideration is requested on the disallowance of an amount already paid to a State, no action will be taken to recover the Federal funds pending the reconsideration decision.

(2) If reconsideration is requested on the disallowance of an amount not already paid to a State, that amount will not be paid pending the reconsideration decision.

(c) *Commissioner's review before reconsideration.* A State agency may, as specified by SSA, request the Commissioner to review a disallowance before seeking reconsideration by the Grant Appeals Board. The Commissioner may decline. The State agency may also withdraw its review request at any time. If the Commissioner reviews a disallowance, his or her decision is SSA's final action on the matter, and time devoted to that review does not count toward the 45-day period for requesting reconsideration under paragraph (a) of this section.

DEFERRAL OF CLAIMS PAYMENT

§ 200.230 What deferral is.

As used in this subpart C, "deferral" refers to suspension of the decision on the allowability of a claim for FFP pending the inspection and analysis of further information. The Regional Commissioner can defer the inclusion of a claim in the computation of a grant award (see 200.210) if it is of questionable allowability.

§ 200.231 How deferral occurs.

(a) *Notice to State agency.* The Regional Commissioner takes deferral action within 60 days after receiving an acceptable quarterly statement of expenditures. Within 15 days after the deferral action, the Regional Commissioner sends the State agency written notification identifying the type and amount of the claim and the reason for deferral. The notice will also request the State agency to make available for inspection all materials which the Regional Commissioner considers necessary to determine the allowability of the claim.

(b) *How State agency responds.* Within 60 days of the date of the Regional Commissioner's deferral notice, the State agency shall make any requested materials available to the regional office in readily reviewable form. If the State agency requires additional time to make materials available, the Regional Commissioner, upon request, will give it an additional period of no more than 60 days.

§ 200.232 How decision is made on a deferred claim.

(a) *Review of State agency materials.* The Regional Commissioner will review all materials furnished under § 200.231 and, within 30 days of their receipt, notify the Stage agency if they are not readily reviewable or need supporting information. The State agency has 15 days from the date of this notification to make available revised or additional materials. If the state agency does not make the required materials available, the Regional Commissioner will promptly disallow the claim.

(b) *How action is taken on deferred claim.* After the State agency has made all required materials available in acceptable form, the Regional Commissioner will allow or disallow a deferred claim and notify the State agency in writing of the decision. If the Regional Commissioner does not notify the Stage agency within 90 days after the required materials become available, SSA will include the claim in the computation of a grant award, subject to a possible disallowance later.

INSTALLMENT REPAYMENT OF FEDERAL FUNDS

§ 200.240 General.

(a) *When Federal funds must be repaid.* When a claim has been paid and is later determined to be unallowable, the State must repay the unallowable amount.

(b) *When the State may repay in installments.* A State may repay in installments if:

(1) The total amount to be repaid exceeds 2½ percent of the State's share of annual expenditures under the program in which the unallowable expenditures occurred; and

(2) Before repayment is otherwise due, the State notifies the Regional Commissioner in writing of its intention to repay in installments.

(c) *Exclusion of other installment repayments.* For purposes of §§ 200.240–200.243, the amount of a repayment does not include any amount previously approved for installment repayment.

§ 200.241 How to set the repayment schedule.

(a) *How many quarters the repayment may cover.* In order to determine the number of quarters over which repayment may be spread, the State computes this repayment as a percentage of the State agency's share of annual expenditures under the program in which the unallowable expenditures occurred. Using that percentage, the maximum number of calendar quarters over which a State may spread repayment is:

Total repayment amount as percentage of state agency share of annual expenditures for the specific program	Number of quarters to make repayment
2.5 or less	1
Greater than 2.5, but no greater than 5	2
Greater than 5, but not greater than 7.5	3
Greater than 7.5, but not greater than 10	4
Greater than 10, but not greater than 15	5
Greater than 15, but not greater than 20	6
Greater than 20, but not greater than 25	7
Greater than 25, but not greater than 30	8
Greater than 30, but not greater than 47.5	9
Greater than 47.5, but not greater than 65	10
Greater than 65, but not greater than 82.5	11
Greater than 82.5, but not greater than 100	12
Greater than 100	13 plus

(b) *How much must be repaid in an installment.* (1) Except for the final repayment, the amount due for each quarter in a repayment schedule shall not be less than the following percentages of the State agency's share of annual expenditures for the program in which the unallowable expenditures occurred:

For each of the following quarters	Repayment amount may not be less than these percentages
1 to 4	2.5
5 to 8	5.0
9 plus	17.5

(2) If the State pays higher percentages during the early quarters of its repayment schedule, it applies any corresponding reduction in the minimum percentages first to the last repayment scheduled, then to the next to last, and so on.

§ 200.242 How to determine a State agency's share of expenditures.

(a) *General.* A State agency's share of annual expenditures under a program in which unallowable expenditures occurred is based on its most recent estimate a shown in the quarterly statement of financial plan for that program. The State agency's share is the sum of its shares for four quarters, beginning with the quarter in which the first repayment is due.

(b) *Exception.* If the program in which the unallowable expenditures occurred has been terminated, the State agency's share is based on its quarterly statements of expenditures for that program. The State agency's share is the sum of its shares of allowable actual expenditures for the last four quarters preceding the date on which the program was terminated.

§ 200.243 How to make repayment.

(a) *General.* SSA will deduct the appropriate repayment amount from each quarterly grant in accordance with the repayment schedule.

(b) *Retroactive claims.* If SSA has allowed a State's retroactive claim for FFP, SSA will offset the amount of that claim against any amounts to be repaid by the State in installments under the same financial assistance program. (For purposes of this section, a retroactive claim is one applicable to any period ending 12 months or more prior to the beginning of the quarter in which Federal funds are to be paid.) Under this provision, a State may:

(1) Suspend repayments until the retroactive claim has been offset; or

(2) Continue repayments until the reduced amount of its debt (remaining after the offset) has been paid in full.

(c) *When interest is charged on repayments.* SSA will not charge interest on repayments unless required by court order.

Subpart D—Federal Program and Financial Reviews and Audits

Federal Reviews and Audits in General

§ 200.300 What Federal reviews and audits are.

As used in this Subpart D, a Federal review or audit is any examination necessary to determine whether a State plan continues to be approvable and whether State agency operations and claims for FFP are proper under Federal requirements and the approved State plan. A review or audit may cover any aspect of a financial assistance program and may be performed by SSA or by another Federal agency. Audits are not limited to those performed by the General Accounting Office and the HEW Audit Agency.

§ 200.301 Types and effects of reviews and audits.

(a) *Types.* The types of Federal reviews and audits most often conducted are:

(1) Program and financial reviews as described in §§ 200.305-200.306; and

(2) HEW Audit Agency audits as described in § 200.310.

(b) *Effects.* Any review or audit may result in a disallowance or in formal compliance or conformity action.

Program and Financial Reviews

§ 200.305 Program and financial reviews in general.

(a) *Responsibility for review.* The Regional Commissioner will conduct program and financial reviews at whatever times he or she considers appropriate. In doing so, the Regional Commissioner may make use of any procedures (including onsite review) or specialized assistance needed.

(b) *Purpose of review.* The purpose of a program or financial review is to determine the nature and scope of a State's financial assistance program in relation to Federal requirements and the State plan. Program and financial reviews include:

(1) Determining the allowability of claims;

(2) Evaluating a program's quality and the State agency's need for technical assistance;

(3) Determining whether a State plan conforms with Federal requirements. (A question of conformity may arise when a State agency fails to submit an approvable plan amendment to implement a new Federal requirement; when previously approved plan material no longer meets Federal requirements; or when plan material has been approved in error.)

(4) Determining whether the State's operating practices are in substantial compliance with the approved State plan and with Federal requirements.

(c) *Review findings.* SSA will make all review findings available in writing to the State agency so that it can correct any unacceptable policy or practice. If a review results in disallowance of a claim, the procedures in §§ 200.222-200.223 will apply.

§ 200.306 Issues of compliance or conformity after review.

(a) *Regional Commissioner tries to resolve.* If the Regional Commissioner believes there is a compliance or conformity issue, he or she will try to obtain needed changes in the State agency's operating practice or the State plan.

(b) *Issues not resolved.* If the State agency does not make the changes necessary to bring about compliance or conformity:

(1) The Regional Commissioner will recommend that the Commissioner begin formal action; and

(2) If the Commissioner agrees that there is an issue of compliance or conformity, he or she will notify the State agency and give it an opportunity for a hearing under Subpart E.

HEW Audit Agency Reviews and Audits

§ 200.310 What the HEW Audit Agency does.

The HEW Audit Agency (Audit Agency) in the HEW Inspector General's Office conducts both routine and special reviews and audits. These are to assure that Federal funds are being spent properly and prudently.

§ 200.311 Audit Agency reports.

Upon completion of an audit or review, the Audit Agency releases its final report. The report contains the Audit Agency's findings and recommendations on the practices reviewed and the allowability of expenditures audited.

§ 200.312 Action on Audit Agency reports.

When the Audit Agency questions a claim, the Regional Commissioner may disallow FFP and notify the State agency accordingly. (See § 200.220(b) for exception.) When the Audit Agency finds problems of compliance, the Commissioner decides whether to take formal compliance action and notifies the State agency accordingly.

Subpart E—Hearing Procedures for State Agencies

General

§ 200.400 Scope.

(a) *General.* The act requires that a State agency be given an opportunity for hearings on certain matters. Hearing procedures described in this Subpart E apply to:

(1) Reconsideration of a disapproved State plan or plan amendment which is treated as a new plan; and

(2) Notification of formal compliance or conformity action.

(b) *Negotiations.* Nothing in this Subpart limits negotiations between the Department and the State. Negotiations on hearing issues are not part of the hearing and are not subject to the rules in this Subpart unless there is a specific indication to the contrary.

§ 200.401 General rules.

(a) *How to get records.* All papers filed in connection with a hearing are available for inspection and copying in the Office of the SSA Hearing Clerk. Individuals should direct inquiries to the Central Information Center, Department of Health, Education, and

Welfare, 200 Independence Avenue SW., Washington, D.C. 20201.

(b) *How to file and serve papers.* (1) Anyone who wishes to submit papers for the docket shall file with the SSA Hearing Clerk an original and two copies, but only originals of exhibits and testimony transcripts.

(2) Anyone who wishes papers to be part of the record shall also serve copies on all parties by personal delivery or by mail. Service on a party's designated attorney is the same as service on the party.

(c) *When rules are suspended.* The Commissioner or the presiding officer may, after notifying all parties, modify or waive any rule in §§ 200.401—200.421 if he or she decides the action is equitable and will not unduly prejudice the rights of any party.

ARRANGEMENTS FOR HEARING

§ 200.405 How to request hearing.

A State agency has 60 days, from receipt of SSA's written notice of plan disapproval or intended compliance or conformity action, to request a formal hearing. The State agency makes its request in writing to the Commissioner with a copy to the Regional Commissioner.

§ 200.406 How request is acknowledged.

(a) *Notice of hearing.* Within 30 days of receiving a hearing request, the Commissioner will notify the State agency in writing of the date, time, and place of the hearing and of the issues to be considered. The Commissioner will publish the hearing notice in the FEDERAL REGISTER.

(b) *When the hearing must be set.* the date set for a hearing will be at least 20, but no more than 60, days from the date the State agency receives the hearing notice. However, the State agency and the Commissioner may agree in writing to a different date.

§ 200.407 What the hearing issues are.

(a) *General.* The issues at a hearing are those included in the notice to the State agency described in § 200.406.

(b) *How the Commissioner may add issues.* At least 20 days before a scheduled hearing, the Commissioner will notify the State agency in writing of any additional issues to be considered. The Commissioner will also publish this notice in the FEDERAL REGISTER. If the State agency does not receive its notice in the required time, any party may request the Commissioner to postpone the hearing. If a request is made, the Commissioner will set a new hearing date which is at least 20, but not more than 60, days from the date the State agency receives the hearing notice.

(c) *How actions by the State may cause the Commissioner to add, modify, or remove issues.* The Commissioner may add, modify, or remove issues if, for example, the State agency:

(1) Changes its practices to comply with Federal requirements and its State plan; or

(2) Conforms its State plan to Federal requirements and pertinent court decisions.

(d) *What happens when State action causes the Commissioner to add, modify, or remove issues.*

(1) If the Commissioner specifies new or modified issues, the hearing will proceed on these issues.

(2)(i) If the Commissioner removes an issue, the hearing will proceed on the remaining issues. If the Commissioner removes all the issues, he or she will terminate the hearing proceedings. The Commissioner may terminate hearing proceedings or remove issues before, during, or after the hearing.

(ii) Before removing any issue, the Commissioner will notify all parties other than the Department and the State. This notice contains the reasons for removing the issue. Within 20 days of the date of this notice, the parties may submit comments in writing on the merits of the proposed removal. The Commissioner will consider these comments and they become a part of the record.

§ 200.408 What the purpose of a hearing is.

The purpose of the hearing is to receive factual evidence and testimony, including expert opinion testimony, related to the issues. The presiding officer will not allow argument as evidence.

§ 200.409 Who presides.

The presiding officer at a hearing is the Commissioner or a person he or she appoints. If the Commissioner appoints a presiding officer, the Commissioner will send copies of the appointment notice to all parties.

§ 200.410 How to be a party or an amicus curiae to a hearing.

(a) *HEW and State agency.* HEW and the State agency are parties to a hearing without having to request participation.

(b) *Other parties of amici curiae.* Any individual or group wishing to be a party or amicus curiae to a hearing must file a petition with the SSA Hearing Clerk no more than 15 days following publication of the hearing notice in the FEDERAL REGISTER. A petitioner who wishes to be a party must also provide a copy of the petition to each party of record at that time.

(c) *What must be in a petition.* A petition must state concisely:

(1) The petitioner's interest in the proceedings:

(2) Who will appear for the petitioner;

(3) The issue on which the petitioner wishes to participate; and

(4) Whether the petitioner intends to present witnesses, if the petitioner wishes to be a party.

(d) *What happens to a petition.* (1) The presiding officer will determine promptly whether each petitioner has the necessary interest in the proceedings and permit or deny the petition accordingly and in writing. Before making this determination, the presiding officer will allow any party to file comments on the petition to be a party. Any party who wishes to file comments must do so within 5 days of receiving the petition. If the presiding officer denies the petition, he or she will state the reasons.

(2) The presiding officer may decide that individuals or groups who have become parties on petition have common interests. He or she may then request that they designate a single representative or may recognize two or more of those parties to represent all of them.

(e) *What rights parties have.* Any party may:

(1) Appear by counsel or other authorized representative in all hearing proceedings;

(2) Participate in any prehearing conference held by the presiding officer;

(3) Stipulate facts which, if uncontested, will become part of the record;

(4) Make opening statements;

(5) Present relevant evidence;

(6) Present witnesses who must be available for cross-examination;

(7) Present oral arguments at the hearing; and

(8) Submit written briefs, proposed findings of fact, and proposed conclusions of law, after the hearing.

(f) *What rights amici curiae have.* Any amicus curiae may:

(1) Present an oral statement at the hearing at the point in the proceedings specified by the presiding officer;

(2) Submit a written statement of position to the presiding officer before the hearing begins; and

(3) Submit a brief or written statement at the same time as the parties submit briefs.

If an amicus curiae submits a written statement or brief, he or she shall serve a copy on each party.

CONDUCT OF HEARING

§ 200.415 Authority of presiding officer.

(a) *General.* It is the duty of the presiding officer to conduct a fair hearing, avoid delay, maintain order, and make a record of the proceedings. He

or she has authority to carry out these duties. This includes the authority to:

(1) Regulate the course of the hearing;

(2) Regulate the participation and conduct of parties, amici curiae, and others at the hearing;

(3) Rule on procedural matters and, if necessary, issue protective orders or other relief to a party against whom discovery is sought;

(4) Take any action authorized by the rules in this Subpart;

(5) Make a final decision if the Commissioner is the presiding officer;

(6) Administer oaths and affirmations;

(7) Examine witnesses; and

(8) Receive or exclude evidence or rule on or limit evidence or discovery.

(b) *What the presiding officer cannot do.* The presiding officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(c) *When the presiding officer's authority is limited.* If the presiding officer is not the Commissioner, he or she does not have authority to:

(1) Make a final decision but shall certify the entire record to the Commissioner, including recommended findings and proposed decisions;

(2) Recommend reduction or withholding of FFP in matters of compliance or conformity.

§ 200.416 Discovery.

Any party has the right to conduct discovery against other parties. These discovery proceedings are subject to rules 26-37, Federal Rules of Civil Procedure. The presiding officer shall promptly rule on any written objection to discovery and may restrict or control discovery so as to prevent undue delay in the hearing. If any party fails to respond to discovery procedures, the presiding officer may issue any order and impose any sanction (other than contempt orders) authorized by rule 37 of the Federal Rules of Civil Procedure.

§ 200.417 How evidence is handled.

(a) *Testimony.* Witnesses, under oath or affirmation, give oral testimony at a hearing. All witnesses must be available at the hearing for cross-examination by all parties.

(b) *Rules of evidence.* Technical rules of evidence do not apply to hearings described in this subpart E. The presiding officer applies whatever rules or principles are necessary to assure disclosure of the most credible evidence available and to subject testimony to cross-examination. Cross-examination may be on any material matter regardless of the scope of direct examination.

§ 200.418 What happens to unsponsored written material.

Letters and other written material regarding matters at issue, when not submitted specifically on behalf of one of the parties, will become part of the correspondence section of the docket. This material is not part of the evidence or the record.

§ 200.419 What the record is.

(a) *Official transcript.* HEW designates the official reporter for a hearing. The SSA Hearing Clerk has the official transcript of testimony, as well as any other materials submitted with the official transcript. The parties and the public may obtain transcripts of testimony from the official reporter at rates which do not exceed the maximum fixed by contract between the official reporter and HEW. Upon notice to all parties, the presiding officer may authorize corrections to the transcript which involve matters of substance.

(b) *Record.* The record for the hearing decision consists of the transcript of testimony, exhibits, and all papers and requests filed in the proceedings except for the correspondence section of the docket. The record includes rulings and any decisions.

AFTER THE HEARING

§ 200.420 Posthearing briefs.

The presiding officer shall fix the time for filing posthearing briefs. These may contain proposed findings of fact and conclusions of law. The presiding officer may permit filing of reply briefs.

§ 200.421 Decisions.

(a) *When the Commissioner is presiding officer.* If the Commissioner is the presiding officer, he or she will issue a final decision within 60 days after expiration of the time allowed for filing of posthearing or reply briefs.

(b) *When the Commissioner appoints a presiding officer.* If the Commissioner appoints a presiding officer:

(1) After the time for filing posthearing or reply briefs has expired, the presiding officer shall certify the entire record, including his or her recommended findings and proposed decision, to the Commissioner.

(2) The Commissioner will provide a copy of the recommended findings and proposed decision to all parties and any amici curiae. Within 20 days, a party may file with the Commissioner exceptions to the recommended findings and proposed decision. The party must file a supporting brief or statement with the exceptions.

(3) The Commissioner will review the presiding officer's recommended findings and proposed decision and, within 60 days of receiving them, issue a final decision. The Commissioner will provide copies of that decision to all parties and any amici curiae.

(c) *When the decision involves nonconformity or noncompliance.* When the Commissioner decides, after a formal hearing, that nonconformity or substantial noncompliance exists, the final decision will state whether payments to the State will be withheld for the entire program or for specified portions of it.

§ 200.422 When a decision involving nonconformity or noncompliance becomes effective.

The Commissioner's decision will specify the effective date for any withholding of Federal payments because of nonconformity or substantial noncompliance. This effective date cannot be earlier than the date of the Commissioner's decision or later than the first day of the next calendar quarter.

PART 201—[REMOVED]

2. Part 201 is deleted.

PART 205—GENERAL ADMINISTRATION—PUBLIC ASSISTANCE PROGRAMS

3. 45 CFR Part 205 is further amended by deleting paragraph (b) of § 205.5 redesignating paragraph (a) § 205.5, and revising it to read as follows:

§ 205.5 State plan requirements on when to amend.

A State plan under title I, IV-A, X, XIV, XVI, or XIX of the Social Security Act must provide that the plan will be amended whenever necessary to reflect new or revised Federal statutes or regulations, U.S. Supreme Court decisions, or significant changes in State law, organization, policy, or agency operations.

PART 213—[REMOVED]

4. Part 213 is deleted.

[FR Doc. 78-23945 Filed 8-24-78; 8:45 am]

[4110-92]

Office of Human Development Services

[45 CFR Parts 201, 204, 213, and 228a]

POLICIES AND PROCEDURES ON GRANTS TO STATES FOR SOCIAL SERVICE PROGRAMS

Titles I, IV-A, X, XIV, XVI (AABD) and XX

AGENCY: Administration for Public Services (APS), Office of Human Development Services (HDS), Department of Health, Education, and Welfare.

ACTION: Proposed rule.

SUMMARY: This proposed regulation would clarify, simplify, modify, and reorganize into a single part 228a, existing procedural rules, located in several parts of this Code, on administration of grants to States for social services programs under six titles of the Social Security Act. The rules also fill some gaps in existing policies on appeal procedures for State agencies. Comparable revisions, appearing in part V of this issue are proposed for programs of child support enforcement and medical and financial assistance. The revisions reflect the 1977 HEW reorganization and separate social services program rules from those covering the same subject matter for other types of programs.

DATES: Consideration will be given to written comments or suggestions received on or before October 24, 1978. Agencies or organizations are requested to submit their comments in duplicate.

ADDRESS: Address comments to: Commissioner, Administration for Public Services, Department of Health, Education, and Welfare, P.O. Box 1923, Washington, D.C. 20013. Comments will be available for public inspection in room 2225 of the Department's offices at 330 C Street SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m.to 5 p.m., area code 202-245-9415.

FOR FURTHER INFORMATION CONTACT:

Mrs. Jonnie Brooks, 202-245-9415.

SUPPLEMENTARY INFORMATION:

BACKGROUND

This proposed regulation deals with certain portions of 45 CFR Parts 201, 204, 205, and 213 which directly governs policies and procedures for social services programs under titles I, IV-A, X, XIV, and XVI (AABD), and with those portions of part 201 and all of part 213 which apply to the title XX program because of reference to them in the title XX regulation, 45 CFR Part 228. The Administration for Public Services (APS) administers social services programs in the 50 States and the District of Columbia under title XX of the Act. APS also administers social services programs in Puerto Rico, Guam, and the Virgin Islands, and, potentially, in the Northern Marianas, under titles I, IV-A, X, XIV, and XVI (AABD) of the Act. Prior to March 8, 1977, APS was a bureau of the Social and Rehabilitation Service (SRS). An HEW reorganization order of that date disbanded (SRS). Its bureaus were dispersed to other major Administrations of the Department of Health, Education, and Welfare. The order transferred APS to the Office of Human Development Services (HDS).

On September 12, 1977, the Secretary of HEW announced two major efforts at improving Departmental regulations. The first, "Operation Common Sense," is a 5-year effort to review and revise existing regulations to make them clearer and more useful. The second effort changed Departmental procedures for developing new regulations.

The Department's organization, coupled with the Secretary's directives prompted this proposal which is the result of a joint effort by the bureaus formerly in SRS and their current parent Administrations.

This proposal combines provisions and procedures for administering grants-in-aid for social services programs into a single part. Other proposals combine similar provisions and procedures for financial assistance, medical assistance, and child support. As revisions of other parts of the regulations occur, this separation by program will continue so that eventually each program will have a complete body of regulations in a single location in the Code of Federal Regulations.

Titles I, IV-A, X, XIV, and XVI (AABD) govern social services programs in Puerto Rico, Guam, the Virgin Islands, and the Northern Marianas (the territories). Under these titles, a State plan is a comprehensive written commitment by the State agency to administer, or supervise the administration of, its social services program in conformity with all applicable Federal laws and regulations. This commitment covers all aspects of operation of the program including administrative, programmatic, and fiscal requirements. This State plan is subject to approval by the Office of Human Development (HDS), the arm of the Department that administers federally-funded social services programs.

Title XX governs social services programs in the 50 States and the District of Columbia (the States) and requires two State plans. One is the Comprehensive Annual Services Plan (CASP) which covers all programmatic and fiscal aspects of a State's program for the coming year. Included are such important programmatic items as coverage—i.e., those who are eligible, and program content—i.e., what services will be provided to which families and individuals in which areas of the State. HDS does not have the power to approve or disapprove the CASP. The CASP is published and made available to the public for review and comment. Changes in the CASP may result from this process. The regulations this rule proposes to revise do not control the CASP in any way.

The other title XX plan, the State plan, is subject to HDS approval but it is very narrow in scope. It deals only with administrative aspects of the title XX program. When the title XX regulations (45 CFR Part 228) were issued, the Department recognized that the board requirements of part 201 relating to State plans and amendments were not really appropriate for the narrow-gauge title XX State plan. However, because of the urgency to issue regulations governing the new social services program, it was expedient to apply the provisions of part 201 insofar as submittal of State plans and amendments was concerned. This proposed rewrite of part 201 presents an opportunity to provide regulations precisely suited to the distinctive nature of the title XX administrative State plan.

PROPOSED MODIFICATION OF THE REGULATIONS

This proposed rule contains several modifications of present requirements, as follows:

1. *Deletion of title VI.* Prior to the enactment of title XX, social services programs in the States were governed by titles IV-A (assistance payments and services for families and children) and VI (social services for the aged, blind, and disabled). Pub. L. 93-647 enacted title XX, effective October 1, 1975, and repealed title VI. Although title VI no longer exists, references to it had not been deleted from the portions of parts 201, 204, and 205 dealing with State plans and plan amendments.

The proposed rule deletes all references to title VI which was repealed when title XX became effective.

2. *Definitions.* We propose to add several definitions. Because of the distinct differences between the State plans for titles I, IV-A, X, XIV, and XVI (AABD) and the State plan for title XX, we believe it advisable to divide the definitions into three groups: those that apply to all the social services titles—i.e., titles I, IV-A, X, XIV, XVI (AABD), and XX (§ 228a.1); those that apply only to titles I, IV-A, X, XIV, and XVI (AABD) (§ 228a.2); and a definition that applies only to title XX (§ 228a.3).

3. *Partial approval of State plans and plan amendments.* Part 201 does not now deal with this subject. It is possible that a territory may wish to replace its present State plan with an entirely new one; or that the Northern Marianas will decide to submit a State plan for the initiation of a social services program. In either case, we propose to allow partial approval or disapproval of all optional provisions of State plans under titles I, IV-A, X, XIV or XVI (AABD). At the same time, we believe that the law requires

that if all mandatory provisions of the State plan are not approvable, we must disapprove the plan in its entirety. The proposed rule spells out this concept for the first time, but it is not a truly new requirement because it merely articulates, in regulations, a policy position that has always prevailed.

All title XX plan requirements are mandatory. This precludes partial approval or disapproval of title XX plan materials.

4. *Disapproval of State plans and plan amendments.* Part 201 provides that the Administrator, Social and Rehabilitation Service (SRS), will disapprove State plans and plan amendments after prior consultation and discussion with the Secretary. The proposed rule would authorize the Regional Administrator, HDS, to disapprove State plan materials, with concurrence of the Commissioner, Administration for Public Services. The title XX State plan, as previously pointed out, is so narrow in scope that the decision to disapprove should prove to be clearcut. The possibility of complicated problems in connection with disapproval of titles I, IV-A, X, XIV, and XVI (AABD) State plans still exists but now these plans apply only to the territories. In the past, the approval of these plans has presented no serious difficulties. The proposed rule also clarifies procedures which the State agency may take in appealing decisions made by the Regional Administrator to disallow State claims.

5. *Governor's review of State plan.* 45 CFR 204.1 now requires that a State plan provide for review of certain amendments and of certain reports by the Governor. This is being incorporated as a new section 228a.110(c).

6. *Format of a State plan.* 45 CFR 204.2 now requires that State plans be submitted in a certain format and within prescribed time limits. This is being incorporated as a new section 228a.110(a).

7. *Decisions on plan amendments not treated as new plans.* Procedures for approval of plan amendments not treated as new plans are clarified and modified in these regulations. A decision to approve or disapprove will be made within 90 days of receipt in the regional office just as if the amendment were treated like a new plan. In cases of disapproval, a new provision assures the State agency of the right to a reconsideration by the Assistant Secretary or designee.

There is now no specific regulatory provision for appeals on disapproved plan amendments of this type although the procedure applicable to disallowances (45 CFR 201.14) has been used. The new reconsideration process for these amendments is simpler and can produce decisions more promptly. We believe that it assures the State agency of a thorough review and a carefully considered decision.

8. *Establishing the submittal date of a plan or amendment.* A new section has been added explaining how the submittal date is officially determined. This is important to States for purposes of claiming Federal funds once the plan or amendment has been approved. Existing regulations are silent on this point.

9. *Effective date for claiming Federal funds.* 45 CFR 205.5(b) now tells when Federal funding becomes available under an amended plan provision. This is incorporated into part 228a and clarified to distinguish between the period for which Federal funds can be claimed and the time at which they can be claimed (i.e., not until the new provision has been approved).

10. *State cost allocation plans.* Responsibility for State cost allocation plans has been assumed directly by HEW rather than have it spread among several HEW agencies. Therefore, these regulations make it clear that rules applicable to cost allocation plans appear in part 205 and that part 228a does not include such plans.

11. *Authority to allow or disallow a State claim for payment.* These amendments reflect redelegations of secretarial authority to permit both allowance and disallowance decisions to be made by the Regional Administrator, HDS, this gives States a single focus for fiscal decisions. Previously the regional office could allow a claim but disallowances were the prerogative of the central office. The Regional Administrator, HDS, also continues to have the authority to defer payment decisions in certain situations.

12. *Changes in the reconsideration procedure.* When a State agency's claim for reimbursement of expenditures for any of the social services programs covered by this proposed regulation is denied, the State agency may request a reconsideration of the disallowance. The changes in subpart C have been made to accommodate the new HEW system of processing reconsiderations under the provisions of 45 CFR Part 16 which now completely replaces 45 CFR 201.14. The changes in the proposed regulations follow:

a. Under § 201.14, the Administrator of the now-defunct Social and Rehabilitation Service was the official who provided the final administrative action upon reconsiderations. Now the final arbiter is the Departmental Grant Appeals Board.

b. A new step in the reconsideration process is that the State agency may request a discussion with the Assistant Secretary, HDS, prior to requesting reconsideration by the Departmental Grant Appeals Board.

c. The period of time a State has to request a discussion with the Assistant Secretary or a reconsideration has been extended to 45 days from the 30 days set forth in 45 CFR 16.6(a). (45 CFR 16.6(a) authorizes the head of a program bureau to extend this time period, if desired.) This gives the State agency more time to assemble the needed information and decide whether or not it wants to appeal and in what way.

13. *Changes in the deferral of claims procedure.* Deferral of a claim for reimbursement of expenditures occurs when there is question about the allowabiity of a claim. A procedure is available to enable a State agency to make a case for allowability of the claim and for the Department to determine its validity. Subpart C deals with the procedure. Three changes from the procedure in the current § 201.15 are made in the proposed regulation:

a. The proposed regulation decreases from 60 days to 30 days the time extension period allowed for the State to prepare the requested materials to make its case (see § 228a.231(c)). The Department considers a 60-day extension period an excessive length of time and detrimental to the expeditious processing of deferral actions.

b. 45 CFR 201.15 does not speak to the time period within which the regional office has to communicate with the State agency about inadequate materials submitted by the State. Clarification was considered necessary on this point and so § 228.232 sets a limitation of 60 days on the Regional Administrator to notify the State agency if the materials have not been provided in the manner prescribed or if supplemental information is required.

c. The amount of time in which the Regional Administrator is required to make a decision on a deferral has been increased from 90 to 120 days. This is to permit a more thorough examination of the issues in a deferral.

14. *Calling of noncompliance and nonconformity.* Part 201 calls for procedures that may drag on for years before a State ever receives notification that its State plan is out of conformity, or that its operations do not comply with the approved State plan or Federal requirements. If the regional office believed that an issue of noncompliance or nonconformity existed, and it proved to be impossible to resolve the issue by negotiations, the regional office recommended that the Administrator, SRS, make a finding of noncompliance or nonconformity. The Administrator notified the State that a potential issue existed and that the State was entitled to a full due process hearing under 45 CFR Part 213 (now rewritten and recoded, for social ser-

vices programs, as subpart E). Only after conclusion of the hearing was the notice issued. This procedure has proved to be somewhat awkward and the proposed rule suggests a different approach.

The Regional Administrator, HDS, still must exhaust all possibilities of resolving the difficulties but, if resolution proves impossible, he would have the authority, with concurrence of the Commissioner, APS, to notify the State agency that there is an issue of compliance or conformity. The proposed rule envisions this notice not as a final decision, but as an action that, at the option of the State, merely starts the formal decisionmaking process. If the State believes that its position is valid, it may request a full-scale due process hearing under new subpart E. Only after such a hearing may the Assistant Secretary, HDS, make a final finding as to noncompliance or nonconformity. If the State agency does not request a formal hearing within 60 days of the Regional Administrator's notice, the Assistant Secretary will notify the State agency, in writing, what the sanctions will be.

15. *Substitution of Assistant Secretary, HDS, for Administrator, SRS.* The present rule designates the Administrator, SRS, or designee, as the individual responsible for providing hearings and for making final determinations upon completion of the hearings. This proposed rule substitutes the Assistant Secretary, HDS, for the Administrator, SRS.

(Secs. 2, 3, 402, 403, 1002, 1003, 1102, 1116, 1402, 1403, 1602 (AABD), 1603 (AABD), and 2002 of the Social Security Act; 42 U.S.C. 302, 303, 602, 603, 1202, 1203, 1352, 1353, footnote to 1381, 1397 and 1397(a).)

(Catalog of Federal Domestic Assistance Programs No. 13.642, Public Assistance—Social Services, No. 13.642, Social Services for Low Income and Public Assistance Recipients, and No. 13.644, Public Assistance Training Grants—Title XX.)

NOTE.—It has been determined that this document does not require preparation of an inflationary impact statement under Executive Order 11821 and OMB Circular A-107.

Dated: July 6, 1978.

T. M. PARHAM,
Acting Assistant Secretary for Human Development Services.

Approved: August 19, 1978.

HALE CHAMPION,
Acting Secretary.

Chapter II of 45 CFR is amended as follows:

1. 45 CFR parts 201, 204, and 213, as they apply to social services programs under titles I, IV-A, X, XIV, XVI (AABD), and XX of the Social Security Act, are redesignated as part 228a and are revised to read as follows:

PART 228a—POLICIES AND PROCEDURES ON GRANTS TO STATES FOR SOCIAL SERVICES PROGRAMS—TITLES I, IV-A, X, XIV, XVI (AABD) AND XX OF THE SOCIAL SECURITY ACT

Subpart A—Scope and Definitions

Sec.
228a.0 Scope.
228a.1 Definitions applicable to titles I, IV-A, X, XIV, XVI (AABD), and XX.
228a.2 Definitions applicable only to titles I, IV-A, X, XIV, and XVI (AABD).
228a.3 Definition applicable only to title XX.

Subpart B—State Plans and Plan Amendments

STATE PLANS AND AMENDMENTS IN GENERAL

228a.100 What a State plan is.
228a.101 Amendment of a State plan.

SUBMISSION OF PROPOSED STATE PLANS AND PLAN AMENDMENTS

228a.110 How to submit a proposed State plan or plan amendment.
228a.111 How to determine submittal dates.

APPROVAL AND DISAPPROVAL OF PROPOSED STATE PLANS AND PLAN AMENDMENTS

228a.120 Who can approve or disapprove.
228a.121 Partial or total approval or disapproval.
228a.122 What the decision deadline is.
228a.123 Effective dates and FFP under approved State plan or plan amendments.
228a.124 How State is notified.

RECONSIDERATION OF DISAPPROVALS OF STATE PLANS AND PLAN AMENDMENTS

228a.130 What reconsideration procedures apply.
228a.131 What happens to FFP pending outcome of reconsideration.
228a.132 Prehearing procedures of disapproval of new plan material.

Subpart C—Awards and Payments to States

AWARDS AND PAYMENTS IN GENERAL

228a.200 When FFP may be claimed.
228a.201 What the State agency is responsible for.
228a.202 Administration of grants.

SUBMISSION OF CLAIMS

228a.210 How grant awards are issued.
228a.211 How estimates are made.
228a.212 How expenditues are claimed.

ALLOWANCE AND DISALLOWANCE OF CLAIMS

228a.220 Who can allow or disallow.
228a.221 How a decision is made on a claim.
228a.222 What happens when a claim is disallowed.
228a.223 How to appeal disallowance of a claim.

DEFERRAL OF CLAIMS PAYMENT

228a.230 What deferral is.
228a.231 How deferral occurs.
228a.232 How decision is made on a deferred claim.

INSTALLMENT REPAYMENT OF FEDERAL FUNDS

228a.240 General.
228a.241 How to set the repayment schedule.
228a.242 How to determine the State agency's share of expenditures.
228a.243 How to make payments.

Subpart D—Federal Program and Financial Reviews and Audits

FEDERAL REVIEWS AND AUDITS IN GENERAL

228a.300 What Federal reviews and audits are.
228a.301 Types and effects of reviews and audits.

PROGRAM AND FINANCIAL REVIEWS

228a.305 Program and financial reviews in general.
228a.306 Issues of compliance or conformity after review.

HEW AUDIT AGENCY REVIEWS AND AUDITS

228a.310 What an HEW Audit Agency review is.
228a.311 Audit Agency's reports.
228a.312 Action after Audit Agency report.

Subpart E—Hearing Procedures for State Agencies

GENERAL

228a.400 Scope.
228a.401 Preliminary matters.

ARRANGEMENTS FOR HEARING

228a.405 How to request hearing.
228a.406 How request is acknowledged.
228a.407 What the hearing issues are.
228a.408 What the purpose of a hearing is.
228a.409 Who presides.
228a.410 How to be a party or amicus curiae to a hearing.

CONDUCT OF HEARING

228a.415 Authority of presiding officer.
228a.416 Discovery.
228a.417 How evidence is handled.
228a.418 What happens to unsponsored written material.
228a.419 What the record is.

AFTER THE HEARING

228a.420 Posthearing briefs.
228a.421 Decisions.
228a.422 When decision involving nonconformity or noncompliance becomes effective.

Authority: Secs. 2, 3, 402, 403, 1002, 1003, 1102, 1116, 1402, 1403, 1602 (AABD), 1603 (AABD), and 2002 of the Social Security Act; 42 U.S.C. 302, 303, 602, 603, 1202, 1203, 1352, 1353, footnote to 1381, 1397 and 1397(a).

Subpart A—Scope and Definitions

§ 228a.0 Scope.

Part 228a contains rules on grants for social services programs under six titles of the Social Security Act: Titles I, IV-A, X, XIV, XVI, (AABD), and XX. Title XX authorizes Federal/State sharing of the costs of providing social services to needy families and individuals in the 50 States and the District of Columbia. Titles I, IV-A, X, XIV, and XVI (AABD) authorize Federal/State sharing of the costs of providing social services to needy families with dependent children and needy

aged, blind, and disabled persons in the territories (Guam, Puerto Rico, the Virgin Islands, and the Northern Marianas (90 Stat. 277)). This part is divided into five Subparts as follows:

(a) Subpart A sets forth the scope of the regulation. It includes definitions applicable to all the social services programs under these titles; a definition applicable to title XX alone; and a set of definitions that applies to titles I, IV-A, X, XIV, and XVI (AABD).

(b) Subpart B describes State plans for social services programs. It tells when to amend a plan, how to submit and process a proposed State plan or plan amendment, and how to appeal disapprovals.

(c) Subpart C contains rules for computing and authorizing payment of Federal grants. This includes rules on when to defer or disallow State claims for Federal funds, and how to appeal disallowances.

(d) Subpart D describes the types and effects of reviews conducted by Federal officials.

(e) Subpart E sets forth hearing procedures on appeals of compliance and conformity issues. It also sets forth procedures on appeals of disapprovals of proposed State plans and amendments which are treated as new plans.

§ 228a.1 Definitions applicable to titles I, IV-A, X, XIV, XVI (AABD), and XX.

APS means the Administration for Public Services.

Assistant Secretary means the Assistant Secretary for Human Development Services.

Act means the Social Security Act, and titles referred to are titles of that Act.

Compliance means that the State agency is carrying out in practice the requirements of Federal statutes, regulations, and pertinent court decisions, and the commitments in the approved State plan.

Conformity means that a State plan meets the requirements of Federal and State statutes, Federal regulations, and pertinent court decisions.

Department or HEW means the Department of Health, Education, and Welfare.

FFP means Federal financial participation—the Federal Government's share of expenditures made by a State under a social services program.

Federal requirements means Federal statutes, regulations and instructions.

HDS means the Office of Human Development Services.

Plan amendment means an amendment to the approved social services State plan under the six titles of the Act.

Regional Administrator or RA means the Regional Administrator of the Office of Human Development Services (HDS) of which the Administration for Public Services is a program bureau.

State means the 50 States and the District of Columbia.

State agency means the State agency administering or supervising the administration of the State social services plan under titles I, IV-A, X, XIV, or XVI (AABD) in Puerto Rico, Guam, the Virgin Islands and the Northern Marianas; and under title XX in the 50 States and the District of Columbia.

Title XVI means grants to States for social services for the Aged, Blind, or Disabled (AABD), the combined program the territories may conduct instead of a separate program under titles I, X, and XIV.

§ 228a.2 Definitions applicable only to titles I, IV-A, X, XIV, and XVI (AABD).

Approvable State plan or plan amendment means one that requires no substantive changes to meet all applicable Federal requirements.

State plan means a comprehensive written statement describing the nature and scope of the program and a commitment by the State agency to administer, or supervise the administration of, a social services program in conformity with the relevant requirements of part 205 and the specific requirements of 45 CFR 220 for title IV-A, of 45 CFR 222 for titles I, X, XIV, or title XVI (AABD), and of part 226 for all five titles, and other applicable issuances of the Department. The commitment covers all aspects of operation of the program including administrative, programmatic, and fiscal requirements. This kind of State plan for social services programs applies only to Puerto Rico, Guam, the Virgin Islands, and the Northern Marianas. This State plan does not include a cost allocation plan as described in 45 CFR 205.150.

Substantive change means a change which is necessary in order to bring a proposed State plan or plan amendment into conformity with applicable Federal requirements.

Territory means Guam, Puerto Rico, the Virgin Islands, or the Northern Marianas.

§ 228a.3 Definition applicable only to title XX.

State plan means a written commitment by the State agency to administer, or supervise the administration of, a social services program in conformity with the specific requirements of § 228.6 through § 228.16 of part 228. The commitment is limited to requirements of an administrative nature and does not include cost allocation as described in 45 CFR 205.150. This kind of State plan applies only to title XX social services programs in the 50 States and the District of Columbia.

Subpart B—State Plans and Plan Amendments

State Plans and Amendments in General

§ 228a.100 What a State plan is.

(a) A title IV-A State plan and a title I, X, XIV, or XVI (AABD) State plan, as defined in § 228a.2, is a detailed description of the nature and scope of a territory's social services program. It commits the State agency to administer or supervise the administration of the program in accordance with Federal requirements. Only proper program expenditures which the State agency makes under an approved plan are eligible for FFP. The State agency must keep an approved plan current by amending it.

(b) A title XX State plan, as defined in § 228a.3, contains specific written commitments by the State agency to comply with the requirements of § 228.6 through § 228.16. The State agency must keep an approved plan current by amending it.

(c) Each State which establishes a comprehensive annual services program plan (service plan) under title XX, and each territory which wishes to administer a services program under title IV-A, or title I, X, XIV, or XVI (AABD) shall operate in accordance with a State plan or plans as defined in § 228a.2 or § 228a.3.

(d) HDS will not consider material as State plan material unless the State agency submits it as part of a State plan or plan amendment and the Regional Administrator, HDS, approves it. The State agency shall submit copies of current State operating manuals and other program materials to the Regional Administrator, as requested.

§ 228a.101 Amendment of a State plan.

(a) *When to amend a State plan.* A State agency must amend its plan whenever.

(1) A new or amended Federal law or regulation requires a new provision, or conflicts with an existing plan provision;

(2) A U.S. Supreme Court decision changes the interpretation of a law or regulation or conflicts with an existing plan provision; or

(3) State law, organization, policy, or agency operation undergoes a significant change. (See section 45 CFR 205.5(a) for requirements on amending State plans for the territories.)

(b) *Automatic changes in plans.* When a Federal statute or a U.S. Supreme Court decision invalidates, modifies, or changes the interpretation of a plan provision, the statute or decision, on its effective date, automatically nullifies or modifies any con-

flicting provisions of any approved State plans.

SUBMISSION OF PROPOSED STATE PLANS AND PLAN AMENDMENTS

§ 228a.110 How to submit a proposed State plan or plan amendment.

(a) *General.* A State agency must submit a proposed State plan or plan amendment to the Regional Administrator in accordance with HDS instructions concerning format, content, time limits, transmittal forms, and procedures.

(b) *How to treat plan amendments.* In its transmittal, the State agency may request treatment of the plan amendments as a new State plan:

(1) If the State agency makes this request and the amendment is disapproved, the State agency has a right to a hearing under section 1116 of the Act and to judicial review. (See § 228a.132.)

(2) If the State does not make this request and the amendment is disapproved, the State agency may appeal as described in § 228a.133.

(c) *Review by Governor.* When submitting a proposed State plan or plan amendment to the Regional Administrator, the State agency specifies that the Governor or designee:

(1) Was given 45 days to review the material and that resulting comments, if any, are included in the submittal; or

(2) Did not wish to review the material. (See section 45 CFR 204.1 for State plan requirements on Governor's review of State plans for the territories.)

§ 228a.111 How to determine submittal dates.

(a) *Submittal date.* The submittal date of a proposed State plan or plan amendment is the date the State agency mails it to the regional office as established by a postmark, registered mail date, or affidavit of mailing. If the State agency delivered the material by hand, the regional office date stamps it on receipt and that date is the submittal date.

(b) *When submittal date changes.* If a proposed State plan or amendment is not approvable because it does not meet a Federal requirement, the date on which the required change is mailed or delivered to the regional office becomes the submittal date.

(c) *When submittal date remains unchanged.* If a proposed State plan or plan amendment submitted by the State agency of a territory is approvable but requires clearer wording, the clarifying revision retains the date of the original submittal.

APPROVAL AND DISAPPROVAL OF PROPOSED STATE PLANS AND PLAN AMENDMENTS

§ 228a.120 Who can approve or disapprove.

The Regional Administrator has the authority to approve or disapprove a proposed State plan or plan amendment. Before disapproving it, the Regional Administrator obtains the concurrence of the Commissioner, APS. (See § 228a.306 for rules on deciding that a previously approved plan provision no longer meets Federal requirements.)

§ 228a.121 Partial or total approval or disapproval.

(a) *State plan.* (1) The Regional ADminstrator approves a title XX State plan only if it totally meets the requirements of 45 CFR § 228.6 through § 228.16.

(2) The Regional Adminstrator approves a State plan submitted by a territory only when it meets all mandatory Federal requirements. If any section pertinent to any of these requirements is unapprovable or is omitted, the Regional Administrator, with concurrence of the Commissioner, APS, disapproves the entire plan. The Regional Administrator may disapprove, after concurrence of the Commissioner, APS, sections or parts of sections of a State plan which relate to optional Federal provisions without affecting approval of the rest of the plan.

(b) *Plan amendments.* (1) The Regional Administrator approves a title XX State plan amendment only if it totally meets all appropriate requirements. However, if a State agency submits amendments to more than one section of the plan at one time, the Regional Administrator may approve an amendment to one section while he or she disapproves amendments to other sections.

(2) The Regional Administrator need not approve or disapprove a proposed plan amendment submitted by a territory in its entirety, regardless of whether the State agency has asked to have it treated as a new State plan.

§ 228a.122 What the decision deadline is.

(a) *General.* The Regional Administrator has 90 days following receipt of the State agency's submittal to issue a decision approving or disapproving a proposed State plan or plan amendment.

(b) *Extension.* The Regional Administrator and the State agency may agree in writing to an extension of the 90-day period.

§ 228a.123 Effective dates and FFP under approved State plans or plan amendments.

(a) *When a plan or plan amendment becomes effective.* An approved State plan or plan amendment which affects FFP becomes effective on the later of the following dates:

(1) The first day of the calendar quarter in which an approvable plan or amendment was submitted (see § 228a.111 for submittal date); or

(2) The first date on which the plan or amendment is in operation Statewide.

(b) *When an amendment not affecting FFP becomes effective.* When an amendment does not affect FFP, it becomes effective on the date set by the State agency.

(c) *When State may submit claims for FFP.* A State may not submit claims for new or additional expenditures made under a plan or amendment until the Regional Administrator approves it.

§ 228a.124 How State is notified.

(a) *Approval.* When the Regional Administrator approves a proposed State plan or plan amendment, he or she notifies the State agency in writing.

(b) *Disapproval.* When the Regional Administrator after concurrence of the Commissioner, APS, disapproves part or all of a proposed State plan or plan amendment, he or she notifies the State agency in writing. That notice gives the reason for disapproval and informs the State Agency that it has 60 days to request reconsideration by the Assistant Secretary (see § 228a.130).

RECONSIDERATION OF DISAPPROVALS OF STATE PLANS AND PLAN AMENDMENTS

§ 228a.130 What reconsideration procedures apply.

(a) *For new plans and plan amendments treated as new plans.* A State may request reconsideration of disapproval of a proposed State plan or a plan amendment which is treated as a new State plan under § 228a.132. For purposes of this subpart, the term "new plan material" includes both categories.

(b) *For plan amendments not treated as new plans.* A State agency also may request reconsideration of disapproval of a plan amendment which is not treated as a new plan under § 228a.133.

§ 228a.131 What happens to FFP pending outcome of reconsideration.

When a State agency requests consideration of disapproval of a State plan or plan amendment, FFP in any new or increased expenditures under the disapproved plan or amendment is not available until a final decision is

made. If the decision is favorable to the State agency, the Assistant Secretary will certify lump-sum payment of any amount due.

§ 228a.132 Prehearing procedures of disapproval of new plan material.

(a) *How to request.* A State agency has 60 days from receipt of the Regional Administrator's written notice of disapproval of new plan material to request a reconsideration. The State agency shall make the request in writing to the Assistant Secretary, HDS, with a copy to the Regional Administrator.

(b) *Acknowledgement of request.* Within 30 days of receiving a reconsideration request, the Assistant Secretary notifies the State agency in writing of the date, time, and place of the hearing. That date will be at least 20, but not more than 60, days from the date the State agency receives the hearing notice. However, the State agency and the Assistant Secretary may agree in writing to a different date. (See subpart E for hearing procedures.)

(c) *The hearing decision.* Within 60 days of the conclusion of a hearing, the Assistant Secretary will issue a decision. That decision is final administrative action on the matter.

(d) *Judicial review.* If a State agency is not satisfied with a hearing decision, it may seek judicial review in the U.S. Court of Appeals for the circuit in which the State is located.

§ 228a.133 Procedures for reconsideration of a proposed plan amendment not treated as a new plan.

(a) *How to request.* A State agency has 60 days from receipt of the Regional Administrator's written notice of disapproval to request a reconsideration of a disapproved plan amendment as a new State plan. The State agency shall make the request in writing to the Assistant Secretary, HDS, with a copy to the Regional Administrator.

(b) *Acknowledgement of request.* The Assistant Secretary acknowledges a State agency's request for reconsideration promptly and in writing.

(c) *Submittal of information:*

(1) The Regional Administrator and the State agency have 30 days from receipt of the Assistant Secretary's acknowledgement to provide the Assistant Secretary with all material they consider relevant to the reconsideration issues. If either submits new information, the other shall have and additional 15 days to respond.

(2) The Assistant Secretary will promptly send the State agency a list of all the material that is part of the record. The Assistant Secretary also makes this material available for the State agency's inspection and copying.

(3) The Regional Administrator and the State agency have 30 days from the date of this list to submit any additional supporting materials to the Assistant Secretary and to each other.

(4) If the Regional Administrator or the State agency submits additional material, the other party has 20 days from transmittal date to respond in writing to the Assistant Secretary.

(d) *Right to a conference.* (1) At any time during the period allowed under paragraph (c) of this section, the State agency may request a conference with the Assistant Secretary to discuss the issues.

(2) The State agency may have the conference transcribed at its own expense. Upon its request, the transcript becomes part of the record.

(e) *What the record is.* All materials considered in reaching the decision constitute the record of a reconsideration. The record closes on the later of the following dates:

(1) Expiration of the period(s) allowed under paragraph (c) of this section;

(2) If there is a conference and the transcript becomes part of the record, when the Assistant Secretary receives the transcript; or

(3) If there is a conference and the transcript does not become part of the record, 30 days after the conference.

(f) *How the decision is issued.* Within 90 days after the record is closed, the Assistant Secretary or the person designated to preside at the conference will issue a written decision. The Assistant Secretary will send that decision to the head of the State agency.

(g) *Extension of time limits.* Either the State agency or the Regional Administrator may, for good cause, request an extension of any of the time limits in this section.

Subpart C—Awards and Payments to States

Awards and Payments in General

§ 228a.200 When FFP may be claimed.

(a) For title XX, a State agency which establishes a comprehensive annual services program plan (services plan) and operates it under an approved State plan, and other Federal requirements, including prior approval of certain classes of expenditures as required, and in conformity with an approved cost allocation plan, may claim Federal funds for expenditures for social services, training, and related administration for each.

(b) For titles I, IV-A, X, XIV, and XVI (AABD), a State agency may claim Federal funds for expenditures for social services, training, and related administration under an approved State plan and other Federal requirements, including prior approval of certain classes of expenditures as required, and in conformity with an approved cost allocation plan. (See § 228a.123 for effective date of a new plan amendment.)

§ 228a.201 What the State agency is responsible for.

The State agency is responsible for submitting (or at the option of APS, making available) all documentation required by APS in the format specified to establish the allowability of its claim for FFP. (See § 228a.230-228a.232 on deferrals and § 228a.223 on disallowances.)

§ 228a.202 Administration of grants.

(a) *General.* All grants made to jurisdictions under titles I, IV-A, X, XIV, or XVI (AABD), and XX are subject to the provisions of 45 CFR part 74, Administration of Grants.

(b) *Exception.* Subparts G, Matching and Cost Sharing, and I, Financial Reporting Requirements, of part 74 of this title do not apply to these grants.

Submission of Claims

§ 228a.210 How grant awards are issued.

(a) *Amount of grant.* Subject to the availability of Federal funds, the Commissioner, APS, or designee issues a grant award for each quarter. The grant award is based upon the Regional Administrator's estimate for that quarter reduced or increased to the extent of any overpayment or underpayment made for any prior quarter, and with respect to which adjustment has not already been made. Examples of adjustments which reduce or increase a grant award include:

(1) The difference between the estimate for a quarter and the amount claimed by the State on the expenditure statement for that quarter;

(2) Amounts, including penalties and audit exceptions, which the Regional Administrator disallows;

(3) Amounts which the Regional Administrator defers;

(4) Amounts which the Regional Administrator has deferred and later finds allowable;

(5) Amounts of recoveries, refunds and collections as determined by the Regional Administrator; and

(6) Amounts which exceed statutory limitations on funds.

(b) *How the State is notified.* The Commissioner, APS, issues to the State agency a grant award which shows the amount awarded for each quarter for each program. Accompanying the grant award is a form showing the basis on which the grant was computed. The Commissioner also notifies the State central information reception agency of the grant award, in accordance with section 201 of the Intergovernmental Cooperation Act of 1968.

(c) *How the grant is paid.* The Departmental Federal Assistance Financing System (DFAFS) pays the grant. Subpart K of 45 CFR Part 74, Treasury Circular No. 1075, and the DFAFS Recipient Users Manual govern payment procedures.

§ 228a.211 How estimates are made.

(a) At least 45 days before the beginning of each quarter for which it is estimating funds, the State agency shall submit estimates to the Regional Administrator of the total amount and Federal share of expenditures for social services, training, and their related administrative costs.

(b) This quarterly estimate of expenditures and any investigations which the Regional Administrator may find necessary form the basis for APS's estimate of expenditures. The Regional Administrator's estimate is the basis for making a grant award for that quarter.

§ 228a.212 How expenditures are claimed.

(a) *What the quarterly statement of expenditures is.* This statement is an accounting for expenditures by the State agency under the social services program made during the quarter, and the State agency's claim for Federal reimbursement.

(b) *How to submit the statement.* The State agency shall submit the expenditure statement and necessary supporting schedules and documentation to the Commissioner, APS, and the Regional Administrator no later 30 days after the end of each quarter. APS will postpone any steps leading to the issuance of a grant award until a proper expenditure statement is received.

(c) *Rejection of statement.* Expenditure statements based on estimated expenditures will be rejected. However, indirect costs calculated under approved rates or cost allocation plans may be included in the statement.

ALLOWANCE AND DISALLOWANCE OF CLAIMS

§ 228a.220 Who can allow or disallow.

The Regional Administrator has the authority to allow or disallow a claim, paid or unpaid, for FFP.

§ 228a.221 How a decision is made on a claim.

A State's claim for FFP is allowed or disallowed based on review and analysis of its quarterly statement of expenditures. In determining whether expenditures are allowable, the Regional Administrator may conduct onsite reviews involving examination of State agency accounting and operational records and discussions with State officials. (See Subpart D on Federal reviews and audits.)

§ 228a.222 What happens when a claim is disallowed.

(a) *General.* A disallowance is a finding by the Regional Administrator that a claim by the State agency for FFP in expenditures is not properly chargeable to the program. Because of statutory penalties and limitations, the Regional Administrator may also disallow expenditures for claims which are otherwise properly chargeable to the program.

(b) *How State agency is notified.* If any portion of the amount claimed on a quarterly statement of expenditures is disallowed, the Regional Administrator sends a letter to the State agency which will:

(1) Includes pertinent information on the amounts, dates, and reasons for the disallowance;

(2) Indicate that the State agency may request reconsideration of the disallowance by the Departmental Grant Appeals Board under 45 CFR 16; and

(3) Indicate that the State agency may request a discussion of the disallowance with the Assistant Secretary, HDS, prior to its request for reconsideration by the Departmental Grant Appeals Board.

§ 228a.223 How to appeal disallowance of a claim.

(a) A State agency shall, within 45 days from the date of the Regional Administrator's notice of disallowance, send either a request for discussion of this disallowance to the Assistant Secretary, HDS, or a request for reconsideration to the Executive Secretary, Departmental Grant Appeals Board. (As authorized at 45 CFR 16.6(a), HDS is extending the 30-day time period to 45 days for the initial request for discussion or reconsideration.)

(b) If the State agency wishes to request a reconsideration by the Departmental Grant Appeals Board following the discussion with the Assistant Secretary, it shall file the request within 30 days of the date of a letter from the Assistant Secretary to the State agency confirming the understandings reached in the discussion.

DEFERRAL OF CLAIMS PAYMENT

§ 228a.230 What deferral is.

As used in this subpart C, "deferral" refers to the suspension of the decision on the allowability of a claim for FFP pending the inspection of and analysis of further information.

§ 228a.231 How deferral occurs.

(a) *Basis for deferral.* The Regional Administrator may defer inclusion of a claim in the computation of a grant award (see §228a.210) if the claim is of questionable allowability.

(b) *Notice to State agency.* The Regional Administrator takes deferral action within 60 days after receiving an acceptable quarterly statement of expenditures. Within 15 days of the deferral action, the Regional Administrator sends the State agency written notification identifying the type and amount of the claim and the reason for deferral. The notice will also request the State agency to make available for inspection in a prescribed manner all materials which the Regional Administrator considers necessary to determine the allowability of the claim.

(c) *How State agency responds.* Within 60 days of the RPD's notice of deferral, the State agency shall make any requested materials available to the regional office in readily reviewable form. If the State agency requires additional time to make materials available, the Regional Administrator will give, upon request, an additional period of no more than 60 days.

§ 228a.232 How decision is made on a deferred claim.

(a) *Review of State agency materials.* The Regional Administrator will review all materials furnished under § 228a.231 and, within 30 days of their receipt, notify the State agency if they are not readily reviewable or need supporting information. The State agency has 15 days from date of this notification to make available revised or additional materials. If the State agency does not make the required materials available, the Regional Administrator will promptly disallow the claim.

(b) *How action is taken on a deferred claim.* After the State agency has made all required material available in acceptable form, the Regional Administrator will allow or disallow a deferred claim and notify the State agency in writing of the decision. If the Regional Administrator does not notify the State agency within 120 days of the time the required materials became available, APS will include the claim in a grant award, subject to a later determination of allowability.

(c) If the deferred claim is disallowed, the Regional Administrator advises the State agency of its right to a reconsideration.

(d) A decision to pay a deferred claim shall not preclude a subsequent disallowance resulting from an audit exception or financial management review. If a subsequent disallowance occurs, the State agency may request a reconsideration under 45 CFR Part 16.

INSTALLMENT REPAYMENT OF FEDERAL FUNDS

§ 228a.240 General.

(a) *When Federal funds must be repaid.* When a claim has been reim-

bursed and is later determined to be unallowable, the State must repay the unallowable amount.

(b) *When the State may repay in installments.* A State may repay in installments if:

(1) The total amount to be repaid exceeds 2½ percent of the State's share of annual social services expenditures under the program in which the unallowable expenditures occurred; and

(2) Before repayment is otherwise due, the State notifies the regional program director in writing of its intention to repay in installments.

(c) *Exclusion of other installment repayments.* For purposes of § 228a.240–§ 228a.243, the amount of a repayment does not include any amount previously approved for installment repayment.

§ 228a.241 How to set the repayment schedule.

(a) *How many quarters the repayment may cover.* In order to determine the number of quarters over which repayment may be spread, the State computes this repayment as a percentage of the State agency's share of annual expenditures under the program in which the unallowable expenditures occurred. Using that percentage, the maximum number of calendar quarters over which a State may spread repayment is:

Total repayment amount as percentage of State agency's share of annual expenditures for the specific program	Number of quarters to make repayment
2.5 or less	1
Greater than 2.5, but not greater than 5	2
Greater than 5, but not greater than 7.5	3
Greater than 7.5, but not greater than 10	4
Greater than 10, but not greater than 15	5
Greater than 15, but not greater than 20	6
Greater than 20, but not greater than 25	7
Greater than 25, but not greater than 30	8
Greater than 30, but not greater than 47.5	9
Greater than 47.5, but not greater than 65	10
Greater than 65, but not greater than 82.5	11
Greater than 82.5, but not greater than 100	12
Greater than 100	13+

(b) How much must be repaid in an installment.

(1) Except for the final repayment, the amount due for each quarter in a repayment schedule shall not be less than the following percentages of the State agency's share of annual expenditures for the program in which the unallowable expenditures occurred:

For each of the following quarters	Repayment amount may not be less than these percentages
1 to 4	2.5
5 to 8	5.0
9 plus	17.5

(2) If the State pays higher percentages during the early quarters of its repayment schedule, it applies any corresponding reduction in the minimum percentages first to the last repayment scheduled, then to the next to last, and so on.

§ 228a.242 How to determine the State agency's share of expenditures.

(a) *General.* A State agency's share of annual expenditures under a program in which unallowable expenditures occurred is based on its most recent State agency quarterly statement of financial plan. The State agency's share is the sum of its shares for four quarters, beginning with the quarter in which the first repayment is due.

(b) *Exception.* If the program in which the unallowable expenditures occurred has been terminated, the State agency's share is based on its quarterly statements of expenditures for that program. The State agency's share is the sum of its shares of allowable actual expenditures for the last four quarters preceding the date on which the program was terminated.

§ 228a.243 How to make payments.

(a) *General.* APS deducts the repayment amount from each quarterly grant award, in accordance with the repayment schedule.

(b) *Retroactive claims.* If APS has allowed a State's retroactive claim for FFP, APS affects the amount of that claim against any amounts to be repaid by the State in installments under the same social services program of the act. (For purposes of this section, a retroactive claim is one applicable to any period ending 12 months or more prior to the beginning of the quarter in which Federal funds are to be paid.) Under this provision, a State may:

(1) Suspend repayments until the retroactive claim has been offset; or

(2) Continue repayments until the reduced amount of its debt (remaining after the offset) has been paid in full.

(c) *When interest is charged on repayments.* APS will not charge interest on repayments unless required by court order.

Subpart D—Federal Program and Financial Review and Audits

Federal Reviews and Audits in General

§ 228a.300 What Federal reviews and audits are.

(a) *Reviews.* As used in this subpart D, a Federal review is any type of review necessary to determine whether a State plan is still approvable, and whether State agency operations and claims for FFP are proper under Federal requirements, the approved State plan, and additionally for title XX, the final services plan. A review may cover any aspect of a social services program.

(b) *Audits.* As used in this subpart D, an audit is any type of audit necessary to determine whether State agency operations and claims for FFP are proper under Federal requirements, the approved State plan, and additionally for title XX, the final services plan. An audit may cover any aspect of a social services program. The term "audit" includes, but is not limited to, audits by the General Accounting Office and the HEW Audit Agency.

§ 228a.301 Types and effects of reviews and audits.

(a) *Types.* The types of Federal reviews and audits most often conducted are:

(1) Program and financial reviews as described in § 228a.305–§ 228a.306; and

(2) HEW Audit Agency audits as described in § 228a.310.

(b) *Effects.* Any review or audit may result in a disallowance or in formal compliance or conformity action.

Program and Financial Reviews

§ 228a.305 Program and financial reviews in general.

(a) *Responsibility for review.* The Regional Administrator will conduct program and financial reviews at whatever times he or she considers appropriate. In doing so, the Regional Administrator may make use of any procedures (including onsite review) or specialized assistance needed.

(b) *Purpose of review.* The purpose of a program or financial review is to determine the nature and scope of a State's social services programs in relation to Federal and State plan requirements, and additionally for title XX, the final services plan. Program and financial reviews include:

(1) Determining the allowability of claims;

(2) Evaluating a program's quality and the State agency's need for technical assistance;

(3) Determining whether a State plan conforms with Federal requirements. (A question of conformity may arise when a State agency fails to

submit an approvable plan amendment to implement a new Federal requirement; when previously approved plan material no longer meets Federal requirements; or when plan material has been approved in error); and

(4) Determining whether the State's operating practices are in substantial compliance with the approved State plan and with Federal requirements.

(c) *Review findings.* APS will make all review findings available in writing to the State agency so that it can correct any unacceptable policy or practice. If a review results in disallowance of a claim, the procedures in § 228a.222–§ 228a.224 will apply.

§ 228a.306 Issues of compliance or conformity after review.

(a) *Regional Administrator tries to resolve.* If the Regional Administrator believes there is a compliance or conformity issue, he or she will try to obtain needed changes in the State agency's operating practice or the State plan.

(b) *Issues not resolved.* If the State agency does not make the changes necessary to bring about compliance or conformity:

(1) The Regional Administrator, with concurrence of the Commissioner, APS, will notify the State agency in writing that there is an issue of compliance or conformity and advise it of its opportunity for a hearing under Subpart E.

(2) If the State agency does not avail itself of the opportunity for a hearing within the time allowed by § 228a.405, the Assistant Secretary will notify the State agency by letter whether APS will withhold further Federal payments for all of the program, for specified portions of it, or reduce the rate of FFP (See subparagraph (c) for details).

(c) *Consequences of noncompliance or nonconformity:* (1) Noncompliance or nonconformity by a State under title XX. The provisions of 45 CFR 228.19 set forth the consequences of a final decision that a State with an approved title XX State plan is in noncompliance or nonconformity.

(2) Noncompliance or nonconformity by a Territory. After a final decision that a Territory is in noncompliance or nonconformity, the following provisions apply:

(i) The Assistant Secretary may withhold further payments for expenditures for social services until satisfied that the State agency has corrected the deficiency that was the subject of the finding.

(ii) The Assistant Secretary may limit payments to the State agency to parts of the plan not affected by the deficiency.

(iii) Under titles I, X, XIV, or XVI of the Act, the Assistant Secretary may reduce FFP in approved costs of social services, administration, and training from 75 percent to 50 percent if he or she finds that a plan provision for self-care services does not comply with Federal requirements (under 45 CFR 222, subparts A and B) for such services, or that in the administration of the plan, there is a failure to comply substantially with the plan provisions for those services.

HEW AUDIT AGENCY REVIEWS AND AUDITS

§ 228a.310 What an HEW Audit Agency review is.

The HEW Audit Agency (Audit Agency) in the HEW Inspector General's Office conducts both routine and special reviews and audits. These are to assure that Federal funds are being spent properly and prudently.

§ 228a.311 Audit Agency's reports.

Upon completion of an audit, the Audit Agency releases its final report. The report contains the Audit Agency's findings on the practices reviewed and the allowability of expenditures audited.

§ 228a.312 Action after Audit Agency report.

When the Audit Agency questions a claim, the Regional Administrator decides whether to disallow or allow FFP and notifies the State agency accordingly. When the Audit Agency finds problems of compliance, the Regional Administrator, with the concurrence of the Commissioner, APS, decides whether to take formal compliance action and notifies the State agency accordingly.

Subpart E—Hearing Procedures for State Agencies

GENERAL

§ 228a.400 Scope.

(a) *General.* The Act requires that a State agency be given an opportunity for hearings on certain matters. Hearing procedures described in this subpart E appply to:

(1) Reconsideration of a disapproved State plan or plan amendment which is treated as a new plan; and

(2) Notification of formal compliance or conformity action.

(b) *Negotations.* Nothing in this subpart E limits negotiations between the Department and the State. The rules in this subpart do not apply to negotiations.

§ 228a.401 Preliminary matters.

(a) *How to get records.* All papers filed in connection with a hearing are available for inspection and copying in the office of the HDS hearing clerk. Individuals should direct inquiries to the Central Information Center, Department of Health, Education, and Welfare, 200 Independence Avenue SW., Washington, D.C. 20201.

(b) *How to file and serve papers:* (1) Anyone who wishes to submit papers for the docket shall file with the HDS hearing clerk an original and two copies (but only originals of exhibits and testimony transcripts).

(2) Anyone who wishes papers to be part of the record shall also serve copies on all parties by personal delivery or by mail. Service on a party's designated attorney is the same as service on the party.

(c) *When rules are suspended.* The Assistant Secretary or the presiding officer, after notifying all parties, may modify or waive any rule in sections 228a.401–421 if he or she decides that the action is equitable and will not unduly predudice the rights of any part.

ARRANGEMENTS FOR HEARING

§ 228a.405 How to request hearing.

A State agency has 60 days from receipt of written notice of plan disapproval or intended compliance or conformity action to request a formal hearing. The State agency makes its request in writing to the Assistant Secretary, with a copy to the regional program director.

§ 228a.406 How request is acknowledged.

(a) *Notice of hearing.* Within 30 days of receiving a hearing request, the Assistant Secretary will notify the State agency in writing of the date, time, and place of the hearing and of the issues to be considered. The Assistant Secretary will also publish the hearing notice in the FEDERAL REGISTER.

(b) *When the hearing must be set.* The date set for a hearing will be at least 20, but no more than 60 days from the date the State agency receives the hearing notice. However, the State agency and the Assistant Secretary may agree in writing to a different date.

§ 228a.407 What the hearing issues are.

(a) *General.* The issues at a hearing are those included in the notice to the State agency described in § 228a.406.

(b) *How the Assistant Secretary may add issues.* At least 20 days before a scheduled hearing, the Assistant Secretary will notify the State agency by letter of any additional issues to be considered. The Assistant Secretary will also publish this notice in the FEDERAL REGISTER. If the State agency does not receive its notice in the required time, any party may request the Assistant Secretary to postpone the hearing. If a request is made, the Assistant Secretary will set a new hearing date which is at least 20, but

not more than 60 days from the date the State agency receives the hearing notice.

(c) *How actions by the State may cause the Assisant Secretary to add, modify, or remove issues.* The Assistant Secretary may add, modify or remove issues if, for example, the State agency:

(1) Changes its practices to comply with Federal requirements and its State plan; or

(2) Conforms its State plan to Federal requirements and pertinent court decisions.

(d) What happens when State action causes the Assistant Secretary to add, modify, or remove issues:

(1) If the Assistant Secretary specifies new or modified issues, the hearing will proceed on these issues.

(2) (i) If the Assistant Secretary removes an issue, the hearing will proceed on the remaining issues. If the Assistant Secretary removes all the issues, he or she will terminate the hearing proceedings. The Assistant Secretary may terminate hearing proceedings or remove issues before, during, or after the hearing.

(ii) Before removing any issue, the Assistant Secretary will notify all parties other than the Department and the State. This notice contains the reasons for removing the issue. Within 20 days of the date of this notice, the parties may submit comments in writing on the merits of the proposed removal. (The Assistant Secretary will consider these comments and they become a part of the record.)

§ 228a.408 What the purpose of a hearing is.

The purpose of the hearing is to receive factual evidence and testimony, including expert opinion testimony, related to the issues. The presiding officer will not allow argument as evidence. However, he or she may allow argument in statements, memoranda, or briefs.

§ 228a.409 Who presides.

The presiding office at a hearing is the Assistant Secretary or a person he or she appoints. If the Assistant Secretary appoints a presiding officer, the Assistant Secretary will send copies of the appointment notice to all parties.

§ 228a.410 How to be a party or amicus curiae to a hearing.

(a) *HEW and State agency.* HEW and the State agency are parties to a hearing without having to request participation.

(b) *Other parties or amici curiae.* Any individual or group wishing to be a party or amicus curiae to a hearing shall file a petition with the HDS hearing clerk no more than 15 days following publication of the hearing notice in the FEDERAL REGISTER. A petitioner who wishes to be a party shall also provide a copy of the petition to each party of record at that time.

(c) *What must be in a petition.* The petition must state concisely: (1) The petitioner's interest in the proceedings; (2) Who will appear for the petitioner; (3) The issue on which the petitioner wishes to participate; and (4) Whether the petitioner intends to present witnesses if the petitioner wishes to be a party.

(d) *What happens to a petition:* (1) The presiding officer will determine promptly whether each petitioner has the necessary interest in the proceedings and permit or deny the petition accordingly and in writing. Before making this determination, the presiding officer will allow any party to file comments on the petition to be a party. If the presiding officer denies the petition, he or she will state the reasons. Any party wishing to file comments must do so within 5 days of receiving the petition.

(2) The presiding officer may decide that individuals or groups who have become parties on petition have common interests. The presiding officer may then request that they designate a single representative, or may recognize one or more of these parties to represent them all.

(e) *What rights parties have.* Any party may: (1) Appear by counsel or other authorized representative in all hearing proceedings;

(2) Participate in any prehearing conference held by the presiding officer;

(3) Stipulate facts which, if uncontested by other parties, will become part of the record;

(4) Making opening statements;

(5) Present relevant evidence;

(6) Present witnesses who must be available for cross-examination by all other parties;

(7) Present oral arguments at the hearing; and

(8) Submit written briefs, proposed findings of fact, and proposed conclusions of law, after the hearing.

(f) *What rights amici curiae have.* Any amicus curiae may: (1) Present an oral statement at the hearing at the point in the proceedings specified by the presiding officer;

(2) Submit a written statement of position to the presiding officer before the hearing begins; and

(3) Submit a brief or written statement at the same time as the parties submit briefs.

If an amicus curiae submits a written statement or brief, he or she shall serve a copy on each party.

CONDUCT OF HEARING

§ 228a.415 Authority of presiding officer.

(a) *General.* It is the duty of the presiding officer to conduct a fair hearing, avoid delay, maintain order, and make a record of the proceedings. He or she has authority to carry out these duties. This includes: (1) Regulate the course of the hearing;

(2) Regulate the participation and conduct of parties, amici curiae, and others at the hearings;

(3) Rule on procedural matters and, if necessary, issue protective orders or other relief to a party against whom discovery is sought;

(4) Take any action authorized by the rules in this subpart or in conformance with 5 U.S.C. 551–559;

(5) Make a final decision, if the Assistant Secretary is the presiding officer;

(6) Administer oaths and affirmations;

(7) Examine witnesses; and

(8) Receive or exclude evidence or rule on or limit evidence or discovery.

(b) *What the presiding officer cannot do.* The presiding officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(c) *When the presiding officer's authority is limited.* If the presiding officer is not the Assistant Secretary, he or she does not have the authority to: (1) Make a final decision but shall certify the entire record to the Assistant Secretary including recommended findings and decisions; or

(2) Recommend reduction or withholding of FFP in matters of compliance or conformity.

§ 228a.416 Discovery.

Any party has the right to conduct discovery against other parties. These discovery proceedings are subject to Rules 26–37, Federal Rules of Civil Procedure. The presiding officer shall promptly rule on any written objection to discovery and may restrict or control discovery so as to prevent undue delay in the hearing. If any party fails to respond to discovery procedures, the presiding officer may issue any order and impose any sanctions (other than contempt orders) authorized by rule 37 of the Federal Rules of Civil Procedure.

§ 228a.417 How evidence is handled.

(a) *Testimony.* Witnesses, under oath or affirmation, give oral testimony at a hearing. All witnesses must be available at the hearing for cross-examination.

(b) *Rules of evidence.* Technical rules of evidence do not apply to hearings described in this subpart E. The presiding officer applies whatever rules or principles are necessary to

assure disclosure of the most credible evidence available and to subject testimony to cross-examination. Cross-examination may be on any material matter regardless of the scope of direct examination.

§ 228a.418 What happens to unsponsored written material.

Letters and other written material regarding matters at issue, when not submitted specifically on behalf of one of the parties, become part of the correspondence section of the docket. This material is not part of the evidence or the record.

§ 228a.419 What the record is.

(a) *Official transcript.* HEW designates the official reporter for a hearing. The HDS hearing clerk has the official transcript of testimony, as well as any other materials submitted with the official transcript. The parties and the public may obtain transcripts of testimony from the official reporter at rates which do not exceed the maximum fixed by contract between the reporter and HEW. Upon notice to all parties, the presiding officer may authorize corrections to the transcript which involve matters of substance.

(b) *Record.* The record for the hearing decision consists of the transcript of testimony, exhibits, and all papers and requests filed in the proceedings except for the correspondence section of the docket. The record includes rulings and any decisions.

AFTER THE HEARING

§ 228a.420 Posthearing briefs.

The presiding officer shall fix the time for filing posthearing briefs. These may contain proposed findings of fact and conclusions of law. The presiding officer may permit filing of reply briefs.

§ 228a.421 Decisions.

(a) *When the Assistant Secretary is presiding officer.* If the Assistant Secretary is the presiding officer, he or she will issue a final decision within 60 days after expiration of the time allowed for filing of posthearing or reply briefs.

(b) *When the Assistant Secretary appoints a presiding officer.* If the Assistant Secretary appoints a presiding officer: (1) After the time for filing posthearing or reply briefs has expired, the presiding officer shall certify the entire record, including his or her recommended findings and proposed decision, to the Assistant Secretary.

(2) The Assistant Secretary shall provide a copy of the recommended findings and proposed decision to all parties and any amici curiae. Within 20 days, a party may file with the Assistant Secretary, exceptions to the recommended findings and proposed decision. The party must file a supporting brief or statement with the exceptions.

(3) The Assistant Secretary will review the presiding officer's recommended findings and proposed decision and, within 60 days of receiving them, issue a decision. The Assistant Secretary will provide copies of that decision to all parties and any amici curiae.

(c) *When the decision involves nonconformity or noncompliance.* When the Assistant Secretary decides, after a formal hearing, the nonconformity or substantial noncompliance exists, the final decision will state whether further payments to the State will be withheld entirely, will be limited to categories not affected by the decision, or whether the rate of FFP will be reduced. (See § 228a.306 for details.)

§ 228a.422 When decision involving nonconformity or noncompliance becomes effective.

The Assistant Secretary's decision will specify the effective date for any withholding of Federal payments or reduction of the rate of FFP because of nonconformity or substantial noncompliance. This effective date cannot be earlier than the date of the Assistant Secretary's decision, or later than the first day of the next calendar quarter.

[FR Doc. 78-23943 Filed 8-24-78; 8:45 am]

[4410-07]

Office of Child Support Enforcement

[45 CFR Parts 300, 301, and 304]

GENERAL POLICIES AND PROCEDURES ON GRANTS TO STATES FOR THE CHILD SUPPORT ENFORCEMENT PROGRAM

AGENCY: Office of Child Support Enforcement (OCSE), HEW.

ACTION: Notice of proposed rulemaking.

SUMMARY: These proposed regulations clarify and reorganize into a single part existing procedural rules on administration of grants to States for the child support enforcement program. They also further define existing policies on appeal procedures for State agencies. Comparable regulations, appearing in part V of this issue are proposed for the medical assistance, social services, and financial assistance programs.

DATE: Comments must be received by October 24, 1978.

ADDRESSES: Address comments to Director, Office of Child Support Enforcement, Department of Health, Education, and Welfare, P.O. Box 23526, Washington, D.C. 20024. Comments will be available for public inspection in Room 2323 of the Department's offices at 330 C Street SW., Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT:

Mr. John M. Sacchetti, Policy Branch, OCSE, telephone 202-472-4510.

SUPPLEMENTARY INFORMATION: General program description title IV-D of the Social Security Act authorizes Federal/State sharing of the costs of providing child support enforcement services to families eligible for the aid to families with dependent children program and to any other individuals who apply for these services. Federal reimbursement is available for child support enforcement services provided under a State's approved title IV-D State plan. These proposed regulations contain policies and procedures for the approval and disapproval of State plans and plan amendments, for deferring, allowing and disallowing State expenditures, for program and financial reviews by Federal officials, and for appeal of adverse decisions.

REASONS FOR REVISING REGULATIONS

When the original child support enforcement regulations were adopted on June 26, 1975, they included separate provisions (part 301) for State plan approval and grant procedures. Subsequently, on February 17, 1976, in an amendment to the regulations (§ 304.29) OCSE incorporated by reference the disallowance, deferral, and reconsideration of claims provisions contained in 45 CFR Chapter II (§§ 201.14 and 201.15) which were applicable to the programs administered by the Social and Rehabilitation Service (SRS). Under the HEW reorganization order of March 8, 1977, SRS was disbanded and responsibility for its various programs was divided among several HEW agencies. This reorganization necessitates OCSE adopting its own complete set of administrative regulations. In addition, this proposal is in furtherance of the Secretary's "Operation Common Sense" directive on writing HEW regulations in clear, simple language. This proposed rule combines procedures now contained in parts 301, 302, and by reference 201 into a single part 300 which would apply only to the child support enforcement program. Additional content and format changes are described below.

PROPOSED REGULATION FORMAT

Under this proposal, procedures for administering grants to States for child support enforcement programs will all be in a new part 300. Regulations or procedures for administering

grants to States for financial assistance, social services, and medical assistance are also proposed in similar formats, each in a single part.

PROPOSED CONTENT CHANGES

1. *Definitions.* The definitions section has been expanded to cover more terms commonly used throughout this and other parts of chapter III.

2. *Authority to approve or disapprove a State plan or amendment.* Authority to approve and disapprove State plans and amendments is vested in the regional representative. He will, however, consult with the Deputy Director before issuing a disapproval notice. Under prior regulations, the regional representative could approve plans but disapproval was reserved to the Director of OCSE after consultation with the Secretary. The proposed policy places responsibility for both positive and negative actions on a single organizational level; i.e., the region. At the same time, we believe it continues to protect States by retaining a requirement for consultation at the national level to assure uniformity in such decisions.

3. *Partial approval of plans and amendments.* A new provision reflects the existing practice of approving certain parts of a new plan or plan amendment even though other parts are disapproved. We believe this procedure can expedite incorporation of approvable provisions into State plans and, in some cases, result in earlier availability of Federal funds.

4. *Decisions on plan amendments not treated as new plans.* The regulation clarify and modify procedures for approval of plan amendments not treated as new plans. A decision to approve or disapprove will be made within 90 days of receipt in the regional office as if the amendment were a new plan. In cases of disapproval, a new provision assures the State of the right to a reconsideration by the Director or his designee. The new reconsideration process for these amendments is simpler and can produce decisions more promptly.

5. *Establishing the submittal date of a plan or amendment.* A new section explains how to determine the submittal date of a proposed State plan or amendment. This is important to States for purposes of claiming Federal funds once the plan or amendment has been approved, and is not specified by existing regulations.

6. *Authority to allow or disallow a State claim for payment.* These amendments reflect redelegations of secretarial authority to permit the regional representative to allow and disallow State claims for Federal reimbursement. This arrangement and that in item 3 above give States a single focus for fiscal decisions. The regional representative also continues to have the authority to defer payment decisions in certain situations.

7. *Reconsideration of disallowances.* These regulations incorporate by reference new procedures for reconsideration of disallowances of State claims for Federal reimbursement. The new procedures contained in 45 CFR Part 16, Subpart C, and published on March 6, 1978, give final decision authority to the Departmental Grant Appeals Board rather than to the program administrators as provided in existing regulations. The regulations would also allow 45 days, rather than the present 30, for a State to request reconsideration of a disallowance.

REQUEST FOR PUBLIC COMMENT

We invite comments on these regulations, particularly in the following areas:

1. Usefulness of having regulations for a specific program in a single chapter of the CFR, versus "joint" regulations governing the child support enforcement, medicaid, financial assistance, and social services program.

2. The usefulness of regulations versus other methods such as action transmittals for disseminating procedures on administering grants to States for the child support enforcement program.

3. Effectiveness of proposed revision of regulations affecting several programs whose rules have previously been intermingled. (See proposed rules from the Social Security Administration, the Health Care Financing Administration, and the Assistant Secretary for Human Development Services.)

The proposed regulations are to be issued under the authority of section 1102 of the Social Security Act; 45 Stat. 647; 42 U.S.C. 1302.

(Catalog of Federal Domestic Assistance Program No. 13.679, Child Support Enforcement Program.)

Dated: July 20, 1978.

DON WORTMAN,
Acting Director, Office of Child Support Enforcement.

Approved: August 19, 1978.

HALE CHAMPION,
Acting Secretary of Health, Education, and Welfare.

It is proposed that chapter III of title 45 of the Code of Federal Regulations be amended by revoking part 301 and § 304.29 and § 304.40 of part 304 and republishing these provisions in a new part 300, to read as follows:

PART 300—GENERAL POLICIES AND PROCEDURES ON GRANTS TO STATES FOR THE CHILD SUPPORT ENFORCEMENT PROGRAM

Subpart A—Introduction

Sec.
300.0 Scope.
300.1 Definition.

Subpart B—State Plans and Plan Amendments

STATE PLANS AND PLAN AMENDMENTS IN GENERAL

300.100 What a State plan is.
300.101 When to amend a State plan.

SUBMISSION OF PROPOSED STATE PLANS AND PLAN AMENDMENTS

300.110 How to submit a proposed State plan or plan amendment.
300.111 How submittal date is determined.

APPROVAL AND DISAPPROVAL OF PROPOSED STATE PLANS AND PLAN AMENDMENTS

300.120 Who can approve or disapprove.
300.121 Partial or total approval.
300.122 What the decision deadline is.
300.123 Effective dates and FFP under an approved State plan or plan amendment.
300.124 How State is notified.

RECONSIDERATION OF DISAPPROVED STATE PLANS AND PLAN AMENDMENTS

300.130 What reconsideration procedures apply.
300.131 What happens to FFP pending outcome of reconsideration.
300.132 Prehearing procedures for reconsideration of disapproved new plan material.
300.133 Procedures for reconsideration of disapproved plan amendments not treated as a new plan.

Subpart C—Awards and Payments to States

AWARDS AND PAYMENTS IN GENERAL

300.200 When FFP can be claimed.
300.201 What the IV-D agency is responsible for.
300.202 Administration of grants.

SUBMISSION OF CLAIMS

300.210 How grant awards are issued and paid.
300.211 How estimates are made.
300.212 How expenditures are claimed.

ALLOWANCE AND DISALLOWANCE OF CLAIMS

300.220 Who can allow or disallow.
300.221 How a decision is made on a claim.
300.222 What happens when a claim is disallowed.
300.223 How to appeal disallowance of a claim.

DEFERRAL OF CLAIMS

300.230 What deferral is.
300.231 How deferral occurs.
300.232 How decision is made on a deferred claim.

INSTALLMENT REPAYMENT OF FEDERAL FUNDS

300.240 General.
300.241 How to set the repayment schedule.
300.242 How to determine the IV-D agency's share of expenditures.

Sec.
300.243 How to make repayment.

Subpart D—Reserved

Subpart E—Hearing Procedures for IV-D Agencies

GENERAL

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300.401 General rules.

ARRANGEMENTS FOR HEARING

300.405 How a IV-D agency is notified of a hearing.
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300.407 What the hearing issues are.
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300.410 How to be a party or amicus curiae to a hearing.

CONDUCT OF HEARING

300.415 Authority of presiding officer.
300.416 Discovery.
300.417 How evidence is handled.
300.418 What happens to unsponsored written materials.
300.419 What the record is.

AFTER THE HEARING

300.420 Posthearing briefs.
300.421 Decisions.
300.422 When decision becomes effective.

AUTHORITY: Sec. 1102, 49 Stat. 647; 42 U.S.C. 1302; unless otherwise indicated.

Subpart A—Introduction

§ 300.0 Scope.

This part 300 contains rules on grants to States under title IV-D of the Social Security Act. This title authorizes Federal/State sharing of the costs of providing child support enforcement services to families eligible for the aid to families with dependent children program and to any other individuals applying for these services in the 50 States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and the Northern Mariana Islands (90 Stat. 277). This part is divided into five subparts as follows:

(a) Subpart A contains a description of the child support enforcement program under part D of title IV of the Act. It includes general definitions related to this program.

(b) Subpart B describes State plans for the child support enforcement program. It tells when a plan must be amended and how a new State plan or plan amendment is submitted, processed, and appealed when it is disapproved.

(c) Subpart C contains rules for computing and authorizing payment of Federal grants. This includes rules on when State claims for Federal funds may be deferred or disallowed and how disallowances may be appealed.

(d) Subpart D describes the types of reviews conducted by Federal officials.

(e) Subpart E describes hearing procedures available to State agencies.

§ 300.1 Definitions.

As used in this part:

"Act" means the Social Security Act and titles referred to are titles of that Act.

"AFDC" means a program of aid to families with dependent children under part A of title IV.

"Approvable State plan or plan amendment" means a proposed plan or amendment which meets all applicable Federal requirements.

"Central office" means the central office of the Office of Child Support Enforcement.

"Department" or "HEW" means the Department of Health, Education, and Welfare.

"Director" and "Deputy Director" means the Director and Deputy Director, Office of Child Support Enforcement. The Director is the Secretary's designee to administer the child support enforcement program under part D of title IV.

"FFP" or "Federal financial participation" means the Federal Government's share of expenditures made by a State under the child support enforcement program.

"Federal PLS" means the Parent Locator Service operated by the Office of Child Support Enforcement pursuant to section 452(a)(9) of the Act.

"Federal requirements" means Federal statutes, regulations, and instructions.

"IV-D agency" means the single and separate organizational unit in the State that has the responsibility for administering or supervising the administration of the State's approved title IV-D State plan.

"IV-D program" means the State's child support enforcement program under title IV-D.

"Office" or "OCSE" means the Office of Child Support Enforcement, which is the separate organizational unit within the Department with the responsibility for administering the child support enforcement program under title IV-D.

"New State plan" means a plan which, if approved, would establish a federally aided program under part D of title IV of the Act where none existed before.

"Plan" or "State plan" means a comprehensive written commitment by a IV-D agency to administer, or supervise the administration of, title IV-D. This does not include a cost allocation plan as described in 45 CFR 302.16.

"Plan amendment" or "amendment" means an amendment to an approved State plan under title IV-D.

"Regional office" means one of the regional offices of OCSE.

"Regional representative" means a regional representative of OCSE.

"Secretary" means the Secretary of Health, Education, and Welfare.

"State" means a political jurisdiction which is eligible to submit a child support enforcement State plan to HEW for approval. It includes the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and the Northern Mariana Islands.

"State PLS" means the service established by the IV-D agency pursuant to section 454(8) of the Act to locate absent parents.

Subpart B—State Plans and Plan Amendments

STATE PLANS AND PLAN AMENDMENTS IN GENERAL

§ 300.100 What a State plan is.

(a) A State plan is a detailed description of the nature and scope of a State's child support enforcement program. It commits a IV-D agency to administering the program in accordance with Federal requirements. Only proper program expenditures, which are made under an approved plan, are eligible for Federal financial participation. The IV-D agency must keep its approved plan current.

(b) OCSE will not consider materials submitted by a IV-D agency as State plan material unless they are submitted as part of a State plan or plan amendment and approved by the regional representative. The IV-D agency will also submit copies of current State operating manuals and other program materials to the regional representative, as requested.

§ 300.101 When to amend a State plan.

(a) A IV-D agency must amend its plan whenever:

(1) A new or amended Federal law or regulation requires a new provision or conflicts with an existing plan provision; or

(2) A U.S. Supreme Court decision changes the interpretation of a law or regulation; or

(3) State law, organization, policy, or IV-D agency operation undergoes a significant change.

(b) *When a provision is automatically nullified.* When a Federal statute or a U.S. Supreme Court decision invalidates or changes the interpretation of a plan provision, it also, on its effective date, automatically nullifies any conflicting provisions of an approved State plan. (See 45 CFR 302.13.)

SUBMISSION OF PROPOSED STATE PLANS AND PLAN AMENDMENTS

§ 300.110 How to Submit a proposed State plan or plan amendment.

(a) *General.* A IV-D agency must submit a proposed State plan or plan amendment to the regional representative, in accordance with OCSE instructions concerning format, content, time limits, transmittal forms, and procedures.

(b) *How plan amendments may be treated.* At the time of submittal, a IV-D agency may ask to have a proposed plan amendment treated as a new State plan.

(1) If such a request is made and the amendment is disapproved, the IV-D agency has a right to a hearing as described in § 300.132 and subpart E.

(2) If a proposed plan amendment is not treated as a new State plan and the amendment is disapproved, the IV-D agency may request a reconsideration ad described in § 300.133.

(c) *Review by Governor.* When submitting a proposed State plan or plan amendment to the regional representative, the IV-D agency shall specify that the Governor or the Governor's designee:

(1) Was given 45 days to review the material and that resulting comments, if any, are included in the submittal; or

(2) Did not wish to review the material.

§ 300.111 How submittal date is determined.

(a) *General.* The submittal date of a proposed State plan or plan amendment is the date it is mailed to the regional office, as established by the IV-D agency (for example, in the form of a postmark, registered mail date, or affidavit of mailing). If the material is delivered by hand, the submittal date is that shown by the regional office date stamp.

(b) *When submittal date changes.* If a proposed State plan or plan amendment is not approvable because it does not meet a Federal requirement, the date on which the required change is mailed or delivered to the regional office becomes the submittal date.

(c) *When submittal date remains unchanged.* If a proposed State plan or plan amendment is approvable but requires clearer wording, that clarifying revision retains the date of the original submittal.

APPROVAL AND DISAPPROVAL OF PROPOSED STATE PLANS AND PLAN AMENDMENTS

§ 300.120 Who can approve or disapprove.

The regional representative has the authority to approve or disapprove a proposed State plan or plan amendment. Before disapproving, the regional representative consults with the Deputy Director.

§ 300.121 Partial or total approval.

(a) *State plan.* OCSE approves a proposed State plan only if it meets all Federal requirements. If any required provision is unapprovable or is omitted, OCSE will disapprove the entire plan. However, OCSE may disapprove sections of a proposed State plan which relate to optional Federal provisions without affecting approval of the rest of the plan.

(b) *Plan amendment.* OCSE need not approve or disapprove a proposed plan amendment in its entirety, regardless of whether the IV-D agency asks to have it treated as a new State plan. OCSE can approve amendments to specific parts of a State plan and disapprove amendments to other parts.

§ 300.122 What the decision deadline is.

(a) *General.* The regional representative has 90 days from receipt of a IV-D agency's submittal to issue a decision approving or disapproving a proposed State plan or plan amendment.

(b) *Extension.* The IV-D agency and the regional representative may agree in writing to an extension of the 90-day period.

§ 300.123 Effective dates and FFP under an approved State plan or plan amendment.

(a) *When a plan or amendment affecting FFP becomes effective.* An approved State plan or plan amendment which affects FFP becomes effective on the later of the following dates:

(1) The first day of the calendar quarter in which an approvable plan or amendment was submitted (see § 300.111 for submittal date); or

(2) The first date on which the plan or plan amendment becomes effective in the State.

(b) *When an amendment not affecting FFP becomes effective.* When an amendment does not affect FFP, it becomes effective on the date set by the IV-D agency.

(c) *When claim for FFP can be submitted.* A IV-D agency may not submit claims for new or additional expenditures made under a plan or amendment until that plan or amendment has been approved.

§ 300.124 How State is notified.

(a) *Approval.* When the regional representative approves a proposed State plan or plan amendment, he or she notifies the IV-D agency in writing.

(b) *Disapproval.* When the regional representative, after consulting with the Deputy Director, disapproves part or all of a proposed State plan or plan amendment, he or she notifies the IV-D agency in writing. This notice gives the reason for disapproval and informs the IV-D agency that it has 60 days to request the Director to reconsider the decision (see § 300.130).

RECONSIDERATION OF DISAPPROVED STATE PLANS AND PLAN AMENDMENTS

§ 300.130 What reconsideration procedures apply.

(a) *For new State plans and plan amendments treated as new plans.* A IV-D agency may request reconsideration of disapproval of a State plan or plan amendment which is treated as a new State plan under section 300.132. For purposes of this subpart, the term "new plan material" includes both categories.

(b) *For plan amendments not treated as new plans.* A IV-D agency also may request reconsideration of a disapproved plan amendment which is not treated as a new plan under § 300.133.

§ 300.131 What happens to FFP pending outcome of reconsideration.

When a IV-D agency requests reconsideration of a disapproval of a proposed State plan or plan amendment, FFP in any new or increased expenditures under the disapproved plan or amendment is not available until a final decision is made. If the decision is favorable to the IV-D agency, the Director will certify lump/sum payment of any amount due.

§ 300.132 Prehearing procedures for reconsideration of disapproved new plan material.

(a) *How to request.* A IV-D agency has 60 days from receipt of OCSE's written notice of disapproval of new plan material to request a reconsideration. The IV-D agency shall make the request in writing to the Director, with a copy to the regional representative.

(b) *Acknowledgment of request.* Within 30 days of receiving the reconsideration request, the Director notifies the IV-D agency in writing of the date, time, and place of a hearing and of the issues to be considered. (See subpart E for hearing procedures.)

§ 300.133 Procedures for reconsideration of disapproved plan amendments not treated as a new plan.

(a) *How to request.* A IV-D agency has 60 days from receipt of OCSE's written notice of disapproval to request reconsideration of a plan amendment not treated as a new plan. The IV-D agency shall make the request in writing to the Director, with a copy to the regional representative.

(b) *Acknowledgment of request.* The Director acknowledges a IV-D agency's request for reconsideration promptly and in writing.

(c) *Submittal of information.* (1) OCSE will promptly send the IV-D agency a list of all material that is part of the record. OCSE will also make this material available for the IV-D agency's inspection and copying.

(2) The regional representative and the IV-D agency have 30 days from the date of the OCSE list to submit any additional supporting material to the Director and to each other. If the regional representative or the IV-D agency submits additional material, the other party has 20 days from the transmittal date to respond in writing to the Director.

(d) *Right to conference.* (1) At any time during the periods allowed under paragraph (c) of this section, the IV-D agency may request a conference with the Director or his designee to discuss the issues.

(2) The IV-D agency may have the conference transcribed at its own expense. Upon its request, the transcript becomes part of the record.

(e) *What the record is.* All materials considered in reaching a decision constitute the record of a reconsideration. The record closes on the later of the following dates:

(1) Expiration of the periods allowed under paragraph (c) of this section; or

(2) If there is a conference and the transcript becomes part of the record, upon the Director's receipt of the transcript; or

(3) If there is a conference and the transcript does not become part of the record, 30 days after the conference.

(f) *How the decision is issued.* Within 90 days after the record is closed, the Director or the person designated to preside at the conference will issue a written decision. He or she will send that decision to the head of the IV-D agency.

(g) *Extension of time limits.* Either the IV-D agency or the regional representative may, for good cause, request an extension of the time limits in this section.

Subpart C—Awards and Payments to States

Awards and Payments in General

§ 300.200 When FFP can be claimed.

A IV-D agency may claim Federal funds for a share of the cost of child support enforcement services and related administrative expenditures made under an approved State plan and other Federal requirements, including prior approval of certain classes of expenditures as required and in conformity with an approved cost allocation plan. In submitting a claim, expenditures under plan provisions pending approval must be separate from those plan provision already approved. (See § 300.123 for the effective date of a new plan or amendment.)

§ 300.201 What the IV-D agency is responsible for.

The IV-D agency is responsible for submitting (or, at the option of OCSE, making available) all documentation required by OCSE in the format specified to establish the allowability of its claim for FFP. (See §§ 300.230-300.232 on deferrals and § 300.222 on disallowances.)

§ 300.202 Administration of grants.

(a) *General.* Unless otherwise indicated, all grants made to States under this part are subject to the provisions of part 74 of this title, Administration of Grants.

(b) *Exception*-Subparts G, Matching and Cost Sharing, and I, Financial Reporting Requirements, of part 74 of this title do not apply to these grants.

Submission of Claims

§ 300.210 How grant awards are issued and paid.

(a) *Amount of grant.* Subject to the availability of Federal funds, the Director or his Deputy issues a grant award for each quarter. The grant award is based upon the regional representative's estimate for that quarter, reduced or increased to the extent that the estimate for any prior quarter was greater or less than the amount which should have been paid for that quarter. Examples of adjustments which reduce or increase a grant award include:

(1) The difference between the estimate and the amount claimed by the State;

(2) Amounts (including penalties and audit exceptions) which the regional representative disallows;

(3) Amounts which the regional respresentative defers;

(4) Amounts which the regional representative has deferred and later finds allowable;

(5) Amounts of recoveries, refunds, and collections as determined by the regional representative; and

(6) Amounts which exceed statutory limitations on funds.

(b) *How State is notified.* The Director or his Deputy issues to the IV-D agency a grant award showing the amounts awarded for each quarter. Accompanying the grant award is a form showing basis on which the grant was computed. The Director or this Deputy also notifies the State Central Information Reception Agency of the grant award, in accordance with section 201 of the Intergovernmental Cooperation Cooperation Act of 1968.

(c) *How the grant is paid.* The Departmental Federal Assistance Financing System (DFAFS) pays the grant. Subpart K of 45 CFR Part 74, Treasury Circular No. 1075, and the DFAFS Recipient Users Manual govern payment procedures.

§ 300.211 How estimates are made.

(a) At least 45 days before the beginning of the estimate quarter the IV-D agency shall submit to the Deputy Director (with a copy to the appropriate regional representative):

(1) Estimates of the total amount, and the Federal share of expenditures, for the IV-D program; and

(2) A certification of the amount of State funds (and local funds, if applicable) appropriated or made available for the estimated expenditures, signed by:

(i) A fiscal officer of the State, if required by State law or regulations; or

(ii) The IV-D agency's executive officer or a person that officer has officially designated.

(3) If the funds certified as appropriated or made available are insufficient to cover the State's share of the estimated expenditures, the IV-D agency must indicate in the certification the source from which the balance of funds will be obtained and when.

§ 300.212 How expenditures are claimed.

(a) *What the quarterly statement of expenditures is.* The quarterly statement of expenditures is an accounting by the IV-D agency for expenditures made during a quarter under its IV-D program and the IV-D agency's claim for Federal reimbursement.

(b) *How to submit the statement.* Within 30 days after the end of each calendar quarter, the IV-D agency shall submit to the Deputy Director, with a copy to the regional representative, a quarterly statement of expenditures for that quarter, along with the necessary supporting schedules.

(c) *Rejection of statement.* If the quarterly statement of expenditures is based on estimates, it will be rejected. Indirect costs calculated in conformance with approved cost allocation plans are acceptable.

Allowance and Disallowance of Claims

§300.220 Who can allow or disallow.

(a) *General.* The regional representative has the authority to allow or disallow a claim, paid or unpaid, for FFP.

(b) *Exception.* The Director and Deputy Director retain authority to allow FFP in expenditures which have been questioned by the General Accounting Office or the HEW Audit Agency.

§300.221 How a decision is made on a claim.

The regional representative allows or disallows a State's claim for FFP based on review and analysis of the quarterly statement of expenditures. In determining whether expenditures are allowable, either regional or central office officials may conduct onsite reviews involving examination of IV-D agency accounting and operational records and discussion s with State officials.

§ 300.222 What happens when a claim is disallowed.

(a) *General.* A disallowance is a finding by the regional representative that a IV-D agency's claim for FFP is not properly chargeable to the program. Because of statutory penalties and limitations, the regional representative may also disallow expenditures which are properly chargeable to the program.

(b) *How IV-D agency is notified.* If any portion of the amount claimed on a quarterly statement of expenditures is disallowed, the regional representative's notice to the IV-D agency includes pertinent information on the amounts, dates and reasons for the disallowance. The notice also indicates that the IV-D agency may request reconsideration of the disallowance as described in section 300.223.

§ 300.223 How to appeal disallowance of a claim.

(a) *How to request.* A IV-D agency has 45 days from the postmark date of OCSE's disallowance notice to request reconsideration under 45 CFR Part 16. The request shall be addressed to the Executive Secretary, Departmental Grant Appeals Board, with copies to the Director and the regional representative.

(b) *What happens to a claim pending reconsideration decision.*

(1) If reconsideration is requested on the disallowance of an amount already awarded to a State, no action will be taken to recover the Federal funds pending the reconsideration decision.

(2) If reconsideration is requested on the disallowance of an amount not already awarded to a State, that amount will not be awarded pending the reconsideration decision.

(c) *Director's review before reconsideration.* A IV-D agency may, as specified by OCSE, request the Director to review a disallowance before seeking reconsideration by the Grant Appeals Board. The Director may decline. The IV-D agency may also withdraw its review request at any time. If the Director reviews a disallowance, his or her decision is OCSE's final action on the matter, and time devoted to that review does not count toward the 45-day period for requesting reconsideration under paragraph (a) of this section.

Deferral of Claims

§ 300.230 What deferral is.

As used in this subpart, "deferral" refers to the suspension of the decision on the allowability of a claim for FFP, pending the inspection and analysis of further information.

§ 300.231 How deferral works.

(a) *Basis for deferral.* The regional representative can defer the inclusion of a claim in the computation of a grant award (see § 300.210) if it is of questionable allowability.

(b) *Notice to IV-D agency.* The regional representative takes deferral action within 60 days after receiving an acceptable quarterly statement of expenditures. Within 15 days of the deferral action, the regional representative sends the IV-D agency written notification identifying the type and amount of claim and the reason for deferral. The notice will also request the IV-D agency to make available for inspection all material which the regional representative considers necessary to determine the allowability of the claim.

(c) *How IV-D agency responds.* Within 60 days of the date of the Regional Representative's notice of deferral, the IV-D agency shall make any requested materials available to the regional office in readily reviewable form. If the IV-D agency requires additional time to make materials available, the regional representative, upon request, will give the agency an additional period of no more than 60 days.

§ 300.232 How decision is made on a deferred claim.

(a) *Review of IV-D agency material.* The regional representative will review all materials furnished under § 300.231 and, within 30 days of their receipt, notify the IV-D agency if they are not readibly reviewable or need supporting information. The IV-D agency has 15 days from the date of this notification to make available revised or additional materials. If the IV-D agency does not make the required materials available, the regional representative will promptly disallow the claim (see § 300.222(b)).

(b) *How action is taken on deferred claim.* After the IV-D agency has made all required materials available in acceptable form, the regional representative will allow or disallow a deferred claim and notify the IV-D agency in writing of the decision. If the regional representative does not notify the IV-D agency within 90 days after all required materials have been made available, the Deputy Director will include the claim in the computation of a grant award, subject to a possible later disallowance.

Installment Repayment of Federal Funds

§ 300.240 General.

(a) *When Federal funds must be repaid.* When a claim has been reimbursed and is later determined to be unallowable, the State must repay the unallowable amount.

(b) *When the IV-D agency may repay in installments.* A IV-D agency may repay in installments if:

(1) The total amount to be repaid exceeds 2½ percent of the IV-D agency's share of annual expenditures; and

(2) Before repayment is otherwise due, the IV-D agency notifies the regional representative in writing of its intention to repay in installments.

(c) *Exclusion of other installment repayments.* For purposes of § 300.240-§ 300.243, the amount of a repayment does not include any amount previously approved for installment repayment.

§ 300.241 How to set the repayment schedule.

(a) *How many quarters the repayment may cover.* In order to determine the number of quarters over which repayment may be spread, the State computes this repayment as a percentage of the IV-D agency's share of annual expenditures. Using that percentage, the maximum number of calendar quarters over which a State can spread repayment is:

NUMBER OF QUARTERS TO MAKE REPAYMENT

Total repayment amount as percentage of IV-D agency's share of annual expenditures:	*No.*
2.5 or less	1
Greater than 2.5, but not greater than 5	2
Greater than 5, but not greater than 7.5	3
Greater than 7.5, but not greater than 10	4
Greater than 10, but not greater than 15	5
Greater than 15, but not greater than 20	6
Greater than 20, but not greater than 25	7
Greater than 25, but not greater than 30	8
Greater than 30, but not greater than 47.5	9
Greater than 47.5, but not greater than 65	10
Greater than 65, but not greater than 82.5	11
Greater than 82.5, but not greater than 100	12
Greater than 100	13+

(b) *How much must be repaid in an installment.*

(1) Except for the final repayment, the amount due for each quarter in a repayment schedule shall not be less than the following percentages of the IV-D agency's share of annual expenditures:

REPAYMENT AMOUNT MAY NOT BE LESS THAN THESE PERCENTAGES

For each of the following quarters:	
1 to 4	2.5
5 to 8	5.0
9 plus	17.5

(2) If the State pays higher percentages during the early quarters of its repayment schedule, it applies any corresponding reduction in the minimum percentages first to the last repayment scheduled, then to the next to last, and so on.

§ 300.242 How to determine a IV-D agency's share of expenditures

(a) *General.* A IV-D agency's share of annual expenditures is based on the agency's most recent quarterly statement of financial plan. The IV-D agency's share is the sum of its shares for four quarters, beginning with the quarter in which the first repayment is due.

§ 300.243 How to make repayment.

(a) *General.* OCSE will deduct the appropriate repayment amount from each quarterly grant in accordance with the repayment schedule.

(b) *Retroactive claims.* If OCSE has allowed a State's retroactive claim for FFP, OCSE will offset the amount of that claim against any amounts to be repaid by the State in installments. (For purposes of this section, a retroactive claim is one applicable to any period ending 12 months or more prior to the beginning of the quarter in which Federal funds are to be paid.) Under this provision, a State may:

(1) Suspend repayments until the retroactive claim has been offset; or

(2) Continue repayments until the reduced amount of its debt (remaining after the offset) has been paid in full.

(c) *When interest is charged on repayments.* OCSE will not charge interest on repayments unless required by court order.

Subpart E—Hearing Procedures for IV-D Agencies

General

§ 300.400 Scope.

(a) Hearing procedures described in this subpart apply to reconsideration of a disapproved proposed State plan or plan amendment which is treated as a new plan.

(b) Nothing in this subpart limits negotiations between the Department and the State.

§ 300.401 General rules.

(a) *How to get records.* All papers filed in connection with a hearing are available for inspection and copying in the office of the OCSE hearing clerk. Individuals should direct inquiries to the Central Information Center, Department of Health, Education, and Welfare, 200 Independence Avenue SW., Washington, D.C. 20201.

(b) *How to file and serve papers.* (1) Anyone who wishes to submit papers for the docket shall file with the OCSE hearing clerk an original and two copies, but only originals of exhibits and testimony transcripts.

(2) Anyone who wishes papers to be part of the record shall also serve copies on all parties by personal delivery or by mail. Service on a party's designated attorney is the same as service on the party.

(c) *How rules are suspended.* The Director or the presiding officer may, after notifying all parties, modify or waive any rule in § 300.401-300.421 if he or she decides the action is equitable and will not unduly prejudice the rights of any party.

Arrangements for Hearing

§ 300.405 How to request hearing

AIV-D agency has 60 days from receipt of written notice of State plan disapproval to request a formal hearing. The IV-D agency makes its request in writing to the Director, with a copy to the regional representative.

§ 300.406 How request is acknowledged.

(a) *Notice of hearing.* Within 30 days of receiving a hearing request, the Director will notify the IV-D agency in writing of the date, time, and place of the hearing and of the issues to be considered. The Director will also publish the hearing notice in the Federal Register.

(b) *When the hearing must be set.* The date set for a hearing will be at least 20, but not more than 60 days from the date the IV-D agency receives the hearing notice. However, the IV-D agency and the Director may agree in writing to a different date.

§ 300.407 What the hearing issues are.

(a) *General.* The issues at a hearing are those included in the notice to the IV-D agency described in § 300.406.

(b) *How the Director may add issues.* At least 20 days before a scheduled hearing, the Director will notify the IV-D agency in writing of any additional issues to be considered. The Director will also publish this notice in the Federal Register. If the IV-D agency does not receive its notice in the required time, any party may request the Director to postpone the hearing. If a request is made, the Director will set a new hearing date which is at least 20, but not more than 60 days, from the date the State agency receives the hearing notice.

(c) *How actions by the State may cause the Director to add, modify, or remove issues.* The Director may add, modify or remove issues if, for example, the State agency:

(1) Changes its practices to comply with Federal requirements and its State plan; or

(2) Conforms its State plan to Federal requirements and pertinent court decisions.

(d) *What happens when State action causes the Director to add, modify, or remove issues.*

(1) If the Director specifies new or modified issues, the hearing will proceed on these issues.

(2) (i) If the Director removes an issue, the hearing will proceed on the remaining issues. If the Director removes all the issues, he or she will terminate the hearing proceedings. The Director may terminate hearing proceedings or remove issues before, during, or after the hearing.

(ii) Before removing any issue, the Director will notify all parties other than the Department and the State. This notice will contain the reasons for removing the issue. Within 20 days of the date of this notice, the parties may submit comments in writing on the merits of the proposed removal. The Director will consider these comments and they will become a part of the record.

§ 300.408 What the purpose of a hearing is.

A hearing is held to receive factual evidence and testimony, including expert opinion testimony related to the issues. The presiding officer will not allow arguments as evidence. However, he or she may allow arguments in statements, memoranda, or briefs.

§ 330.409 Who presides.

The presiding officer at a hearing is the Director or a person he or she appoints. If the Director appoints a presiding officer, the Director will send copies of the appointment notice to all parties.

§ 300.410 How to be a party or amicus curiae to a hearing.

(a) *HEW and IV-D agency.* HEW and the IV-D agency are parties to a hearing without having to request participation.

(b) *Other parties or amici curiae.* Any individual or group wishing to be a party or amicus curiae to a hearing must file a petition with the OCSE hearing clerk no more than 15 days following publication of the hearing notice in the Federal Register. A petitioner who wishes to be a party must also provide a copy of the petition to each party of record at that time.

(c) *What must be in a petition.* The petition must state concisely:

(1) The petitioner's interest in the proceedings;

(2) Who will appear for the petitioner;

(3) The issue on which the petitioner wishes to participate; and

(4) Whether the petitioner intends to present witnesses, if the petitioner wishes to be a party.

(d) *What happens to a petition.* The presiding officer will determine

promptly whether each petitioner has the necessary interest in the proceedings, and permit or deny the petition accordingly and in writing. Before making this determination, the presiding officer will allow any party to file comments on the petition to be a party. Any party who wishes to file comments must do so within 5 days of receiving the petition. If the presiding officer denies the petition, he or she will state the reason.

(2) The presiding officer may decide that individuals or groups who have become parties on petition have common interests. He or she may then request that they designate a single representative, or may recognize two or more of those parties to represent all of them.

(e) *What rights parties have.* Any party may:

(1) Appear by counsel or other authorized representative in all hearing proceedings;

(2) Participate in any prehearing conference held by the presiding officer;

(3) Stipulate facts which, if not contested by other parties, will become part of the record;

(4) Make opening statements;

(5) Present relevant evidence;

(6) Present witnesses who must be available for cross-examination by all other parties;

(7) Present oral arguments at the hearing; and

(8) After the hearing submit written briefs, proposed findings of fact, and proposed conclusions of law.

(f) *What rights amici curiae have.* Any amicus curiae may:

(1) Present an oral statement at the hearing at the point in the proceedings specified by the presiding officer;

(2) Submit a written statement of position to the presiding officer before the hearing begins; and

(3) Submit a brief or written statement at the same time as the parties submit briefs. If an amicus curiae submits a written statement or brief, he or she shall serve a copy on each party.

CONDUCT OF HEARING

§ 300.415 Authority of presiding officer.

(a) *General.* It is the duty of the presiding officer to conduct a fair hearing, avoid delay, maintain order, and make a record of the proceedings. He or she has authority to carry out these duties. This includes the authority to:

(1) Regulate the course of the hearing;

(2) Regulate the participation and conduct of the parties, amici curiae and others at the hearing;

(3) Rule on procedural matters and, if necessary, issue protective orders or other relief to a party against whom discovery is sought;

(4) Take any action authorized by the rules in this Subpart or in conformance with 5 U.S.C. 551-559;

(5) Make a final decision if the Director is the presiding officer;

(6) Administer oaths and affirmations;

(7) Examine witnesses; and

(8) Receive or exclude evidence or rule on or limit evidence or discovery.

(b) *What the presiding officer cannot do.* The presiding officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(c) *When the presiding officer's authority is limited.* If the presiding officer is not the Director, he or she does not have the authority to make the final decision, but shall certify the entire record to the Director, including recommended findings and proposed decisions.

§ 300.416 Discovery.

Any party has the right to conduct discovery against other parties. These discovery proceedings are subject to rules 26-37, Federal Rules of Civil Procedure. The presiding officer shall promptly rule on any written objection to discovery and may restrict or control discovery so as to prevent undue delay in the hearing. If any party fails to respond to discovery procedures, the presiding officer may issue any order and impose any sanction (other than contempt orders) authorized by rule 37 of the Federal Rules of Civil Procedure.

§ 300.417 How evidence is handled.

(a) *Testimony.* Witnesses, under oath or affirmation, give oral testimony at a hearing. All witnesses must be available at the hearing for cross-examination by all parties.

(b) *Rules of evidence.* Technical rules of evidence do not apply to hearings described in this subpart. The presiding officer applies whatever rules or principles are necessary to assure disclosure of the most credible evidence available and to subject testimony to cross-examination. Cross-examination may be on any material regardless of the scope of direct examination.

§ 300.418 What happens to unsponsored written materials.

Letters and other written material regarding matters at issue, when not submitted specifically on behalf of one of the parties, will become part of the correspondence section of the docket. This material is not part of the evidence or the record.

§ 300.419 What the record is.

(a) *Official transcript.* HEW designates the official reporter for a hearing. The OCSE hearing clerk has the official transcript of testimony, as well as any other materials submitted with the official transcript. The parties and the public may obtain transcripts of testimony from the official reporter at rates which do not exceed the maximum fixed by contract between the official reporter and HEW. Upon notice to all parties, the presiding officer may authorize corrections to the transcript which involve matters of substance.

(b) *Record.* The record for the hearing decision consists of the transcript of testimony, exhibits, and all papers and requests filed in the proceedings except for the correspondence section of the docket. The record includes any rulings and any decisions on the issues.

AFTER THE HEARING

§ 300.420 Posthearing briefs.

The presiding officer shall fix the time for filing posthearing briefs. These may contain proposed findings of fact and conclusions of law. The presiding officer may permit filing of reply briefs.

300.421 Decisions.

(a) *When the Director is presiding officer.* If the Director is the presiding officer, he or she will issue a final decision within 60 days after expiration of the time allowed for filing of posthearing or reply briefs.

(b) *When the Director appoints a presiding officer.*

(1) The presiding officer, after the time for filing posthearing or reply briefs has expired, shall certify the entire record, including his or her recommended findings and proposed decision, to the Director.

(2) The Director will provide a copy of the recommended findings and proposed decision to all parties and any amici curiae. Within 20 days, a party may file with the Director exceptions to the recommended findings and proposed decision. The party must file a supporting brief or statement with the exceptions.

(3) The Director will review the presiding officer's recommended findings and proposed decision and, within 60 days of receiving them, issue a final decision. The Director will provide copies of that decision to all parties and any amici curiae.

§ 300.422 When decision becomes effective.

If the Director decides to uphold the disapproval of a proposed State plan or plan amendment treated as a new plan, any claims already paid under the disapproved material may later be disallowed. (See § 300.123 for effective date and availability of FFP when the

Director approves a plan or amendment which has been at issue.)

[FR Doc. 78-23942 Filed 8-24-78; 8:45 am]

[4110-35]

Health Care Financing Administration

[42 CFR Parts 201, 204, 205, 213, 430]

GENERAL POLICIES AND PROCEDURES ON GRANTS FOR MEDICAL ASSISTANCE

AGENCY: Health Care Financing Administration (HCFA), HEW.

ACTION: Proposed rule.

SUMMARY: These proposed regulations would reorganize and clarify existing procedural rules on administration of grants to medicaid State agencies. They cover submittal and approval of State plans and plan amendments, Federal payment of State claims, Federal reviews and audits of State medicaid programs, and State agency appeals of Federal decisions on these plans, payments, reviews, and audits. These regulations include new procedures for approval and disapproval of plans and amendments, new provisions for immediate recovery of funds upon disallowance, new procedures for reconsideration of disallowed State claims, changes in time periods for deferrals of claims payment, and changes in routing of payment for survey and certification of long term care facilities. Comparable regulations, appearing today in part V are proposed for the child support enforcement, social services, and financial assistance programs. Existing regulations which are modified and incorporated into these proposed rules are in 45 CFR Parts 201, 204, 213, and portions of 205.

DATES: Closing date for receipt of comments: October 24, 1978.

ADDRESSES: Address comments in writing to: Administrator, Health Care Financing Administration, Department of Health, Education, and Welfare, P.O. Box 2366, Washington, D.C. 20013. Please refer to file code MMB-206. Agencies and organizations are requested to submit comments in duplicate. Beginning 2 weeks from today, the public may review the comments Monday through Friday of each week, from 8:30 a.m. to 5 p.m.: Health Care Financing Administration, Room 5231, 330 C Street SW., Washington, D.C. 20201, 202-245-0950.

FOR FURTHER INFORMATION CONTACT:

Eileen Brooks, 202-245-0722.

SUPPLEMENTARY INFORMATION:

GENERAL PROGRAM DESCRIPTION

The Social Security Act, title XIX, provides formulas for Federal/State sharing in the costs of the medicaid program. Each State and territory is entitled to a Federal grant award for this program when it is operated under a State plan approved by HEW. The agency within HEW which is responsible for Federal administration of medicaid is the Health Care Financing Administration (HCFA). These proposed regulations cover the policies and procedures for HCFA approval and disapproval of State plans, for allowance and disallowance of State claims for payment, for Federal reviews and audits of State medicaid programs, and for State agency appeals of Federal decisions in these areas.

REASONS FOR REVISING REGULATIONS

Under the HEW reorganization order of March 8, 1977, the Social and Rehabilitation Service was disbanded and Federal responsibility for medicaid was transferred to HCFA.

On September 12, 1977, the Secretary of HEW announced two major efforts at improving the departmental regulations. The first, "Operation Common Sense," is a 5-year effort to review and revise existing regulations to make them clearer and more useful. The second effort changed departmental procedures for developing new regulations.

The Department's reorganization coupled with the Secretary's directives on improving HEW regulations prompted this proposed rule. It reflects HEW organizational changes, combines procedures now spread through several parts in title 45 of the CFR into a single part 430 in title 42, that applies only to the medicaid program, and uses clearer, simpler language. Additional content and format changes are outlined below.

PROPOSED REGULATION FORMAT

Under this proposal, procedures for administering grants for medical assistance programs are in a single part 430 in title 42 of the CFR where all other medicaid regulations are or will be located. Regulations on procedures for administering grants to States for financial assistance, social services, and child support enforcement are also proposed in similar formats, each in a single part in the appropriate CFR title and chapter. (See part V of this issue.)

PROPOSED CONTENT CHANGES

1. *Definitions.* The definitions section has been expanded to cover more terms commonly used throughout this and other parts of 42 CFR Chapter IV, Subchapter C.

2. *Authority to approve or disapprove a State plan or amendment.* Secretarial authority is redelegated to the Regional Medicaid Director for approval of State plans and plan amendments, and to the Bureau Director for their disapproval. Under prior delegations, the Regional Medicaid Director could approve but disapproval was reserved to the Administrator of the Health Care Financing Administration after consultation with the Secretary. The proposed policy places responsibility for approvals at the level where the plan enters the approval process, but protects the States in cases of disapproval by requiring that a regional office recommendation be reviewed and decided upon at the central office to assure uniformity and objectivity in these decisions.

3. *Partial approval of plans and amendments.* A new provision permits approval of certain parts of a new plan or plan amendment even though other parts are disapproved. We felt this would expedite incorporation of approvable provisions into State plans and, in some cases, result in earlier availability of Federal funds.

4. *Decisions on plan amendments not treated as new plan material.* Procedures for approval of plan amendments not treated as a new plans are clarified and modified in these regulations. A decision to approve or disapprove will be made within 90 days of receipt in the regional office, just as if the amendment were treated as a new plan. In cases of disapproval, a new provision assures the State of the right to a reconsideration by the Administrator, HCFA. There is now no specific regulatory provision for appeals on disapproved plan amendments of this type although the procedure applicable to disallowances (45 CFR 201.14) has been used. The new reconsideration process for these amendments is simpler and can produce decisions more promptly.

5. *Establishing the submittal date of a plan or amendment.* A new section has been added explaining how the submittal date is officially determined. This is important to States for purposes of claiming Federal funds once the plan or amendment has been approved. Existing regulations are silent on this.

6. *Authority to allow or disallow a State claim for payment.* These amendments reflect redelegations of Secretarial authority to permit both allowance and disallowance decisions to be made by the Administrator. This gives States a single focus for fiscal decisions. The Regional Medicaid Director has the authority to defer payment decisions on claims of questionable allowability, and to review related materials from the State agency, prior to making a recommendation on the

allowability of the claim to the Administrator.

7. *Immediate recovery of disallowed State claims for payment.* A new section has been added to these regulations providing for the immediate recovery of funds upon disallowance. Under existing regulations, if a State agency has been reimbursed for expenditures that are later disallowed, the disallowed funds are not recovered until after a reconsideration decision has been made. This new procedure is being added to the regulations so that the large sums which are often involved in these cases will be available to HEW during the reconsideration period.

8. *Reconsideration of disallowances.* These regulations incorporate by reference new procedures for reconsideration of disallowances of State claims for Federal reimbursement. The new procedures at 45 CFR Part 16, Subpart C, published March 6, 1978, give reconsideration authority to the Departmental Grant Appeals Board, rather than to the program Administrator as previously provided.

9. *Time periods for claim deferrals.* Two 30-day periods have been added to the claim deferral procedures. The first allows State agencies time to submit additional documentation after the Administrator's notice of findings on the allowability of the deferred claim. The second allows the Administrator time to consider the additional material before issuing a final decision.

10. *Reimbursement for survey and certification of long term care facilities.* Reimbursement to State agencies responsible for long term care facility surveys and certifications will no longer flow through Medicaid State agencies. HCFA will reimburse the responsible State agencies directly for these surveys and certifications.

11. *Formal hearing procedures.* Section 1116 of the Act requires that States be given an opportunity for formal hearings on disapprovals of new plans and on compliance and conformity actions. the formal procedures are now at 45 CFR part 213. They are being incorporated into these regulations, so that the regulations cover the full sequence of processing events.

REQUEST FOR PUBLIC COMMENT

We invite comments on these regulations, particularly in the following areas:

1. Usefulness of having regulations for a specific program in a single chapter of the CFR versus joint regulations governing the medicaid, financial assistance, social services, and child support enforcement programs.

2. The usefulness of regulations versus other methods, such as action transmittals, for disseminating procedures on administering grants to States for medical assistance programs.

3. Effectiveness of the current revision of regulations affecting several programs whose rules have previously been intermingled. (See proposed rules beginning on page from the Social Security Administration, the Office of Child Support Enforcement, and the Office of Human Development Services.)

42 CFR chapter IV, subchapter C, is amended by adding a new part 430 to read as set forth below:

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

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430.0 Scope.
430.1 Definitions.

Subpart B—State Plans and Amendments

STATE PLANS AND AMENDMENTS IN GENERAL

430.100 What a State plan is.
430.101 When to amend a State plan.

SUBMISSION OF STATE PLANS AND PLAN AMENDMENTS

430.110 How to submit a proposed State plan or plan amendment.
430.111 How submittal date is determined.

APPROVAL AND DISAPPROVAL OF PROPOSED STATE PLANS AND PLAN AMENDMENTS

430.120 Who can approve or disapprove.
430.121 Partial or total approval.
430.122 What the decision deadline is.
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RECONSIDERATION OF PLAN MATERIAL DISAPPROVALS

430.130 What reconsideration procedures apply.
430.131 What happens to FFP pending outcome of reconsideration.
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Subpart C—Awards and Payments to States

AWARDS AND PAYMENTS IN GENERAL

430.200 When FFP may be claimed.
430.201 What the State agency is responsible for.
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SUBMISSION OF CLAIMS

430.210 How grant awards are issued.
430.211 How estimates are made.
430.212 How expenditures are claimed.
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ALLOWANCE AND DISALLOWANCE OF CLAIMS

430.220 Who can allow or disallow.
430.221 How a decision is made on a claim.
430.222 What happens when a claim is disallowed.
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DEFERRAL OF CLAIMS PAYMENT

430.230 What deferral is.
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430.301 Types and effects of reviews and audits.

PROGRAM AND FINANCIAL REVIEWS

430.305 Program and financial reviews in general.
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HEW AUDIT AGENCY REVIEWS AND AUDITS

430.310 What the HEW Audit Agency does.
430.311 Audit Agency reports.
430.312 Action after Audit Agency review.

Subpart E—Hearing Procedures for State Agencies

GENERAL

430.400 Scope.
430.401 General rules.

ARRANGEMENTS FOR HEARINGS

430.405 How to request hearing.
430.406 How request is acknowledged.
430.407 What the hearing issues are.
430.408 What the purpose of a hearing is.
430.409 Who presides.
430.410 How to be a party or an amicus curiae to a hearing.

CONDUCT OF HEARING

430.415 Authority of presiding officer.
430.416 Discovery.
430.417 How evidence is handled.
430.418 What happens to unsponsored written material.
430.419 What the record is.

AFTER THE HEARING

430.420 Posthearing briefs.
430.421 Decisions.
430.422 When a decision involving nonconformity or noncompliance becomes effective.

AUTHORITY: Sec. 1102 of the Social Security Act; 49 Stat. 647 (42 U.S.C. 1302).

Subpart A—Introduction

§ 430.0 Scope.

This part contains rules on grants to States under title XIX of the Social Security Act. This title authorizes Federal/State sharing of the costs of providing medical assistance to eligible individuals in the 50 States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and the Northern Mariana Islands (90 Stat. 277). This

part is divided into five subparts as follows:

(a) Subpart A gives an overview of what is contained in this part and includes general definitions related to the medicaid program.

(b) Subpart B describes State plans for medicaid. It tells when a plan must be amended and how a new plan or plan amendment is submitted, processed, and appealed when it is disapproved.

(c) Subpart C contains rules for computing and authorizing payment of Federal grants. It includes rules on when State claims for Federal funds may be deferred or disallowed and on how disallowances may be appealed.

(d) Subpart D describes the types of State program reviews and audits conducted by Federal officials.

(e) Subpart E describes hearing procedures available to State agencies.

§ 430.1 Definitions.

As used in this subchapter, unless the context indicates otherwise:

"Act" means the Social Security Act and titles referred to are the titles of that act.

"Administrator" means the Administrator, Health Care Financing Administration.

"Approvable State plan or plan amendment" means a proposed plan or amendment which meets all applicable Federal requirements.

"Bureau Director" means the director of the Federal medicaid program within HCFA.

"Central office" means the headquarters office of HCFA.

"Compliance" means that a State agency is carrying out in practice what is required by Federal statutes, regulations, and pertinent court decisions and contained in the approved State plan.

"Conformity" means that a State plan meets the requirements of Federal and State statutes, Federal regulations, and pertinent court decisions.

"Department" or "HEW" means the Department of Health, Education, and Welfare.

"Federal requirements" means Federal statutes, regulations, and instructions.

"FFP" or "Federal financial participation" means the Federal Government's share of a State's expenditures under the medicaid program.

"HCFA" means the Health Care Financing Administration of HEW.

"Medicaid" means medical assistance provided under a State plan approved under title XIX of the act.

"Plan" or "State plan" means a comprehensive written commitment by a State agency, submitted under section 1902(a) of the act, to administer, or supervise the administration of, a medicaid program in accordance with Federal requirements. This does not include a State cost allocation plan as described in 45 CFR 205.150.

"Plan amendment" or "amendment" means an amendment to an approved State plan under title XIX of the act.

"Regional Medicaid Director" means the Regional Medicaid Director of the medicaid program.

"Regional Office" means one of the regional offices of HCFA.

"Secretary" means the Secretary of Health, Education, and Welfare.

"State" means a political jurisdiction which is eligible to submit a medicaid State plan to HEW for approval. It includes the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and the Northern Mariana Islands.

"State agency" means the single State agency administering, or supervising the administration of, a State medicaid plan.

Subpart B—State Plans and Plan Amendments

State Plans and Amendments in General

§ 430.100 What a State plan is.

(a) A State plan is a detailed description of the nature and scope of a State's medicaid program. It commits a State agency to administer the program in accordance with Federal requirements. Only proper program expenditures which are made under an approved plan are eligible for Federal financial participation. Once a plan is approved, it must be kept current through amendments so that HCFA can determine whether the plan continues to meet Federal requirements.

(b) HCFA will not consider any material as State plan material unless it is submitted as part of a State plan or plan amendment and approved by the Regional Medicaid Director. The State agency shall submit copies of current State operating manuals and other program materials to the Regional Medicaid Director as requested.

§ 430.101 When to amend a State plan.

(a) A State agency must amend its plan whenever:

(1) A new or amended Federal law or regulation requires a new provision or conflicts with an existing plan provision;

(2) A U.S. Supreme Court decision changes the interpretation of a law or regulation; or

(3) State law, organization, policy, or agency operation undergoes a significant change.

Submission of State Plans and Plan Amendments

§ 430.110 How to submit a proposed State plan or plan amendment.

(a) *General.* A State agency must submit a proposed State plan or plan amendment to the Regional Medicaid Director in accordance with HCFA instructions concerning format, content, time limits, transmittal forms, and procedures.

(b) *How plan amendments may be treated.* At the time of submittal, the State agency may ask to have a proposed plan amendment treated as a new plan.

(1) If such a request is made and the amendment is disapproved, the State agency has a right to a hearing under section 1116 of the Act and to judicial review. (See § 430.132.)

(2) If a proposed plan amendment is not treated as a new plan and the amendment is disapproved, the State agency may appeal as described in § 430.133.

(c) *Review by Governor.* When submitting a proposed plan or plan amendment to the Regional Medicaid Director, the State agency shall specify that the Governor:

(1) Was given 45 days to review the material and that the resulting comments, if any, are included in the submital; or

(2) Did not wish to review the material.

(See 45 CFR 204.1 for State plan requirements regarding Governor's review.)

§ 430.111 How submittal date is determined.

(a) *General.* The submittal date of a proposed State plan or plan amendment is the date it is mailed to the regional office as established by the State agency (for example, in the form of a postmark, registered mail date, or affidavit of mailing). If the material is delivered by hand, the submittal date is that shown by the regional office date stamp.

(b) *When submittal date changes.* If a proposed State plan or amendment is not approvable because it does not meet a Federal requirement, the date on which the required change is mailed or delivered to the regional office becomes the submittal date.

(c) *When submittal date remains unchanged.* If a proposed State plan or amendment is approvable but requires clearer wording, that clarifying revision retains the date of the original submittal.

APPROVAL AND DISAPPROVAL OF PROPOSED STATE PLANS AND PLAN AMENDMENTS

§ 430.120 Who can approve or disapprove.

The Regional Medicaid Director has the authority to approve a proposed State plan or plan amendment, except in subject areas for which the Bureau Director has specifically reserved this authority. The Baureau Director has the authority to disapprove a plan or plan amendment. (See § 430.306 for rules on deciding that a previously approved plan provision no longer meets Federal requirements.)

§ 430.121 Partial or total approval.

(a) *State plan.* HCFA approves a State plan only if it meets all mandatory Federal requirements. If any required provision is unapprovable or is omitted, HCFA disapproves the entire plan. However, HCFA may disapprove sections of a plan which relate to optional Federal provisions without affecting approval of the rest of the plan.

(b) *Plan amendment.* HFCA need not approve or disapprove a proposed plan amendment in its entirety, regardless of whether the State agency has asked to have it treated as a new State plan. HCFA can approve amendments to specific parts of a State plan, and disapprove amendments to other parts.

§ 430.122 What the decision deadline is.

(a) *General.* Within 45 days of receipt in the regional office, the Regional Medicaid Director will approve a proposed State plan or plan amendment or forward it to the Bureau Director recommending disapproval. The date or receipt is the date shown by the regional office date stamp. The Bureau Director will issue a decision on approval or disapproval within 90 days of receipt in the regional office.

(b) *Extensions.* The State agency and the Regional Medicaid Director, or Bureau Director, may agree in writing to an extension of the 90-day period.

§ 430.123 Effective dates and FFP under approved State plans or amendments.

(a) *When a plan or amendment affecting FFP becomes effective.* An approved State plan or plan amendment which affects FFP becomes effective on the later of the following dates:

(1) The first day of the calendar quarter in which an approvable plan or amendment was submitted (see § 430.111 for submittal date); or

(2) The first date on which the plan or amendment is in operation statewide.

(b) *When an amendment not affecting FFP becomes effective.* When an amendment does not affect FFP, it becomes effective on the date set by the State agency.

(c) *When a State may submit claims for FFP.* A State agency may not submit claims for new or additional expenditures made under a plan or amendment until it has been approved.

§ 430.124 How State is notified.

(a) *Approval.* When the Regional Medicaid Director approves a proposed State plan or plan amendment, he or she notifies the State agency in writing.

(b) *Disapproval.* When the Regional Medicaid Director submits part or all of a proposed plan or plan amendment to the Bureau Director with a recommendation for disapproval, he or she notifies the State agency in writing of the recommendation. When the Bureau Director disapproves a proposed plan or amendment, he or she notifies the State agency in writing. The notice gives the reason for disapproval and informs the State agency that it has 60 days to request the Administrator to reconsider the decision (see § 430.130).

RECONSIDERATION OF PLAN MATERIAL DISAPPROVALS

§ 430.130 What reconsideration procedures apply.

(a) *For new State plans and plan amendments treated as new plans.* A State agency may request reconsideration of a disapproved State plan or plan amendment which is treated as a new State plan. For purposes of this subpart, the term "new plan material" includes both categories.

(b) *For plan amendments not treated as new plans.* A State agency also may request reconsideration of disapproval of a plan amendment which is not treated as a new plan under § 430.133.

§ 430.131 What happens to FFP pending outcome of reconsideration.

When a State agency requests reconsideration of a disapproval of a new State plan or plan amendment, FFP in any new or increased expenditures under the disapproved plan or amendment is not available while the disapproval is under reconsideration. If the reconsideration decision is favorable to the State agency, the Bureau Director will certify lump-sum payment of any amount due.

§ 430.132 Prehearing procedures for reconsideration of new plan material.

(a) *How to request.* A State agency has 60 days from receipt of HCFA's written notice of disapproval of new plan material to request a reconsideration. The State agency must make the request in writing to the Administrator with a copy to the Regional Medicaid Director.

(b) *Acknowledgement of request.* Within 30 days of receiving a reconsideration request under paragraph (a) of this section, the Administrator notifies the State agency by letter of the date, time, and place of a hearing and of the issues to be considered. (See subpart E for hearing procedures.)

(c) *Judicial review.* If a State agency is not satisfied with a prehearing decision, it may seek judicial review in the U.S. Court of Appeals for the circuit in which the State is located.

(d) *Administrator determines related issues exist.* If a State agency requests a prehearing on the disapproval of a proposed plan or plan amendment, the Administrator may also determine whether a related compliance issue exists. If it does, that issue may be included in the hearing as described in § 430.407.

§ 430.133 Procedures for reconsideration of a disapproved plan amendment not treated as a new plan.

(a) *How to request.* A State agency has 60 days from receipt of the Bureau Director's written notice of disapproval to request a reconsideration. The State agency shall make the request in writing to the Administrator with a copy to the Regional Medicaid Director.

(b) *Acknowledgement of request.* The Administrator acknowledges a State agency's request for reconsideration promptly and in writing.

(c) *Submittal of information.* (1) The Administrator will promptly send the State agency a list of all material that is part of the record. The Administrator will also make this material available for the State agency's inspection and copying.

(2) The Regional Medicaid Director and the State agency have 30 days from the date of the Administrator's list to submit any additional supporting material to the Administrator and to each other. If the Regional Medicaid Director or the State agency submits additional material, the other party has 20 days from the transmittal date to respond in writing to the Administrator.

(d) *Right to conference.* (1) At anytime during the period allowed under paragraph (c) of this section, the State agency may request a conference with the Administrator to discuss the issues.

(2) The State agency may have the conference transcribed at its own expense. Upon its request, the transcript becomes part of the record.

(e) *What the record is.* All materials considered in reaching a decision constitute the record of a reconsideration. The record closes on the later of the following dates:

(1) Expiration of the period allowed under paragraph (c) of this section;

(2) If there is a conference and the transcript becomes part of the record, upon the Administrator's receipt of the transcript; or

(3) If there is a conference and the transcript does not become part of the record, 30 days after the conference.

(f) *How the decision is issued.* Within 60 days after the record is closed, the Administrator or the person designated to preside at the conference will send a written decision to the head of the State agency.

(g) *Extension of time limits.* Either the State agency or the Regional Medicaid Director may, for good cause, request an extension of the time limits in this section.

Subpart C—Awards and Payments to States

AWARDS AND PAYMENTS IN GENERAL

§ 430.200 When FFP may be claimed.

(a) *General.* A State agency may claim Federal funds for expenditures for medical services, training, and related administration under an approved State plan and other Federal requirements including prior approval of certain classes of expenditures as required, and conformity with an approved cost allocation plan.

(b) *Reimbursement for survey and certification of long term care facilities.* Grants to States under this subpart do not cover reimbursement for survey and certification of skilled nursing and intermediate care facilities for participation in Medicaid. Reimbursement for these activities will be made by HCFA directly to the State agencies responsible for establishing and maintaining health standards in these institutions.

§ 430.201 What the State agency is responsible for.

The State agency is responsible for making available all documentation required by HCFA in the format specified to establish the allowability of its claims for FFP. (See §§ 430.230–430.232 on deferrals and §§ 430.220–430.223 on disallowances.)

§ 430.202 Administration of grants.

(a) *General.* Unless otherwise indicated, all grants made to States under this part are subject to the provisions of 45 CFR Part 74, Administration of Grants.

(b) *Exception.* Subparts G, Matching and Cost Sharing, and I, Financial Reporting Requirements, of part 74 do not apply to these grants.

SUBMISSION OF CLAIMS

§ 430.210 How grant awards are issued.

(a) *Amount of grant.* The Bureau Director, subject to the availability of Federal funds, issues a grant based on the estimated expenditures for each quarter. This estimate is reduced or increased to the extent of any overpayment or underpayment for any prior quarter for which adjustment has not already been made. Examples of adjustments which reduce or increase the grant award include:

(1) The difference between the estimate for a quarter and the amount claimed by the State agency on the expenditure statement for that quarter;

(2) Amounts (including penalties and audit exceptions) which the Administrator disallows;

(3) Amounts which the Regional Medicaid Director defers;

(4) Amounts which the Regional Medicaid Director has deferred and the Administrator later finds allowable;

(5) Amounts of recoveries, refunds, and collections as determined by the Administrator; and

(6) Amounts which exceed statutory limitations.

(b) *How State agency is notified.* The Bureau Director issues to the State agency a grant award which shows the amount awarded for each quarter. Accompanying the grant award is a form showing the basis on which the grant was computed. The Bureau Director also notifies the State Central Information Reception Agency of the grant award in accordance with section 201 of the Intergovernmental Cooperation Act of 1968.

(c) *How the grant is paid.* The Departmental Federal Assistance Financing System (DFAFS) pays the grant. Payment procedures are governed by subpart K of 45 CFR Part 45, Treasury Circular No. 1075, and the DFAFS Recipient Users Manual.

§ 430.211 How estimates are made.

(a) In accordance with HCFA instructions, at least 45 days before the beginning of the estimate quarter, a State agency shall submit to the Bureau Director, with a copy to the Regional Medicaid Director:

(1) Estimates of the total amount, and the Federal share, of expenditures for the program;

(2) A certification of the amount of State funds (and local funds, if applicable) appropriated or made available for the estimated expenditures signed by:

(i) A fiscal officer of the State, if required by State law or regulations; or

(ii) The agency's executive officer or designee; and

(3) If the funds certified as appropriated or made available are insufficient to cover the State's share of the estimated expenditures, a statement of the source from which the balance will be derived and when.

(b) This estimate and any investigation that the Bureau Director finds necessary form the basis for making the grant award for that quarter.

§ 430.212 How expenditures are claimed.

(a) *What the quarterly statement of expenditures is.* The quarterly statement of expenditures is an accounting for expenditures made during the quarter by the State agency and the State agency's claim for reimbursement.

(b) *How to sumit the statement.* Within 30 days after the end of each calendar quarter, in accordance with HCFA instructions, the State agency shall submit to the Bureau Director, with a copy to the Regional Medicaid Director, a statement of expenditures for that quarter along with the necessary supporting schedules.

(c) *Rejection of statement.* If the quarterly statement of expenditures is based on estimates, it will be rejected. Indirect costs calculated under approved rates or in conformance with approved cost allocation plans are acceptable.

§ 430.213 How a grant award is computed.

(a) *Amount of grant.* The amount of each quarterly estimate of expenditures is:

(1) Increased or decreased by the amount by which the estimate for any prior quarter, as determined under § 430.211, was greater or less than the amount which should have been paid for that quarter; and

(2) Decreased by the Federal share of the net amount of recoveries, refunds, or collections made by the State during any quarter.

ALLOWANCE AND DISALLOWANCE OF CLAIMS

§ 430.220 Who can allow or disallow.

The Administrator has the authority to allow or disallow a paid or unpaid claim for FFP. As used in this subpart, the term "disallowance" does not include implementation of a decision to reduce or withhold FFP for lack of compliance or conformity. (See §§ 430.305–430.306 on compliance and conformity.)

§ 430.221 How a decision is made on a claim.

A State agency's claim for FFP is allowed or disallowed based on review and analysis of its quarterly statement of expenditures. In determining whether expenditures are allowable, either regional or cental office officials may conduct onsite reviews involving examination of State agency accounting and operational records and discussions with State officials. (See subpart D on Federal Reviews.)

§ 430.222 What happens when a claim is disallowed.

(a) *General.* A disallowance is a finding by the Administrator that a claim by a State agency for FFP in expenditures is not properly chargeable to the program. Because of statutory penalties and limitations, the Administrator may also disallow expenditures on claims which are properly chargeable to the program.

(b) *How State agency is notified.* If any portion of the amount claimed on a quarterly statement of expenditures is disallowed, the Administrator's notice to the State agency includes pertinent information on amounts, dates, and reasons for the disallowance. The Administrator's notice also indicates that the State agency may request reconsideration of the disallowance as described in § 430.223 of this subpart.

(c) *How the State's grant for a disallowance is adjusted.* When a State agency's claim for FFP is disallowed, the Bureau Director will either amend the current grant or adjust the grant for the following quarter, subject to the provisions of §§ 430.240–430.243, to reduce the State's grant authority by the amount of the disallowance. Where the disallowed amount was previously deferred, no further adjustment will be made.

§ 430.223 How to appeal disallowance of a claim.

(a) *How to request.* A State agency has 45 days from the postmark date of HCFA's notice of disallowance to request reconsideration by the Departmental Grant Appeals Board under 45 CFR Part 16. The request shall be addressed to the Executive Secretary, Departmental Grant Appeals Board, with copies to the Bureau Director and the Regional Medicaid Director.

DEFERRAL OF CLAIMS PAYMENT

§ 430.230 What deferral is.

As used in this subpart, "deferral" means suspending the inclusion of a claim in the computation of a grant award pending the inspection and analysis of further information needed to establish the claim's allowability for FFP.

§ 430.231 How deferral occurs.

(a) *Basis for deferral.* The Regional Medicaid Director can defer including a claim in the computation of a grant award (see § 430.210) if it is of questionable allowability.

(b) *Notice to State agency.* The Regional Medicaid Director takes deferral action within 60 days after receiving an acceptable quarterly statement of expenditures. Within 15 days of the deferral action, the Regional Medicaid Director sends the State agency written notification identifying the type and amount of the claim and the reason for deferral. The notice also requests the State agency to make available for inspection all materials that the Regional Medicaid Director considers necessary to determine the allowability of the claim.

(c) *How State agency responds.* Within 60 days of the Regional Medicaid Director's notice of deferral, the State agency makes any requested materials available to the Regional Office in readily reviewable form. If the State agency requests additional time to make materials available, the Regional Medicaid Director will give an additional period of no more than 60 days.

§ 430.232 How decision is made on a deferred claim.

(a) *Review of State agency materials.* The Regional Medicaid Director will review all materials furnished under § 430.231 and, within 30 days of their receipt, notify the State agency that it has 15 days from the date of this notice to make available revised or additional materials. If the State agency does not make the required materials available in readily reviewable form, the Regional Medicaid Director will promptly recommend disallowance of the claim (see § 430.220).

(b) *How action is taken on deferred claim.* (1) Within 90 days after the State agency has made all required material available in acceptable form, the Regional Medicaid Director will provide the Administrator written findings and recommendations on the allowability of the claim. The Regional Medicaid Director will at the same time notify the State agency of the findings and recommendations when the recommendations are to disallow the State agency's claim or any part of it.

(2) The State agency has 30 days from the date of the Regional Medicaid Director's notice of findings and recommendations to disallow to submit in writing to the Administrator any new relevant evidence, documentation, or arguments in support of the allowability of the deferred claim.

(3) Whether or not the State agency submits additional material, the Administrator will notify the State agency in writing of the decision on the allowability of the deferred claim within 30 days after the State agency has made any new relevant evidence, documentation, arguments, or other material available, or upon expiration of the 30 day submission period.

(4) When the Regional Medicaid Director's notice to the State agency is not issued within the 90 day period required by paragraph (b)(1) of this section, or the Administrator's notice is not issued within the 30 day limit required by paragraph (b)(3) of this section, the Bureau Director will include the amount of the claim in a grant award, subject to a later determination of allowability.

INSTALLMENT REPAYMENT OF FEDERAL FUNDS

§ 430.240 General.

(a) *When Federal funds must be repaid.* When a claim has been reimbursed and is later determined to be unallowable, the State agency must repay the unallowable amount.

(b) *When the State agency may repay in installments.* A State agency may repay in installments if:

(1) The total amount to be repaid exceeds 2½ percent of the State agency's share of annual expenditures incurred; and

(2) Before payment is otherwise due, the State agency notifies the Regional Medicaid Director in writing of its intention to repay in installments.

(c) *Exclusion of other installment repayments.* For purposes of §§ 430.240–430.243, the amount of a repayment does not include any amount previously approved for installment repayment.

§ 430.241 How to set the repayment schedule.

(a) *How many quarters the repayment may cover.* In order to determine the number of quarters over which repayment may be spread, the State agency computes this repayment as a percentage of the State agency's share of annual Medicaid expenditures. Using that percentage, the maximum number of calendar quarters over which a State agency may spread repayment is:

Total repayment amount as percentage of State share of annual Medicaid expenditures	Number of quarters to make repayment
2.5 pct. or less	1
Greater than 2.5, but not greater than 5	2
Greater than 5, but not greater than 7.5	3
Greater than 7.5, but not greater than 10	4
Greater than 10, but not greater than 15	5
Greater than 15, but not greater than 20	6
Greater than 20, but not greater than 25	7
Greater than 25, but not greater than 30	8
Greater than 30, but not greater than 47.5	9
Greater than 47.5, but not greater than 65	10
Greater than 65, but not greater than 82.5	11
Greater than 82.5, but not greater than 100	12
Greater than 100	13+

(b) *How much must be repaid in an installment.* (1) Except for the final repayment, the installment due for each quarter in a repayment schedule shall not be less than the following percentages of the State agency's share of annual medicaid expenditures:

For each of the following quarters	Repayment installment may not be less than these percentages
1 to 4	2.5
5 to 8	5.0
9 plus	17.5

(2) If the State agency pays higher percentages during the early quarters of its repayment schedule, it applies any corresponding reduction in the minimum percentages first to the last repayment scheduled, then to the next to last, and so on.

§ 430.242 How to determine the State agency's share of expenditures.

(a) *General.* A State agency's share of annual expenditures is based on its most recently submitted quarterly State Agency statement of financial plan for medicaid. The State agency's share is the sum of its shares for four quarters, beginning with the quarter in which the first repayment is due.

(b) *Exception.* If the State's medicaid program has been terminated, the State agency's share, based on its quarterly statements of expenditures, is the sum of its shares of allowable actual expenditures for the last four quarters preceding the date on which the program was terminated.

§ 430.243 How to make repayment.

(a) *General.* The Bureau Director will deduct the repayment amount from each quarterly grant award in accordance with the repayment schedule.

(b) *Retroactive claims.* If the Administrator has allowed a State agency's retroactive claim for FFP, the Bureau Director will offset the amount of that claim against any amounts to be repaid by the State agency in installments under the medicaid program. (For purposes of this section, a retroactive claim is one applicable to any period ending 12 months or more prior to the beginning of the quarter in which Federal funds are to be paid). Under this provision, a State agency may:

(1) Suspend repayments until the retroactive claim has been offset; or

(2) Continue repayments until the reduced amount of its debt (remaining after the offset) has been paid in full.

(c) *When interest is charged on repayments.* HCFA will not charge interest on repayments unless required by court order.

Subpart D—Federal Program and Financial Reviews and Audits

Federal Reviews and Audits in General

§ 430.300 What Federal reviews and audits are.

(a) *Reviews.* As used in this subpart D, a Federal review is any type of review necessary to determine whether a State plan continues to be approvable and whether State agency operations and claims for FFP are proper under Federal requirements and the approved State plan. A review may cover any aspect of the medicaid program.

(b) *Audits.* As used in this subpart D an audit is any type of audit necessary to determine whether State agency operations and claims for FFP are proper under Federal requirements and the approved State plan. An audit may cover any aspect of the medicaid program. The term "audit" includes, but is not limited to, audits by the General Accounting Office and the HEW Audit Agency.

§ 430.301 Types and effects of reviews and audits.

(a) *Types.* The types of Federal reviews and audits most often conducted are:

(1) Program and financial reviews as described in §§ 430.305—430.306; and

(2) HEW Audit Agency audits as described in § 430.310.

(b) *Effects.* Any review or audit may result in a disallowance or in formal compliance or conformity action.

Program and Financial Reviews

§ 430.305 Program and financial reviews in general.

(a) *Responsibility for review.* The Regional Medicaid Director will conduct program and financial reviews at whatever times he or she considers appropriate. In doing so, the Regional Medicaid Director may make use of any procedures (including onsite review) or specialized assistance needed.

(b) *Purpose of review.* The purpose of a program or financial review is to determine the nature and scope of a State's medicaid program in relation to Federal requirements. Program and financial reviews include:

(1) Determining the allowability of claims;

(2) Evaluating a program's quality and the State agency's need for technical assistance;

(3) Determining whether a State plan conforms with Federal requirements. (A question of conformity may arise when a State agency fails to submit an approvable plan amendment to implement a new Federal requirement; when previously approved plan material no longer meets Federal requirements; or when plan material has been approved in error); and

(4) Determining whether the State's operating practices are in substantial compliance with the approved State plan and with Federal requirements.

(c) *Review findings.* HCFA will make all review findings available in writing to the State agency so that it can correct any unacceptable policy or practice. If a review results in disallowance of a claim, the procedures in §§ 430.222–430.223 will apply.

§ 430.306 Issues of compliance or conformity after review.

(a) *Regional Medicaid Director tries to resolve.* If the Regional Medicaid Director believes there is a compliance or conformity issue, he or she will try to obtain needed changes in the State agency's operating practice or the State plan.

(b) *Issue not resolved.* If the State agency does not make the change necessary to bring about compliance or conformity:

(1) The Regional Medicaid Director will recommend that the Bureau Director begin formal action;

(2) If the Bureau Director agrees that there is an issue of compliance or conformity, he or she will notify the State agency and give it an opportunity for a hearing under subpart E.

HEW Audit Agency Reviews and Audits

§ 430.310 What the HEW Audit Agency does.

The HEW Audit Agency (Audit Agency) in the HEW Inspector General's Office conducts both routine and special reviews and audits. These are to assure that Federal funds are being spent properly and prudently.

§ 430.311 Audit Agency reports.

Upon completion of an audit or other review, the Audit Agency releases its final report. The report contains the Audit Agency's findings on the practices reviewed and the allowability of expenditures audited.

§ 430.312. Action after Audit Agency review.

When the Audit Agency questions a claim, the Administrator may disallow FFP and notify the State agency accordingly. When the Audit Agency finds problems of compliance, the Bureau Director decides whether to take formal compliance action and notifies the State agency accordingly.

Subpart E—Hearing Procedures for State Agencies

GENERAL

§ 430.400 Scope.

(a) *General.* The act requires that a State agency be given an opportunity for a hearing on certain matters. Hearing procedures described in this subpart apply to:

(1) Reconsideration of a disapproved State plan or plan amendment that is treated as a new plan; and

(2) Notification of formal compliance or conformity action.

(b) *Negotiations.* Nothing in this subpart limits negotiations between the Department and the State agency.

§ 430.401 General rules.

(a) *How to get records.* All papers filed in connection with a hearing are available for inspection and copying in the office of the HCFA hearing clerk. Individuals should direct inquiries to the Central Information Center, Department of Health, Education, and Welfare, 200 Independence Avenue SW., Washington, D.C. 20201.

(b) *How to file and serve papers.* Anyone who wishes to submit papers for the docket shall file with the HCFA hearing clerk an original and two copies, but only originals of exhibits and testimony transcripts. Anyone who wishes papers to be part of the record shall also serve copies on all parties by personal delivery or by mail. Service on a party's designated attorney is the same as service on the party.

(c) *When rules are suspended.* The Administrator or the presiding officer may, after notifying all parties, modify or waive any rule in §§ 430.401–430.421 if he or she decides the action is equitable and will not unduly prejudice the rights of any party.

ARRANGEMENTS FOR HEARINGS

§ 430.405 How to request hearing.

A State agency has 60 days from receipt of HCFA's written notice of State plan disapproval or intended compliance or conformity action to request a formal hearing. The State agency makes its request in writing to the Administrator with a copy to the Regional Medicaid Director.

§ 430.406 How request is acknowledged.

(a) *Notice of hearing.* Within 30 days of receiving a hearing request, the Administrator will notify the State agency in writing of the date, time, and place of the hearing and of the issues to be considered. The Administrator will also publish the hearing notice in the FEDERAL REGISTER.

(b) *When the hearing must be set.* The date set for a hearing will be at least 20, but not more than 60, days from the date the State agency receives the hearing notice. However, the State agency and the Administrator may agree in writing to a different date.

§ 430.407 What the hearing issues are.

(a) *General.* The issues at a hearing are those included in the notice to the State agency described in § 430.405.

(b) *How the Administrator may add issues.* At least 20 days before a scheduled hearing, the Administrator will notify the State agency by letter of any additional issues to be considered. The Administrator will also publish this notice in the FEDERAL REGISTER. If the State agency does not receive its notice in the required time, any party may request the Administrator to postpone the hearing. If a request is made, the Administrator will set a new hearing date that is at least 20, but not more than 60, days from the date the State agency receives the hearing notice.

(c) *How actions by the State agency may cause the Administrator to add, modify, or remove issues.* The Administrator may add, modify or remove issues if, for example, the State agency:

(1) changes its practices to comply with Federal requirements and its State plan; or

(2) conforms its State plan to Federal requirements and pertinent court decisions.

(d) *What happens when State action causes the Administrator to add, modify, or remove issues.*

(1) If the Administrator specifies new or modified issues, the hearing will proceed on these issues.

(2)(i) If the Administrator removes an issue, the hearing will proceed on the remaining issues. If the Administrator removes all the issues, he or she will terminate the hearing proceedings. The Administrator may terminate hearing proceedings or remove issues before, during, or after the hearing.

(ii) Before removing any issue the Administrator will notify all parties other than the State of the issue. This notice contains the reasons for removing the issue. Within 20 days of the date of this notice the parties may submit comments in writing on the merits of the proposed removal. The Administrator will consider these comments and they become a part of the record.

§ 430.408 What the purpose of a hearing is.

The purpose of the hearing is to receive factual evidence, including expert opinion testimony, related to the issue. The presiding officer will not allow argument as evidence. However, he or she may allow argument in statements, memoranda, or briefs.

§ 430.409 Who presides.

The presiding officer at a hearing is the Administrator or a person he or she appoints. If the Administrator appoints a presiding officer, the Administrator will send copies of the appointment notice to all parties.

§ 430.410 How to be a party or an amicus curiae to a hearing.

(a) *HEW and State agency.* HEW and the State agency are parties to a hearing without having to request participation.

(b) *Other parties or amici curiae.* Any individual or group wishing to be a party or amicus curiae to a hearing must file a petition with the HCFA hearing clerk no more than 15 days following publication of the hearing notice in the FEDERAL REGISTER. A petitioner who wishes to be a party must also provide a copy of the petition to each party of record at that time.

(c) *What must be in a petition.* The petition must state concisely:

(1) The petitioner's interest in the proceedings;

(2) Who will appear for the petitioner;

(3) the issue on which the petitioner wishes to participate; and

(4) Whether the petitioner intends to present witnesses, if the petitioner wishes to be a party.

(d) *What happens to a petition.* (1) the presiding officer will determine promptly whether each petitioner has the necessary interest in the proceedings and permit or deny the petition accordingly and in writing. Before making this determination the presiding officer will allow any party to file comments on the petition to be a party. Any party wishing to file comments must do so within 5 days of receiving the petition. If the presiding officer denies the petition, he or she will state the reasons.

(2) The presiding officer may decide that individuals or groups, who have become parties on petition, have common interests. He or she may then request that they designate a single representative or may recognize one or more of the parties to represent all of them.

(e) *What rights parties have.* Any party may:

(1) Appear by counsel or other authorized representative in all hearing proceedings;

(2) Participate in any prehearing conference held by the presiding officer;

(3) Stipulate facts that, if uncontested, will become part of the record;

(4) Make opening statements;

(5) Present relevant evidence;

(6) Present witnesses who must be available for cross-examination by other parties;

(7) Present oral arguments at the hearing; and

(8) Submit written briefs, proposed findings of fact, and proposed conclusions of law, after the hearing.

(f) *What rights amici curiae have.* Any amicus curiae may:

(1) Present an oral statement at the hearing at the point in the proceedings specified by the presiding officer;

(2) Submit a written statement of position to the presiding officer before the hearing begins;

(3) Submit a brief or written statement at the same time as the parties submit briefs.

If an amicus curiae submits a written statement or brief, he or she shall serve a copy on each party.

CONDUCT OF HEARING

§ 430.415 Authority of presiding officer.

(a) *General.* It is the duty of the presiding officer to conduct a fair hearing, avoid delay, maintain order, and make a record of the proceedings. He or she has authority to carry out these duties. This includes the authority to:

(1) Regulate the course of the hearing;

(2) Regulate the participation and conduct of parties, amici curiae, and others at the hearing.

(3) Rule on procedural matters and, if necessary, issue protective orders or other relief to a party against whom discovery is sought;

(4) Take any action authorized by the rules in this subpart or in conformance with 5 U.S.C. 551-559;

(5) Make a final decision, if the Administrator is the presiding officer;

(6) Administer oaths and affirmations;

(7) Examine witnesses; and

(8) Receive or exclude evidence, or rule on or limit evidence or discovery.

(b) *What the presiding officer cannot do.* The presiding officer does not have the authority to compel by subpena the production of witnesses, papers, or other evidence. 000

(c) *When the presiding officer's authority is limited.* If the presiding officer is not the Administrator, he or she does not have the authority to:

(1) Make a final decision, but shall certify the entire record to the Administrator, including recommended findings and decisions;

(2) Recommend reduction or withholding of FFP in matters of compliance and conformity.

§ 430.416 Discovery.

Any party has the right to conduct discovery against other parties. These discovery proceedings are subject to rules 26-37, Federal Rules of Civil Procedure. The presiding officer shall promptly rule on any written objection to discovery and may restrict or control discovery so as to prevent undue delay in the hearing. If any party fails to respond to discovery procedures, the presiding officer may issue any order and impose any sanction (other than contempt orders) authorized by rule 37 of the Federal Rules of Civil Procedure.

§ 430.417 How evidence is handled.

(a) *Testimony.* Witnesses, under oath or affirmation, give oral testimony at a hearing. All witnesses must be available at the hearing for cross-examination by all parties.

(b) *Rules of evidence.* Technical rules of evidence do not apply to hearings described in this subpart. The presiding officer applies whatever rules or principles are necessary to assure disclosure of the most credible evidence available and to subject testimony to cross-examination. Cross-examination may be on any material matter regardless of the scope of direct examination.

§ 430.418 What happens to unsponsored written material.

Letters and other written material regarding matters at issue, when not submitted specifically on behalf of one of the parties, become part of the correspondence section of the docket. This material is not part of the evidence or the record.

§ 430.419 What the record is.

(a) *Official transcript.* HEW designates the official reporter for a hearing. The HCFA hearing clerk has the official transcript of testimony, as well as any other materials submitted with the official transcript. The parties and the public may obtain transcripts of testimony from the official reporter at rates which do not exceed a maximum fixed by contract between the reporter and HEW. Upon notice to all parties, the presiding officer may authorize corrections to the transcript which involve matters of substance.

(b) *Record.* The record for the hearing decision consists of the transcript of testimony, exhibits, and all papers and requests filed in the proceedings except for the correspondence section of the docket. The record includes rulings and any decisions.

AFTER THE HEARING

§ 430.420 Posthearing briefs.

The presiding officer shall fix the time for filing posthearing briefs. These may contain proposed findings of fact and conclusions of law. The presiding officer may permit filing of reply briefs.

§ 430.421 Decisions.

(a) *When the Administrator is presiding officer.* If the Administrator appoints a presiding officer:

(1) After the time for filing posthearing or reply briefs has expired, the presiding officer shall certify the entire record including his or her recommended findings and proposed decision to the Administrator.

(2) The Administrator will provide copies of the recommended findings and proposed decisions to all parties and amici curiae. Within 20 days, a party may file with the Administrator exceptions to the recommended findings and proposed decision. The party must file a supporting brief or statement with the exceptions.

(3) The Administrator will review the presiding officer's recommended findings and proposed decision and, within 60 days of receiving them, issue a final decision. The Administrator will provide copies of that decision to all parties and amici curiae.

(c) *When the decision involves nonconformity or noncompliance.* When the Administrator decides, after a formal hearing, that nonconformity or substantial noncompliance exists, the final decision will state whether further payments to the State agency will be withheld entirely or will be limited to categories not affected.

§ 430.422 When a decision involving nonconformity or noncompliance becomes effective.

The Administrator's decision will specify the effective date for any withholding of Federal payments because of nonconformity or substantial noncompliance. This effective date cannot be earlier than the date of the Administrator's decision or later than the first day of the next calendar quarter.

(Sec. 1102 of the Social Security Act; 49 Stat. 647 (42 U.S.C. 1302).)

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program.)

Dated: June 12, 1978.

WILLIAM D. FULLERTON,
Acting Administrator, Health Care Financing Administration.

Approved: August 19, 1978.

HALE CHAMPION,
Acting Secretary.

[FR Doc. 78-23944 Filed 8-24-78; 8:45 am]

FRIDAY, AUGUST 25, 1978
PART VI

federal register

DEPARTMENT OF ENERGY

Bonneville Power Administration

■

WHOLESALE POWER RATES

Availability of Environmental Impact Statement; Opportunities for Public Review and Comment

[3128-01]

DEPARTMENT OF ENERGY

Bonneville Power Administration

PROPOSED 1979 WHOLESALE RATE INCREASE

Availability of Draft Environmental Impact Statement

AGENCY: Department of Energy.

ACTION: Notice of Availability.

SUMMARY: Notice is hereby given that the Bonneville Power Administration (BPA), Department of Energy (DOE), has issued a draft environmental impact statement (EIS) on its Proposed 1979 Wholesale Rate Increase. This EIS is issued pursuant to DOE's implementation of the National Environmental Policy Act of 1969. BPA has prepared a draft proposal which calls for a 90-percent revenue increase reflected in the wholesale rates charged to public utilities, direct service industries, and other customers in its service area, as well as to customers outside that area. The draft EIS discusses the proposal, the reasons for it, alternatives to it, the methods by which the proposed rates were determined, and the possible environmental effects.

Public comments will be received on both the draft environmental statement and the rate proposal. A notice is being published in the FEDERAL REGISTER concurrently with this Notice, announcing the rate proposal and giving the dates of the public information and public comment meetings which will be held in conjunction with the proposal.

Those meetings will also serve as public meetings on the draft EIS. A final EIS will be prepared, reflecting the comments received during the review period, and a final rate proposal will be transmitted to the Economic Regulatory Administration within DOE.

Copies of the draft EIS statement are available for public inspection at designated Federal depositories (for locations, contact the Environmental Manager, BPA, P.O. Box 3621, Portland, Oreg. 97208) and at DOE public document rooms located at:

Library, DOE, Room 1223, 20 Massachusetts Avenue NW., Washington, D.C.
BPA, Washington, D.C. Office, Interior Building, 18th and C Streets NW., Washington, D.C.
Library, BPA Headquarters, 1002 Northeast Holladay Street, Portland, Oreg.

And in the following BPA Area and District Offices:

Eugene District Office, U.S. Federal Building, 211 East Seventh Street, Room 206, Eugene, Oreg.
Idaho Falls District Office, 531 Lomax Street, Idaho Falls, Idaho.
Kalispell District Office, Highway 2 (East of Kalispell), Kalispell, Mont.
Portland Area Office, Lloyd Plaza Building, 919 Northeast 19th Avenue, Room 210, Portland, Oreg.
Seattle Area Office, 415 First Avenue North, Room 250, Seattle, Wash.
Spokane Area Office, U.S. Court House, Room 561, West, 920 Riverside Avenue, Spokane, Wash.
Walla Walla Area Office, West 101 Poplar, Walla Walla, Wash.
Wenatchee District Office, U.S. Federal Building, Room 314, 301 Yakima Street, Wenatchee, Wash.

This document is being furnished to various Federal, State, and local agencies with environmental expertise, or which are otherwise likely to be interested in, or affected by, the proposed program. Copies of the document are also being furnished to State and local clearinghouses and to other interested groups and individuals.

A limited number of single copies are available for distribution by contacting the Environmental Manager, Bonneville Power Administration, P.O. Box 3621, Portland, Oreg. 97208; and the BPA Area and District Offices mentioned above.

Questions concerning the draft EIS may be addressed to Mr. John Kiley, Environmental Manager, at the Portland, Oreg., post office box address above.

DATE: Comments by November 30, 1978.

ADDRESS: Comments to P.O. Box 3621, Portland, Oreg. 97208.

FOR FURTHER INFORMATION CONTACT:

John Kiley, Environmental Manager, Bonneville Power Administration, P.O. Box 3621, Portland, Oreg. 97208, 503-429-5137.

Issued in Washington, D.C., August 23, 1978.

WILLIAM S. HEFFELFINGER,
Director of Administration.

[FR Doc. 78-24092 Filed 8-24-78; 8:45 am]

[3128-01]

PROPOSED WHOLESALE POWER RATES AND OPPORTUNITIES FOR PUBLIC REVIEW AND COMMENT

AGENCY: Bonneville Power Administration (BPA), Department of Energy.

ACTION: Notice of Proposed Wholesale Power Rates and Opportunities for Public Review and Comment.

SUMMARY: The BPA Administrator has made a repayment study of the Federal Columbia River Power System (FCRPS) showing the need for approximately a 90-percent increase in revenues to meet cost recovery criteria. The proposed wholesale power rate schedules plus an increase in transmission rates, which will be proposed at a later date, will produce the necessary revenues. Opportunities will be presented for interested persons to review the studies made in developing the proposed rates, to participate in public information and public comment forums, and to submit written comments. BPA will evaluate all written and oral comments and other information received for consideration in the development of the proposed wholesale power rates which BPA submits through the Assistant Secretary for Resource Applications (AS—RA) to the Economic Regulatory Administration (ERA) for confirmation and approval. As a result of public participants' comments, the proposed rates ultimately submitted to ERA may vary from those tentatively proposed in this Notice.

DATES: The Public Information Forums and Public Comment Forums will be held on the following dates at the locations indicated. On September 11 and November 1, 1978, at the BPA Auditorium, 1002 NE. Holladay Street, Portland, Oreg.; on September 12 and November 2, 1978, at the Eugene Hotel, 222 East Broadway, Eugene, Oreg.; on September 13 and November 13, 1978, at the Blakeley Room, Seattle Center, Seattle, Wash.; on September 14 and November 6, 1978, at the Federal Building Auditorium, 825 Jadwin Avenue, Richland, Wash.; on September 18, 1978, at the Wenatchee Room, Thunderbird Motor Inn, 1225 North Wenatchee, Wenatchee, Wash., and on November 8, 1978, at City Hall, Chelan Avenue and Yakima Street, Wenatchee, Wash.; on September 19 and November 14, 1978, at the Terrace Rooms, Ridpath Hotel, West 515 Sprague, Spokane, Wash.; on September 20 and November 15, 1978, at the Tudor-Burgundy Room, Holiday Inn, Highway 10 West and Mullan Road, Missoula, Mont.; and on September 21 and November 7, 1978, at the Intermountain Science Experience Center Auditorium, 1776 Science Center Drive, Idaho Falls, Idaho. The forums will begin at 7 p.m.

Written comments on the proposed rate schedules are due on or before November 30, 1978.

ADDRESSES: Written comments not submitted at the Public Comment Forums should be submitted to the Public Involvement Coordinator, Bonneville Power Administration, P.O. Box 12999, Portland, Oreg. 97212.

FOR FURTHER INFORMATION CONTACT:

Ms. Donna Lou Geiger, Public Involvement Coordinator, P.O. Box 12999, Portland, Oreg. 97212, 503-234-3361, ext. 4715.
Mr. John H. Alberthal, Area Man-

ager, Room 201, 919 NE. 19th Avenue, Portland, Oreg. 97208, 503-234-3361, ext. 4551.
Mr. Ladd Sutton, District Manager, Room 206, 211 East Seventh Avenue, Eugene, Oreg. 97401, 503-345-0311.
Mr. Norman A. Gilchrist, Area Manager, Room 561, West 920 Riverside Avenue, Spokane, Wash. 99201, 509-456-2500, ext. 2518.
Mr. Ronald H. Wilkerson, District Manager, P.O. Box 758, Kalispell, Mont. 59901, 406-755-6202.
Mr. Joseph J. Anderson, District Manager, Room 314, 301 Yakima Street, Wenatchee, Wash. 98801, 509-662-4377, ext. 379.
Mr. George A. Tupper, Area Manager, Room 250, 415 First Avenue North, Seattle, Wash. 98109, 206-442-4130.
Mr. Harold M. Cantrell, Area Manager, West 101 Popular, Walla Walla, Wash. 99362, 509-525-5500, ext. 701.
Mr. Martin C. Derksema, District Manager, 531 Lomax Street, Idaho Falls, Idaho 83401, 208-523-2706.

SUPPLEMENTARY INFORMATION: On January 18, 1978, the Bonneville Power Administration (BPA) published in the FEDERAL REGISTER (43 FR 2659) a "Notice of Intent to Develop Revised Wholesale Power Rates." In that Notice, BPA announced it would follow procedures similar to BPA's "Procedure for Public Participation in Marketing Policy Formulation" (42 FR 62950) to afford members of the public an opportunity to participate in the formulation of the wholesale power rates.

The BPA Administrator has conducted a repayment study of the Federal Columbia River Power System (FCRPS) to determine the revenue necessary to recover the cost of producing and transmitting the electric power BPA markets and to repay with interest the Federal investment in the FCRPS as required by statute. Results of the study show the need for approximately a 90-percent increase in revenues. The proposed wholesale power rates plus an increase in transmission rates, which will be proposed at a later date, will produce the necessary increase in total revenues. The proposed rates reflect consideration of recommendations received from BPA customers and the public following announcement of BPA's Notice of Intent to Develop Revised Wholesale Power Rates and were prepared by the Administrator pursuant to 16 U.S.C. 832 e and f; 835 j, k, and l; 837 d; and 838 g and h.

In the process of developing its proposed wholesale power rates, BPA considered revenue requirements, cost of service, marginal costs, conservation, environmental impact, ease of administration, stability and continuity, and consumer understanding and acceptance. Specifically, the major studies which were conducted and are available for review at BPA headquarters located at 1002 NE. Holaday Street, Portland, Oreg., are:

1. Cost-of-Service Methodology Study.
2. FCRPS Repayment Study.
3. FCRPS Average Cost-of-Service Study.
4. FCRPS Long-Run Incremental Cost-of-Service Study.
5. Irrigation Impact Study.
6. Time-Differentiated Average Cost Rate Study.
7. Rate Design Study.

Environmental impacts of the rate proposal also have been considered, and a draft Environmental Impact Statement (EIS) on the 1979 Rate Proposal has been prepared.

Pursuant to Secretarial Delegation Order No. 0204-4, and the joint rule entitled "Transfer of Proceedings to the Secretary of Energy and the Federal Energy Regulatory Commission," the Secretary delegated rate approval authority to the Economic Regulatory Administration (ERA). Following public review of and comment on the proposed rates, BPA will modify the proposal to the extent appropriate. On or about June 1, 1979, BPA will file its final rate proposal with ERA through AS-RA in time for review, confirmation, and approval by December 20, 1979. It is further contemplated that proposed new transmission rates will be developed and submitted for approval in time to be placed into effect by July 1, 1980, which is the earliest date that the transmission contracts currently permit a rate adjustment.

BPA's proposed rate schedules are:

I. PROPOSED RATE SCHEDULES AND GENERAL RATE SCHEDULE PROVISIONS

A. SCHEDULE EC-8—WHOLESALE FIRM POWER RATE

Section 1. *Availability:* This schedule is available for the purchase of firm power for resale or for direct consumption by purchasers other than direct-service industrial purchasers covered under rate Schedules IF-2 or MF-2.

Sec. 2. *Rate:*

a. *Demand charge:* (1) for the billing months December through May, Monday through Saturday, 7 a.m. through 10 p.m.: $1.55 per kilowatt of billing demand; (2) for the billing months June through November, Monday through Saturday, 7 a.m. through 10 p.m.: $1.30 per kilowatt of billing demand; and (3) all other hours: no demand charge.

b. *Energy charge:* 4.9 mills per kilowatt-hour of billing energy.

Sec. 3. *Billing factors:* The factors to be used in determining the billing for firm power purchased under this schedule are as follows:

a. For any purchaser designated by the Administrator to purchase on a computed demand basis because of such purchaser's potential ability either to sell generation from its resources in such a manner as to increase the Administrator's obligation to deliver firm power to such purchaser in an amount in excess of the Administrator's obligation prior to such sale, or to redistribute the generation from its resources over time in such a manner as to cause losses of power or revenue on the Federal system: provided, how- ever, that when a purchaser operates two or more separate systems, only those systems designated by the Administrator will be covered by this subsection:

(1) the peak computed demand for the month; (2) the average energy computed demand for the month; (3) 60 percent of the highest peak computed demand during the previous 11 months; (4) 60 percent of the highest average energy computed demand for the previous 11 months; (5) the measured demand for the month; (6) the measured energy for the month; and (7) the contract demand as specified in an agreement between a purchaser and the Administrator for a specified period of time.

b. For any purchaser not designated to purchase under subsection 3a: (1) the contract demand as specified in the contract; (2) the measured demand for the month; and (3) the measured energy for the month.

c. For any purchaser contractually limited to an allocation of capacity and/or energy as determined by the Administrator pursuant to the terms of a purchaser's power sales contract: (1) the allocated demand for the month, as specified in the contract; (2) the measured demand for the month; (3) the allocated energy for the month, as specified in the contract; (4) the measured energy for the month.

Sec. 4. *Determination of billing demand and billing energy:*

a. For a purchaser governed by subsection 3a:

(1) the billing demand for the month during peak load hours shall be the largest of factors 3a(3), 3a(4), and 3a(5), or 3a(7). Factor 3a(5), before adjustment for power factor, shall not exceed the largest of factors 3a(1), 3a(2), or 3a(7) if applicable. At such time as the Administrator determines that the limitation in such section 3c is necessary, the billing demand for the month shall be factor 3c(2). Billing demand factor 3c(2), before adjustment for power factor, shall not exceed factor 3c(1).

(2) the billing factor for energy used during the month shall be factor 3a(6) except that at such time as the Ad-

ministrator determines that the limitation in section 3c is necessary, the billing factor for energy shall be factor 3c(4), provided, however, that factor 3c(4) shall not exceed factor 3c(3).

(b) For a purchaser governed by subsection 3b:

(1) The billing demand for the month shall be factor 3b(1) or 3b(2), as appropriate to the terms of the power sales contract. At such time as the Administrator determines that the limitation in subsection 3c is necessary, the billing demand for the month shall be factor 3c(2). Billing demand factor 3c(2), before adjustment for power factor, shall not exceed factor 3c(1).

(2) The billing factor for energy used during the month shall be factor 3b(3) except that at such time as the Administrator determines that the limitation in subsection 3c is necessary, the billing factor for energy shall be factor 3c(4), provided, however, that factor 3c(4) shall not exceed factor 3c(3).

Sec. 5. *Adjustments:*

a. *Power factor:* Except as hereinafter provided, the adjustment for power factor wherever specified in this rate schedule shall be made by increasing the appropriate billing factors for each month by ½ percent for each 1 percent or major fraction thereof by which the average lagging power factor at which energy is supplied during such month is less than 95 percent, such average power factor to be computed to the nearest whole percent from the formula given in § 9.1 of the General Rate Schedule Provisions.

The Administrator may, if he considers it desirable, determine the average leading power factor. If leading power factor as well as lagging power factor is determined, the adjustment for power factor shall be made by increasing the appropriate billing factors for the month by 1 percent for each 1 percent or major fraction thereof by which the average lagging or the average leading power factor is less than 95 percent, whichever results in the larger adjustment.

The adjustment for power factor may be waived in whole or in part to the extent that the Administrator determines that an average power factor of less than 95 percent lagging or 95 percent leading would in any particular case be beneficial to the Government. Unless specifically otherwise agreed, the Administrator may, if necessary to maintain acceptable operating conditions on the Federal system, restrict deliveries of power to a purchaser at a point of delivery or for a system at any time that the power factor for all classes of power delivered to a purchaser at such point of delivery or for such system is below 75 percent lagging or 75 percent leading.

b. *At-site power:* At-site power purchased for consumption by a purchaser shall be used within 15 miles of the powerplant specified in the power sales contract. At least 90 percent of any at-site power purchased for resale shall be used within 15 miles of the specified powerplant.

The monthly demand charge for at-site firm power will be reduced by $0.257 per kilowatt of billing demand.

At-site firm power will be made available at a Federal hydroelectric generating plant or at a point adjacent thereto, and at a voltage, all as designated by the Administrator. If deliveries are made from an interconnection with the Federal system other than at one of such designated points, the purchaser shall pay an amount adequate to cover the annual cost of the facilities which would have been required to deliver such power to such point from either the generator bus at the generating plant, or from the adjacent point as designated by the Administrator. This charge shall be in addition to the charge determined by application of section 2 of the rate schedule as reduced by the provisions of this subsection. The total amount of at-site firm power sold from any plant shall not exceed the amount of such power determined by the Administrator to be available at such plant.

Sec. 6. *Unauthorized increase:* Any amount by which a. any 60-minute clock-hour integrated or scheduled demand exceeds the sum of the applicable contract, computed, or allocated demand, plus any applicable scheduled, measured, or contract demand for power which the purchaser acquires from sources other than the Administrator during such hour, or b. the excess of deliveries to a computed demand purchaser in any billing month above the amount of firm energy to which a purchaser is entitled (average computed demand multiplied by the number of hours in the month) may be considered an unauthorized increase (overrun).

The charge for each overrun or the excess kilowatthours over the amount of firm energy the purchaser is entitled to shall be $0.10 per kilowatthour. Each 60-minute clock-hour integrated demand or scheduled demand so overrunning the sum of the demands herein described shall be considered separately.

Sec. 7. *General provisions:* Sales of power under this schedule shall be subject to the provisions of the Bonneville Project Act, as amended, and to the applicable General Rate Schedule Provisions.

B. SCHEDULE EC-9—RESERVE POWER RATE

Section 1. *Availability:* This schedule is available for the purchase of:

a. Firm power to meet a purchaser's unanticipated load growth as provided in a purchaser's power sales contracts;

b. Power for which the Administrator determines no other rate schedule is applicable;

c. Power to serve a purchaser's firm power loads in circumstances where the Administrator does not have a power sales contract in force with a purchaser.

Sec. 2. *Rate:*

a. *Monthly demand charge:* (1) For the period Monday through Saturday, 7 a.m. through 10 p.m.: $4.10 per kilowatt of billing demand; (2) all other hours: No demand charge.

b. *Energy charge:* 17.0 mills per kilowatt-hour of billing energy.

Sec. 3. *Billing factors:* The factors to be used in determining the billing for reserve power purchased under this schedule are as follows:

a. The contract demand as specified in the contract;

b. The measured demand;

c. The contract amount of energy for the month;

d. The measured energy for the month;

e. Power factor.

Sec. 4. *Determination of billing demand and billing energy:* The billing demand and billing energy shall be determined as provided in a purchaser's power sales contract. If the Administrator does not have a power sales contract in force with a purchaser, the billing demand and billing energy shall be the measured demand adjusted for power factor and measured energy.

Sec. 5. *Unauthorized increase:* Any amount by which a. any 60-minute clock-hour integrated or scheduled demand exceeds the sum of the applicable contract, computed, or allocated demand, plus any applicable scheduled, measured, or contract demand for power which the purchaser acquires from sources other than the Administrator during such hour, or b. the excess of deliveries to a computed demand purchaser in any billing month above the amount of firm energy to which a purchaser is entitled (average computed demand multiplied by the number of hours in the month) may be considered an unauthorized increase (overrun). The charge for each overrun or the excess kilowatt-hours over the amount of firm energy the purchaser is entitled to shall be $0.10 per kilowatt-hour. Each 60-minute clock-hour integrated demand or scheduled demand so overrunning the sum of the demands herein described shall be considered separately.

Sec. 6. *Power factor adjustment:* Except as hereinafter provided, the adjustment for power factor, wherever specified in this rate schedule or in the power sales contract, shall be made by increasing the appropriate billing factors for each month by 1 percent for each 1 percent or major fraction thereof by which the average lagging power factor at which energy is supplied during such month is less than 95 percent, such average power factor to be computed, to the nearest whole percent, from the formula given in § 9.1 of the General Rate Schedule Provisions.

The Administrator may, if he considers it desirable, determine the average leading power factor. If leading power factor as well as lagging power factor is determined, the adjustment for power factor shall be made by increasing the appropriate billing factors for the month by 1 percent for each 1 percent or major fraction thereof by which the average lagging or the average leading power factor is less than 95 percent, whichever results in the larger adjustment.

The adjustment for power factor may be waived in whole or in part to the extent that the Administrator determines that an average power factor of less than 95 percent lagging or 95 percent leading would in any particular case be beneficial to the Government. Unless specifically otherwise agreed, the Administrator may, if necessary to maintain acceptable operating conditions on the Federal System, restrict deliveries of power to a purchaser at a point of delivery or for a system at any time that the power factor for all classes of power delivered to a purchaser at such point of delivery or for such system is below 75 percent lagging or 75 percent leading.

Sec. 7. *General provisions:* Sales of power under this schedule shall be subject to the provisions of the Bonneville Project Act, as amended, and to the applicable General Rate Schedule Provisions.

C. SCHEDULE IF-2—WHOLESALE POWER RATE FOR INDUSTRIAL FIRM POWER

Section 1. *Availability:* This schedule is available for the purchase of industrial firm power and/or authorized increase on a contract demand basis.

Sec. 2. *Rate:*

a. *Demand charge:* (1) For the billing months December through May, Monday through Saturday, 7 a.m. through 10 p.m.: $1.55 per kilowatt of billing demand; (2) for the billing months June through November, Monday through Saturday, 7 a.m. through 10 p.m.: $1.30 per kilowatt of billing demand; and (3) all other hours: No demand charge.

b. *Energy charge:* 4.9 mills per kilowatt-hour of billing energy.

Sec. 3. *Billing factors:* The factors to be used in determining the billing for firm power purchased under this rate schedule are as follows: a. Contract demand, b. curtailed demand, c. restricted demand, and d. measured energy.

Sec. 4. *Determination of billing demand and billing energy:* The billing demands for industrial firm power and authorized increase, respectively, and for additional power requested by the purchaser and made available by the Administrator on an intermittent basis will be the lowest of the respective contract demand, curtailed demand, or restricted demand after each such demand is adjusted for power factor. The billing energy associated with each of the respective billing demands will be the measured energy.

Sec. 5. *Adjustments:*

a. *Availability credit:* The purchaser may be entitled to an annual billing credit for a restriction to its load. The amount of the credit for such a restriction will be the product of one-twelfth of the sum of the monthly billing demands and the value of the availability credit factor determined from the appropriate formula below. Availability credit will be separately determined for industrial firm power and authorized increase power.

Annual availability A		Formula for availability credit factor
but less than		
.99	1.00	F=0
.90	.99	F=145 (.99-A)
.75	.90	F=49-40A
.00	.75	F=19

b. *Power factor:* Except as hereinafter provided, the adjustment for power factor wherever specified in this rate schedule shall be made by increasing the appropriate billing factors for each month by 1 percent for each 1 percent or major fraction thereof by which the average lagging power factor at which energy is supplied during such month is less than 95 percent.

The Administrator may, if he considers it desirable, determine the average leading power factor. If leading power factor as well as lagging power factor is determined, the adjustment for power factor shall be made by increasing the measured demand for the month by 1 percent for each 1 percent or major fraction thereof by which the average lagging or the average leading power factor is less than 95 percent, whichever results in the larger adjustment.

The adjustment for power factor may be waived in whole or in part to the extent that the Administrator determines that an average power factor of less than 95 percent lagging or 95 percent leading would in any particular case be beneficial to the Government. Unless specifically otherwise agreed, the Administrator may, if necessary to maintain acceptable operating conditions on the Federal system, restrict deliveries of power to a purchaser at a point of delivery or for a system at any time that the power factor for all classes of power delivered to a purchaser at such point of delivery or for such system is below 75 percent lagging or 75 percent leading.

c. *At-site power:* At-site industrial firm power shall be used within 15 miles of the powerplant.

The monthly demand charge for at-site industrial firm power will be reduced by $0.257 per kilowatt of billing demand.

At-site industrial firm power will be made available at a Federal hydroelectric generating plant or at a point adjacent thereto, and at a voltage, all as designated by the Administrator. If deliveries are made from an interconnection with the Federal system other than at one of such designated points, the purchaser shall pay an amount adequate to cover the annual cost of the facilities which would have been required to deliver such power to such point from either the generator bus at the generating plant, or from the adjacent point as designated by the Administrator. This charge shall be in addition to the charge determined by application of section 2 of the rate schedule. The total amount of at-site industrial firm power sold from any plant shall not exceed the amount of such power determined by the Administrator to be available at such plant.

Sec. 6. *Unauthorized increase:* Deliveries in excess of the sum of the billing demands before adjustment for power factor and any applicable scheduled demands which the purchaser acquires through other contracts will be assessed a charge of $0.10 per kilowatt-hour.

Sec. 7. *Special conditions—Advance of energy:* The Administrator may elect to advance energy under terms and conditions of the purchaser's power sales contract.

Sec. 8. *General provisions:* Sales of power under this schedule shall be subject to the provisions of the Bonneville Project Act, as amended, and to the applicable General Rate Schedule Provisions.

D. SCHEDULE MF-2—WHOLESALE POWER RATE FOR MODIFIED FIRM POWER

Section 1. *Availability:* This schedule is available for the purchase of modified firm power on a contract demand basis for direct consumption by existing direct-service industrial customers until existing contracts terminate. This schedule is also available for the purchase of authorized in-

crease power on a contract demand basis.

Sec. 2. *Rate:*

a. *Demand charge:* (1) For the billing months December through May, Monday through Saturday, 7 a.m. through 10 p.m.: $1.55 per kilowatt of billing demand; (2) for the billing months June through November, Monday through Saturday, 7 a.m. through 10 p.m.: $1.30 per kilowatt of billing demand; and (3) all other hours: No demand charge.

b. *Energy charge:* 4.9 mills per kilowatt-hour of billing energy.

Sec. 3. *Billing factors:* The factors to be used in determining the billing for firm power purchased under this rate schedule are as follows: a. Contract demand, b. curtailed demand, c. restricted demand, and d. measured energy.

Sec. 4. *Determination of billing demand and billing energy:* The billing demand for modified firm power will be the lower of the contract demand or the curtailed demand after each such demand is adjusted for power factor. The billing demands for authorized increase power and for additional power requested by the purchaser and made available by the Administrator on an intermittent basis will be the lowest of the contract demand, curtailed demand, or restricted demand. The billing energy associated with each of the respective billing demands will be the measured energy.

Sec. 5. *Adjustments:*

a. *Power factor:* Except as hereinafter provided, the adjustment for power factor wherever specified in this rate schedule shall be made by increasing the appropriate billing factors for each month by 1 percent for each 1 percent or major fraction thereof by which the average lagging power factor at which energy is supplied during such month is less than 95 percent, such average power factor to be computed, to the nearest whole percent, from the formula given in § 9.1 of the General Rate Schedule Provisions.

The Administrator may, if he considers it desirable, determine the average leading power factor. If leading power factor as well as lagging power factor is determined, the adjustment for power factor shall be made by increasing the appropriate billing factors for the month by 1 percent for each 1 percent or major fraction thereof by which the average lagging or the average leading power factor is less than 95 percent, whichever results in the larger adjustment.

The adjustment for power factor may be waived in whole or in part to the extent that the Administrator determines that an average power factor of less than 95 percent lagging or 95 percent leading would in any particular case be beneficial to the Government. Unless specifically otherwise agreed, the Administrator may, if necessary to maintain acceptable operating conditions on the Federal system, restrict deliveries of power to a purchaser at a point of delivery or for a system at any time that the power factor for all classes of power delivered to a purchaser at such point of delivery or for such system is below 75 percent lagging or 75 percent leading.

b. *At-site power:* At-site modified firm power shall be used within 15 miles of the powerplant.

The monthly demand charge for at-site modified firm power will be reduced by $0.257 per kilowatt of billing demand.

At-site modified firm power will be made available at a Federal hydroelectric generating plant or at a point adjacent thereto, and at a voltage, all as designated by the Administrator. If deliveries are made from an interconnection with the Federal system other than at one of such designated points, a purchaser shall pay an amount adequate to cover the annual cost of the facilities which would have been required to deliver such power to such point from either the generator bus at the generating plant, or from the adjacent point as designated by the Administrator. This charge shall be in addition to the charge determined by application of section 2 of the rate schedule. The total amount of at-site modified firm power sold from any plant shall not exceed the amount of such power determined by the Administrator to be available at such plant.

Sec. 6. *Unauthorized increase:* Deliveries in excess of the sum of the billing demands before adjustment for power factor and any applicable scheduled demands which the purchaser acquires through other contracts will be assessed a charge of $0.10 per kilowatt-hour.

Sec. 7. *General provisions:* Sales of power under this schedule shall be subject to the provisions of the Bonneville Project Act, as amended, and to the applicable General Rate Schedule Provisions.

E. SCHEDULE F-7—WHOLESALE FIRM CAPACITY RATE

Sec. 1. *Availability:* This schedule is available for the purchase of firm capacity without energy on a contract demand basis for supply during a contract year of no less than 12 months, or during a contract season of no less than a 5-month period each June 1 through October 31.

Sec. 2. *Rate:*

a. *Contract year service:* $17.10 per kilowatt per year of contract demand. Interim bills will be rendered monthly at the rate of $1.425 per kilowatt of contract demand;

b. *Contract season service:* $9.50 per kilowatt per season of contract demand. Interim bills will be rendered monthly at the rate of $1.90 per kilowatt of contract demand;

c. A purchaser's capacity rate shall be increased by $0.18 per kilowatt-month of billing demand for each hour of monthly demand duration in excess of 6 hours. A purchaser's demand duration shall be determined by dividing the kilowatt-hours supplied under this rate schedule to a purchaser on the day of maximum kilowatt-hour use between the hours of 7 a.m. and 10 p.m., excluding Sundays during the month by a purchaser's contract demand effective at that time. If, however, the Administrator does not require the delivery of peaking return energy by a purchaser pursuant to the contract during certain periods, the additional hourly charge above will not be made during such periods;

d. In addition to the charges above, a purchaser's capacity rate shall be increased by $0.20 per kilowatt per month of contract demand for power transmitted over the Pacific Northwest-Pacific Southwest Intertie and made available at the Oregon-California border or the Oregon-Nevada border.

Sec. 3. *Billing factors:* The billing demand will be the contract demand.

Sec. 4. *Special provision:* Contracts for the purchase of firm capacity under this schedule will include provisions for replacement by a purchaser of energy accompanying the delivery of such capacity.

Sec. 5. *General provisions:* Sales of power under this schedule shall be subject to the provisions of the Bonneville Project Act, as amended, and to the applicable General Rate Schedule Provisions.

F. SCHEDULE J-2—WHOLESALE FIRM ENERGY RATE

Section 1. *Availability:* This schedule is available for contract purchase of firm energy, to be delivered for the uses, in the amounts, and during the period or periods specified in such contract.

Sec. 2. *Rate:* 6.0 mills per kilowatt-hour of billing energy.

Sec. 3. *Billing factors:* The contract energy is the billing factor.

Sec. 4. *Determination of billing energy:* The billing energy shall be determined as provided in a purchaser's power sales contract.

Sec. 5. *Delivery:* Delivery of energy under this rate schedule is assured during the contract period. However, the Administrator may interrupt the delivery of firm energy hereunder, in whole or in part, at any time that he determines that he is unable because of system operating conditions, includ-

ing lack of generation or transmission capacity, to effect such delivery.

Sec. 6. *Power factor adjustment:* Except as hereinafter provided, the adjustment for power factor, wherever specified in this rate schedule, shall be made by increasing the appropriate billing factors for each month by 1 percent for each 1 percent or major fraction thereof by which the average lagging power factor at which energy is supplied during such month is less than 95 percent, such average power factor to be computed to the nearest whole percent from the formula given in section 9.1 of the General Rate Schedule Provisions.

The Administrator may, if he considers it desirable, determine the average leading power factor. If leading power factor as well as lagging power factor is determined, the adjustment for power factor shall be made by increasing the appropriate billing factors for the month by 1 percent for each 1 percent or major fraction thereof by which the average lagging or the average leading power factor is less than 95 percent, whichever results in the larger adjustment.

The adjustment for power factor may be waived in whole or in part to the extent that the Administrator determines than an average power factor of less than 95-percent lagging or 95-percent leading would in any particular case be beneficial to the Government. Unless specifically otherwise agreed, the Administrator may, if necessary to maintain acceptable operating conditions on the Federal system, restrict deliveries of power to a purchaser at a point of delivery or for a system at any time that the power factor for all classes of power delivered to a purchaser at such point of delivery or for such system is below 75-percent lagging or 75-percent leading.

Sec. 7. *General provisions:* Sales of energy under this schedule shall be subject to the provisions of the Bonneville Project Act, as amended, and to the applicable General Rate Schedule Provisions.

G. SCHEDULE H-6—WHOLESALE NONFIRM ENERGY RATE

Section 1. *Availability:* This schedule is available for the purchase of nonfirm energy both within and outside the Pacific Northwest. This schedule is also available for energy delivered for emergency use under the conditions set forth in section 5.1 of the General Rate Schedule Provisions. This schedule is not available for the purchase of energy which the Administrator has a firm obligation to supply.

Sec. 2. *Rate:*

a. For energy sales to any purchaser for use in the Pacific Northwest as defined in Pub. L. 88-552: (1) 6 mills per kilowatt-hour during the period Monday through Saturday, 7 a.m. through 10 p.m.; and (2) 4.5 mills per kilowatt-hour for all hours of the year not included in subsection a(1) above.

b. For contracts which refer to this schedule for determining a value of energy, the rate is 5.3 mills per kilowatt-hour.

c. For all sales not subject to the conditions in subsections a. or b. above, the rate, exclusive of the increase in the charge provided for in subsection e(1) below, for each sale will be established within the following limits as agreed to by the Administrator and a purchaser prior to the delivery. This rate applies to all sales to customers whose contract provisions designate a 1-year rate review period beginning July 1, 1981.

(1) The lower rate limits for these sales are: (a) 6 mills per kilowatt-hour during the period Monday through Saturday, 7 a.m. through 10 p.m.; and (b) 4.5 mills per kilowatt-hour for all hours of the year not included in subsection c(1)(a) above.

(2) The upper rate limit for these sales is 15 mills per kilowatt-hour.

d. For all sales not subject to the conditions in subsections a., b., or c. above, the rate, exclusive of the increase in the charge provided for in subsection e(2) below, for each sale will be established within the following limits as agreed to by the Administrator and a purchaser prior to the delivery. This rate applies to all sales to customers whose contract provisions designate a 5-year rate review period.

(1) The lower rate limits for these sales are: (a) 8 mills per kilowatt-hour during the period Monday through Saturday, 7 a.m. through 10 p.m.; and (b) 6 mills per kilowatt-hour for all hours of the year not included in subsection d(1)(a) above.

(2) The upper rate limit for these sales is 24 mills per kilowatt-hour.

e. (1) The charge provided for in subsection c. above will be increased by 0.3 mill per kilowatt-hour for energy transmitted over the Pacific Northwest-Pacific Southwest Intertie and made available at the Oregon-California or the Oregon-Nevada border for a purchaser whose contract provisions designate a 1-year rate review period beginning July 1, 1981.

(2) The charge provided for in subsection d. above will be increased by 0.4 mill per kilowatt-hour for energy transmitted over the Pacific Northwest-Pacific Southwest Intertie and made available at the Oregon-California or the Oregon-Nevada border for a purchaser whose contract provisions designate a 5-year rate review period.

Sec. 3. *Delivery:* The Administrator shall determine the avialibility of energy hereunder and the rate of delivery thereof.

Sec. 4. *General provisions:* Sales of energy under this schedule shall be subject to the provisions of the Bonneville Project Act, as amended, and to the applicable General Rate Schedule Provisions.

H. GENERAL RATE SCHEDULE PROVISIONS

1.1 *Firm power:* Firm power is electric power which the Administrator will make continuously available to a purchaser to meet its load requirements except when restricted because the operation of generation or transmission facilities used by the Administrator to serve such purchaser is suspended, interrupted, interfered with, curtailed, or restricted as the result of the occurence of any condition described in the Uncontrollable Forces or Continuity of Service Sections of the General Contract Provisions of the contract. Such restriction of firm power shall not be made until industrial firm power has been restricted in accordance with section 1.4 and until modified firm power has been restricted in accordance with section 1.2.

1.2 *Modified firm power:* Modified firm power is electric power which the Administrator will make continuously available to a purchaser on a contract demand basis subject to: a. the restriction applicable to firm power, and b. the following:

When a restriction is made neessary because the operation of generation or transmission facilities used by the Administrator to serve such purchaser and one or more firm power purchasers is suspended, interrupted, interfered with, curtailed, or restricted as a result of the occurrence of any condition described in the Uncontrollable Forces or Continuity of Service Sections of the General Contract Provisions of the contract, the Administrator shall restrict such purchaser's contract demand for modified firm power to the extent necessary to prevent, if possible, or minimize restriction of any firm power, provided, however, that: a. such restriction of modified firm power shall not exceed at any time 25 percent of the contract demand therefor, and b. the accumulation of such restrictions of modified firm power during any calendar year, expresed in kilowatt hours, shall not exceed 500 times the contract demand therefor. When possible, restrictions of modified firm power will be made ratably with restrictions of industrial firm power based on the proportion that the respective contract demands bear to one another. The extent of such restrictions shall be limited for modified firm power by this subsection and for industrial firm power by the Restriction of Deliveries Section of the Gen-

eral Contract Provisions of the contract.

1.3 *Firm capacity:* Firm capacity is capacity which the Administrator assures will be available to a purchaser on a contract demand basis except when operation of generation or transmission facilities used by the Administrator to serve such purchaser is suspended, interrupted, interfered with, curtailed, or restircted as the result of the occurence of any condition described in the Uncontrollable Forces or Continuity of Service Sections of the General Contract Provisions of the contract.

1.4 *Industrial firm power:* Industrial firm power is electric power which the Administrator will make continuously available to a purchaser on a contract demand basis subject to: a. the restriction applicable to firm power, and b. the following:

(1) The restrictions given in the Restriction of Deliveries Section of the General Contract Provisions of the contract.

(2) When a restriction is made necessary because of the operation of generation or transmission facilities used by the Administrator to serve such purchaser and one or more firm power purchasers is susupended, interrupted, interfered with, curtailed, or restricted as a result of the occurrence of any condition described in the Uncontrollable Forces or Continuity of Service Sections of the General Contract Provisions of the contract, the Administrator shall restrict such purchaser's contract demand for industrial firm power to the extent necessary to prevent, if possible, or minimize restriction of firm power. When possible, restrictions of industrial firm power will be made ratably with restrictions of modified firm power based on the proportion that the respective contracat demands bear to one another. The extent of such restrictions shall be limited for modified firm power by section 1.2 b. of these General Rate Schedule Provisions and for industrial firm power by the Restriction of Deliveries Section of the General Contract Provisions of the contract.

1.5 *Authorized increase:* An authorized increase is an amount of electric power specified in the contract in excess of the contract demand for firm power, modified firm power, or industrial firm power that the Administrator may be able to make available to the purchaser upon its request. The purchaser shall make such request in writing stating the amount of increase requested, the purpose for which it will be used, and the period for which it is needed. Such request shall be made prior to the first calendar month beginning such specified period. The Administrator will then determine whether such increase can be made available, but he shall retain the right to restrict the delivery of such increase if he determines at any subsequent time that such increase will no longer be available.

The purchaser may curtail an authorized increase, in whole or in part, at the end of any billing month within the period such authorized increase is to be made available.

1.6 *Firm energy:* Firm energy is energy which the Administrator assures will be available to a purchaser during the period or periods specified in the contract except during such hours as specified in the contract and when the operation of the Government's facilities used to serve the purchaser are suspended, interrupted, interfered with, curtailed, or restricted by the occurrence of any condition described in the Uncontrollable Forces or Continuity of Service Sections of the General Contract Provisions of the contract.

2.1 *Contract demand:* The contract demand shall be the number of kilowatts that the purchaser agrees to purchase and the Administrator agrees to make available. The Administrator may agree to make deliveries at a rate in excess of the contract demand at the request of the purchaser (authorized increase), but shall not be obligated to continue such excess deliveries.

2.2 *Measured demand:* Except where deliveries are scheduled as hereinafter provided, the measured demand in kilowatts shall be the largest of the 60-minute clock-hour integrated demands at which electric energy is delivered to a purchaser at each point of delivery during each time period specified in the applicable rate schedule during any billing period. Such largest 60-minute integrated demand shall be determined from measurements made as specified in the contract, or as determined in § 3.2 herein. The Administrator, in determining the measured demand, will exclude any abnormal 60-minute integrated demands due to or resulting from a. emergencies or breakdowns on, or maintenance of, the Federal system facilities, and b. emergencies on the purchaser's facilities, provided that such facilities have been adequately maintained and prudently operated as determined by the Administrator. For those contracts, to which the Administrator is a party and which provide for delivery of more than one class of electric power to the purchaser at any point of delivery, the portion of each 60-minute integrated demand assigned to any class of power shall be determined as specified in the contract. The portion of the total measured demand so assigned shall constitute the measured demand for each such class of power.

If the flow of electric energy to a purchaser's system through two or more points of delivery cannot be adequately controlled because such points are interconnected within the purchaser's system, or the purchaser's system is interconnected directly or indirectly with the Federal system, the purchaser's measured demand for each class of power for such system for any billing period shall be the largest of the hourly amounts of such class of power which are scheduled for delivery to the purchaser during each time period specified in the applicable rate schedule.

2.3 *Peak computed demand and energy computed demand:* The purchaser's peak computed demand for each billing month shall be the largest amount during such month by which the purchaser's 60-minute system demand exceeds its assured peaking capability.

The purchaser's average energy computed demand for each billing month shall be the amount during such month by which the purchaser's actual system average load exceeds its assured average energy capability.

a. *General principles:*

(1) The assured peaking and average energy capability of each of the purchaser's systems shall be determined and applied separately.

(2) As used in this section, "year" shall mean the 12-month period commencing July 1.

(3) The critical period is that period, determined for the purchaser's system under adverse streamflow conditions adjusted for current water uses, assured storage operation, and appropriate operating agreements, during which the purchaser would have the maximum requirement for peaking or energy after utilizing the firm capability of all resources available to its system in such a manner as to place the least requirement for capacity and energy on the Administrator.

(4) Critical water conditions are those conditions of streamflow based on historical records, adjusted for current water uses, assured storage operation, and appropriate operating agreements, for the year or years which would result in the minimum capability of the purchaser's firm resources during the critical period.

(5) Prior to the beginning of each year the purchaser shall determine the assured capability of each of the purchaser's systems in terms of peaking and average energy for each month of each year or years within the critical period. The firm capability of all resources available to the purchaser's system shall be utilized in such a manner as to place the least requirement for capacity and energy on the Administrator. Such assured capa-

bility shall be effective after review and approval by the Administrator.

(6) The purchaser's assured energy capability shall be determined by shaping its firm resources to its firm load in a manner which places a uniform requirement on the Administrator within each year of the critical period with such requirement increasing each year not in excess of the purchaser's annual load growth.

(7) As used herein, the capability of a firm resource shall include only that portion of the total capability of such resource which the purchaser can deliver on a firm basis to its load. The capabilities of all generating facilitiers which are claimed as part of the purchaser's assured capability shall be determined by test or other substantiating data acceptable to the Administrator. The Administrator may require verification of the capabilities of any or all of the purchaser's generating facilities. Such verification will not be required more often than once each year for operating plants, or more often than once each third year for thermal plants in cold standby status, if the Administrator determines that adequate annual preventive maintenance is performed and the plant is capable of operating at its claimed capability.

(8) The purchaser shall at any time, if required by the Administrator, demonstrate the ability of its claimed hydroelectric resources to develop the assured capability previously approved for the remainder of the critical period based on critical water conditions. If such ability cannot be demonstrated to the satisfaction of the Administrator, the purchaser's assured capability shall be reduced for the remainder of the critical period by the amount which cannot be developed, unless such deficiency is the result of operation required by firm obligations under contracts to which the Administrator is a party.

(9) In determining assured capability, the aggregate capability of the purchaser's firm resources shall be appropriately reduced to provide adequate reserves.

b. *Determination of assured capability:* The purchaser's assured peaking and energy capabilities shall be the respective sums of the capabilities of its hydroelectric generating plants based on the most critical water conditions on the purchaser's system, the capabilities of its thermal generating plants based on the most adverse fuel or other conditions reasonably to be anticipated; and the firm capabilities of other resources made available under contracts prior to the beginning of the year, after deduction of adequate reserves. Assured capabilities shall be determined for each month if the purchaser has seasonal storage. The capabilities of the purchaser's firm resources shall be determined as follows:

(1) *Hydroelectric generating facilities:* The capability of each of the purchaser's hydroelectric generating plants shall be determined in terms of both peaking and average energy using critical water conditions. The average energy capability shall be that capability which would be available under the storage operation necessary to produce the claimed peaking capability.

Seasonal storage shall mean storage sufficient to regulate all the purchaser's hydroelectric resources in such a manner that when combined with the purchaser's thermal generating facilities, if any, and with firm capacity and energy available to the purchaser under contracts, a uniform energy computed demand for a period of 1 month or more would result.

A purchaser having seasonal storage shall, within 10 days after the end of each month in the critical period, notify the Administrator in writing of the assured energy capability to be applied tentatively to the preceding month; such notice shall also specify the purchaser's best estimate of its average system energy load for such month. If such notice is not submitted, or is submitted later than 10 days after the end of the month to which it applies, subject to the limitations stated herein, the assured energy capability determined for such month prior to the beginning of the year shall be applied to such month and may not be changed thereafter.

If notice has been submitted pursuant to the preceding paragraph, the purchaser shall, within 30 days after the end of the month, submit final specification of the assured energy capability to be applied to the preceding month; provided that the assured energy capability so specified shall not differ from the amount shown in the original notice by more than the amount by which the purchaser's actual average system energy load for such month differs from the estimate of that load shown in the original notice. If the assured energy capability for such month differs from that determined prior to the beginning of the year for such month, the purchaser, if required by the Administrator, shall demonstrate by a suitable regulation study based on critical water conditions that such change could actually be accomplished, and that the remaining balance of its total critical period assured energy capability could be developed without adversely affecting the firm capability of other purchaser's resources. The algebraic sum of all such changes in the purchaser's assured energy capability shall be zero at the end of the critical period or year, whichever is earlier. Appropriate adjustments in the assured peaking capability shall be made if required by any change in reservoir operation indicated by such revisions in the monthly distribution of critical period energy capability.

(2) *Thermal generating facilities:* The capability of each of the purchaser's thermal generating plants shall be determined in terms of both peaking and average energy. Such capabilities shall be based on the most adverse fuel or other conditions reasonably to be anticipated. The effect of limitations on fuel supply due to war or other extraordinary situations will evaluated at the time of occurrence, and appropriate changes will be made in the monthly plant capabilities by the Administrator.

(3) *Other sources of power:* The assured capability of other resources available to the purchaser on a firm basis under contracts shall be determined prior to each year in terms of both peaking and average energy.

3. *Determination of computed demand:* The purchaser's computed demand for each billing month shall be the greater of:

(1) The largest amount during such month by which the purchaser's actual 60-minute system demand, excluding any loads otherwise provided for in the contract, exceeds its assured peaking capability for such month, or period within such month, or

(2) The largest amount for such month, or period within such month, by which the purchaser's actual system average energy load, excluding the average energy loads otherwise provided for in the contract, exceeds its assured average energy capability.

The use of computed demands as one of the alternatives in determining billing demand is intended to assure that each purchaser who purchases power from the Administrator to supplement its own firm resources will purchase amounts of power substantially equivalent to the additional capacity and energy which the purchaser would otherwise have to provide on the basis of normal and prudent operations, viz: Sufficient capacity and energy to carry the load through the most critical water or other conditions reasonably to be anticipated, with an adequate reserve.

Since the computed demand depends on the relationship of capability of resources to system requirements, the computed demand for any month cannot be determined until after the end of the month. As each purchaser must estimate its own load, and is in the best position to follow its development from day to day, it will be the purchaser's responsibility to request scheduling of firm power, including any increase over previously estab-

lished demands, on the basis estimated by the purchaser to result in the most advantageous purchase of the power to be billed at the end of the month.

Each contract in which computed demand may be a factor in determining the billing demand shall have attached to it as an exhibit a sample calculation of the computed demand of the purchaser for the period having the highest computed demand during the 12 months immediately preceding the effective date of the contract.

2.4 *Restricted demand:* A restricted demand shall be the number of kilowatts of firm power, modified firm power, industrial firm power, or authorized increase of any of the preceding classes of power which results when the Administrator has restricted delivery of such power for 1 clock-hour or more. Such restrictions by the Administrator are made pursuant to section 8 of the General Contract Provisions for industrial firm power and pursuant to §§ 1.1 and 1.2 of the General Rate Schedule Provisions for firm power and modified firm power, respectively. Such restricted demand shall be determined by the Administrator after the purchaser has made its determination to accept or curtail the purchaser's contract demand for the month in accordance with § 2.5 of the General Rate Schedule Provisions.

2.5 *Curtailed demand:* A curtailed demand shall be the number of kilowatts of firm power, modified firm power, industrial firm power, or authorized increase of any of the preceding classes of power which results from the purchaser's request for such power in amounts less than the contract demand therefor. Each industrial purchaser of firm power or modified firm power may curtail its demand in accordance with section 9 of the General Contract Provisions of the contract. Each purchaser of industrial firm power may curtail its demand in accordance with section 7 of the General Contract Provisions of the contract. Each purchaser of an authorized increase of firm power, modified firm power, or industrial firm power may curtail its demand in accordance with § 1.5 of the General Rate Schedule Provisions.

3.1 *Billing:* Unless otherwise provided in the contract, power made available to a purchaser at more than one point of delivery shall be billed separately under the applicable rate schedule or schedules. The contract may provide for combined billing under specified conditions and terms when a. delivery at more than one point is beneficial to the Administrator, or b. the flow of power at the several points of delivery is reasonably beyond the control of the purchaser.

If deliveries at more than one point of delivery are billed on a combined basis for the convenience of the customer, a charge will be made for the diversity between the measured demands at the several points of delivery. The charge for the diversity shall be determined in a uniform manner and shall be specified in the contract.

3.2 *Determination of estimated billing data:* If the purchased amounts of capacity, energy, or the 60-minute integrated demands for energy must be estimated from data other than metered or scheduled quantities, the Administrator and the purchaser will agree on billing data to be used in preparing the bill. If the parties cannot agree on the estimated billing quantities, a determination binding on both parties shall be made in accordance with the arbitration provisions of the contract.

4.1 *Application of Rates During Initial Operation Period:* For an initial operating period, not in excess of 3 months, beginning with the commencement of operation of a new industrial plant, a major addition to an existing plant, or reactivation of an existing plant or important part thereof, the Administrator may agree (a) to bill for service to such new or reactivated plant facilities on the basis of the measured demand for each day, adjusted for power factor, or (b) if such facilities are served by a distributor purchasing power therefor from the Administrator, to bill for that portion of such distributor's load which results from service to such facilities on the basis of the measured demand for each day, adjusted for power factor. Any rate schedule provisions regarding contract demand, billing demand, and minimum monthly charge which are inconsistent with this section shall be inoperative during such initial operating period.

The initial operating period and the special billing provisions may, on approval by the Administrator, be extended beyond the initial 3-month period for such additional time as is justified by the developmental character of the operations.

5.1 *Energy Supplied For Emergency Use:* A purchaser taking firm power shall pay in accordance with Wholesale Nonfirm Energy Rate Schedule H-6 for any electric energy which has been supplied (a) for use during an emergency on the purchaser's system, or (b) following an emergency to replace energy secured from sources other than the Administrator during such emergency, except that mutual emergency assistance may be provided and settled under exchange agreements.

6.1 *Billing Month:* Meters will normally be read and bills computed at intervals of 1 month. A month is defined as the interval between meter-reading dates which normally will be approximately 30 days. If service is for less or more than the normal billing month, the monthly charges stated in the applicable rate schedule will be appropriately adjusted. Winter and summer periods identified in the rate schedules will begin and end with the beginning and ending of the purchaser's billing month having meter-reading dates closest to the periods so identified.

7.1 *Payment of Bills:* Bills for power shall be rendered monthly and shall be payable at the office of the Administrator. Failure to receive a bill shall not release the purchaser from liability for payment. Demand and energy billings under each rate schedule application shall be rounded to whole dollar amounts, by elimination of any amount of less than 50 cents and increasing any amount from 50 cents through 99 cents to the next higher dollar.

If the Administrator is unable to render the purchaser a timely monthly bill which includes a full disclosure of all billing factors, he may elect to render an estimated bill for that month to be followed at a subsequent billing date by a final bill. Such estimated bill, if so issued, shall have the validity of and be subject to the same repayment provisions as shall a final bill.

Bills not paid in full on or before the close of business of the 20th day after the date of the bill shall bear an additional charge which shall be the greater of one-fourth percent (0.25%) of the amount unpaid or $50. Thereafter a charge of one-twentieth percent (0.05%) of the sum of the initial amount remaining unpaid and the additional charge herein described shall be added on each succeeding day until the amount due is paid in full. The provisions of this paragraph shall not apply to bills rendered under contracts with other agencies of the United States.

Remittances received by mail will be accepted without assessment of the charges referred to in the preceding paragraph provided the postmark indicates the payment was mailed on or before the 20th day after the date of the bill. If the 20th day after the date of the bill is a Sunday or other nonbusiness day of the purchaser, the next following business day shall be the last day on which payment may be made to avoid such further charges. Payment made by metered mail and received subsequent to the 20th day must bear a postal department cancellation in order to avoid assessment of such further charges.

The Administrator may, whenever a power bill or a portion thereof remains unpaid subsequent to the 20th day after the date of the bill, and after giving 30 days advance notice in writing, cancel the contract for service to

the purchaser, but such cancellation shall not affect the purchaser's liability for any charges accrued prior thereto.

8.1 *Approval of Rates:* Schedules of rates and charges, or modifications thereof, for electric energy sold by the Administrator shall become effective only after confirmation and approval by the Economic Regulatory Administration.

9.1 *Average Power Factor:* The formula for determining average power factor is as follows:

$$\text{Average Power Factor} = \frac{\text{Kilowatt-hours}}{\sqrt{(\text{Kilowatt-hours})^2 + (\text{Reactive Kilovolt-ampere-hours})^2}}$$

The data used in the above formula shall be obtained from meters which are ratcheted to prevent reverse registration.

When deliveries to a purchaser at any point of delivery include more than one class of power or are under more than one rate schedule, and it is impracticable to separately meter the kilowatt-hours and reactive kilovolt-ampere-hours for each class, the average power factor of the total deliveries for the month will be used, where applicable, as the power factor for each of the separate classes of power and rate schedules.

10.1 *Temporary Curtailment of Contract Demand:* The Administrator may include in contracts with industrial purchasers, provisions for temporary curtailment of contract demand by the purchaser. The reduction of charges for power so curtailed shall be applied in a uniform manner.

11.1 *General Provisions:* The Wholesale Rate Schedules and General Rate Schedule Provisions of the Bonneville Power Administration effective December 20, 1979, supersede in their entirety the Administration's Wholesale Power Rate Schedules and General Rate Schedule Provisions effective December 20, 1974.

II. Major Issues

The rate schedules included in this Notice are BPA's initial proposals for wholesale power rates which, upon approval, will become effective December 20, 1979.

BPA has conducted three basic categories of studies in preparation of the proposals. They include a fully allocated cost-of-service study and repayment study to determine revenue requirements, a long-run incremental cost-of-service study, and a set of rate design studies developed to examine alternative rate structures and rate levels. The cost-of-service studies and repayment study were developed as a foundation for the rate schedules. Other factors considered for the initial rate proposal include conservation, value of service, ease of comprehension, continuity, and ease of administration.

A discussion of the alternatives considered in developing the rate proposals and the important issues raised by the proposals is included under three topics: Average cost-of-service study, long-run incremental cost-of-service study, and rates.

a. *Average Cost-of-Service Study:* The form and magnitude of the proposed initial schedules are strongly influenced by results of the average cost-of-service study.

The cost-of-service study is based on generally accepted electric utility industry practice. Test years were selected (fiscal year 1977 through fiscal year 1983) and cost data were gathered. Fiscal year 1980 was used as the basis for the proposed rates because it most closely matches the period during which the rates are expected to be effective. Costs for each of the test years were then functionalized to generation, transmission, and metering and billing. Costs were then classified to the components of capacity and energy. The final major step was to allocate costs to customer classes. While in each of these steps, alternative methods could have been employed, the methods selected during each of the steps are appropriate to BPA's system. The methods chosen have a significant impact on the results of the cost-of-service study and the rates BPA has proposed.

A decision was made not to use the traditional utility industry fixed cost/variable cost method for classifying costs to capacity and energy in the cost-of-service study, but instead to adopt a cost causation approach. This method, determined by BPA staff to be more appropriate to the nature of a hydroelectric system such as the Federal Columbia River Power system (FCRPS), apportions the cost of generation between capacity and energy in relation to the causes underlying the construction and operation of various generating plants.

In applying this method, BPA staff classified all hydro peaking units to capacity. All other hydro units were classified to capacity and energy in the ratio of the peaking capacity of the base system to the energy production capability under average streamflow conditions converted to 100 percent. This resulted in classification of 59 percent of base system hydro costs to capacity and 41 percent to energy.

The cost to BPA for its purchase of thermal plant capability was classified by crediting total thermal plant costs by an amount equal to the cost of hydro peaking capacity. As a result, 10 percent of thermal purchase costs were classified to capacity and 90 percent to energy.

Exhibit 2 of the cost-of-service study discusses the alternative classification methods which were considered.

The final step in the cost-of-service study process is allocation of costs to customer classes. Before this step could be completed, transmission system costs had to separated into components, or treated as a single unit using the "rolled in" method. BPA chose the "rolled in" method. Under this approach, transmission facilities are considered to be a part of an integrated system. The alternative to the "rolled in" method is to directly assign costs of facilities to customer classes based on specific uses of such facilities.

Following selection of the "rolled in" method for transmission capacity costs, both generation and transmission capacity costs were allocated based on the average of the 12 monthly coincidental peak demands, including losses, to reflect the demands at the point of generation. This method is widely used in the electric utility industry, but other methods which would produce somewhat different results also could have been applied. With respect to energy, the FCRPS energy production costs were allocated in direct proportion to energy loads including losses.

b. *Long-Run Incremental Cost-of-Service Study:* A long-run incremental cost-of-service (LRIC) study was conducted by BPA to develop an indicator of the incremental costs BPA is incurring for new generation and transmission. The LRIC study provides a basis for developing rates from economic efficiency criteria. Rates based on long-run incremental costs provide a different and controversial approach to electric utility ratemaking.

Considerable disagreement exists about how the concept should be used in establishing rates. At issue are questions relating to measurement of marginal costs, application of marginal costs to rates, and the adjustment of such rates to the revenue requirement. All of these issues have been considered in development of BPA's LRIC study.

c. *Wholesale Power Rates:* There are several issues related to each of the rate schedules. Each issue is discussed separately by rate schedule. Issues which relate to all of the rates are discussed under a separate heading. Because the proposed rates significantly reflect the results of the average cost-of-service study, the issues related to that study which were discussed above are pertinent. However, they are not repeated in this section.

1. *Wholesale Firm Power Rate, EC-8:* There are three major issues associated with this rate schedule.

(a) The schedule includes time differentiation on a daily and seasonal basis in the demand charge, but not in the energy charge. The daily and seasonal differences in demand charges reflect the results of a study completed by BPA which demonstrated that the peaking capacity of the FCRPS is associated with summer and winter on-peak hours. The costs of these resources are assigned to peak periods and are reflected in the rate.

(b) The revenues in excess of costs which would be collected based on the rate in section 2c of Wholesale Nonfirm Energy Rate, H-6, have been credited against the off-peak (the 9-hour periods from 10 p.m. to 7 a.m. commencing at 10 p.m. on Monday and ending at 7 a.m. on Saturday, and the 33-hour period from 10 p.m. on Saturday ending at 7 a.m. on Monday) demand charge.

The remaining costs associated with the off-peak demand charge have been assigned to the energy charge. The credit from the revenues generated from the H-6 rate was applied to the off-peak demand charge to simplify the demand charge and billing requirements and to reflect the incremental cost relationship between capacity and energy which resulted from the long-run incremental cost and rate studies. Incremental costs of energy compared with average costs of energy are higher than incremental costs of capacity compared with average costs of capacity.

(c) A separate charge for transformation is no longer included in the rate schedule. The cost of transformation is included in the transmission component of the demand charge due to the use of the "rolled in" approach in treating transmission costs in the cost-of-service study.

2. *Reserve Power Rate, EC-9:* The major issue associated with this rate schedule is that the rate is based directly on the results of the long-run incremental cost-of-service study.

3. *Wholesale Power Rate for Industrial Firm Power, IF-2:* There are three major issues associated with this rate schedule.

(a) The demand charge is the same as that shown in the EC-8 and F-7 rates. The cost-of-service study results indicate a slightly higher demand charge for direct-service industrial customers. An adjustment was made to reflect the benefits the FCRPS derives from delivering energy to these high load factor customers during off-peak hours. This allows the system to utilize the output of base load thermal plants and to accept the return of energy during off-peak hours.

(b) This schedule contains an availability credit to account for the reserves provided by direct-service industrial customers. This credit applies when the customer's load is restricted below 99 percent of its contract demand. The credit applies to all power sales to the customer. However, a limit in the credit is reached once the restriction is equal to 25 percent of the purchaser's contract demand.

(c) A credit from the revenue from the H-6 schedule for sales outside the Pacific Northwest is applied in the same manner as was applied in the EC-8 rate schedule.

4. *Wholesale Power Rate for Modified Firm Power, MF-2:* The issues related to this rate schedule are similar to those associated with the IF-2 schedule. However, availability credits are not allowed under this rate schedule.

5. *Wholesale Firm Capacity Rate, F-7:* There are two major issues associated with this rate schedule.

(a) This schedule includes a base charge which reflects the approximate cost of providing a given amount of Federal capacity (6 hours per day) and a variable charge established between costs and value of the peaking service provided, based on alternative costs. The variable charge is included to provide encouragement to peaking customers to operate their share of the system in a manner which will reduce the burdens on the Federal System and optimize overall operations.

(b) The capacity rate for contract season service is established midway between the cost of service and the value of service to the purchaser based on the purchaser's alternative costs.

6. *Wholesale nonfirm energy rate, H-6:* This rate schedule was based on both value of service and cost of service. In addition, the rate is time-differentiated on a daily basis. The rate for sales to meet Pacific Northwest nonfirm energy requirements is based on the results of the cost-of-service study. The onpeak rate is equal to the average cost of power as derived from the cost-of-service study. The offpeak rate includes an energy component and a transmission capacity component, but excludes a generation capacity component. For sales of energy not for use in the Pacific Northwest as defined in Pub. L. 88-552, the rate is flexible within limits. The rate for each sale is based on an agreed upon price between BPA and the purchasing utility, within defined limits. The lower limit is the same as that charged for sales to meet Pacific Northwest nonfirm energy requirements. The upper limit is equal to the Pacific Northwest nonfirm rate plus approximately 50 percent of the difference between the Pacific Northwest nonfirm rate and the alternative cost of energy for the purchasing utility.

7. *Wholesale firm energy rate, J-2:* This rate is derived from the cost-of-service study and includes a component for energy, transmission capacity, and generation capacity. Most of this energy is delivered during offpeak hours on a firm basis.

8. *Other rate issues:*

(a) *Adjustment for fixed contract revenue deficiencies:* Rates for some transactions are not subject to change because of contractual obligations. The cost-of-service study for fiscal year 1980 indicates that a revenue deficiency of approximately $30 million would result if this amount were not recovered from other rates. Consequently, all power rate schedules have been adjusted upward to recover the revenue deficiency associated with these fixed contracts.

(b) *Rate increase impacts on customers:* The impact of the proposed rate increase varies by customer. Because of changes in rate design from those in current rate schedules, some customers and customer groups would experience a larger percentage increase in their costs of power purchased from BPA than other customers and customer groups. This is an issue associated with rate continuity and rate stability.

III. Public Forums

A. *Public information forums:* BPA will conduct public information forums to describe how BPA determined the need for new rates, to explain the proposed wholesale power rates and the supporting analyses, and to answer questions. Questions raised at the forums will be answered at that time, if possible, or in writing at a later date. Each forum proceeding will be transcribed. The forum transcripts, all documents introduced at the forums, and questions and written answers will become part of the official record. The official record will be available for review and copying at BPA headquarters, 1002 Northeast Holladay Street, Portland, Oreg., in accordance with the provisions of the Freedom of Information Act, 5 U.S.C. 552. The forums will begin at 7 p.m. at the following locations and on the dates listed:

BPA Auditorium, 1002 Northeast Holladay Street, Portland, Oreg., Monday, September 11;

Eugene Hotel, 222 East Broadway, Eugene, Oreg., Tuesday, September 12;

Blakely Room, Seattle Center, Seattle, Washington, Wednesday, September 13;

Federal Building Auditorium, 825 Jadwin Avenue, Richland, Wash., Thursday, September 14;

Wenatchee Room, Thunderbird Motor Inn, 1225 North Wenatchee, Wenatchee, Wash., Monday, September 18;

Terrace Room C, Ridpath Hotel, West 515 Aprague, Spokane, Wash., Tuesday, September 19;

Tudor-Burgundy Room, Holiday Inn, Hwy 10 West and Mulluan Road, Missoula, Mont., Wednesday, September 20;

Intermountain Science Experience Center Auditorum, 1776 Science Center Drive, Idaho Falls, Idaho, Thursday, September 21.

B. *Public comment forums:* BPA will conduct public comment forums to permit customers and the public to submit written comments and orally present views and proposals regarding the proposed rates or associated studies. The forums will be conducted by a chairperson who will be responsible for an orderly procedure.

Persons wishing to speak must notify the BPA official designated below at least 3 days before a forum so that a list of forum participants can be prepared and time limitations for oral presentations established. Written comments may also be submitted at the forums or following the forums until November 30, 1978, for inclusion in the official record. The forum chairperson may question forum participants and, at his discretion, permit others a like privilege.

Questions raised at the forums will be answered at the forums or in writing. Each forum will be transcribed. The forum transcripts, all documents introduced at the forums, and questions and written will become part of the official record. The official record will be available for review and copying in accordance with the provisions of the Freedom of Information Act, 5 U.S.C. 552.

The forums will begin at 7 p.m. at the following locations and on the dates listed. Persons interested in speaking should contact the BPA official listed for each meeting.

BPA Auditorium, 1002 Northeast Holladay Street, Portland, Oreg., Wednesday, November 1. Contact: BPA Area Manager, Room 201, 919 Northeast 19th Avenue, Portland, Oreg. 97208.

Eugene Hotel, 222 East Broadway, Eugene, Oreg., Thursday, November 2. Contact: BPA District Manager, Room 206, 211 East Seventh Street, Eugene, Oreg. 97401, 503-345-0311.

Federal Building Auditorium, 825 Jadwin Avenue, Richland, Wash., Monday, November 6. Contact: BPA Area Manager, West 101 Poplar, Walla Walla, Wash. 99362, 509-525-5500, ext. 701.

Intermountain Science Experience Center Auditorium, 1776 Science Center Drive, Idaho Falls, Idaho, Tuesday, November 7. Contact: BPA District Manager, 531 Lomax Street, Idaho Falls, Idaho 83401, 208-523-2706.

City Hall, Chelan Avenue and Yakima Street, Wenatchee, Wash., Wednesday, November 8. Contact: BPA District Manager, Room 314, 301 Yakima Street, Wenatchee, Wash. 98801, 509-662-4377, ext. 379.

Blakely Room, Seattle Center, Seattle, Wash., Monday, November 13. Contact: BPA Area Manager, Room 250, 415 First Avenue North, Seattle, Wash. 98109, 206-442-4130.

Terrace Rooms A and B, Ridpath Hotel, West 515 Sprague, Spokane, Wash., Tuesday, November 14. Contact: BPA Area Manager, Room 561, West 920 Riverside Avenue, Spokane, Wash., 99201, 509-456-2500, ext. 2518.

Tudor-Burgundy Room, Holiday Inn, Highway 10 West and Mullan Road, Missoula, Mont., Wednesday, November 15. Contact: BPA District Manager, Box 758, Kalispell, Mont. 59901, 406-755-6202.

In addition to the opportunities presented above for submitting comments and questions at the public forums, customers and the public may also send written comments and questions on the proposed wholesale power rates to BPA from the date of this Notice until November 30, 1978, which is 15 days after the last scheduled Public Comment Forum. The written comments, questions, and answers will become part of the Official Record; customers and the public are asked to submit 5 copies of any written comments which exceed 10 pages. Written comments and questions should be submitted to the Public Involvement Coordinator, Bonneville Power Administration, P.O. Box 12999, Portland, Oreg. 97212.

BPA will evaluate the contents of the Official Record, including all written comments, questions, and answers, and the forum transcripts, for consideration in the development of the proposed wholesale power rates which BPA submits through the Assistant Secretary for Resource Applications to ERA for confirmation and approval by June 1, 1979. As a result of public participants' comments, the proposed rates submitted to ERA may vary from those tentatively proposed in this Notice. In addition, the cost estimates used to determine revenue requirements will be updated prior to the actual filing in June 1979. As a result of the updating of the cost estimates, the amount of the rate increase may be either more or less than presently estimated.

Dated: August 23, 1978.

WILLIAM S. HEFFELFINGER,
Director of Administration.

[FR Doc. 78-24093 Filed 8-24-78; 8:45 am]

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