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Federal Register

TUESDAY, AUGUST 8, 1978



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The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday). This is a voluntary program. (See OFR notice 41 FR 32914, August 6, 1976.)

Monday	Tuesday	Wednesday	Thursday	Friday
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	CSC			CSC
	LABOR			LABOR
	HEW/FDA			HEW/FDA

Documents normally scheduled for publication on a day that will be a Federal holiday will be published the next work day following the holiday.

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

NOTE: As of July 3, 1978, documents from the following agencies in the Department of Health, Education, and Welfare are no longer being assigned to the Tuesday/Friday schedule: Alcohol, Drug Abuse and Mental Health Administration (ADAMHA); Center for Disease Control (CDC); Health Resources Administration (HRA); Health Services Administration (HSA); National Institutes of Health (NIH); and Public Health Service (PHS).

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A Cumulative List of CFR Sections Affected is published separately at the end of each month. The guide lists the parts and sections affected by documents published since the revision date of each title.

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NOTE: There were no items eligible for inclusion in the list of RULES GOING INTO EFFECT TODAY.

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To provide for a temporary increase in the public debt limit. (August 3, 1978; 92 Stat. 419) Price: $.50.

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Alcohol and Drug Abuse Education Amendments of 1978. (August 4, 1978; 92 Stat. 451) Price: $.60.

S. 785 ..... Pub. L. 95-337
To declare that all right, title and interest of the United States in two thousand seven hundred acres, more or less, are hereby held in trust for the Paiute and Shoshone Tribes of the Fallon Indian Reservation and Colony, Fallon, Nevada, to promote the economic self-sufficiency of the Paiute and Shoshone Tribes, and for other purposes. (August 4, 1978; 92 Stat. 455) Price: $.50.

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

[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: This amendment transfers the exception of one position of Director, Division of Education Programs, National Endowment for the Humanities, from schedule A to schedule B because noncompetitive examination is practicable for this position.

EFFECTIVE DATE: July 25, 1978.

FOR FURTHER INFORMATION CONTACT:

Michael Sherwin, 202-632-4533.

Accordingly, 5 CFR 213.3182 (b)(11) is revoked and 5 CFR 213.3282 (b)(18) is added, as follows:

§ 213.3182 National Foundation on the Arts and the Humanities.

* * * * *

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

(11) [Revoked].

* * * * *

§ 213.3282 National Foundation on the Arts and the Humanities.

* * * * *

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

(18) Until September 30, 1980, one position of Director, Division of Education Programs.

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

[FR Doc. 78-22103 Filed 8-7-78; 8:45 am]

[6325-01]

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

Transfers From Retired Employees Health Benefits Program

AGENCY: Civil Service Commission.

ACTION: Final rulemaking.

SUMMARY: On March 31, 1978, proposed rulemaking was published in the FEDERAL REGISTER (43 FR 13583) to permit persons currently enrolled in the retired Federal employees health benefits (RFEHB) program to enroll in the Federal employees health benefits (FEHB) program. This opportunity will enable uniform plan enrollees to avoid a substantial premium increase effective January 1, 1979, and will permit RFEHB enrollees who did not change enrollment during the 1974 open season to do so.

DATE: Effective August 8, 1978.

FOR FURTHER INFORMATION CONTACT:

Craig Pettibone, Office of Policy Development and Technical Services, Bureau of Retirement, Insurance and Occupational Health, 202-632-4682.

SUPPLEMENTARY INFORMATION: The comments, suggestions and objections received in response to the March 31, 1978, notice have been given careful consideration. In addition to minor clarifying changes, a suggestion to delete the provision which allows former RFEHB enrollees who transferred to FEHB in 1974 to return to the retired program has been adopted to prevent confusion on the part of the annuitants, and to insure equal treatment to all RFEHB enrollees who transfer to FEHB. The following suggestions, nevertheless, have not been adopted for the reasons stated.

1. It was suggested that the date of registration and the effective date of enrollment be postponed to allow for delays incurred in receiving enrollment notices from the Commission, and to enable the carriers to establish premium rates appropriate to this unique group. The proposed regulations cited the effective date of enrollment as being not earlier than April 1, 1978. This date has been changed to not earlier than January 1, 1979. Nevertheless, the earliest date of registration will be August 8, 1978. The Commission prefers to allow the annuitants to register for enrollment in the FEHB program as soon as possible. Early registration by annuitants will enable the Commission to provide notification of enrollment to the health benefits carriers prior to the effective date of January 1, 1979. Further, the fact that the majority of these enrollees are covered by Medicare greatly reduces the total costs for which the carriers will be accountable. Accordingly, no special premium rates need be established.

2. A suggestion that a one-year limitation be placed on the open enrollment period to avoid adverse selection has not been adopted because of the confusion which may arise on the part of the enrollees. Should the annuitants fail to transfer to FEHB and subsequently change their minds, the Commission intends to ensure that there is an opportunity to elect the health benefits coverage most beneficial to them. Additionally, since most of this group is covered by Medicare, the carrier will be accountable for only a small portion of the total costs involved.

3. It was suggested that the provision restricting limitation of benefits for persons who were confined in a hospital or institution on the effective date of enrollment in a plan in the FEHB program be deleted, and that the plans in the RFEHB be responsible for the confined person for a period after the enrollment change. The carriers argued that a restriction on the limitation of benefits would be a violation of their contracts. However, the contracts stipulate that the carriers must abide by Commission regulations. It was also suggested that these annuitants be considered new enrollees, with benefits consistent with present FEHB program regulations for new enrollees. These recommendations cannot be enforced because they would apply to the private plan and Medicare options under the RFEHB program as well as to the uniform plan. Since the Commission cannot control private plan or Medicare benefits, it is quite possible that annuitants under these other two options would be left without coverage during their confinement. Nevertheless, because the majority of these en-

rollees are covered by Medicare, it is not believed that the carriers will be adversely affected by the small number of annuitants who would have a need to utilize this coverage.

Accordingly, 5 CFR § 890.602 and § 890.603 are amended, § 890.604 is revoked, and § 890.605 is added as set out below:

§ 890.602 Opportunity to change enrollment.

An annuitant eligible to enroll under § 890.601 may register on and after August 8, 1978.

§ 890.603 Effective date.

The effective date of an enrollment under § 89.602 is the first day of the first pay period after the election is received by the retirement system, but not earlier than January 1, 1979.

§ 890.604 [Revoked]

§ 890.605 Persons confined on effective date.

Benefits may not be limited for persons who, on the effective date of an enrollment under § 890.602, are confined in a hospital or institution.

(5 U.S.C. 8913)

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

[FR Doc. 78-22104 Filed 8-7-78; 8:45 am]

[6325-01]

PART 891—RETIRED FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

Increase in Government Contribution and Miscellaneous Changes

AGENCY: Civil Service Commission.

ACTION: Final rulemaking.

SUMMARY: On March 31, 1978, proposed rulemaking was published in the FEDERAL REGISTER (43 FR 13583) to increase the Government contribution toward the cost of coverage under the retired Federal employees health benefits (RFEHB) program. This increase will offset, to the extent possible under law, a uniform plan premium increase which will be effective January 1, 1979, and will ensure an equal Govenment contribution to all enrollees in the retired program.

DATE: Effective January 1, 1979.

FOR FURTHER INFORMATION CONTACT:

Craig Pettibone Office of Policy Development and Technical Services, Bureau of Retirement, Insurance and Occupational Health 202-632-4682.

SUPPLEMENTARY INFORMATION: Previously, annuitants who enrolled in the uniform plan prior to January 1, 1973, automatically received basic plus major medical coverage and annuitants who enrolled subsequent to that time could receive basic coverage only. Because of the greater benefits provided under basic plus major medical, all uniform plan enrollees will automatically have this coverage effective January 1, 1979. Basic only and major medical only will no longer be offered under the uniform plan after that date in view of the inadequacy of the benefits in meeting today's medical expenses. Minor changes have been made to rectify technical oversights in this regard. In addition, a suggestion to delete the provision which allows former RFEHB enrollees who transferred to FEHB in 1974 to return to the retired program has been adopted to prevent confusion on the part of the annuitants, and to ensure equal treatment to all RFEHB enrollees who transfer to FEHB.

Accordingly, 5 CFR 891.103(a), §§891.202(c), 891.401(a) and (b), and 891.501 are amended, and § 891.202(d) and subpart F are deleted, as set out below:

§ 891.103 Eligibility.

(a) *General conditions of eligibility.*
* * *

(3) An annuitant who enrolled under § 890.601, and who later cancels such enrollment, is ineligible to subscribe to the uniform plan or to receive a Government contribution toward the cost of a private health benefits plan.

* * * * *

§ 891.202 Change of election.

* * * * *

(c) An annuitant may change his or her election in accordance with the following table by notifying his or her retirement system at any time:

Table of optional changes

Change permitted	Type of election from which changing	Effective date of change
(1) Change to not participating	Election for self alone or self and family for uniform or private health benefits plan.	1st day of the month specified in notice to retirement system, or 1st day of the month following receipt of notice by retirement system, whichever is later. Changes in withholdings and contributions are effective for annuity or compensation accruing for the month preceding the effective date of the change.
(2) Change to self alone in same plan	Election for self and family for uniform plan or private health benefits plan.	Same as above.
(3) Change to private health benefits plan for self alone or self and family.	Election for self alone or self and family for uniform plan.	Do.
(4) Change to self and family in same plan	Election for self alone for uniform or private health benefits plan.	1st day of the 4th month following the month in which the notice is received by the retirement system. Changes in withholdings and contributions are effective for annuity or compensation accruing for the 3d month following the month in which the notice is received by the retirement system.
(5) Change to self alone or self and family for uniform plan or private health benefits plan.	Election not to participate	Same as above.

(d) [Revoked]

§ 891.401 Government contributions.

(a) The Commission shall pay, through the retirement office, $4 monthly to each retired employee receiving annuity and to each survivor receiving compensation who elects to receive a Government contribution toward the cost of a private health benefits plan in which he or she is a subscriber for self alone, and $8 monthly to each retired employee receiving annuity and to each survivor receiving compensation who so elects toward the cost of a private health benefits plan in which he or she is a subscriber for self and family. The Commission shall pay, through the

office of workers' compensation programs $3.73 each 4-week period to each retired employee, other than a survivor, who is receiving compensation and who elects to receive a Government contribution toward the cost of a private health benefits plan in which he or she is a subscriber for self alone, and $7.47 each 4-week period to each who so elects toward cost of a private health benefits plan in which he or she is a subscriber for self and family. The Commission shall not pay, in any case, more than the cost of a private health benefits plan each month or 4-week period, as the case may be.

(b) The Commission shall contribute to the cost of the uniform plan $4 monthly for each retired employee receiving annuity and each survivor receiving compensation, and $3.73 each 4-week period for any other retired employee receiving compensation, for an election for self alone; and $8 monthly for each retired employee receiving annuity and each survivor receiving compensation, and $7.47 each 4-week period for any other retired employee receiving compensation, for an election for self and family. Election to subscribe to the uniform plan constitutes agreement by the retired employee that the retirement office may withhold from his or her annuity or compensation his or her share of the cost of the plan, as provided by this part.

* * * * *

§ 891.501 Standards for uniform plan.

The uniform plan shall be open to all eligible retired employees and members of their families, without regard to race, sex, health status, or age. It shall not deny or limit benefits because of any preexisting condition. It shall offer basic plus major medical coverage. * * *

§§ 891.601-891.602 (Subpart F)—[Revoked]

(Pub. L. 86-724)

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

[FR Doc. 78-22105 Filed 8-7-78; 8:45 am]

[3410-02]

Title 7—Agriculture

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

PART 967—CELERY GROWN IN FLORIDA

Handling Regulation

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This handling regulation establishes the quantity of Florida celery to be marketed fresh during the 1978-79 season, with the objective of assuring adequate supplies and orderly marketing.

EFFECTIVE DATE: August 8, 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. 149 and order No. 967, both as amended (7 CFR 967) regulate the handling of celery grown in Florida. It is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674). The Florida Celery Committee, established under the order, is responsible for local administration.

Notice was published in the July 13 FEDERAL REGISTER (43 FR 30066) inviting written comments by July 28, 1978. None was received.

This regulation is based upon the unanimous recommendations made by the committee at its public meeting in Orlando on June 7.

The committee recommended a marketable quantity of 8,433,388 crates of fresh celery for the 1978-79 season. This recommendation is based on the appraisal of the expected supply and prospective market demand for the 1978-79 season.

The recommended 8.4 million crate marketable quantity is 40 percent more than the approximately 6 million crates expected to be marketed during the season ending July 31, 1978. Each producer registered pursuant to § 967.37(f) would have an allotment equal to 100 percent of his historical marketings. This recommendation provides the industry an opportunity to (1) produce to its fullest capacity for the benefit of the consumer, and (2) determine its actual or potential maximum production capacity.

As required by § 967.37(d)(1) a reserve of 6 percent of the total base quantities is authorized for new producers and for increases by existing producers, with 276,705 crates to be allotted to each category. After consideration of applications submitted pursuant to § 967.151 the committee allocated 100,000 crates to a new producer and 50,000 crates each to 2 existing producers.

Findings. On the basis of all considerations it is believed that this regulation 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 publication in the FEDERAL REGISTER (5 U.S.C. 553) in that (1) notice was given of the handling regulation set forth in this section through publicity in the production area and by publication in the July 13 FEDERAL REGISTER, (2) as provided in the marketing agreement and order, this regulation applies to celery marketed during the 1978-79 season, (3) compliance with this section will not require any special preparation by handlers which cannot be completed prior to the time actual handling of harvested celery begins, approximately the latter part of October, (4) prompt issuance of this regulation will be beneficial to all interested persons because it should afford producers and handlers maximum time to plan their operations accordingly, and (5) no useful purpose will be served by postponing such issuance.

The regulation is as follows:

§ 967.314 Handling regulation; marketable quantity; and uniform percentage for the 1978-79 season ending July 31, 1979.

(a) The marketable quantity is established under § 967.36(a) as 8,433,388 crates of celery.

(b) As provided in § 967.38(a), the uniform percentage shall be 100 percent.

(c) Pursuant to § 967.36(b), no handler shall handle any harvested celery unless it is within the marketable allotment of a producer who has a base quantity and such producer authorizes the first handler thereof to handle it.

(d) as required by § 967.37(d)(1) a reserve of 6 percent of the total base quantities is hereby authorized for (1) new producers and (2) increases for existing base quantity holders with 276,705 crates allotted to each category.

(e) Terms used herein shall have the same meaning as when used in the said marketing agreement and order.

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

Dated August 3, 1978 to become effective August 8, 1978.

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

[FR Doc. 78-22101 Filed 8-7-78; 8:45 am]

[3410-34]

Title 9—Animals and Animal Products

CHAPTER I—ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

PART 73—SCABIES IN CATTLE

Release of Areas Quarantined

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The purpose of this amendment is to release portions of Chaves, Colfax, De Baca, Eddy, Guadalupe, Quay, and Union Counties and all of Curry, Lea, and Roosevelt Counties in New Mexico from areas quarantined because of cattle scabies. Surveillance activity indicates that cattle scabies no longer exists in the areas quarantined. No areas in the State of New Mexico remain under quarantine.

EFFECTIVE DATE: August 3, 1978.

FOR FURTHER INFORMATION CONTACT:

Dr. Glen O. Schubert, chief Staff Veterinarian, Sheep, Goat, Equine, and Ectoparasites Staff, USDA, APHIS, VS, room 737, 6505 Belcrest Road, Federal Building, Hyattsville, Md. 20782, 301-436-8322.

SUPPLEMENTARY INFORMATION: This amendment releases portions of Chaves, Colfax, De Baca, Eddy, Guadalupe, Quay, and Union Counties and all of Curry, Lea, and Roosevelt Counties in New Mexico from the areas quarantined because of cattle scabies. Therefore, the restrictions pertaining to the interstate movement of cattle from quarantined areas contained in 9 CFR Part 73, as amended, will not apply to the excluded areas, but the restrictions pertaining to the interstate movement of cattle from nonquarantined areas contained in said part 73 will apply to the excluded areas. No areas in New Mexico remain under quarantine.

Accordingly, Part 73, Title 9, Code of Federal Regulations, as amended, restricting the interstate movement of cattle because of scabies, is hereby amended as follows:

In § 73.1a, paragraph (e) relating to the State of New Mexico is deleted.

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132; (21 U.S.C. 111-113, 115, 117, 120, 121, 123-126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141.)

The amendment relieves restrictions no longer deemed necessary to prevent the spread of cattle scabies and should be made effective promptly in order to be of maximum benefit to affected persons. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable and unnecessary, and good cause is found for making the amendment effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Wasington, D.C., this 3d day of August 1978.

NOTE.—The Animal and Plant Health Inspection 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.

J. K. ATWELL,
Acting Deputy Administrator, Veterinary Services.

[FR Doc. 78-22097 Filed 8-7-78; 8:45 am]

[3128-01]

Title 10—Energy

CHAPTER II—DEPARTMENT OF ENERGY

PART 470—APPROPRIATE TECHNOLOGY SMALL GRANTS PROGRAM

Program Guidelines

AGENCY: Department of Energy.

ACTION: Final rule.

SUMMARY: This rule prescribes guidelines for the implementation of a program of financial support for appropriate technology under the Energy Research and Development Administration Appropriation Authorization of 1977.

EFFECTIVE DATE: August 8, 1978.

FOR FURTHER INFORMATION CONTACT:

Ann Hegnauer (Buildings and Community Systems), Office of Conservation and Solar Applications, 20 Massachusetts Avenue NW., Washington, D.C. 20545, 202-376-4711.

Bradley Byers, Office of Public Affairs, 20 Massachusetts Avenue NW., Washington, D.C. 20545, 202-376-5729.

Joshua Smith, Office of General Counsel, 12th and Pennsylvania Avenue NW., Washington, D.C. 20461, 202-566-9380.

SUPPLEMENTARY INFORMATION:

A. BACKGROUND

On April 12, 1978, the Department of Energy (DOE) issued proposed guidelines for implementing an appropriate technology financial support program (43 FR 16185, April 17, 1978), as required under section 112 of the Energy Research and Development Administration Appropriation Authorization of 1977 (Act) (Pub. L. 95-39, 91 Stat. 180, 42 U.S.C. 5907a). A public hearing on the proposal was held on May 15, 1978. DOE received 29 written and 3 oral comments nearly all of which strongly supported the goals and general concepts of the proposed guidelines. However, a number of suggestions were made which have resulted in some changes in the guidelines issued today.

B. DISCUSSION OF COMMENTS

1. DISSEMINATION OF INFORMATION—§ 470.20

While most of the comments DOE received were addressed to specific provisions in the proposed rule, some comments were more general. Several expressed the view that inadequate provision was made in the proposed guidelines for the dissemination of information with respect to appropriate technology systems and supporting technologies and for the providing of assistance for the commercialization of successful systems and technologies. Several comments suggested that the guidelines include a mechanism for providing "technical assistance" to proposers before and during the preparation of their proposals, as well as to recipients during and after the period of the awards.

DOE believes that the guidelines, as the comments suggest, should provide for the dissemination of information with respect to energy-related systems and supporting technologies related to appropriate technology, as required by subsections (a) and (c) of section 112 of the Act to be part of the program implemented by DOE. Expanding the scope of this requirement to commit DOE to make funds available for "commercialization" and "technical assistance" appears, however, to exceed the information dissemination, or any other, requirements of section 112.

Accordingly, DOE has added a new § 470.20 to the final rule to implement the dissemination of information re-

quirements of section 112 of the Act. This new section requires DOE to disseminate to the public information on the projects developed or demonstrated under the program. It is to be noted that use will be made of all appropriate information dissemination channels including standard DOE information channels such as the Energy Extension Service, the regional newsletters sponsored by the National Center for Appropriate Technology and trade and professional journals and newsletters. While it does not provide for "technical assistance" or "commercialization" programs, it does require DOE to provide recipients with information on sources of possible assistance "for further development and commericalization of their projects."

2. DEFINITIONS—§ 470.2

One comment suggested that the term "small business" be defined as in the current regulations of the Small Business Administration (SBA), instead of the 100 employee limit in the proposed rule. The current SBA definition of small business may require a determination not only of the number of employees in each business, but also of such other variables as the annual receipts of the business, the type of business (e.g., retail, service, contractor), and the location of the business (e.g., whether it is in a labor surplus area), etc. Since section 112(d)(1) of the Act requires DOE to "develop simplified procedures with respect to application for support," DOE considers a simpler definition more appropriate than the complex formulation of the SBA, as well as a definition which is appropriate to the size and nature of the project involved.

For purposes of clarity, the definition of "State government" has been revised and a definition of "State" has been added. A definition of "support" has also been added for clarification. "Support" is defined to mean "financial support or award under the program by grants or cooperative agreements." The use of contracts is authorized by the act, but grants and cooperative agreements appear to be the instruments that must appropriate for the financial support purposes of this program.

3. ESTABLISHMENT OF PROGRAM—§ 470.10

One comment suggested adding to § 470.10 a new item (f), dealing with the creation of jobs at skill levels and locations applicable to the local economic base, as an additional criterion for determining projects appropriate for funding under the program. The criteria in items (a) through (e) were drawn directly from subsection 112(c) of the act. Since section 112 does not contain the suggested criterion and since § 470.14(c)(9) of the rule includes utilization of "local resources, material and manpower" as a criterion for consideration, DOE has determined not to adopt this suggestion.

Another comment suggested that provisions be added to section 470.10 to indicate support for energy conservation in existing structures, particularly historic buildings. DOE believes that this consideration is adequately accommodated by the general provisions concerning the environment, as set forth in §§ 470.10(d) and 470.14(c)(7), and would be inappropriate for inclusion as a separate category in § 470.10.

4. ELIGIBILITY REQUIREMENTS—§ 470.11

Some comments suggested that a category be added to § 470.11(c) to permit support for projects which are intended solely to educate the public. Section 112(c) of the act, however, specifically limits the program to financial support for encouraging development and demonstration projects. While section 112 does permit funds made available under it to be used for the dissemination of information with respect to appropriate energy-related systems and supporting technologies, dissemination of information is applicable to all three categories presently contained in § 470.11 and, therefore, DOE believes that a separate category solely for public education should not be added.

Some comments suggested that the funding limits of paragraph (d) were too high and that, if they were lower, a greater number of proposals could be funded in each region. Another comment suggested that the rule should emphasize that a participant could only obtain support for a "one-time grant." DOE believes that the funding limits are not excessive as ceilings, but that the ability of a participant to obtain funding within these limits required clarification. Accordingly, the funding limits in paragraph (d) have been maintained while paragraph (c) has been revised and paragraph (e) added in order to spell out more clearly the applicability of the limits.

5. MANAGEMENT—§ 470.12

Several comments suggested that the States should be the direct recipients of "block funding" in order that each State receive a specific grant of funds to run its own appropriate technology program, instead of the program being run regionally by DOE program managers. This issue was carefully considered in developing the pilot program and in formulating these national guidelines. However, DOE decided that it would manage the program on a regional basis in order to assure the most equitable distribution of funds within each region and to provide the maximum degree of impartiality and uniformity in evaluating and selecting projects for support.

Several comments suggested that the proposed guidelines be changed to insure that regional program managers coordinate their activities with State Energy Offices, the appropriate technology community and/or other groups familiar with appropriate technology and State and local energy needs. Since it was always intended that such coordination take place, § 470.12(b) has been revised to make explicit this intent.

Some comments suggested that special advisory boards, made up of State and technical panel members and others, be required to be established to work with the regional program manager in planning and implementing the program. While the rules do not preclude the lawful establishment of this type of board, DOE believes it would be inappropriate to require the establishment of an advisory panel of this nature due to the need for economical and simplified procedures and the revisions to § 470.12, discussed above.

6. PROGRAM ANNOUNCEMENT—§ 470.13

One comment suggested that providing notice of the program in the *Commerce Business Daily* was inappropriate since those parties interested in the program would not necessarily be familiar with, or have access to, such a publication. The *Commerce Business Daily* is generally recognized as a widely circulated official organ for the announcement of competitive Government-wide programs, and the applicable DOE procurement regulation, ERDA-PR 9-4.5802-(d), requires that DOE program announcements be synopsized in it. Section 470.13(c) does not limit publication to this journal, but it also requires that the program announcement shall be announced to appropriate newspapers, trade and technical publications, and State and local governments, and shall be circulated directly to interested individuals, entities and associations thereof, to the maximum extent feasible. DOE considers these opportunities for notice of the program to be adequate.

7. EVALUATION AND SELECTION—§ 470.14

Some comments suggested that the guidelines should allow obvious or inadvertent mistakes in a proposal to be corrected rather than subjecting the proposal to summary rejection. DOE agrees and has revised paragraph (a) to make it clear that proposers may correct minor informalities or irregularities, which are merely a matter of form and not of substance, and apparent clerical mistakes prior to the en-

tering into of grants or cooperative agreements.

Some comments suggested that the guidelines require that some or all of the reviews of proposals be performed within certain specified time periods, e.g., 30 days. While DOE realizes the importance of evaluating proposals in as timely a manner as feasible, in view of the large number of proposals expected and the several review processes required, DOE has decided to retain flexibility in the guidelines for the evaluation and selection procedure, rather than to impose specific time requirements.

A large number of comments raised questions about the procedures proposed for the technical and State reviews. In particular, they questioned the number of panels, the composition of the panels, and the adequacy of the criteria to be considered by the panels in the evaluation of proposals.

Accordingly, paragraph (b) has been revised to make clear that there may be more than one technical evaluation panel, and paragraph (c) has been revised to have each State, or combination of States, nominate a panel which shall be selected by the regional program manager and to require that the nominations and selections take into account a balanced membership. Both paragraphs (b) and (c) have been revised to make clear that the technical evaluation and State review panels are to consider the general criteria set forth in § 470.10 which have been taken directly from section 112(c) of the act. In addition, the criterion "(3)" which is to be considered by the technical evaluation panel has been clarified.

DOE learned from its pilot program that some proposals were without technical merit and found that State review of these technically defective proposals was, therefore, unnecessary and time consuming. Due to this experience, DOE has revised paragraph (e) to require the selection panel to send to the State review panel only those proposals found to be of sufficient technical merit to warrant State review. In response to a comment, paragraph (e) has also been revised to make explicit that the selection panel shall be comprised of DOE personnel.

One comment raised a question as to who was intended to be the "DOE selection official" in § 470.14(f). The selection official for each region will be chosen by DOE in accordance with DOE's financial assistance rules and other requirements for exercising such responsibility and, therefore, will be a person well qualified to serve in that capacity.

Some comments suggested that additional specified categories be added to those participants which paragraph (f)(3) appeared to favor for program policy reasons. DOE believes that the selection process should take into account diversity of participants without emphasizing any category and, accordingly, has revised paragraph (f)(3) to make diversity of participants, without mention of particular participants, a program policy factor.

8. ALLOCATION OF FUNDS—§ 470.15

Some comments were concerned that fiscal year (FY) 1978 funds were not allocated equally among the Federal regions. As noted in the preamble to the proposed guidelines, DOE decided to implement the program on a phased-in regional basis to maximize the use of limited funds.

Several comments were concerned that funding might not be appropriately allocated in the event of combining regions under section 470.12(b) in implementing a regional program. Section 470.12(b) is permissive and does not require the combining of any particular regions. It does allow combining however, particularly where the appropriate technology needs of regions will be better served. In the event of combining regions, the same population formula for the allocation of funds applies, so that the level of funding will be unaffected by the merging of the regions for administration of the program.

Some comments objected to the allocation of funds to regions according to population and suggested that other factors, such as the potential for the use of renewable resources in the region, be included in the allocation formula. It was also suggested that a minimum amount of funding should be set aside for each State in a region.

After carefully considering these comments, DOE continues to believe that an allocation of available funds according to population is the most expeditious and equitable means for implementing the program to avoid the possibility of time consuming and subjective judgments on a number of regional variables. However, a new paragraph (c) has been added to provide for the allocation of FY 1980 and subsequent FY funds among the regions according to population, with each State within a region receiving a minimum level of financial support for its projects from these funds in order to ensure that the program reaches all areas of the United States.

Some comments requested that DOE consider using more up-to-date population data in allocating funds according to regional population. Proposed paragraph (c), relettered (d), has been revised to accommodate this suggestion and provides that the most current official population data available from the Bureau of Census will be used.

9. COST SHARING AND FUNDS FROM OTHER SOURCES—§ 470.16

Several comments questioned the scope of § 470.16 and its impact on the evaluation and selection process. This provision is intended to encourage proposers to offer to share in the cost of projects or to arrange for others to provide cost sharing for their projects, but is not meant to impose any specific requirement that a proposer make such an offer in order to be eligible for consideration. Moreover, while DOE considers it in the best public interest to encourage proposers to share in projects' costs where appropriate, an offer of funds sharing or funds from other sources is not a criterion to be considered in the evaluation and selection process.

10. GENERAL REQUIREMENTS—§ 470.17

Some comments suggested that language be included to provide flexibility in interpreting or deviating from general financial assistance and procurement requirements that the program not be unduly restricted in its operations. DOE fully appreciates that simplified procedures are important to the program, and the program will endeavor to employ the simplest procedures permitted by these requirements and, where necessary, to provide for deviation from any unduly onerous requirements.

Section 470.17(a) has been revised to make clear that the program will be governed by the applicable general financial assistance and procurement requirements, except when the program guidelines provide otherwise.

11. PROPOSAL INFORMATION—§ 470.18

Some comments suggested that debriefings be provided to unsuccessful proposers. In response to this suggestion, § 470.18 has been revised to make clear that the debriefing provision of DOE's procurement regulations, which allows for debriefing on written request, applies.

C. FINAL REGULATIONS

The regulations are adopted as proposed except for the modifications described above and minor clarifying and conforming modifications.

(Energy Research and Development Administration Appropriation Authorization of 1977, Pub. L. 94-438; Department of Energy Organization Act, Pub. L. 95-91.)

In consideration of the foregoing, Chapter II of Title 10, Code of Federal Regulations, is amended by establishing part 470 as set forth below, effective August 8, 1978.

Issued in Washington, D.C., August 3, 1978.

WILLIAM P. DAVIS,
Deputy Director of Administration.

Chapter II of Title 10, Code of Federal Regulations, is amended by establishing Part 470 as follows:

Sec.
470.1 Purpose and scope.
470.2 Definitions.
470.10 Establishment of program.
470.11 Eligibility requirements.
470.12 Management.
470.13 Program announcements.
470.14 Evaluation and selection.
470.15 Allocation of funds.
470.16 Cost sharing and funds from other sources.
470.17 General requirements.
470.18 Proposal information.
470.19 Inventions and patents.
470.20 Dissemination of information.

AUTHORITY: Energy Research and Development Administration Appropriation Authorization of 1977, Pub. L. 95-39; Energy Reorganization Act of 1974, Pub. L. 93-438; Department of Energy Organization Act, Pub. L. 95-91.

§ 470.1 Purpose and scope.

This part contains guidelines for the implementation of the appropriate technology small grants program required to be prescribed by section 112 of the Act.

§ 470.2 Definitions.

As used in this part—

"Act" means the Energy Research and Development Administration Appropriation Authorization of 1977, Pub. L. 95-39, 91 Stat. 180, 42 U.S.C. 5907a.

"Affiliate" means a small business concern which, either directly or indirectly, controls or has the power to control another concern, is controlled by or is within the power to control of another concern or, together with another business concern, is controlled by or is within the power to control of a third party, taking into consideration all appropriate factors, including common ownership, common management and contractual relationships.

"DOE" means the Department of Energy.

"ERDA-FAM" means the Energy Research and Development Administration Federal Assistance Manual (42 FR 27630, May 31, 1977), or its DOE successor.

"ERDA-PR" means the Energy Research and Development Administration Procurement Regulations (42 FR 48878, September 26, 1977), or its DOE successor.

"Indian tribe" means any tribe, and, nation, or other organized group or community of Indians (including any Alaska native village, or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act, Pub. L. 92-203, 85 Stat. 688, which (1) is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians; or (2) is located on, or in proximity to, a Federal or State reservation or rancheria, acting through its tribal organization.

"Local agency" means an agency or instrumentality of a local government.

"Local government" means a local unit of government including specifically a county, municipality, city, town, township, local public authority, special district, intrastate district, council of governments, sponsor group representative organization, and other regional or intrastate government entity.

"Local nonprofit organization or institution" means any corporation, trust, foundation, trade association, or other institution (1) which is entitled to exemption under section 501(c)(3) of the Internal Revenue Code or (2) which is not organized for profit and no part of the net earnings of which inure to the benefit of any private shareholder or individual.

"Program" means the appropriate technology small grants program.

"Small business" means a concern, including its affiliates, which is organized for profit, is independently owned and operated, is not dominant in the field of operation in which it is submitting a proposal to DOE, and has 100 employees or less.

"Standard Federal regions" means the 10 standard Federal regions established by Office of Management and Budget Circular A-105, entitled "Standard Federal Regions."

"State" means any of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, and any territory or possession of the United States.

"State agency" means an agency or instrumentality of a State government.

"State government" means the government of the several States, or interstate organization.

"Support" means financial support or award under the program by grants or cooperative agreements.

"Tribal organization" means the recognized governing body of an Indian tribe, or any legally established organization of Native Americans which is controlled, sanctioned, or chartered by such governing body.

§ 470.10 Establishment of program.

There is established, under direction of the Assistant Secretary for Conservation and Solar Applications of DOE, an appropriate technology small grants program for the purpose of encouraging development and demonstration of, and the dissemination of information with respect to, energy-related systems and supporting technologies appropriate to—

(a) The needs of local communities and the enhancement of community self-reliance through the use of available resources;

(b) The use of renewable resources and the conservation of nonrenewable resources;

(c) The use of existing technologies applied to novel situations and uses;

(d) Applications which are energy conserving, environmentally sound, small scale and low cost; and

(e) Applications which demonstrate simplicity of installation, operation and maintenance.

§ 470.11 Eligibility requirements.

(a) Support under this part may be made to individuals, local nonprofit organizations and institutions, State and local agencies, Indian tribes and small businesses.

(b) The aggregate amount of support made available to any participant in the program, including affiliates, shall not exceed $50,000 during any 2-year period. This limitation applies only to support for projects and not to funds received by participants from DOE for other purposes, such as performance of services.

(c) Projects which shall be considered for support are those which carry out the purposes of the program as expressed in § 470.10 and which are within the following categories—

(1) Concept development, i.e., the development of an idea or concept or an investigative finding in areas ranging from development of new concepts of energy sources to the utilization of old procedures or systems for a new application;

(2) Development, i.e., the systematic use and practical application of investigative findings and theories of a scientific or technical nature toward the production of, or improvements in, useful products to meet specific performance requirements but exclusive of manufacturing and production engineering. The dominant characteristic is that the effort be pointed toward specific energy problem areas to develop and evaluate the feasibility and practicability of proposed solutions and determine their parameters. Development includes studies, investigations, initial hardware development and ultimately development of hardware, systems, or other means for experimental or operational test; or

(3) Demonstration, i.e., the testing of a system or technique under operation conditions to show that commercial application is technically, economically and environmentally feasible.

(d) Support for each category in paragraph (c) shall not, for a single

participant in the program, including affiliates, exceed the following limits for any project—

(1) For concept development, $10,000;

(2) For development, $50,000; and

(3) For demonstration, $50,000.

(e) A participant may receive, under a subsequent program announcement, (i) additional support for a funded project or (ii) initial support for a new project, subject to the support limits set forth in paragraphs (b) and (d) of this section.

§ 470.12 Management.

(a) The program shall be managed by a National Program Director within the Office of the Assistant Secretary for Conservation and Solar Applications of DOE.

(b) The program shall be implemented regionally, based on the 10 standard Federal regions or combinations thereof, to insure substantial consideration of the needs, resources, and special circumstances of local communities. Regions may be combined provided the requirements of Office of Management and Budget Circular A-105 entitled "Standard Federal Regulations" are met. Regional Program Managers shall design and manage the regional programs as directed by the National Program Director and shall consult, as appropriate, with State and local officials, the appropriate technology community and other interested parties.

§ 470.13 Program announcements.

(a) The Regional Program Managers shall be responsible for the preparation of program announcements which solicit proposals for support under the program pursuant to simplified application procedures. Projects may be supported under the program only if they have successfully competed under a program announcement.

(b) Each program announcement shall include—

(1) A summary of the area(s) of program interest, expanded as appropriate, to include problems and objectives;

(2) An identification of the type(s) of support instruments that DOE may use;

(3) A time schedule for submission of, and action on, proposals;

(4) Information to be provided in the proposals, including, as appropriate, the information set forth in ERDA-PR 9-4.5802-4(a);

(5) Evaluation criteria, along with a narrative description of their relative importance;

(6) Program policy factors;

(7) Other applicable information, terms and conditions, including the desired budget format;

(8) Place for, and manner of, submission;

(9) A unique number for identification purposes;

(10) A statement notifying potential proposers that an announcement does not commit DOE to pay any proposal preparation costs and that DOE reserves the right to select for support any, all, or none of the proposals received in response to an announcement; and

(11) A late proposal provision.

(c) Each program announcement shall be synopsized in the *Commerce Business Daily* prior to or concurrent with release. The program announcement also shall be announced to appropriate newspapers, trade and technical publications, and State and local governments, and shall be circulated directly to interested individuals, entities, and associations thereof, to the maximum extent feasible.

§ 470.14 Evaluation and selection.

(a) Prior to making a comprehensive evaluation of a proposal, the receiving office shall determine that it contains sufficient technical, cost, and other information to enable comprehensive evaluation and that it has been properly signed. If the proposal does not meet these requirements, a prompt reply shall be sent to the proposer, indicating the reason(s) for the proposal not being selected for support under the program announcement. A proposer may correct any minor informality or irregularity or apparent clerical mistake prior to the entering into of grants or cooperative agreements. A minor informality or irregularity is one which is merely a matter of form and not of substance or pertains to some immaterial or inconsequential defect or variation from the exact requirements of the program announcement.

(b) The Regional Program Manager shall select one or more technical evaluation panel(s) representing several different disciplines to ensure adequate technical review of the proposals. Each technical evaluation panel shall provide its findings and comments to the selection panel established pursuant to paragraph (e) of this section. In addition to the general criteria underlying the establishment of the program as set forth in § 470.10, the major criteria to be considered by each technical evaluation panel include—

(1) Whether the proposal is technically feasible, including a determination as to whether the proposed energy savings or energy production can be technically achieved;

(2) Whether the results being proposed are capable of being measured;

(3) Whether the proposal has a potential environmental impact; and

(4) From a technical standpoint, whether the proposal can be carried out within the funds being requested.

(c) Each State or combination of States shall nominate, and the Regional Program Manager shall select, a State review panel for each State or combination, respectively. The nominations and selections shall take into consideration representation on the panels of persons from a variety of backgrounds, including persons who, in the aggregate, are able to evaluate proposals of potential merit in various fields and from various types of proposers. Each State review panel shall evaluate those proposals received by it from the selection panel pursuant to paragraph (e) of this section, and taking into account the findings and comments of the technical evaluation panel(s), provide its findings and comments to the selection panel. In addition to the general criteria underlying establishment of the program as set forth in § 470.10, the criteria to be considered by each State review panel include—

(1) The potential impact of the proposal on the energy needs and requirements of the community or region;

(2) The energy resource involved and its importance or availability to the community or region;

(3) The expected energy savings or production that will result from the proposal and the significance of those savings or production to the energy requirements of the community or region;

(4) The institutional barriers that may substantially affect the proposal and the potential of the proposal to deal with those barriers;

(5) The likelihood of commercialization or utilization of the technology, process, or items within the proposal and extent of such commercialization/utilization;

(6) The innovative nature of the proposal;

(7) Any potential environmental impacts of the proposal upon the community or region;

(8) The extent to which work beyond the funded project period might be required;

(9) The extent to which local resources, material, and manpower will be utilized; and

(10) The adequacy of the business aspects of the proposal, including as required and/or appropriate, the evaluations set forth in ERDA-FAM 503.

(d) In order to assure that the proposal is accorded objective and impartial review, the technical evaluation and State review panel members shall be selected so as to avoid any actual or apparent conflict of interest.

Panel members are forbidden to use privileged information contained in the proposals for personal gain or

other improper purposes and shall be required to sign a non-disclosure agreement prior to reviewing any proposals as provided in ERDA-PR 9-3.150-4 and to comply with any other applicable conflict of interest and nondisclosure of information requirements.

(e) A selection panel comprised of DOE personnel appointed by the regional program manager, shall, taking into account the findings and comments of the technical evaluation panel(s), forward to the appropriate State review panels for their evaluation those proposals judged to be of sufficient technical merit to warrant review. Following the State reviews, the selection panel shall, taking into account the findings and comments of the technical evaluation and State review panels, evaluate the proposals in accordance with the criteria stated in the program announcement and rank them in order of excellence.

(f) A DOE selection official shall select proposals for support from the ranking established by the selection panel, taking into account the following program policy factors in order to determine the mix of proposed projects which will best further specific program goals—

(1) Regional distribution, including geography, population, and climate;

(2) Project type distribution, including a diversity of methods, approaches, and technologies;

(3) Diversity of participants; and

(4) The best overall use of the funds available.

§ 470.15 Allocation of funds.

(a) DOE shall allocate fiscal year 1978 funds available for support among the standard Federal regions I, II, V, IX, and X, according to population.

(b) DOE shall allocate fiscal year 1979 funds available for support among the standard Federal regions III, IV, VI, VII, and VIII, according to population, with any available funds in excess of the amount of funds allocated under paragraph (a) being allocated among all regions according to population.

(c) DOE shall allocate fiscal year 1980 funds and funds for each subsequent fiscal year, available for support, among the 10 standard Federal regions, according to population. For each fiscal year funds allocated under this paragraph, the minimum level of support for projects for each State within a region shall be 25 percent of the funds allocated to the region, divided by the number of States in the region.

(d) For the purposes of this section, population shall be determined by the most current complete national series, as published by the United States Bureau of the Census in *Current Population Reports*, P-25, P-26, or related series, except where data from the decennial census conducted by the Bureau of the Census is more current.

§ 470.16 Cost sharing and funds from other sources.

Proposers are encouraged to offer to share in the costs of their proposed projects or to arrange that other entities provide cost sharing on their behalf. Regional program managers, with the consent of the proposer, may work with States, local governments or other entities to obtain supplemental funding. Such arrangements shall be handled on a case-by-case basis, taking into account, as appropriate, the applicable cost-sharing provisions of ERDA-FAM and ERDA-PR.

§ 470.17 General requirements.

(a) Except where this part provides otherwise, the submission, evaluation and selection for support of proposals under the program and the entering into and administration of grants and cooperative agreements under the program shall be governed by the provisions of ERDA-FAM and ERDA-PR, as applicable, such other procedures applicable to grants and cooperative agreements under the program as DOE may from time to time prescribe, and any Federal requirements applicable to grants and cooperative agreements under the program.

(b) Each grant, cooperative agreement or contract under this part shall require that a recipient of support under the program submit a full written report of activities supported in whole or in part by Federal funds made available under the program and shall contain any additional report provisions and other provisions dealing with records, allowable expenses, accounting practices, publication and publicity, copyrights, patents, discrimination, conflict of interest, insurance, safety, changes, resolution of disputes and other standard and/or relevant support agreement requirements required by, or appropriate to, the needs of the program.

§ 470.18 Proposal information.

Information contained in proposals shall be treated, handled and disclosed, and information shall be provided to unsuccessful proposers, in accordance with the policies and procedures set forth in ERDA-PR 9-3.150.

§ 470.19 Inventions and patents.

Each grant or cooperative agreement under the program shall be governed by the provisions of section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974, 42 U.S.C. 5908, and any agreements by DOE to waive title to inventions that may be made under the program shall be pursuant to the policies and procedures of the applicable provisions of ERDA-FAM and ERDA-PR.

§ 470.20 Dissemination of information.

DOE shall disseminate to the public, in an appropriate manner, information on the nature, usage and availability of the energy-related systems and supporting technologies developed or dem-onstrated under the program. In addition, DOE shall maintain and make available to recipients of support under the program current information on public and private sources of possible assistance for the further development and commercialization of their projects.

[FR Doc. 78-21948 Filed 8-7-78; 8:45 am]

[6210-01]

Title 12—Banks and Banking

CHAPTER II—FEDERAL RESERVE SYSTEM

SUBCHAPTER A—BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

[Reg Z; FC-0152]

PART 226—TRUTH IN LENDING

Official Staff Interpretations

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Official staff interpretation(s).

SUMMARY: The Board is publishing the following official staff interpretation of regulation Z, regarding methods by which creditors may disclose a hypothetical immediate increase in the annual percentage rate in variable rate mortgage transactions. The agency is taking this action in response to a request for interpretation of this regulation.

EFFECTIVE DATE: On or after September 7, 1978.

FOR FURTHER INFORMATION CONTACT:

Anne Geary, Chief Staff Attorney, Division of Consumer Affairs, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, 202-452-2761.

SUPPLEMENTARY INFORMATION: (1) Identifying details have been deleted to the extent required to prevent a clearly unwarranted invasion of personal privacy. The Board maintains and makes available for public inspection and copying a current index providing identifying information for the public subject to certain limitations stated in 12 CFR part 261.6.

(2) An opportunity for public comment on an official staff interpretation may be provided upon request of interested parties and in accordance with 12 CFR part 226.1(d)(2)(ii). As provided by 12 CFR part 226.1(d)(3) every request for public comment must be in writing, should clearly identify the number of the official staff interpretation in question, should be addressed to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 and must be post-marked or received by the secretary's office before the effective date of the interpretation. The request must also state the reasons why an opportunity for public comment would be appropriate.

(3) 15 U.S.C. 1640(f).

§ 226.8(b)(8), Variable rate hypothetical examples may be based on increases in contract interest rate rather than in APR (partially rescinds Letter 1232).

Variable rate hypothetical examples must assume that rate increase is immediate and in specified amount; examples showing changes in different amounts or at different times may also be given as additional information.

JULY 18, 1978.

This will reply to your letter of * * *, in which you request clarification of Public Information Letter 1232, concerning the provisions of § 226.8(b)(8) with regard to variable rate mortgages. You ask staff to elaborate on methods creditors could use to determine the increased number of payments or the increased payment amount which would result from a hypothetical immediate increase in the annual percentage rate, in order to make the disclosures called for by § 226.8(b)(8) (iii) and (iv). Specifically, you ask whether appendix B to volume I of the Annual Percentage Rate Tables published by the Board of Governors can be used to make such calculations.

Use of the Board's tables is not required in order to comply with the regulation, but the tables do provide fairly simple methods for determining much of the information required to be disclosed under the regulation. Appendix B to volume I of the tables describes a method of determining the amount of the finance charge and the amount of the level payment in cases where the annual percentage rate is known in a single advance transaction involving equal payments and equal payment periods. These formulas can be used to compute the information called for by § 226.8(b)(8)(iii).

For example, assume a loan with an amount financed of $40,000, to be repaid in 360 monthly instalments, with an annual percentage rate of 8 percent. From the annual percentage rate tables we can determine that the finance charge per $100 of amount financed is $164.16. The total finance charge for this loan is $65,664 ($164.16×$40,000=$65,664) and the level monthly payment would be $293.51 (($65,664+$40,000) divided by 360). If we assume a hypothetical immediate increase of one quarter of one percent in the rate, as called for in § 226.8(b)(8)(iii), we can determine from the tables that the finance charge per $100 of amount financed at an annual percentage rate of 8¼ percent is $170.46. The total finance charge under this assumption would be $68,184 ($170.46×$40,000=$68,184). The level monthly payment amount that would be required to amortize this hypothetically increased obligation would be $300.51 (($68,184+$40,000) divided by 360=$300.51), and this figure may be disclosed pursuant to § 226.8(b)(8)(iii). Alternatively, the increase in the payment amount may be expressed as the difference between $300.51 and $293.51, or $7.

Again, we would point out that use of the Board's tables and the calculation methods set out therein is not required in making Truth in Lending disclosures. You may, however, find the method outlined in this letter of some assistance in determining the information required to be disclosed pursuant to § 226.8(b)(8)(iii). You should note that this method cannot be used to determine the information required to be disclosed pursuant to § 226.8(b)(8)(iv); use of volume I of the Board's Annual Percentage Rate Tables requires that you know the number of payments involved, and that is the information that must be calculated.

This information can, however, be estimated in another way. Changes in the annual percentage rate in variable rate mortgages are generally caused by changes in the simple contract interest rate. Since the results from changing the simple contract interest rate on most long-term mortgages are almost equivalent to the result from changing the annual percentage rate, and since § 226.8(b)(8)(iv) calls for a statement of the estimated increase in the number of payments, it is staff's opinion that a creditor may use tables based on simple interest rates to calculate the increased number of payments that would result if the interest rate were increased by one quarter of one percentage point. This approach yields an estimated figure that may be disclosed pursuant to § 226.8(b)(8)(iv). This approach may also be used, as an alternative to that outlined above, to determine the information called for by § 226.8(b)(8)(iii). To the extent that Public Information Letter 1232 states that the disclosures required by § 226.8(b)(8) (iii) and (iv) may never be made by reference to the contract interest rate, it is hereby rescinded. If this calculation approach is taken, the disclosures should be expressed as the effects of a one quarter of one percent increase in the interest rate.

Staff would like to point out that the alternatives expressed in this letter do not prohibit a creditor from basing its calculation on an increase in the annual percentage rate itself, which, we understand, is a calculation that can be made relatively simply on inexpensive calculators that are generally available on the market. The procedures outlined in this letter are merely viewed by staff as reasonable alternatives.

You point out in your letter that lenders frequently do not have the authority under applicable statutes or the underlying contract to increase rates immediately. Rather, you believe that most lenders are required to wait a specified period of time before effecting a change. Moreover, you point out that changes in the rate may often be in increments less than the hypothetical one quarter of one per cent mentioned in § 226.8(b)(8) (iii) and (iv). You ask, therefore, whether creditors may provide additional examples of rate changes pursuant to § 226.6(c). We assume that what you wish to disclose are examples of the effect of rate changes occurring at a time later than consummation of the loan as well as rate changes greater than or less than one quarter of one per cent.

The disclosures called for by § 226.8(b)(8) (iii) and (iv) must be made on the assumptions (1) that the rate increase takes effect immediately upon consummation, and (2) that the increase is in a certain amount, i.e., one quarter of one per cent. Although creditors may not effect an increase in that particular amount or at that particular time, the regulation requires that disclosures be made on these assumptions in order to ensure uniformity among lenders and to facilitate comparisons. If a creditor wishes to provide further examples of the effect of a rate change in a different amount or at a different time in the loan term, this may be done as additional information pursuant to § 226.6(c), provided the additional examples are not stated so as to mislead or confuse the customer or contradict, obscure, or detract attention from the required information.

This is an official staff interpretation of regulation Z, issued in accordance with § 226.1(d)(2) of the regulation. It will become effective 30 days after publication in the FEDERAL REGISTER unless a request for public comment, made in accordance with the Board's procedures, is received and granted. We will notify you if the effective date of the interpretation is suspended because such a request is received.

Sincerely,

NATHANIEL E. BUTLER,
Associate Director.

Board of Governors of the Federal Reserve System, August 2, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 78-21944 Filed 8-7-78; 8:45 am]

[6320-01]

Title 14—Aeronautics and Space

CHAPTER II—CIVIL AERONAUTICS BOARD

SUBCHAPTER F—POLICY STATEMENTS

[Regulation PS-79; Amendment No. 58 to Part 399]

PART 399—STATEMENTS OF GENERAL POLICY

Adopted by the Civil Aeronautics Board at its office in Washington, D.C.

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: This amendment eliminates a policy statement relating to tariff filings, the substance of which is now required by law.

DATES: Effective: August 28, 1978. Adopted: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

John Freeman, Attorney-Advisor, Rates, 1825 Connecticut Avenue

NW., Washington, D.C. 20428, 202-673-5791.

SUPPLEMENTARY INFORMATION: Pub. L. 95-163 now requires the Board to act on domestic and overseas tariff filings at least 15 days before the effective date. It also amended section 403(c) of the Federal Aviation Act to require air carriers and foreign air carriers to file any proposed change in passenger fares 45 days before the effective date of the proposed change. Direct air carriers are now required to file any change in freight rates 60 days before the effective date of the proposed change, and indirect air carriers are requaired to file any change in freight rates 45 days before the effective date of the proposed change. The Board has previously amended § 221.160(a) to replace the prior 30-day notice period with the new statutory notice periods.

As a result of these changes, the Board policy of providing 15 days' notice of the Board's intent to suspend any tariff filed earlier than 30 days prior to the effective date is now mandatory under Pub. L. 95-163.

Accordingly, the Board amends part 399 of its policy statements (14 CFR Part 399) as follows:

1. The table of contents to part 399, as it appears under subchapter F of the Board's regulations, is amended to read as follows:

Sec.

* * * * *

Subpart C—Policies Relating to Rates and Tariffs

* * * * *

399.36 [Reserved]

* * * * *

§ 399.36 [Reserved]

2. Section 399.36 is hereby deleted and reserved to read as follows:

(Secs. 204 and 403 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 758, as amended; 49 U.S.C. 1324, 1373.)

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-21940 Filed 8-7-78; 8:45 am]

[3510-25]

Title 15—Commerce and Foreign Trade

CHAPTER III—INDUSTRY AND TRADE ADMINISTRATION, DEPARTMENT OF COMMERCE

REVIEW OF APPLICATIONS FOR COMMODITIES AND TECHNICAL DATA FOR EXPORT TO CERTAIN TYPES OF FOREIGN NUCLEAR FACILITIES

Final Rule

AGENCY: Office of Export Administration, Bureau of Trade Regulation, U.S. Department of Commerce.

ACTION: Final rule.

SUMMARY: Certain nuclear related commodities previously controlled for export by the Office of Export Administration (OEA) have been transferred to the Nuclear Regulatory Commission, effective July 8, 1978. Multipurpose commodities that might be used in a foreign nuclear facility and related technical data remain under the export licensing jurisdiction of the OEA. Under current regulations, many of these commodities and related technical data may be exported to most destinations under a general license for which no application is required and no validated license issued. Other commodities and technical data which require a validated license may be exported for use or resale abroad under the special licensing procedures of the Export Administration Regulations.

This rule requires an individual license application to be submitted to the OEA for the export of any multipurpose commodity or related technical data, including commodities or data that might otherwise be authorized for export under the special licensing procedures, if they are intended for foreign nuclear facilities engaged in the production of certain sensitive nuclear related materials. This prior review is necessary to assure that the exports will not contravene the nuclear nonproliferation policy of the United States.

EFFECTIVE DATE: August 22, 1978.

SAVING CLAUSE

Shipments of commodities or technical data removed from general license or excluded from the special licensing procedure as a result of changes set forth in this rule which were on dock for lading, on lighter, laden aboard an exporting carrier, or in transit to a port of export pursuant to actual orders for export prior to 12:01 a.m. August 22, 1978 may be exported under the previous general license provisions or special licensing procedure up to and including September 5, 1978. Any such shipment not laden aboard the exporting carrier on or before September 5, 1978, requires an individual validated license for export.

FOR FURTHER INFORMATION CONTACT:

Charles C. Swanson, Director, Operations Division, Office of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230, 202-377-4196.

SUPPLEMENTARY INFORMATION: Four types of nuclear facilities are of particular concern with respect to the nuclear nonproliferation policy of the United States. They are (a) facilities for the chemical processing of irradiated special nuclear or source material, (b) facilities for the production of heavy water, (c) facilities for the separation of isotopes of source and special nuclear material, and (d) facilities for the fabrication of nuclear reactor fuel containing plutonium. Notwithstanding the general license provisions of the Export Administration regulations, an individual validated license is now required for the export of any commodity or technical data if the exporter knows or has reason to know that the commodity or technical data will be used directly or indirectly in designing, constructing, fabricating, or operating the above facilities or components for such facilities or the training of personnel for such facilities. In addition, commodities and technical data may not be exported under the project license procedure if they are related to the chemical processing of irradiated special nuclear or source material, the production of heavy water, the separation of isotopes of source and special nuclear material, or the fabrication of nuclear reactor fuel containing plutonium. Also, commodities may not be supplied under the distribution or the service supply procedure if they are related to the above activities, and approved consignees under the distribution license procedure must be so notified in writing by the U.S. exporter.

Accordingly, the Export Administration regulations (15 CFR Part 368 et seq.) are revised as follows:

PART 371—GENERAL LICENSES

1. Section 371.2(c)(6) is revised as follows:

§ 371.2 General provisions.

* * * * *

(c) * * *

(6) The *commodity* is related to nuclear weapons, nuclear explosive devices, nuclear testing, the chemical processing of irradiated special nuclear or source material, the production of heavy water, the separation of isotopes of source and special nuclear

material, or the fabrication of nuclear reactor fuel containing plutonium, as described in §§ 378.2 and 378.3, or the technical data to be exported is related to any of these activities, as described in § 379.4(c)(1), unless the technical data may be exported under the provisions of general license GTDA;

* * * * *

PART 373—SPECIAL LICENSING PROCEDURES

2. Part 373 is revised as follows:

§ 373.2 Project license.

* * * * *

(b) Commodities, technical data, and activities not eligible for project license.

* * * * *

(3) The commodities are related to nuclear weapons, nuclear explosive devices, nuclear testing, the chemical processing of irradiated special nuclear or source material, the production of heavy water, the separation of isotopes of source and special nuclear material, or the fabrication of nuclear reactor fuel containing plutonium, as described in §§ 378.2 and 378.3;

(4) The technical data are not generally available to the public (see general license GTDA, § 379.3) and relate to nuclear weapons, nuclear explosive devices, nuclear testing, the chemical processing of irradiated special nuclear or source material, the production of heavy water, the separation of isotopes of source and special nuclear material, or the fabrication of nuclear reactor fuel containing plutonium, as described in § 379.4(c)(1);

* * * * *

§ 373.3 Distribution license.

* * * * *

(b) * * *

(1) Commodities related to nuclear weapons, nuclear explosive devices, nuclear testing, the chemical processing of irradiated special nuclear or source material, the production of heavy water, the separation of isotopes of source and special nuclear material, or the fabrication of nuclear reactor fuel containing plutonium, as described in §§ 378.2 and 378.3;

* * * * *

(f) * * *

(2) *Notice to consignee.* The letter of transmittal to the approved consignee shall (i) notify the consignee that he will be receiving from the exporter reprints of the U.S. Department of commerce "Table of Denial and Probation Orders Currently in Effect" and addenda there to listing individuals and firms to whom the consignee may not sell or otherwise dispose of the U.S. commodities received under the distribution License, and (ii) advise the consignee that, in addition to the other requirements set forth in this procedure, he may not sell or otherwise dispose of any such U.S.-origin commodities when he has reason to know the commodities will be used in designing, developing, or fabricating nuclear weapons or nuclear explosive devices; in devising, carrying out, or evaluating nuclear weapons tests or nuclear explosions; in the chemical processing of irradiated special nuclear or source material; in the production of heavy water; in the separation of isotopes of source and special nuclear material, or in the fabrication of nuclear reactor fuel containing plutonium. If a consignee is not approved, the form will be returned to the U.S. exporter with a rider stating the reason for this action.

* * * * *

§ 373.7 Service Supply (SL) Procedure.

* * * * *

(b) * * *

(1) Parts to service commodities related to nuclear weapons, nuclear explosive devices, nuclear testing, the chemical processing of irradiated special nuclear or source material, the production of heavy water, the separation of isotopes of source and special nuclear material, or the fabrication of nuclear reactor fuel containing plutonium, as described in §§ 378.2 and 378.3;

* * * * *

PART 378—SPECIAL NUCLEAR CONTROLS

3. Part 378 is revised as follows:

§ 378.1 Purpose.

This part defines the types of export transactions that may not be made under the general license provisions of part 371 of this chapter because of their relationship to certain foreign nuclear activities.

§ 378.2 Nuclear weapons or nuclear explosive devices.

A validated license is required for export to all destinations, including Canada, of any commodity that:[1,2]

(a) Has not been specifically designed or specifically modified for use in designing, developing, or fabricating nuclear weapons or nuclear explosive devices, but which the exporter knows or has reason to know will be used for one or more of these purposes.

(b) Has not been specifically designed or specifically modified for use in devising, carrying out, or evaluating nuclear weapons tests or nuclear explosions, but which the exporter knows or has reason to know will be used for one or more of these purposes.

(c) Is in normal commercial use for other purposes but which has been specifically designed or specifically modified for use in devising, carrying out, or evaluating nuclear weapons tests or nuclear explosions, if the intermediate or ultimate destination is subject to the jurisdiction of any country which, at the time of export, is not an adherent to the "Treaty Banning Nuclear Weapons Tests in the Atmosphere, Outer Space and Under Water," which was signed at Moscow, U.S.S.R., on August 5, 1963. This treaty is more commonly known as the "Limited Nuclear Test Ban Treaty," and the countries adhering thereto are listed in supplement No. 1 to part 378. The provisions of § 378.2 do not apply to exports of any commodities described in this § 378.2(c) if the exporter knows they will not be used in devising, carrying out, or evaluating nuclear weapons tests or nuclear explosions.

§ 378.3 Certain nuclear facilities.

A validated license is required for export to all destinations, including Canada, of any commodity where the exporter knows, or has reason to know, that the commodity will be used directly or indirectly in designing, constructing, fabricating, or operating the following facilities, or components for such facilities:

(a) Facilities for the chemical processing of irradiated special nuclear or source material;

(b) Facilities for the production of heavy water;

(c) Facilities for the separation of isotopes of source and special nuclear material; or

---

[1] Commodities and technical data specifically designed or specifically modified for use in designing, developing, or fabricating nuclear weapons or nuclear explosive devices are subject to export licensing or other requirements of the Office of Munitions Control. U.S Department of State, or the licensing or other restrictions specified in the Atomic Energy Act of 1954, as amended. Similarly, commodities and technical data specifically designed or specifically modified for use in devising, carrying out, or evaluating nuclear weapons tests or nuclear explosions (except such items as are in normal commercial use for other purposes) are subject to the same requirements.

[2] Also see § 379.5(e) for special provisions relating to technical data for maritime nuclear propulsion plants and other commodities.

(d) Facilities for the fabrication of nuclear reactor fuel containing plutonium.

* * * * *

§ 378.4 Advice of manufacturer.

An exporter who knows the commodities he intends to ship are capable of the uses described in § 378.2 or § 378.3, but is not the manufacturer of the commodities and is not sure whether a validated license is required, shall request a written statement from the manufacturer specifying as to whether or not such manufacturer knows or has reason to know that the intended export requires a validated export license under the provisions of § 378.2 or § 378.3. If the manufacturer believes a validated export license is required, the exporter shall then apply for such license. The exporter shall retain a copy of his letter of inquiry and the manufacturer's reply and make them available for inspection upon demand by the U.S. Department of Commerce, for two years in accordance with the recordkeeping requirements of § 387.11.

§ 378.5 Preparing application.

An application for a license to export commodities subject to the provisions of § 378.2 or § 378.3 shall be prepared and submitted on Form DIB-622P, Application for Export License, in accordance with the instructions set forth in § 372.5 with the following modifications:

(a) *Identification of license application.* Enter the words "NUCLEAR CONTROLS" across the top of the Form DIB-622P, immediately above the printed words Application for Export License;

(b) *Ultimate consignee.* If the ultimate consignee is not also the end user of the commodities, give the name and address of the end user in the "Commodity description" space of the application or on an attachment thereto, and if known, the specific geographic locations of any installations, establishments, or sites at which the commodities will be used;

(c) *Supplier.* If the applicant is not also the manufacturer of the commodities, indicate on the application, in the space entitled "Commodity Description" or on an attachment, whether the advice of the manufacturer has been received regarding the necessity of a validated license;

(d) *Commodity description.* If applicable, include a description of any specific features of design or specific modifications which make the commodity capable of the uses described in § 378.2 or § 378.3 above;

(e) *End-use.* Include in the description of the end-use, the specific end-use(s) the commodities will have in designing, developing, fabricating, or testing nuclear weapons or nuclear explosive devices as described in § 378.2 or in designing, constructing, fabricating, or operating the facilities described in § 378.3. Fully explain the basis for the knowledge or belief that the commodities are intended for the purpose(s) described.

§ 378.6 Effect of other provisions.

If, at the time of export, a validated license is also required under other provisions of the Export Administration regulations, the application shall be submitted in accordance with the provisions of part 378 as well as other applicable provisions. The requirements of part 378 are applicable in addition to, rather than in lieu of, any other validated license requirement set forth in the Export Administration regulations. Insofar as consistent with the provisions of part 378, all of the other provisions of the Export Administration regulations shall apply equally to applications for licenses and licenses issued under these special provisions.

* * * * *

PART 379—TECHNICAL DATA

4. Section 379.4(c) is revised to read as follows:

§ 379.4 General license GTDR: Technical data under restriction

* * * * *

(c) *Technical data restrictions applicable to all destinations.* No technical data [3] (including operating and maintenance instructional material) related to the following may be exported under this general license, and exports of technical data to all destinations, including Canada, require a validated export license: (1) Any commodity where the exporter knows or has reason to know that it is related to or specifically designed for, or intended to be used for developing or testing nuclear weapons or nuclear explosive devices (as described in § 378.2) or will be used directly or indirectly in designing, constructing, fabricating or operating the following facilities, or components for such facilities, or the training of personnel for such facilities (as described in § 378.3):

(i) Facilities for the chemical processing of irradiated special nuclear or source material;

(ii) Facilities for the production of heavy water;

(iii) Facilities for the separation of isotopes of source and special nuclear material, or

(iv) Facilities for the fabrication of nuclear reactor fuel containing plutonium;

* * * * *

(Sec. 4 Pub. L. 91-184, 82 Stat. 842. (50 U.S.C. App. 2403) as amended; E.O. 12002, 42 FR 35623 (1977); Department Organization Order 10-3, dated December 4, 1977, 42 FR 64721 (1977); and Industry and Trade Administration Organization and Function Order 45-1, dated December 4, 1977, 42 FR 64716 (1977).)

Dated: July 3, 1978.

STANLEY J. MARCUSS,
Deputy Assistant Secretary for Trade Regulation.

[FR Doc. 78-22078 Filed 8-7-78; 8:45 am]

[3] This restriction does not apply to data included in the foreign filing of a patent, provided such foreign filing of a patent application is in accordance with the regulations of the U.S. Patent Office.

[3510-12]

CHAPTER IX—NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, DEPARTMENT OF COMMERCE

PART 917—NATIONAL SEA GRANT PROGRAM FUNDING REGULATIONS

Identification of Additional National Needs and Problems

AGENCY: Office of Sea Grant, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

Action: Amendment to final regulations.

SUMMARY: This notice lists 14 additional national needs and problems with respect to ocean and coastal resources which have been identified by the Secretary of Commerce as directed by section 206(a) of the National Sea Grant Program Improvement Act of 1976 (90 Stat. 1961, 1965; 33 U.S.C. 1121, et. seq.). The first such need was published in 15 CFR 917.21 (43 FR 15309), Apr. 11, 1978. Section 206(a) of the act authorizes the Secretary of Commerce to make grants or enter into contracts for the purpose of researching such needs or problems, which grants or contracts may equal up to 100 percent of the individual project cost involved. Further details are provided in 15 CFR 917.21, referenced above.

DATE: Effective August 8, 1978.

FOR FURTHER INFORMATION CONTACT:

Dr. Ned A. Ostenso, Director, Office of Sea Grant, Page Building 1, 3300 Whitehaven Street NW., Washington, D.C. 20235, 202-634-4120.

Section 917.21 is amended in paragraph (c) by adding new subparagraphs (2) through (15).

§ 917.21 National needs and problems.

* * * * *

(c) * * *

(2) Formulate improved schemes for the management of all fisheries within the 200-mile fisheries zone under U.S. jurisdiction.

(3) Expand the mix of seafood products produced in the U.S. and develop appropriate mechanisms for marketing them domestically and in foreign markets.

(4) Improve the prediction of extreme natural events at coastal locations (such as flooding by tsunamis or wind setup and waves and surf resulting from severe storms) and the preparation of coastal communities to avoid property loss and take appropriate action to safeguard life.

(5) Ascertain the potential effects on Federal and State laws of agreement or nonagreement on a comprehensive Law of the Sea Treaty.

(6) Reexamine the ocean as an appropriate place for the disposal of wastes from land-based society.

(7) Reduce the recurring economic loss due to corrosion of structures, vessels, and other devices in the marine environment.

(8) Develop productive and profitable mariculture industries in the United States and technology that can be exported to other regions of the world with different climatic, cultural, and economic constraints.

(9) More fully explore the marine biochemical resources and carry out their pharmacological, chemical, and biological evaluation.

(10) Thoroughly explore, and exploit where possible, all options for practical extraction of energy from the oceans.

(11) Develop rapid, efficient and specific methods for assaying the potential of marine waters or marine animals to communicate disease to humans.

(12) Gain a fundamental understanding of the processes by which biological fouling is initiated upon material surfaces exposed to natural sea water.

(13) Completely and objectively examine the social and economic impacts of marine mammal protection and project these into the future.

(14) Improve understanding of the flow fields and mixing processes on the continental shelves of the United States and the determining mechanisms.

(15) Define the processes that determine ocean variability on the time scale of a few weeks to a few years, and the relationship to fluctuations in global and regional climate and primary productivity.

Dated: August 1, 1978.

T. P. GLEITER,
Assistant Administrator for Administration, National Oceanic and Atmospheric Administration, NOAA.

[FR Doc. 78-21997 Filed 8-7-78; 8:45 am]

[4910-22]

Title 23—Highways

CHAPTER I—FEDERAL HIGHWAY ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

SUBCHAPTER G—ENGINEERING AND TRAFFIC OPERATIONS

PART 626—PAVEMENT DESIGN POLICY

AGENCY: Federal Highway Administration, DOT.

ACTION: Final rule.

SUMMARY: The Federal Highway Administration (FHWA) issues regulations pertaining to the structural design of pavements and guidance for Federal-aid participation in pavement structures.

General pavement design policy has been combined with guidance for determining Federal-aid participation in stage construction projects since stage construction principles are most often used in building the pavement structure. The regulation applies to all Federal-aid projects which involve pavement construction. Procedures are simplified by eliminating lengthy and complex instructions.

EFFECTIVE DATE: August 7, 1978.

FOR FURTHER INFORMATION CONTACT:

Alan R. Steger, Office of Engineering, 202-426-0327; or Lee J. Burstyn, Office of the Chief Counsel, 202-426-0799. Federal Highway Administration, 400 Seventh Street SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m. e.t., Monday through Friday.

SUPPLEMENTARY INFORMATION: This regulation supersedes Policy and Procedure Memoranda (PPM's) 20-4 and 20-4(1); Instructional Memoranda (IM's) 21-1-62 and 21-1-67; and Circular Memoranda (CM's) dated May 9, 1967 and November 23, 1964 (all now located in the Federal-Aid Highway Program Manual (FHPM) volume 6, chapter 3, section 2, subsection 4 and volume 6, chapter 2, section 4, subsection 1.[1]

[1]The Federal-Aid Highway Program Manual (FHPM) is available for inspection and copying as prescribed in 49 CFR part 7, appendix D.

NOTE.—The Federal Highway Administration has determined that this document does not contain a major proposal according to the criteria established by the Department of Transportation pursuant to Executive Order 12044.

This regulation is issued under the authority of 23 U.S.C. sections 109 (a), (b), and (c),' and 315 and the delegation of authority in 49 CFR 1.48(b).

Issued on: July 25, 1978.

H. A. LINDBERG,
Associate Administrator for Engineering and Traffic Operations.

In consideration of the foregoing, Title 23, Code of Federal Regulations, Chapter I, is amended by adding a new part 626 to read as follows:

Sec.
626.1 Purpose.
626.3 Definitions.
626.5 Policy.
626.7 Project procedures.

AUTHORITY: 23 U.S.C. §§ 109 (a), (b), and (c) and 315; 49 CFR 1.48(b).

§ 626.1 Purpose.

The purpose of this regulation is to set forth pavement design policy for Federal-aid highway projects.

§ 626.3 Definitions.

(a) "Stage construction"—construction of portions of the ultimate structural design at separate times.

(b) "Ultimate structural design"—the structural design of the pavement needed to accommodate the types and volumes of traffic, and other conditions, forecast for the design life of the roadway.

§ 626.5 Policy.

(a) *Design procedure*—The "American Association of State Highway and Transportation Officials (AASHTO) Interim Guide for Design of Pavement Structures, 1972" [2] is approved for application on Federal-aid highway projects. Pavement design may be based upon other procedures and practices of individual agencies that by past performance have proved satisfactory for the pertinent conditions; however, the Federal Highway Administration will use this guide to evaluate the adequacy of design.

(b) *Design period*—The design period for pavements on Federal-aid projects should be appropriate for the particular conditions. For interstate projects, the design period shall be 20 years from the date of approval of the plans, specifications, and estimate.

[2]This Interim Guide is available for examination as prescribed in 49 CFR Part 7, Appendix D or for purchase from American Association of State Highway and Transportation Officials, Suite 225, 444 North Capitol Street NW., Washington, D.C. 20001.

(c) *Safety*—Each Federal-aid project involving construction of the pavement surface, including each stage of a stage construction project as described in paragraph (d) of this section, shall have a skid resistant surface.

(d) *Stage Construction*—The ultimate structural design for a pavement may be built by stage construction on any Federal-aid project. Except as provided in § 626.7 of this part, Federal-aid funds of the appropriate class may be used for the construction of each stage.

§ 626.7 Project procedures.

(a) Where stage construction is used on a Federal-aid project, the ultimate structural design shall be documented at the time of approval of the plans, specifications, and estimate (PS&E) for the initial project. If the performance of the first stage indicates a need for revision in the structural design of a subsequent stage, the costs of such a revision are eligible for Federal participation.

(b) Each stage shall be designed to minimize later adjustments to such things as drainage structures, curbs, and guardrails. Where adjustments are necessary, their costs are eligible for Federal participation. Necessary attendant costs for such items as maintaining traffic, pavement marking, and skid resistant surface courses are also eligible.

(c) Regular Federal-aid interstate (I) funds, authorized by section 108(b) of the Federal-Aid Highway Act of 1956, as amended, may be used for additional stages of construction only on mainline roadways and ramps, including shoulders, and only when the original project providing for the pavement construction was:

(1) Identified as a stage construction project and the ultimate structural design documented at the time of approval of the plans, specifications, and estimate, or

(2) Authorized prior to October 24, 1963, and it has since been determined that the pavement structure will not provide satisfactory performance through the original 20-year design period.

(d) Requests for Interstate funding of stage construction projects described in paragraph (c)(2) of this section, shall be limited to the difference between the thickness actually constructed and the thickness that would have been required at the time of approval of the original plans, specifications, and estimate in order to result in a terminal serviceability of 2.0 at the end of 20 years. The extent of participation should be based upon the "AASHTO Interim Guide for Design of Pavement Structures, 1972" with updated traffic and materials data.

(e) Regular Federal-aid interstate (I) funds are eligible for necessary attendant costs in conjunction with stage construction projects but (I) funds shall not be used for rehabilitation or restoration of the existing pavement.

[FR Doc. 78-21949 Filed 8-7-78; 8:45 am]

[4910-22]

PART 650—BRIDGES, STRUCTURES, AND HYDRAULICS

Special Bridge Replacement Program; Revision

AGENCY: Federal Highway Administration, DOT.

ACTION: Final rule.

SUMMARY: This document revises the special bridge replacement program in order to provide a broader and simplified implementation of the program by the Federal aid recipients.

EFFECTIVE DATE: August 9, 1978.

FOR FURTHER INFORMATION CONTACT:

Lester A. Herr, Chief, Bridge Division, Office of Engineering, 202-426-0426; or Lee J. Burstyn, attorney, Office of the Chief Counsel, 202-426-0799; Federal Highway Administration, 400 Seventh Street SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m. e.t., Monday through Friday.

SUPPLEMENTARY INFORMATION: On August 14, 1974, at 39 FR 29174 regulations were established to specify the manner in which, and the conditions upon which, States may apply for, and secure, Federal aid funds for the replacement of deficient bridges on the Federal aid highway systems. The revised regulations published herein modify the existing program by providing more simplified procedures and a broader scope of Federal aid. Eligible projects now include costs of right-of-way, utility relocation or adjustments.

This revision codifies the policies and procedures contained in the Federal-Aid Highway Program Manual, volume 6, chapter 7, section 4, subsection 1.[1]

NOTE.—The Federal Highway Administration has determined that this document does not contain a major proposal according to the criteria established by the Department of Transportation pursuant to E.O. 12044.

Issued on July 25, 1978.

H. A. LINDBERG,
Associate Administrator for Engineering and Traffic Operations.

In consideration of the foregoing, subpart D of part 650, chapter I of title 23 of the Code of Federal Regulations is revised to read as follows:

[1] This document is available for inspection and copying in accordance with the provisions of 49 CFR Part 7, App. D.

Subpart D—Special Bridge Replacement Program

Sec.
650.401 Purpose.
650.403 Definition of terms.
650.405 Eligible projects.
650.407 Application for bridge replacement.
650.409 Evaluation and disposition of applications.
650.411 Procedures for bridge replacement projects.
650.413 Funding.

AUTHORITY: 23 U.S.C. § 144 and 315; 49 CFR 1.48(b).

Subpart D—Special Bridge Replacement Program

§ 650.401 Purpose.

To prescribe policies and outline procedures for administering the special bridge replacement program in accordance with 23 U.S.C. 114.

§ 650.403 Definition of terms.

As used in this regulation:

(a) "Bridge"—a structure, including supports, erected over a depression or an obstruction, such as water, a highway, or a railway, having a track or passageway for carrying traffic or other moving loads, and having an opening measured along the center of the roadway of more than 20 feet between undercopings of abutments or spring lines of arches, or extreme ends of the openings for multiple boxes; it may include multiple pipes where the clear distance between openings is less than half of the smaller contiguous opening.

(b) "Sufficiency rating"—the numerical rating of a bridge based on its structural adequacy and safety, essentiality for public use, and its serviceability and functional obsolescence.

(c) "Topographical barrier"—geographical features such as ravines, gorges, sloughs, valleys, and railroad tracks.

(d) "Waterway"—oceans, gulfs, bays, rivers, streams, creeks, canals, lakes, ponds, swamps, and flood plains.

§ 650.407 Eligible projects.

(a) *General.* Bridges which span waterway and other topographical barriers and are on any of the Federal aid highway systems are eligible for replacement under the special bridge replacement program. The replacement structure must meet the current geometric and construction standards required for the type and volume of traffic which the facility will carry over its design life.

(b) *Types of projects which are eligible.* The following types of work are

eligible for participation in the special bridge replacement program:

(1) Total replacement of a structurally inadequate or functionally obsolete bridge at or very close to its existing location.

(2) Complete relocation of a structurally inadequate or functionally obsolete bridge with a new facility constructed in the same general traffic corridor. A nominal amount of approaches, sufficient to connect the new facility to the existing roadway or to return the gradeline to an attainable touchdown point in accordance with good design practice, is also eligible.

(3) Partial replacement: When the substructure of a bridge is structurally adequate to safely support a new superstructure conforming to current geometric and structural standards, the necessary substructure modifications and the superstructure construction are eligible.

(c) *Ineligible work.* Except as other wise prescribed by the Federal Highway Administrator, the costs of long approach fills, causeways, connecting roadways, interchanges, ramps, and other extensive earth structures, when constructed beyond the attainable touchdown point, are not eligible under the special bridge replacement program.

§ 650.409 Application for bridge replacement.

(a) A State participates in the special bridge replacement program by conducting bridge inspections and submitting the appropriate number of computer cards containing the information called for on the structure inventory and appraisal (SI&A) sheet for bridges on the Federal aid highway systems. These requirements are prescribed in the National Bridge Inspection Standards, 23 CFR 650.307, 650.311. Inventory data and computer cards are submitted to the Division Administrator of the Federal Highway Administration (FHWA) for processing.

(b) Original and revised data relating to bridges which a State has designated as candidates for replacement may be submitted as available and shall be submited at such additional times as the FHWA may request.

(c) Bridges that have been strengthened or repaired to eliminate deficiencies or that have been replaced using other funds shall be withdrawn as candidates by notifying the Office of Engineering through the Division Administrator of the changes along with the reason for the change in status.

§ 650.411 Evaluation and disposition of applications.

(a) *Sufficiency rating of candidate bridges.* Upon receipt and evaluation of applications, a sufficiency rating will be assigned to each bridge in accordance with the approved AASHTO sufficiency rating formula. The sufficiency rating will be used as a basis for establishing priority for replacement of bridges; the lower the rating, the higher the priority.

(b) *Selection of bridges for inclusion in State program.* After evaluation of applications and assignment of sufficiency ratings, FHWA will provide the State with a selection list of bridges within the State that have the highest priority for replacement. From that list or from previously furnished selection lists, the State may select bridge replacement projects.

§ 650.413 Procedures for bridge replacement projects.

(a) *Submission and approval of projects.* Bridge replacement projects shall be submitted by the State and reviewed by the FHWA in accordance with 23 CFR part 630, subpart A, Federal-Aid Programs, Approval and Authorization.

(b) *Completion of projects.* (1) Each approved project will be designed, constructed, inspected for acceptance, and maintained in the same manner as other Federal aid projects on the system on which the project is located.

(2) Whenever a deficient bridge is replaced by a new bridge under the special bridge replacement program, the deficient bridge shall be closed to vehicular traffic at the earliest date possible following the opening of the replacement bridge.

§ 650.415 Funding.

(a) Funds authorized for carrying out the special bridge replacement program are available for obligation at the beginning of the fiscal year for which authorized and remain available until expended. Funds are allocated to the States on the basis of comparative bridge replacement needs. Funds allocated to a State and not obligated within a reasonable period by that State may, after appropriate notification, be withdrawn for redistribution to other States.

(b) The Federal share payable on account of any project carried out under 23 U.S.C. 144 shall not exceed 75 percent of the eligible cost thereof.

[FR Doc. 78-21933 Filed 8-7-78; 8:45 am]

[4510-26]

Title 29—Labor

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Occupational Exposure to Cotton Dust; Corrections

AGENCY: The Occupational Safety and Health Administration, Department of Labor.

ACTION: Final rule; corrections.

SUMMARY: This notice announces further corrections to the cotton dust standard which appeared in the FEDERAL REGISTER on June 23, 1978 (43 FR 27350).

EFFECTIVE DATE: September 4, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Gail Brinkerhoff, Office of Compliance Programs, OSHA, Third Street and Constitution Avenue NW., Room N-3112, Washington, D.C. 20210, telephone 202-523-8034.

SUPPLEMENTARY INFORMATION: On June 23, 1978, an occupational safety and health standard for exposure to cotton dust, with an accompanying explanation, was published in the FEDERAL REGISTER (43 FR 27350, FR Doc. 78-17232) as 29 CFR 1910.1043. There were a number of minor typographical errors and inadvertent omissions in the June 23, 1978, document. On June 30, 1978, a document was published in the FEDERAL REGISTER (43 FR 28473), correcting some of the errors and omissions which were in the cotton dust standard and appendices portion of the June 23, 1978, document. This document corrects errors and omissions which were in the preamble to the cotton dust standard, and a few errors remaining in the standard and appendices of the June 23, 1978, document.

Accordingly, FR Doc. 78-17232 appearing at 43 FR 27350, is corrected as follows:

1. Page 27350, column 2, line 4, "(law)" is corrected to read "(raw)".

2. Page 27350, column 2, line 7, "(d)" is corrected to read "(c)".

3. Page 27350, column 2, line 35, insert "(c) and (e)" after "§ 1910.1043".

4. Page 27351, column 3, line 7, "56212" is corrected to read "S-6212".

5. Page 27352, column 3, line 25, "MIOSH" is corrected to read "NIOSH".

6. Page 27352, column 3, third paragraph, line 7, "Ex. 46" is deleted after "Ex. 41".

7. Page 27353, column 1, second paragraph, line 18, "22" is deleted after "21".

8. Page 27353, column 1, third paragraph, line 10, "Ex. 47, No. 18" is deleted.

9. Page 27353, column 1, third paragraph, line 10, "Ex. 46, p. 1" is corrected to read "Ex. 46, p. 10".

10. Page 27353, column 2, line 3, "Ex. 47, Ref. No. 18" is deleted after "Ex. 41, p. 6".

11. Page 27353, column 2, line 3, "Ex. 46, p. 1" is corrected to read "Ex. 46, p. 10".

12. Page 27354, column 1, second paragraph, line 6, "48" is deleted after "47".

13. Page 27354, column 3, line 15, "Ex. 11" is corrected to read "Ex. 51".

14. Page 27354, column 3, fourth paragraph, lines 3 and 4 "(e.g. Ex. 65a)" is deleted after the word "isolated".

15. Page 27357, column 3, second paragraph, line 11, insert "(Ex. 38d)" after "Dr. Merchant".

16. Page 27357, column 3, third paragraph, line 8, "Tenet" is corrected to read "tenet".

17. Page 27360, column 1, line 2, "Ex. 16, No. 76" is corrected to read "Ex. 6, No. 76".

18. Page 27360, column 1, first paragraph, lines 31 and 32, "(Ex. 6, No. 2)" is corrected to read "(Ex. 6 No. 66)".

19. Page 27360, column 1, first paragraph, line 32, insert "(Ex. 6, No. 14)", after the words "Schrag and Gullett."

20. Page 27360, column 2, first paragraph, line 18, "Ex." is deleted before "TR 460".

21. Page 27360, column 2, second paragraph, line 5, "Ex. 4168" is corrected to read "TR 4168".

22. Page 27360, column 2, second paragraph, line 17, "have" is corrected to read "has".

23. Page 27360, column 3, first paragraph, line 1, "merchant" is corrected to read "Merchant".

24. Page 27360, column 3, first paragraph, lines 4 and 5, "(Ex. a6, No. 55 p. 229)", is corrected to read "(Ex. 6, No. 55)."

25. Page 27361, column 1, line 6, "Burman" is corrected to read "Barman".

26. Page 27361, column 2, line 30, "Ex. 93," is corrected to read "Ex. 93b".

27. Page 27361, column 2, third paragraph, lines 9 and 10, "Ex. 99-C" is deleted after "(e.g. Ex. 128 A,)".

28. Page 27362, column 2, first paragraph, lines 14 and 15, insert "(Ex. 93f)" after "Parnell".

29. Page 27362, column 3, first paragraph, lines 12 and 13, "(Tr. 442)" is deleted after the word "equipment".

30. Page 27363, column 1, third paragraph, line 10, "(ACTWU, p. 35)" is corrected to read "(Ex. 78, p. 35)".

31. Page 27363, column 1, third paragraph, line 17, "(ACTWU, p. 28)" is corrected to read "(Ex. 78, p. 28)".

32. Page 27363, column 2, third paragraph, line 16, "Ex. 37, 7" is corrected to read "Ex. 38, 7".

33. Page 27363, column 2, fourth paragraph, line 19, "Ex. 17" is corrected to read "Ex. 16".

34. Page 27363, column 3, first paragraph, lines 27, 28 and 29 "(National Cotton Council Special Session on Cotton Dust, p. 31)" is corrected to read "(Ex. 72b, p. 31)".

35. Page 27364, column 1, third paragraph, line 5, the word "which" is deleted after the words "fabric bags".

36. Page 27364, column 3, first paragraph, line 17, "(Ex. 16, A-9)" is corrected to read "(IIS, A-9)".

37. Page 27364, column 3, first paragraph, line 17, "(Ex. 16, A-9)" is corrected to read "(IIS, A-9)".

38. Page 27365, column 1, first paragraph, lines 13 and 14, "(Ex. 1, Merchant)" is corrected to read, "(Ex. 1)".

39. Page 27365, column 2, second paragraph, line 8, "(Ex. 16, A-6)" is corrected to read "(IIS, A-6)".

40. Page 27365, column 2, second paragraph, line 14, "(Ex. 16, A-6)" is corrected to read "(Ex. 78, p. 21)".

41. Page 27365, column 2, second paragraph, line 31, "(ACTWU p. 21)." is corrected to read "(Ex. 78, p. 21)".

42. Page 27365, column 3, line 18, "Ex. 37" is corrected to read "Ex. 38, 7".

43. Page 27365, column 3, first paragraph, line 6, "(Ex. 16, A-9)" is corrected to read "(IIS, A-9)".

44. Page 27365, column 3, first paragraph, line 11, "(Ex. 16, A-9)" is corrected to read " "(IIS, A-9)"

45. Page 27365, column 3, third paragraph, line 8, "(ACTWU, Appendix G)" is corrected to read "(Ex. 78, Appendix 7)".

46. Page 27365, column 3, fifth paragraph, line 4, "(Appendix K, ACTWU)" is corrected to read "(Ex. 78, Appendix 11)".

47. Page 27365, column 3, fifth paragraph, lines 8 and 9, "(ACTWU, Appendix G)" is corrected to read, "(Ex. 78, Appendix 7)".

48. Page 27365, column 3, fifth paragraph, line 11, "(ACTWU, p. 21)," is corrected to read "(Ex. 78, p. 21)".

49. Page 27366, column 1, line 6, "(p. 32 ACTWU)" is corrected to read "(Ex. 78, p. 32)".

50. Page 27366, column 1, line 11, "(Ex. 37, 7)" is corrected to read "(Ex. 38, 7)".

51. Page 27366, column 1, fourth paragraph, line 5, "Ex. 37" is corrected to read "Ex. 38, 7".

52. Page 27366, column 1, second paragraph, lines 6 and 7, the word "totally" is deleted, ending the sentence after the words "dust control system."

53. Page 27366, column 1, sixth paragraph, line 13, "(Ex. 37, 7)" is corrected to read "(Ex. 38, 7)".

54. Page 27366, column 2, first paragraph, line 16, "(Ex. 16)" is corrected to read "(IIS, A-31)".

55. Page 27366, column 2, third paragraph, line 13, "(Ex. 16)" is corrected to read "(IIS, A-35)".

56. Page 27366, column 2, sixth paragraph, line 1, "(p. 21)" is corrected to read "(Ex. 78, p. 21)".

57. Page 27366, column 3, first paragraph, line 6, "(Ex. 16)" is corrected to read "(IIS, A-35)".

58. Page 27366, column 3, second paragraph, line 12, "(RTI, Ex. 16)" is corrected to read "(IIS, A-36)".

59. Page 27366, column 3, fourth paragraph, line 7, "(Ex. 37, 7)" is corrected to read "(Ex. 38, 7)".

60. Page 27367, column 1, first paragraph, line 1, "(p. 19)" is corrected to read "(Ex. 78, p. 19)".

61. Page 27367, column 2, second paragraph, line 3, the word "either" is deleted after the words, "which yarn is".

62. Page 27367, column 2, second paragraph, line 9, "Ex. 16, A-40" is corrected to read "IIS, A-40".

63. Page 27367, column 3, first paragraph, line 18, "Ex. 37, 7" is corrected to read, "Ex. 38, 7".

64. Page 27367, column 3, second paragraph, line 17, "Ex. 37, 7" is corrected to read "Ex. 38, 7".

65. Page 27367, column 3, fourth paragraph, lines 10 and 11, "(Ex. 37-7)" is corrected to read "(Ex. 38, 7)".

66. Page 27368, column 2, fourth paragraph, lines 5 and 6, "(Booker, p. 2, Cotton Waste Recyclers)" is corrected to read "(Ex. 97b)".

67. Page 27368, column 3, third paragraph, line 11, "(Ex. 16, IV-17)" is corrected to read "(IIS, IV-17)".

68. Page 27368, column 3, third paragraph, lines 13 and 14, "(Ex. 16, IV-17)" is corrected to read "(IIS, IV-17)".

69. Page 27368, column 3, fourth paragraph, line 14, "(Ex. 16, IV-18)" is corrected to read "(IIS, IV-18)".

70. Page 27369, column 1, lines 16 through 19, "The National Association of Bedding Manufacturers (NABM) conferred with vendors (p. 50)" is corrected to read, "The National Cotton Batting Institute (NCBI) conferred with vendors".

71. Page 27369, column 1, first paragraph, lines 12 and 13, "(National Cotton Council of America, EIS)", is corrected to read, "(Ex. 95f)".

72. Page 27369, column 2, third paragraph, lines 2 and 3, insert "(Ex. 93j)", after the words, "the National Cottonseed Producers Assoc".

73. Page 27369, column 3, first paragraph, line 9, "(pp. 30-39)" is corrected to read "(Ex. 93f, pp. 30-39)".

74. Page 27370, column 3, second paragraph, lines 1, 2 and 3, the first part of the sentence "In addition, testimony (e.g., in statements by Harold Imbus and Hovan Hocutt) made clear" is corrected to read "In addition, statements by Harold Imbus and Hovan Hocutt, (Ex. 47, 60) made clear".

75. Page 27371, column 1, line 4, "(PH 3, App. K)" is corrected to read "(Ex. 143, Appendix K)".

76. Page 27372, column 2, line 6, "Moreover," is corrected to read "However".

77. Page 27372, column 2, line 12, "However," is corrected to read "Moreover".

78. Page 27374, column 1, first paragraph, line 11, "and" is corrected to read "an", after the words "the costs of".

79. Page 27374, column 1, second paragraph, line 2, the word "in" is deleted.

80. Page 27374, column 2, line 20, the words "data available assumptions made by" are corrected to read "data available and assumptions made by".

81. Page 27374, column 3, first paragraph, line 15, "(Ex. 93i)" is corrected to read "(Ex. 93j)".

82. Page 27374, column 3, first paragraph, line 19, insert "(Ex. 93i)" after the word "Industry".

83. Page 27374, column 3, third paragraph, line 12, "(Ex. 93, pp. 305)" is corrected to read "(Ex. 93j, p. 5)".

84. Page 27374, column 3, third paragraph, line 20, "(Ex. 93i, p. 62)" is corrected to read "(Ex. 93j, p. 62)".

85. Page 27375, column 1, third paragraph, lines 14 and 15 "(IISs pp. AA-46, IV-21, V-38, V-39, and V-41)" is corrected to read "(IIS pp. IV-21, V-38, V-39 and V-41)".

86. Page 27375, column 1, fifth paragraph, line 1, "Donald Wiseman" is corrected to read "Donald Wissman".

87. Page 27375, column 1, fifth paragraph, line 19, "Mr. Wiseman" is corrected to read "Mr. Wissman".

88. Page 27375, column 3, lines 2 and 3, "(Ex. 93i, p. 62)" is corrected to read "(Ex. 93j, p. 8, 62)".

89. Page 27375, column 3, lines 9 and 10, "(Ex. 93i p. V11-9)" is corrected to read "(Ex. 93i, p. V11-2)".

90. Page 27375, column 3, line 34, "(Ex. 93J, pp1. 12, 13, 14" is corrected to read "(Ex. 93j, pp. 12, 13, 14)".

91. Page 27375, column 3, second paragraph, line 1, "," is deleted after the word "losses".

92. Page 27375, column 3, second paragraph, line 2, "," is deleted after "8.7 million".

93. Page 27376, column 2, second paragraph, lines 18 and 19, insert "." after "(American Yarn Spinners Association)".

94. Page 27376, column 2, fifth paragraph, line 7, insert the words "in warehouses", after the words "existing exposure levels".

95. Page 27377, column 1, third paragraph, lines 13 and 14, the words "were based on industry estimates" are corrected to read "were not based on industry estimates".

96. Page 27378, column 1, line 11, "(TR 2566-2517)" is corrected to read "(TR 2566-2567)".

97. Page 27378, column 2, first paragraph, line 2, "of the final" is deleted after the word "final".

98. Page 27379, column 1, first paragraph, line 9, the words "or cough, chronic obstructive" are corrected to read "cough, or chronic obstructive".

99. Page 27379, column 1, second paragraph, lines 19 and 20, "I" is deleted after the words "byssinosis prevalence".

100. Page 27379, column 3, first paragraph, line 5, "estimeted" is corrected to read "estimated".

101. Page 27379, column 3, first paragraph, line 6, insert the words "of the" after the words "as a result".

102. Page 27380, column 3, first paragraph, line 15, "1.0 ug/m3" is corrected to read "1.0 mg/m3".

103. Page 27381, column 1, second paragraph, lines 7 and 8, "introduced" is corrected to read "introduction".

104. Page 27381, column 2, second paragraph, line 4, insert "(Ex. 103; Ex. 104)" after the words "brief periods".

105. Page 27381, column 2, second paragraph, line 7, insert "(Ex. 103, Section II)" after the words "hours per year".

106. Page 27381, column 2, third paragraph, lines 4 and 5, insert "(Ex. 103, Section I)" after the words "cotton bale handler".

107. Page 27381, column 2, third paragraph, line 4, insert "(Ex. 103)" after the word "exposure".

108. Page 27381, column 2, fourth paragraph, line 4, insert "(Ex. 103, Section III)" after the words "structure of the industry".

109. Page 27381, column 3, first paragraph, line 6, insert "(41 FR 56503)" after the words "which process cotton."

110. Page 27381, column 3, second paragraph, line 4, insert "(Ex. 56)." after the word "facility."

111. Page 27381, column 3, second paragraph, line 16, insert "(TR 2228)" after the word "compress."

112. Page 27381, column 3, second paragraph, lines 18 and 19, insert "(Ex. 95b, p. 12)" after the words "warehouse operations."

113. Page 27381, column 3, third paragraph, line 1, insert "(Ex. 99f)" after the words "English willowers."

114. Page 27381, column 3, fourth paragraph, line 1, insert "(Ex. 38f, appendix 5)" after the words "A NIOSH survey."

115. Page 27381, column 3, fourth paragraph, line 4, "3.6-10.9 μg/m3" is corrected to read "3.6-10.9 mg/m3."

116. Page 27381, column 3, fourth paragraph, line 6, "0.24-0.43 μg/m3" is corrected to read "0.24-0.43 mg/m3."

117. Page 27381, column 3, fourth paragraph, line 16, insert "(TR 1053)" after the word "symptoms".

118. Page 27381, column 3, fifth paragraph, line 4, insert "(Ex. 6, No. 71)" after the words "among 26 garnetters".

119. Page 27382, column 1, line 5, "1.0 μg/m3" is corrected to read "1.0 mg/m3".

120. Page 27382, column 1, line 5, insert "(Ex. 145)" after the words "respirable dust".

121. Page 27382, column 1, first paragraph, line 4, insert "(Ex. 128M)" after the words "half of the workers".

122. Page 27382, column 1, first paragraph, lines 8 and 9, insert "(Ex. 128K)" after the words "byssinotic symptoms".

123. Page 27382, column 1, third paragraph, line 14, the sentence beginning "The resulting dust levels" is corrected to read "However, in his study the resulting dust levels".

124. Page 27382, column 1, third paragraph, lines 21 and 22, insert "(Ex. 38i, Appendix 8; Ex. 49; Ex. 94; Ex. 96)" after the words "processed cotton."

125. Page 27382, column 1, fourth paragraph, line 4, insert "(Ex. 6, No. 110; *Brit. J. Ind. Med.*, 30:237-47, 1973)" after "Merchant".

126. Page 27382, column 2, lines 3 and 4 "post-preparation areas, due possibly to adherence" is corrected to read "post-preparation areas. This effect was due possibly to adherence".

127. Page 27382, column 2, line 17, insert the word "thoroughly" after the words "only cotton".

128. Page 27383, column 1, second paragraph, line 4, "cotton dust raw" is corrected to read "cotton dust (raw)".

129. Page 27383, column 2, first paragraph, line 6, "(TR. 996)" is deleted after "ACTWU".

130. Page 27383, column 2, first paragraph, line 7, insert "(Ex. 108)" after the words "North Carolina Department of Labor".

131. Page 27383, column 2, third paragraph, lines 15 and 16, "plus or minun 25 percent or 95 percent" is corrected to read "plus or minus 25 percednt for 95 percent".

132. Page 27383, column 3, second paragraph, line 5, insert "(Ex. 108)" after the words "Department of Labor".

133. Page 27383, column 3, second paragraph, lines 13 and 14, the sentence beginning "Dr. Neefus supported this position" is corrected to read "Dr.

John Neefus of Burlington Industries supported this position".

134. Page 27383, column 3, second paragraph, line 17, insert "(Ex. 49)" after the word "determined".

135. Page 27383, column 3, third paragraph, line 3, "(PH No. 36)" is corrected to read "(Ex. 162)".

136. Page 27383, column 3, third paragraph, lines 10 and 11, insert "(Ex. 14)" after the words "performing the measurements."

137. Page 27383, column 3, fourth paragraph, lines 7 and 8, "(2000-20003)" is corrected to read "(TR 2000-2003)."

138. Page 27384, column 1, lines 1 and 2, "(TR 4154)" is corrected to read "(Ex. 198; TR. 4154)".

139. Page 27385, column 2, subparagraph 2 of the first paragraph, line 5, "with one year" is corrected to read "within one year".

140. Page 27385, column 2, fourth paragraph, line 10, "(Ex. Ref 109)" is corrected to read "(Ex. 6, No. 109)".

141. Page 27385, column 2, fifth paragraph, lines 10 and 11, the word "textile" is deleted after the words, "large number of".

142. Page 27387, column 3, line 14, "that employer sassure" is corrected to read "that an employer assure".

143. Page 27387, column 3, first paragraph, line 12, "medical protection" is corrected to read "medical removal protection".

144. Page 27388, column 1, first paragraph, line 30, "Ex. 16, p. IV-30," is corrected to read "(IIS, p. IV-30)".

145. Page 27388, column 1, first paragraph, lines 31 and 32, "Tr. 2369" is deleted after "Ex. 17, pp. 5-7".

146. Page 27388, column 1, first paragraph, line 36, "(Ex. 16, p. IV-26)" is corrected to read "(IIS, p. IV-26)".

147. Page 27388, column 1, second paragraph, lines 9 and 10, "(Ex. 16, pp. IV-30-31)" is corrected to read "(IIS, pp. IV-30-31)".

148. Page 27388, column 1, second paragraph, line 16, "(Ex. 16, p. IV-30)" is corrected to read "(IIS, p. IV-30)".

149. Page 27388, column 1, second paragraph, line 24, "(Ex. 16, p. IV-31)" is corrected to read "(IIS, p. IV-31)".

150. Page 27388, column 2, first paragraph, line 3, "(Ex. 85, p. 2)" is corrected to read "(Ex. 78, p. 2)".

151. Page 27388, column 2, second paragraph, line 1, "At noted above" is corrected to read "As noted above".

152. Page 27388, column 2, second paragraph, line 24, "(Ex. 16, p. IV-27)" is corrected to read "(IIS, p. IV-27)".

153. Page 27388, column 3, first paragraph, lines 11 and 12, "(Ex. 16, p. IV-27; knitting)" is corrected to read "(IIS, p. IV-27)".

154. Page 27388, column 3, first paragraph, line 16, "(Ex. 95d, p. 6)" is corrected to read "(Ex. 95d, p. 8)".

155. Page 27388, column 3, second paragraph, line 2, "(Ex. 78, p. 2)" is corrected to read "(Ex. 95d, p. 3)".

156. Page 27388, column 3, third paragraph, lines 8 and 9, "(Ex. 16, IV-28)" is corrected to read "(IIS, IV-28)".

157. Page 27388, column 3, third paragraph, line 13, "(Ex. 16, IV-28)" is corrected to read "(IIS, IV-28)".

158. Page 27389, column 2, lines 5 and 6, "automatic carousel" is corrected to read "automatic Karousel".

159. Page 27389, column 2, lines 7 and 8, "(Ex. 16, A-6)" is corrected to read "(IIS, A-6)".

160. Page 27389, column 2, line 10, "(Ex. 16, A-9)" is corrected to read "(IIS, A-9)".

161. Page 27389, column 2, lines 19 and 20, "(Ex. 16, A-44)" is corrected to read "(IIS, A-44)".

162. Page 27389, column 2, lines 23 and 24, "(Ex. 16, A-46)" is corrected to read "(IIS, A-46)".

163. Page 27390, column 2, second paragraph, lines 10, 11, 12, 13 and 14, the sentence beginning, "Whatever the ramifications * * *" is corrected to read, "OSHA's adoption of the abbreviated form of the standard retesting questionnaire should reduce the problem no matter what ramifications of employee familiarity there are".

164. Page 27391, column 1, fourth paragraph, line 12, "Appendix B" is corrected to read "Appendix D".

165. Page 27391, column 2, second paragraph, lines 10 and 11, "administrative personnel to conduct testing Burlington Industries". is corrected to read "administrative personnel to conduct testing. (e.g. Burlington Industries)".

166. Page 27391, column 3, first paragraph, lines 25 and 26, "(Ex. 38, pp. 15-16)" is corrected to read "(Ex. 38a, pp. 15-16)".

167. Page 27392, column 1, second paragraph, line 2, "(Tr. 1768-69; p. 1573)" is corrected to read "(TR 1768-69)".

168. Page 27392, column 1, third paragraph, line 6, "(Ex. 39(a) p. 16)" is corrected to read "(Ex. 38a, p. 16)".

169. Page 27392, column 3, first paragraph, line 9, "(Ex. 38 p. 18)" is corrected to read "(Ex. 38a, p. 18)".

170. Page 27392, column 3, first paragraph, line 15, "byssionsis" is corrected to read "byssinosis".

171. Page 27396, column 1, eighth paragraph, line 2, "(i)" is deleted after "(g)(1)".

172. Page 27396, column 2, paragraph (f)(2)(iv), line 3, "50x" is corrected to read "100x".

173. Page 27397, column 1, paragraph (h)(3)(i), line 6, insert "(the abbreviated questionnaire, App. B-III)" after the word "questionnaire".

174. Page 27399, column 1, paragraph III (f), line 3 the phrase "16 inches of mercury" is corrected to read "17 inches of mercury".

175. Page 27399, column 2, paragraph IV(c)(7), line 2, the phrase "14 in. of Hg vacuum" is corrected to read "17 in. of Hg vacuum".

176. Page 27418, column 3, the first full sentence from the top of the page beginning "Persons who successfully complete * * *" is deleted.

177. Page 27362, column 2, first paragraph, lines 13—15, delete "(National Cottonseed Producers Association, Parnell)" and insert "(Ex. 95F; Ex. 97f; Ex. 99e)" after "standard".

178. Page 27368, column 2, second line from the top of the page, insert "(Ex. 72b, p. 32)" after "officers".

179. Page 27372, column 3, second paragraph, line 3, insert "and for all other industries" between "$79,668", and $136,088".

180. Page 27382, column 3, last line, insert "recognizes the use of area sampling for periodic environmental monitoring. Presently, OSHA" after "OSHA".

(Secs. 6, 8, 84 Stat. 1593, 1599 (29 U.S.C. 655, 657); Secretary of Labor's Order 8-76 (41 FR 25059); 29 CFR Part 1911).

Signed at Washington, D.C., this 3d day of August 1978.

EULA BINGHAM,
Assistant Secretary of Labor.

[FR Doc. 78-22136 Filed 8-7-78; 8:45 am]

[4510-26]

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

PART 1928—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR AGRICULTURE

Occupational Exposure to Cotton Dust in Cotton Gins; Corrections

AGENCY: The Occupational Safety and Health Administration, Department of Labor.

ACTION: Final rule; corrections.

SUMMARY: This notice announces further corrections to the occupational safety and health standard on exposure to cotton dust in cotton gins which appeared in the FEDERAL REGISTER on June 23, 1978 (43 FR 27418).

EFFECTIVE DATE: September 4, 1978, except that some provisions are effective September 4, 1979.

FOR FURTHER INFORMATION CONTACT:

Mr. Gail Brinkerhoff, Office of Compliance Programs, OSHA, Third Street and Constitution Avenue NW., Room N-3112, Washington, D.C. 20210, telephone 202-523-8034.

SUPPLEMENTARY INFORMATION: On June 23, 1978, an occupational safety and health standard for exposure to cotton dust in cotton gins, with an accompanying explanation, was published in the FEDERAL REGISTER (43 FR 27418, FR Doc. 78-17233) as 29 CFR 1910.1046. There were a number of minor typographical errors and inadvertent omissions in the document. On June 30, 1978, a document was published (43 FR 28474) which corrected a number of errors and omissions in the standard and appendixes. This document corrects errors in the preamble to the standard on exposure to cotton dust in cotton gins and a few remaining errors in the standard and appendixes of the June 23, 1978, document. Among the corrections is the deletion of all medical questionnaires in appendix B except for Appendix B-II, The Respiratory Questionnaire for Non-Textile Workers for the Cotton Industry. This questionnaire is the appropriate version for cotton gin workers. A Spanish translation of the questionnaire, published as part of this document, is to be used for Spanish-speaking workers.

On June 30, at 43 FR 28474 a new Subpart I—Toxic and Hazardous Substances, consisting of § 1928.113, *Exposure to Cotton Dust in Cotton Gins*, was added to part 1928. The text of section 1928.113 is identical to the text of § 1910.1046 as published in the FEDERAL REGISTER of June 23 (43 FR 27434). - Therefore, the corrections made below to section 1910.1046 are also made to § 1928.113.

Accordingly, FR Doc. 78-17233 appearing at 43 FR 27418 and corrected at 43 FR 28474 is corrected as follows:

1. Page 27419, column 1, second paragraph, line 6, "ball" is corrected to read "boll."

2. Page 27420, column 2, first paragraph, line 5, "39.4%" is corrected to read "38.4%."

3. Page 27425, column 2, third paragraph, line 2, "date" is corrected to read "data."

4. Page 27425, column 3, third paragraph, line 15, insert "$" before ".8 million."

5. Page 27426, column 2, second paragraph, lines 10 and 11, "did not explicity calculate" is corrected to read "did not explicitly calculate."

6. Page 27427, column 1, third paragraph, lines 5 and 6, the words "assured are not current" are deleted. End of sentence is corrected to read "not use current salary data."

7. Page 27427, column 1, third paragraph, line 12, insert the word "differnces" so that sentence is corrected to read "there may be some differences due to types and sizes of gins."

8. Page 27428, Table 1, delete minus signs (−) on "−.8 annual," "−.7 1st year" and "−.5 annual thereafter."

9. Page 27428, column 3, second partial paragraph, lines 1 and 2, "(draft, pp. 62-83)" is deleted after the word "cotton dust."

10. Page 27429, column 1, second paragraph, line 22, "Siroemeter" is corrected to read "Spirometer."

11. Page 27429, column 3, line 10, insert the word "in" after the word "repeated."

12. Page 27431, column 1, first paragraph, line 28, "(Ex. 107a p. 8)" is corrected to read "(Ex. 107, p. 8)."

13. Page 27432, column 1, first paragraph, line 3, "(Appendix B SP II)" is corrected to read "(Appendix B-I)."

14. Page 27432, column 1, first paragraph, line 4, "(Appendix B IV)" is corrected to read "(Appendix B-II)."

15. Page 27432, column 2, second paragraph, line 22, "(Ex. 2, No. 59)" is corrected to read "(Ex. 6, No. 59)."

16. Page 27432, column 2, third paragraph, line 12, insert "of the program now includes" after "part".

17. Page 27434, column 1, second paragraph, lines 12-13, delete "longitudinal dose-response".

18. Page 27434, column 2, second paragraph 2, line 5-7, the words "Appendices A and E contain recommendations and, therefore, are not intended * * *", is corrected to read "Appendix A contains recommendations and, therefore, is not intended * * *"

19. Page 27436, column 3, paragraph (j) is corrected to read as follows: (J) Appendixes (1) Appendixes B, C, and D in this section are incorporated as part of this section and the contents of these appendixes are mandatory.

(2) Appendix A contains information which is not intended to create any additional obligations not otherwise imposed or to detract from any existing obligations.

20. Page 27436, column 3, fifth paragraph, line 1, "Recommendations" is corrected to read "Requirements".

21. Page 27437, "Appendix B-I" is deleted in its entirety.

22. Page 27441, "Appendix B-II" is renumbered "Appendix B-I."

23. Page 27449, a new "Appendix B-II," the text of which is published below, is added to follow after renumbered Appendix B-I (see item 22).

APENDICE B-II

CUESTIONARIO RESPIRATORIO PARA TRABAJADORES

QUE NO SEAN DE TEXTIL DE LA INDUSTRIA ALGODONERA

Numero de identificación _____ Clave del entrevistador _____

Localidad _____ Fecha de entrevista _____

A. IDENTIFICACION

1. NOMBRE (Apellido) (Nombre de pila)

3. Num. de telefono Area ( )

4. * Num. de Seguro Socia

2. DIRECCIÓN ACTUAL (Numero, Calle, Ciudad o Pueblo, Condado, Estado, Zona Postal)

5. Fecha de Nacimiento Mes/Dia/Año

6. Edad

7. SEXO
1 ☐ Varón 2 ☐ Hembra

8. RAZA
1. ☐ Blanco, no de origen hispano
2. ☐ Negro, no de origen hispano
3. ☐ Hispano
4. ☐ Indio Americano o Nativo de Alaska
5. ☐ Asiatico o de islas pacificas
6. ☐ Otro _____

9. ALTURA MEDIDA _____ (cm)

10. PESO MEDIDO _____

11. TURNO DE TRABAJO
1 ☐ 2 ☐ 3 ☐

12. SITIO DE TRABAJO ACTUAL
Indique el sitio de trabajo asignado y el porcentaje de tiempo que pasa en ese lugar. Si trabaja en otros sitios, por favor indique esos lugares y el porcentaje de tiempo que pasa en cada uno.

SITIO DE TRABAJO PRIMARIO _____

TRABAJO ESPECIFICO _____

13. INDUSTRIA APROPIADA
1 ☐ Desperdicios de maquina garnet
2 ☐ Fabrica de aceite de semilla de algodón
3 ☐ Almacen de algodón
4 ☐ Utilización
5 ☐ Clasificacion de algodó
6 ☐ Desmotador

* Proveer su número de seguro social es voluntario. El rehuso de proveer este número no afecta ningun derecho, beneficio, o privilegio al cual ud. podría tener derecho. Su número de seguro social ha sido requerido desde que este permite el uso de determinaciones en el futuro en la busqueda de estudios estaticales.

Registro Federal, Vol. 43, No. 122, Viernes 23 de juino de 1978.

B. TABLA DE HISTORIA LABORAL

Llene la siguiente tabla indicando la historia laboral del individuo desde que lo primero empleo hasta el presente. Períodos de empleo aislados ó de tiempo parcial deben ser agrupados si es posible.

INDUSTRIA Y LOCAL	Tiempo de empleo		TRABAJO ESPECIFICO	Promedio de # de dias trab.por sem.	RIESGO DE SALUD POR CONTACTO ASOCIADO CON EL TRABAJO		
	Desde 19__	Hasta 19__			SI	NO	Si se contesta "SI" expliquese

C. Sintomas

Empléense las palabras exactas de cada pregunta. Póngase una "X" en la casilla que sigue cada pregunta. En case do duda, póngase "No." Donde no hay casilla, póngase un circulo alrededor de la repuesta apropiada.

LA TOS

1. ¿Tose Ud. ordinamente al leventarse por la mañana? (Tenga en eventa la flema arrancada al fumos o al salar de la casa por primera vez. No tenga en eventa los mucos nasales).

1. ☐ Sí 2. ☐ No

2. ¿Tose Ud. ordinariamente de día ó de noche?

1. ☐ Sí 2. ☐ No

Si se contesta "Sí" a las preguntas 1 ó 2, pregúntese:

3. ¿Tose asi la mayoría de los dias por un periodo de por lo menos 3 meses durante el pasado año?

1. ☐ Sí 2. ☐ No

4. ¿Tose Ud. mas de lo ordinario algun día en particular de la semana?

1. ☐ Sí 2. ☐ No

Si contesta "Si"; pregúntese:

5. ¿Que día? Lun. Mar. Mier. Jue. Vie. Sab. Dom.

LA FLEMA

6. ¿Se arranca Ud. flema ó catarro del pecho al levantarse? (Tenga en cuenta la flema arrancada al fumar or al salir de la casa por primera vez. No tenga en cuenta los mucos nasales. Tenga en cuenta la flema que se traga).

1. ☐ Sí 2. ☐ No

7. ¿Se arranca Ud. flema ó catarro del pecho ordinariamente de día ó de noche? (Nótense solo 2 veces o mas)

1. ☐ Sí 2. ☐ No

8. Arroja ud. flemas así la mayor parte de días tanto como tres meses al año?

1. ☐ Sí 2. ☐ No

Si se contesta "Sí" a las preguntas 3 ó 8, preguntese:

9. ¿Cuantos años hace que se arranca flema ó catarro o tose frequentemente?
(Responda en numeros de años)

(1) ☐ 2 años ó menos
(2) ☐ mas de 2 años - 9 años
(3) ☐ 10-19 años
(4) ☐ 20 años ó mas

ENFERMEDADES PULMONARIAS

10. ¿Durante los tres pasados años, ha pasado algún periodo de tos* y flemas que duró 3 semanas ó más?
*Sujetos que ordinariamente se arrancan flemas

☐ No
☐ Sí, un solo periodo
☐ Sí, dos periodos o mas

11. ¿Ha tenido Ud. durante los 3 años pasados alguna enfermedad del pecho que le haya impedido a trabajar o obligado a permanecer en casa ó en cama por tanto como una semana? (por ejemplo, ¿la gripe?)

☐ Sí ☐ No

Si se contesta "Sí" a la pregunta 11, pregúntese:

12. ¿Se arrancó Ud. más flemas que lo general durante alguno de estos ataques?

☐ Sí ☐ No

Si se contesta "Sí" a 12, pregúntese:

13. ¿Ha tenido durante los tres años pasados:

Solo un tal ataque con aumento de flemas?

☐ Sí ☐ No

14. Más de uno? ☐ Sí ☐ No

Br. Grade _____

LA OPRESION DEL PECHO

15. ¿Ha tenido Ud. alguna vez opresión en el pecho ó dificultadad en respirar?

☐Sí ☐No

16. ¿Se le oprime el pecho ó se le hace dificil respirar algún día en la semana en particular? (despues de una semana ó 10 días de ausencia de la planta)

☐Sí ☐No

17. Si se contesta "Sí," ¿Que dia?

Lun. Mar. Mier. Jue. Vie. Sab. Dom. Siempre A veces

18. Si se contesta "Sí" para los lunes, pregúntese: ¿A que hora del lunes siente opresión en el pecho o dificultad en respirar?

a.☐Antes de entrar en la desmotadora

b.☐Despues de entrar en la desmotadora

c.☐Despues de salir de la desmotadora

(Preguntese solo si se contesta "No" a la 15)

19. ¿En el pasado, se le ha oprimido el pecho o hecho dificil respirar algún día de la semana en particular?

☐Sí ☐No

20. Si se contesta "Sí", ¿Que día?

Lun. Mar. Mier. Jue. Vier. Sab. Dom. Siempre A veces

EL DESALIENTO (La Dispnea)

21. Si se inhabilita de caminar a causa de cualquier condición que no sea enfermedad del corazon o de los pulmones, ponga una "X" y ignore las preguntas 22-30.

22. ¿Lo aflige un desaliento al caminar aprisa en terreno llano ó al subir una pequeña cuesta?

☐Sí ☐No

(Si "No", el grado es 1. Si es "Sí", siga a la proxima pregunta)

23. ¿Lo aflige un desaliento al caminar con otros de su propia edad a su paso ordinario en terreno llano?

☐Sí ☐No

(Si "No" el grado es 2. Si es "Sí", prosiga)

24. ¿Tiene que detenerse porque se ahoga al caminar a paso ordinario en terreno llano?

☐Sí ☐No

(Si "No" el grado es 3. Si es "Sí", prosiga)

25. ¿Se desalienta al lavarse ó vestirse?

☐Sí ☐No

(Si "No", el grado es 4. Si es "Sí", el grado es 5.)

26. Dyspnea Grd. _____

LOS LUNES: EL PRIMER DIA DE VUELTA AL TRABAJO DESPUES DE SUS DIAS LIBRES

27. ¿Lo aflige un desaliento al caminar aprisa en terreno llano ó al subir una pequeña cuesta?

☐Sí ☐No

(Si "No", el grado es 1. Si es "Sí", siga a la proxima pregunta)

28. ¿Lo aflige un desaliento al caminar con otros de su propria edad a su paso ordinario en terreno llano?

☐Sí ☐No

(Si "No", el grado es 2. Si es "Sí", prosiga)

29. ¿Tiene que detenerse porque se ahoga al caminar a paso ordinario en terreno llano?

☐Sí ☐No

(Si "No", el grado es 3. Si es "Sí", prosiga)

30. ¿Se desalienta al lavarse o vestirse?

☐ Sí ☐ No

(Si "No", el grado es 4. Si es "Sí", el grado es 5.

31. Br. Grd. _____

OTRAS ENFERMEDADES

32. ¿Tiene Ud. una condición del corazón que requiere los servicios de un medico?

☐ Sí ☐ No

33. ¿Ha tenido alguna vez asma?

☐ Sí ☐ No

Si se contesta "Sí", a la 33, pregúntese si empezó: _____ Antes de los 30 años

_____ Despues do los 30 años

34. Si se contesta "Antes de los 30 años"; ¿Tenia Ud. asma antes de trabajar en una desmotadora de algondón?

☐ Sí ☐ No

35. ¿Ha tenido alguna vez otras alergias (ademas de las de arriba)?

☐ Sí ☐ No

CONSUMO DE TABACO

36. ¿Fuma Ud. actualmente? Indique "Sí" si fumaba regularmente hasta hace un mes (Cigarrillos, puros, o pipa)

☐ Sí ☐ No

Si contesta "No" a la (33), pregúntese:

37. ¿Ha fumado Ud. alguna vez? (Cigarillos, puros, ó pipa. Indique "No" si el sujeto nunca ha fumado ni un cigarillo diario ó una onza de tobaco al mes, por un año)

☐ Si ☐ No

Si se contesta "Sí" a la (33) o (34); ¿que ha fumado Ud. y por cuantos años? (Indique el numero especifico de años en la casilla apropiada)

Años	(<5)	(5-9)	(10-14)	(15-19)	(20-24)	(25-29)	(30-34)	(35-39)	(>40)
38. Cigarillos									
39. Pipa									
40. Puros									

41. ¿Si fuma cigarrillos, cuantas cajetillas fuma diarias? Indique en numero de cigarrillos:

☐ menos de 1/2 cajetilla

☐ 1/2 cajetilla, pero menos de 1

☐ 1 cajetilla, pero menos de 1 1/2

☐ 1 1/2 cajetillas ó más

42. Numero de cajetillas por año _____

43. Si ha dejado de fumar (cigarrillos, pipas ó puros), cuanto tiempo hace que lo dejó. (Indique en numero de años)

☐ 0 - 1 año

☐ 1 - 4 años

☐ 5 - 9 años

☐ 10 años o mas

HISTORIA LABORAL

¿Ha trabajado Ud. alguna vez en:

44. Una fundación (por tanto como un año)? ☐ Sí ☐ No

45. La minería ó elaboración de piedras ó metales (por tanto como un año)? ☐ Sí ☐ No

46. En una planta de asbesto? (alguna vez) ☐ Sí ☐ No

47. En una fabrica de algodón ó de mezclado de algodón ☐ Sí ☐ No

48. En proximidad de otros polvos, emanaciones o humos? Si se contesta "Sí", especifíquese: ☐ Sí ☐ No

Clase de contacto _____

Duración de contacto _____

24. Page 27449, "Appendix B-III" is deleted in its entirety.

25. Page 27451, "Appendix B-IV" is deleted in its entirety.

26. Page 27463, column 3, paragraph IV, lines 6-8, the sentense beginning "Persons who successfully complete * * *" is deleted.

(Secs. 6, 8, 84 Stat. 1593, 1599 (29 U.S.C. 655, 657); Secretary of Labor's order 8-76 (41 FR 25059); 29 CFR Part 1911.)

Signed at Washington, D.C., this 3d day of August 1978.

EULA BINGHAM,
Assistant Secretary of Labor.

[FR Doc. 78-22135 Filed 8-7-78; 8:45 am]

[4510-29]

CHAPTER XXV—PENSION AND WELFARE BENEFIT PROGRAMS

SUBCHAPTER C—REPORTING AND DISCLOSURE UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

PART 2520—RULES AND REGULATIONS FOR REPORTING AND DISCLOSURE

Clarification of Final Regulations

AGENCY: Department of Labor.

ACTION: Clarification of final regulations.

SUMMARY: This document contains a table of contents and clarification of part 2520 of the rules and regulations of the Department of Labor under the Employee Retirement Income Security Act of 1974 (ERISA) applicable to reporting and disclosure by employee benefit plans. This clarification and publication of the table of contents of regulations under part 2520 will remove any confusion which may have arisen as a result of publication on July 19, 1977 and March 10, 1978 of certain regulations which were not revised and of a table of contents which did not contain reference to all reporting and disclosure regulations. Persons required to comply with these regulations should be aware that no substantive changes are being made to the regulations.

FOR FURTHER INFORMATION CONTACT:

Joe Bodner, Office of Regulatory Standards and Exceptions, Pension and Welfare Benefit Programs, U.S. Department of Labor, Washington, D.C. 29216, 202-523-7901.

SUPPLEMENTARY INFORMATION: On March 10, 1978, the Department of Labor adopted certain final regulations concerning annual reporting requirements under section 103 of the Employee Retirement Income Security Act of 1974 (ERISA). In connection with the adoption of these regulations, the table of contents of regulations was amended to include these regulations in the appropriate subparts. The table of contents, in describing these subparts, however, did not repeat referecnces to final regulations previously adopted in these subparts and unchanged by the March 10, 1978 regulations.

On July 19, 1977, the Department adopted certain final and interim regulations concerning the form, content, and distribution of the summary plan description furnished to plan participants and beneficiaries and filed with the Department. In connection with publishing these regulations, certain final sections were republished without change to provide a comprehensive package of regulations which would be helpful to the public.

To avoid any confusion as to which regulations have been revised by the Department respecting reporting and disclosure under ERISA, a guide describing affected sections of the regulations is provided and the table of contents of regulations is reprinted.

In subpart A, no amendments to § 2520.101-1 were issued and therefore it remains unchanged.

In subpart B, § 2520.102-1 was not amended and therefore remains unchanged. At 42 FR 37178, July 19, 1977, §§ 2520.102-2 and 2520.102-4 were reproduced without change and § 2520.102-3 was revised.

In subpart C, §§ 2420.103-1 through 2520.103-11 were revised at 43 FR 10130, March 10, 1978.

In subpart D, no amendments were issued to §§ 2520.104-1, 2520.104-2, 2520.104-3, 2520.104-22, 2520.104-23, 2520.104-24 and 2520.104-25, and therefore they remain unchanged. At 42 FR 37178, July 19, 1977, §§2520.104-4, 2520.104-5, 2520.104-6, 2520.104-26 and 2520.104-27 were revised and 2520.104-28 was added. At 43 FR 10130, March 10, 1978, §§2520.104-20, 2520.104-21, 2520.104-41, 2520.104-42, 2520.104-43, 2520.104-44, 2520.104-45 and 2520.104-46 were revised.

In subpart E, at 42 FR 37178, July 19, 1977, § 2520.104a-1 was reproduced without change, § 2520.104a-2 was not addressed but was set out in full, and §§ 2520.104a-3 and 2520.104a-5 were revised. Subsequently, § 2520.104a-5 was redesignated as 2520.104a-7 at 42 FR 60898, November 29, 1977 and new § 2520.104a-5 was added at 43 FR 10130, March 10, 1978. Sections 2520.104a-4 and 2520.104a-6 were revised at 43 FR 10130, March 10, 1978.

In subpart F, at 42 FR 37178, July 19, 1977 §§ 2520.104b-1 and 2520.104b-3 were reproduced without change and §§ 2520.104b-2 and 2520.104b-4 were revised. No amendments were made to §§ 2520.104b-5, 2520.104b-10, 2520.104b-11, 2520.104b-12 and 2520.104b-30 and therefore they remain unchanged.

For the convenience of the user, following is a table of contents with footnotes indicating the sections published on July 19, 1977, November 29, 1977, and March 10, 1978.

Subpart A—General Reporting and Disclosure Requirements

Sec.
2520.101-1 Duty of reporting and disclosure.

Subpart B—Contents of Plan Description and Summary Plan Description

2520.102-1 Plan description form.
2520.102-2 Style and format of summary plan description.[1]
2520.102-3 Contents of summary plan description.[1]
2520.102-4 Option for different summary plan descriptions.[1]

Subpart C—Annual Report Requirements

2520.103-1 Content of annual report.[2]
2520.103-2 Content of annual report for a group insurance arrangement.[2]
2520.103-3 Exemption from certain annual reporting requirements for assets held in a common or collective trust fund.[2]
2520.103-4 Exemption from certain annual reporting requirements for assets held in an insurance company pooled separate account.[2]
2520.103-5 Transmittal and certification of information to plan administrator for annual reporting purposes.[2]
2520.103-6 Definition of reportable transaction for annual return/report.[2]
2520.103-7 Special accounting rules for plans filing the initial annual report.[2]
2520.103-8 Limitation on scope of accountant's examination.[2]
2520.103-9 Direct filing rules for bank common and collective trusts and insurance carrier pooled separate accounts.[2]
2520.103-10 Format and contents of Annual Return/Report financial schedules.[2]
2520.103-11 Assets held for investment purposes.[2]

Subpart D—Provisions Applicable to Both Reporting and Disclosure Requirements

2520.104-1 General.
2520.104-2 Postponing effective date of annual reporting requirements and extending WPPDA reporting requirements.
2520.104-3 Deferral of certain initial reporting and disclosure requirements.
2520.104-4 Alternative method of compliance for certain successor pension plans.[1]
2520.104-5 Deferral of certain reporting and disclosure requirements relating to the summary plan description for welfare plans.[1]

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[1] 42 FR 37178, July 19, 1977.
[2] 43 FR 10130, March 10, 1978.

Sec.
2520.104-6 Deferral of certain reporting and disclosure requirements relating to the summary plan description for pension plans.[1]
2520.104-20 Limited exemption for certain small welfare plans.[2]
2520.104-21 Limited exemption for certain group insurance arrangements.[2]
2520.104-22 Limited exemption for apprenticeship plans.
2520.104-23 Alternative method of compliance for pension plans for certain selected employees.
2520.104-24 Exemption for welfare plans for certain selected employees.
2520.104-25 Exemption from reporting and disclosure for day care centers.
2520.104-26 Limited exemption for certain dues financed welfare plans maintained by employee organizations.[1]
2520.104-27 Alternative method of compliance for certain dues financed pension plans maintained by employee organizations.[1]
2520.104-28 Extension of time for filing and disclosure of the initial summary plan description.[1]
2520.104-41 Simplified annual reporting requirements for plans with fewer than 100 participants.[2]
2520.104-42 Waiver of certain actuarial information in the annual report.[2]
2520.104-43 Exemption from annual reporting requirement for certain group insurance arrangements.[2]
2520.104-44 Limited exemption and alternative method of compliance for annual reporting by unfunded or insured welfare and pension plans.[2]
2520.104-45 Temporary exemption from reporting insurance fees and commissions for insured plans with fewer than 100 participants.[2]
2520.104-46 Waiver of examination and report of an independent qualified public accountant for employee benefit plans with fewer than 100 participants.[2]

Subpart E—Reporting Requirements

2520.104a-1 Filing with the Secretary of Labor.[1]
2520.104a-2 Plan description reporting requirement.[1]
2520.104a-3 Summary Plan Description.[1]
2520.104a-4 Material modifications to the plan and changes in plan description information.[2]
2520.104a-5 Annual report filing requirements.[2]
2520.104a-6 Annual reporting for plans which are part of a group insurance arrangement.[2]
2520.104a-7 Summary of material modifications.[3]

Subpart F—Disclosure Requirements

2520.104b-1 Disclosure.[1]
2520.104b-2 Summary plan description.[1]
2520.104b-3 Summary of material modifications to the plan and changes in the information required to be included in the summary plan description.[1]
2520.104b-4 Alternative method of compliance for furnishing pension plan documents to retired participants and their beneficiaries and separated participants with vested benefits.[1]
2520.104b-5 ERISA Notice.
2520.104b-10 Summary annual report.
2520.104b-11 Summary annual report for plans which are of a group insurance arrangement.
2520.104b-12 Summary Annual Report for 1975 Plan Year—Optional method of distribution for certain multiemployer plans.
2520.104b-30 Charges for documents.

[3] 42 FR 60898, November 29, 1977—Redesignated from 2520.104a-5 published 42 FR 37178, July 19, 1977.

Signed at Washington, D.C., on this 4th day of August 1978.

J. VERNON BALLARD,
Deputy Administrator, Pension and Welfare Benefit Programs, Labor-Management Services Administration.

[FR Doc. 78-22178 Filed 8-7-78; 8:45 am]

[3710-08]

Title 32—National Defense

CHAPTER V—DEPARTMENT OF THE ARMY

[AR 290-5]

PART 553—ARMY NATIONAL CEMETERIES

Arlington National Cemetery; Eligibility for Inurnment of Cremated Remains in Columbarium

AGENCY: Department of the Army, DOD.

ACTION: Final rule.

SUMMARY: A Columbarium for the inurnment of cremated remains is being constructed in Arlington National Cemetery and is expected to be completed in 1979. The Columbarium will be a sepulchral vault composed of niches each of which is designed to permanently accommodate two urns of cremated remains. A marker will be inscribed and provided at Government expense for attachment to each niche. Although a design for a 50,000 niche modular Columbarium has been completed, only the first 5,000 niches will be constructed next year. Additional modules will be constructed as the need arises. This rule informs the public that the eligibility for inurnment of cremated remains in the Columbarium will include all veterans who served on active duty and whose last service terminated honorably.

EFFECTIVE DATE: Upon completion of the Columbarium.[1]

FOR FURTHER INFORMATION CONTACT:
Lt. Comdr. Ellsworth S. Clarke, 202-693-0882.

[1] NOTE.—The Army Department will publish a subsequent document confirming the effective date of this regulation at the appropriate time. Anticipated completion date is November 1979.

SUPPLEMENTARY INFORMATION: The gravesite space for burial in Arlington National Cemetery is restricted to members and retired members of the Armed Forces, recipients of the Medal of Honor, veterans who have served in major posts in the Federal Government, certain disabled veterans, and veterans who have been awarded certain decorations. Spouses, minor children, and dependent adult children of the foregoing are also eligible. The open eligibility for inurnment of cremated remains in the Columbarium does not affect the present restrictive criteria for gravesite interments in the cemetery.

Dated: August 3, 1978.

By authority of the Secretary of the Army.

THOMAS D. PEARSON, Jr.,
Lieutenant Colonel, United States Army Acting Director, Personal Affairs, TAGCEN.

Accordingly, 32 CFR Part 553 is amended by adding a new § 553.15a after § 553.15 as set forth below:

§ 553.15a Persons eligible for inurnment of cremated remains in Columbarium in Arlington National Cemetery.

(a) Any member of the Armed Forces who dies on active duty.

(b) Any former member of the Armed Forces who served on active duty (other than for training) and whose last service terminated honorably.

(c) Any member of a Reserve component of the Armed Forces, and any member of the Army National Guard or the Air National Guard, whose death occurs under honorable conditions while he is on active duty for training or performing full-time service; performing authorized travel to or from that duty or service; or is on authorized inactive duty training including training performed as a member of the Army National Guard or the Air National Guard. Also included are those members whose deaths occur while hospitalized or undergoing treatment at the expense of the United States for injury or disease contracted or incurred under honorable conditions while on that duty or service or performing that travel or inactive duty training.

(d) Any member of the Reserve Officers' Training Corps of the Army, Navy, or Air Force whose death occurs under honorable conditions while attending an authorized training camp or on an authorized practice cruise, performing authorized travel to or from that camp or cruise, or hospitalized or undergoing treatment at the expense of the United States for

injury or disease contracted or incurred under honorable conditions while attending that camp or cruise, performing that travel, or undergoing that hospitalization or treatment at the expense of the United States.

(e) Any citizen of the United States who, during any war in which the United States has been or may hereafter be engaged, served in the Armed Forces of any government allied with the United States during that war, whose last active service terminated honorably by death or otherwise, and who was a citizen of the United States at the time of entry on such service and at the time of death.

(f) Commissioned officers, United States Coast and Geodetic Survey (now National Oceanic and Atmospheric Administration) who die during or subsequent to the service specified in the following categories and whose last service terminated honorably:

(1) Assignment to areas of immediate military hazard.

(2) Served in the Philippine Islands on December 7, 1941.

(3) Transferred to the Department of the Army or the Department of the Navy under certain statutes.

(g) Any commissioned officer of the United States Public Health Service who served on full-time duty on or after July 29, 1945, if the service falls within the meaning of active duty for training as defined in 38 U.S.C. 101(22) or inactive duty training as defined in 38 U.S.C. 101(23) and whose death resulted from a disease or injury incurred or aggravated in line of duty. Also, any commissioned officer of the Regular or Reserve Corps of the Public Health Service who performed active service prior to July 29, 1945 in time of war; on detail for duty with the Armed Forces; or while the service was part of the military forces of the United States pursuant to Executive order of the President.

(h) Spouses, minor children, and dependent adult children of the persons listed above.

NOTE.—The Department of the Army 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.

(24 U.S.C. 281.)

[FR Doc. 78-21996 Filed 8-7-78; 8:45 am]

[1410-03]

Title 37—Patents, Trademarks, and Copyrights

CHAPTER II—COPYRIGHT OFFICE, LIBRARY OF CONGRESS

[Docket RM 77-15; Rules Doc. A]

PART 201—GENERAL PROVISIONS

Recordation of Transfers and Other Documents

AGENCY: Library of Congress, Copyright Office.

ACTION: Final regulations.

SUMMARY: This notice is issued to advise the public that the Copyright Office of the Library of Congress is adopting a final regulation to implement section 205 of the act for general revision of the copyright law. That section concerns the recordation of transfers of copyright and other documents pertaining to a copyright. The effect of the regulation is to establish requirements governing the recordation of documents.

DATE: The regulation is effective on September 7, 1978.

FOR FURTHER INFORMATION CONTACT:

Jon Baumgarten, General Counsel, Copyright Office, Library of Congress, Washington, D.C. 20559, 703-557-8731.

SUPPLEMENTARY INFORMATION: Section 205(a) of title 17, U.S.C. permits the recordation in the Copyright Office of "any transfer of copyright ownership or other document pertaining to a copyright" if certain conditions of authenticity are met. Recordation will place the document in the public records of the Office, and has important legal consequences in certain cases. On January 4, 1978 (43 FR 771) we published an interim amendment to § 201.4 of our regulations to implement this section. Interested parties were given until March 31, 1978, to comment on the interim amendment.

One comment, from the Authors League of America, Inc., was received in response to our notice.[1] This comment urged that we modify our regulation to refer explicitly to the recordation of a "note or memorandum" (17 U.S.C. 204(a)) of a transfer of copyright ownership.[2] Although a "note or memorandum" of a transfer was subject to recordation under the language of the interim amendment, for purposes of clarity we have accepted this suggestion: Paragraph (c) (formerly paragraph (b)) of § 201.4 has been revised to incorporate the language of 17 U.S.C. 204(a). The Authors League also requested clarification of the meaning of the requirement that a document submitted for recordation be "complete on its face, and include any schedules, appendixes, or other attachments referred to in the document as being a part of it." We have revised the regulation to reflect in some detail our actual practices in this area.

We have also added two new paragraphs to the regulation. The first (§ 201.4(b)) makes clear that the Copyright Office does not provide printed forms for the recordation of documents. The second new paragraph (§ 201.4(c)(3)) requires that documents submitted must be "legible and capable of being reproduced in legible microform copies." The Copyright Office currently maintains its records of transfers and other documents on microfilm. This requirement is intended to insure not only that the document submitted can be read for purposes of examining and cataloging, but also that it can produce a legible microform copy to serve as a permanent public record.

We have deleted the requirement, in § 201.4(c)(1), that the document submitted must be an "original" since that term is ambiguous; it is the presence of a handwritten signature on the document, not the physical nature of the document itself, that is the key to recordability. A signed copy of the document (sometimes called a duplicate original) is perfectly acceptable for recordation.

The interim regulation, as amended, is adopted as final, and is set forth below.

Dated: July 26, 1978.

BARBARA RINGER,
Register of Copyrights.

Approved:

DANIEL J. BOORSTIN,
The Librarian of Congress.

FINAL REGULATIONS

Part 201 of 37 CFR Chapter II is amended by revising § 201.4 to read as follows:

201.4 Recordation of transfers and certain other documents.

(a) *General.* (1) This section prescribes conditions for the recordation

[1] We have also received a helpful letter from E. Fulton Brylawski, Esq., containing a number of suggestions for dealing with our procedures in the recordation of documents. These suggestions are under active review but, since they essentially concern matters of workflow and internal processing, they are being considered separately from this regulatory proceeding.

[2] 17 U.S.C. 204(a) provides: "A transfer of copyright ownership, other than by operation of law, is not valid unless an instrument of conveyance, or a note or memorandum of the transfer, is in writing and signed by the owner of the rights conveyed or such owner's duly authorized agent."

of transfers of copyright ownership and other documents pertaining to a copyright under section 205 of title 17 of the United States Code, as amended by Pub. L. 94-553. The filing or recordation of the following documents is not within the provisions of this section:

(i) Certain contracts entered into by cable systems located outside of the 48 contiguous States (17 U.S.C. 111(e); see 37 CFR 201.12);

(ii) Notices of identity and signal carriage complement, and statements of account, of cable systems (17 U.S.C. 111(d); see 37 CFR 201.11; 201.17);

(iii) Original, signed notices of intention to obtain compulsory license to make and distribute phonorec- ords of nondramatic musical works (17 U.S.C. 115(b); see 37 CFR 201.18);

(iv) License agreements, and terms and rates of royalty payments, voluntarilly negotiated between one or more public broadcasting entities and certain owners of copyright (17 U.S.C 118; see 37 CFR 201.9);

(v) Notices of termination (17 U.S.C. 203.304(c); see 37 CFR 201.10); and

(vi) Statements regarding the identity of authors of anonymous and pseudonymous works, and statements relating to the death of authors (17 U.S.C. 302).

(2) A "transfer of copyright ownership" has the meaning set forth in section 101 of title 17 of the United States Code, as amended by Pub. L. 94-553. A document shall be considered to "pertain to a copyright" if it has a direct or indirect relationship to the existence, scope, duration, or identification of a copyright, or to the ownership, division, allocation, licensing, transfer, or exercise or rights under a copyright. That relationship may be past, present, future, or potential.

(3) For purposes of this section:

(i) A "sworn certification" is an affidavit under the official seal of any officer authorized to administer oaths within the United States, or if the original is located outside of the United States, under the official seal of any diplomatic or consular officer of the United States or of a person authorized to administer oaths whose authority is proved by the certificate of such an officer, or a statement in accordance with section 1746 of title 28 of the United States Code; and

(ii) An "official certification" is a certification, by the appropriate Government official, that the original of the document is on file in a public office and that the reproduction is a true copy or the original.

(b) *Forms.* The Copyright Office does not provide forms for the use of persons recording documents.

(c) *Recordable documents.* Any transfer of copyright ownership (including any instrument of conveyance, or note or memorandum of the transfer), or any other document pertaining to a copyright, may be recorded in the Copyright Office if it is accompanied by the fee set forth in paragraph (d) of this section, and if the requirements of this paragraph with respect to signatures, completeness, and legibility are met. (1) To be recordable, the document must bear the actual signature or signatures of the person or persons who executed it. Alternatively, the document may be recorded if it is a legible photocopy or other full-size facsimile reproduction of the signed document, accompanied by a sworn certification or an official certification that the reproduction is a true copy of the signed document. Any sworn certification accompanying a reproduction shall be signed by at least one of the persons who executed the document, or by an authorized representative of that person.

(2) To be recordable, the document must be complete by its own terms. (i) A document that contains a reference to any schedule, appendix, exhibit, addendum, or other material as being attached to the document or made a part of it shall be recordable only if the attachment is also submitted for recordation with the document or if the reference is deleted by the parties to the document. If a document has been submitted for recordation and has been returned by the Copyright Office at the request of the sender for deletion of the reference to an attachment, the document will be recorded only if the deletion is signed or initialed by the persons who executed the document or by their authorized representatives. In exceptional cases a document containing a reference to an attachment will be recorded without the attached material and without deletion of the reference if the person seeking recordation submits a written request specifically asserting that: (A) The attachment is completely unavailable for recordation; and (B) the attachment is not essential to the identification of the subject matter of the document; and (C) it would be impossible or wholly impracticable to have the parties to the document sign or initial a deletion of the reference. In such exceptional cases, the Copyright Office records of the document will be annotated to show that recordation was made in response to a specific request under this paragraph.

(ii) If a document otherwise recordable under this indicates on its face that it is a self-contained part of a larger instrument (for example: if it is designated "Attachment A" or "Exhibit B"), the Copyright Office will raise the question of completeness, but will record the document if the person requesting recordation asserts that the document is sufficiently complete as it stands.

(iii) When the document submitted for recordation merely identifies or incorporates by reference another document, or certain terms of another document, the Copyright Office will raise no question of completeness, and will not require recordation of the other document.

(3) To be recordable, the document must be legible and capable of being reproduced in legible microform copies.

(d) *Fee.* For a document consisting of six pages or less covering no more than one title, the basic recording fee is $10. An additional charge of 50 cents is made for each page over six and each title over one. For these purposes:

(1) A fee is required for each separate transfer or other document, even if two or more documents appear on the same page;

(2) The term "title" generally denotes "appellation" or "denomination" rather than "registration," "work," or "copyright"; and

(3) In determining the number of pages in a document, each side of a leaf bearing textual matter is regarded as a "page."

(e) *Recordation.* The date of recordation is the date when a proper document under paragraph (c) of this section and a proper fee under paragraph (d) of this section are all received in the Copyright Office. After recordation the document is returned to the sender with a certificate of record.

(17 U.S.C. 205, 702, 708.)

[FR Doc. 78-21942 Filed 8-7-78; 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.

[6325-01]

CIVIL SERVICE COMMISSION

[5 CFR Part 890]

FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

Opportunities To Register To Enroll and Change Enrollment; Open Season

AGENCY: Civil Service Commission.

ACTION: Proposed rulemaking.

SUMMARY: This amendment provides for a Federal employees health benefits (FEHB) program open season from November 13 through December 8, 1978, and in all future years from the second full week in November through the first full week in December. The FEHB open season is a time during which all eligible employees may enroll in the Program, and enrolled employees and annuitants may change plans, options, types of enrollment, or a combination of these changes. The Commission's experience with the 1977 FEHB open season, which was 4 workweeks long (November 14 through December 9, 1977), was favorable. As a result, the Commission has determined that the 1978 open season should be 4 workweeks in length, and that yearly open seasons should be held during similar 4-week periods.

DATE: Comments must be received on or before October 10, 1978.

ADDRESS: Comments should be directed to Craig B. Pettibone, Chief, Office of Policy Development and Technical Services, Bureau of Retirement, Insurance, and Occupational Health, Room 4351, 1900 E Street NW., Washington, D.C. 20415.

FOR FURTHER INFORMATION CONTACT:

Edward G. Borchers, Office of Policy Development and Technical Services, Bureau of Retirement, Insurance, and Occupational Health, Room 4334, 1900 E Street NW., Washington, D.C. 20415, 202-632-4684.

It is proposed to amend § 890.301(d)(1) of Part 890, Title 5, Code of Federal Regulations, as set out below:

§ 890.301 Opportunities to register to enroll and change enrollment.

* * * * *

(d) *Open season.* (1) An open season will be held from November 13, 1978, through December 8, 1978, and in all future years from the Monday of the second full workweek in November through the Friday of the first full workweek in December, as announced by the Civil Service Commission. During this open season:

(i) An unenrolled employee may register to be enrolled;

(ii) An enrolled employee or annuitant may change to another plan, another option, from self only to self and family, or any combination of these changes.

(5 U.S.C. 8913.)

For the United States Civil Service Commission.

Dated: August 8, 1978.

JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc. 78-22106 Filed 8-7-78; 8:45 am]

[6325-01]

[5 CFR Part 890]

FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

To Eliminate the Second review Cycle and Mini Open Season

AGENCY: Civil Service Commission.

ACTION: Proposed rulemaking.

SUMMARY: Response to the mini open season has been disappointing. Federal employees and annuitants have failed to take advantage of the increased access to comprehensive plans. The benefits derived by a few Federal employees and annuitants does not justify the administrative effort and expense necessary to conduct the second review cycle and mini open season. Accordingly, the Civil Service Commission proposes to eliminate the second review cycle and mini open season conducted under the Federal employees health benefits (FEHB) program.

DATE: Comments must be received on or before September 7, 1978.

ADDRESS: Comments should be directed to Craig B. Pettibone, Chief, Office of Policy Development and Technical Services, Bureau of Retirement, Insurance, and Occupational Health, 1900 E Street NW., Washington, D.C. 20415.

FOR FURTHER INFORMATION CONTACT:

Mary Ann Mercer, Office of Policy Development and Technical Services, Bureau of Retirement, Insurance, and Occupational Health, 202-632-4634.

SUPPLEMENTARY INFORMATION: Presently, organizations which offer comprehensive medical plans may apply for approval to participate in the FEHBP at two times during the calendar year. The Commission has issued regulations establishing 90-day application review periods beginning April 1 and October 1. To be considered during these review periods, an organization must submit an application to the Commission on or before March 31 or September 30, respectively. Applicants submitting their applications by March 31 receive notice of approval or disapproval by June 30. Approved plans are offered to Federal employees during the annual open season in November, with participation to be effective the following January 1. Similarly, applicants submitting their applications by September 30 receive notice of approval or disapproval by December 31. Approved plans are offered to Federal employees during a special (or "mini") open season in May, with participation to be effective on July 1. The mini open season was established to provide employees and annuitants increased accessibility to comprehensive plans. The employees and annuitants, however, have not taken advantage of this opportunity. In view of the fact that the next second review cycle will begin October 1, 1978, it will be necessary to shorten the comment period of the proposed rulemaking to 30 days. This will allow us to avert the upcoming second review cycle if the proposed rulemaking is finalized.

Accordingly, it is proposed to revise 5 CFR 890.203(a) by amending the last sentence, and to amend § 890.301(d) by deleting § 890.301(d)(2), as set out below:

§ 890.203 Application for approval of, and proposal of amendments to, health benefits plans.

(a) * * * Participation of an approved plan becomes effective on the January 1 which is: (1) At least 9 months after the Commission receives the application and (2) at least 6 months after the Commission receives all evidence to demonstrate that the plan has met all requirements for approval.

* * * * *

§ 890.301 Opportunities to register to enroll and change enrollment.

* * * * *

(d) *Open season.* * * *

(2) [Revoked]

* * * * *

(5 U.S.C. 8913.)

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

[FR Doc. 78-22107 Filed 8-7-78; 8:45 am]

[6325-01]

[5 CFR Part 890]

FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

Disposition of Contingency Reserves Upon Reorganization or Merger of Plans

AGENCY: Civil Service Commission.

ACTION: Proposed rulemaking.

SUMMARY: The Civil Service Commission proposes to dispose of the contingency reserves of discontinued health plans where there remains a successor organization, and of parent plans from which one or more plans become severed, in a manner equitable to the continuing enrollees remaining in the successor or severed plans. This regulation will clarify 5 U.S.C. 8909 (d) and (e) and will enable the groups that contribute to the accumulation of the contingency reserves (and special reserves, for experience-rated plans) to benefit from them.

DATE: Comments must be received on or before October 10, 1978.

ADDRESS: Comments should be directed to Craig B. Pettibone, Chief, Office of Policy Development and Technical Services, Bureau of Retirement, Insurance, and Occupational Health, 1900 E Street NW., Washington, D.C. 20415.

FOR FURTHER INFORMATION CONTACT:

Mary Ann Mercer, Office of Policy Development and Technical Services, Bureau of Retirement, Insurance, and Occupational Health, 202-632-4634.

It is proposed to add 5 CFR 890.504 as follows:

§ 890.504 Disposition of contingency reserves upon reorganization or merger of plans.

Upon reorganization or merger of a plan, the surviving plan shall have credited to it the reserves of the reorganized or merged plan provided, however, if more than one plan survives, the reserves shall be divided among the surviving plans in proportion to the employees continuing to subscribe to the surviving plans.

(5 U.S.C. 8913.)

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

[FR Doc. 78-22108 Filed 8-7-78; 8:45 am]

[3410-02]

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 1126]

[Docket No. AO-231-A46]

MILK IN THE TEXAS MARKETING AREA

Partial Recommended Decision and Opportunity To File Written Exceptions on Proposed Amendments to Tentative Marketing Agreement and To Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This decision recommends changes in the present order provisions based on industry proposals considered at a public hearing held June 13-14, 1978. The recommended amendments would relax the "dairy farmer for other markets" provision and would modify the provisions relating to diversions of milk to nonpool plants. These provisions are used to determine which dairy farmers are eligible to have their milk pooled and priced under the Federal order. The recommended amendments are necessary to reflect current marketing conditions and to insure orderly marketing in the area.

DATE: Comments are due on or before August 18, 1978.

ADDRESS: Comments (four copies) should be filed with the Hearing Clerk, Room 1077, South Bulding, U.S. Department of Agriculture, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT:

Robert F. Groene, Marketing Specialist, Dairy Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, D.C. 20250, 202-447-4824.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding:

Notice of hearing issued May 26, 1978, published June 1, 1978 (43 FR 23725).

PRELIMINARY STATEMENT

Notice is hereby given of the filing with the hearing clerk of this partial recommended decision with respect to proposed amendments to the tentative marketing agreement and order regulating the handling of milk in the Texas marketing area, and of the opportunity to file written exceptions thereto. This notice is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR part 900).

Interested parties may file written exceptions to this decision with the Hearing Clerk, U.S. Department of Agriculture, Washington, D.C. 20250, on or before August 18, 1978. The exceptions should be filed in quadruplicate. All written submissions made pursuant to this notice will be made available for public inspection at the office of the hearing clerk during regular business hours (7 CFR 1.27(b)).

This relatively limited time for filing exceptions is neessary if the industry is to be informed on a timely basis of the final action on the issues dealt with in this decision. The changes adopted herein could affect the manner in which producers may wish to market their milk beginning September 1, 1978.

The hearing on the record of which the proposed amendments, as hereinafter set forth, to the tentative marketing agreement and to the order as amended, were formulated, was conducted at Dallas, Tex., on June 13-14, 1978, pursuant to notice thereof which was issued May 26, 1978 (43 FR 23725).

The material issues on the record of the hearing relate to:

1. The "dairy farmer for other markets" provision.
2. Diversions to nonpool plants.
3. Diversions between pool plants.
4. Producer-handler provisions.
5. Classification of shrinkage and products that are dumped or sold for animal feed.
6. Partial payments to a cooperative association.

This partial decision deals only with issues 1 and 2. The remaining issues are reserved for a later decision.

FINDINGS AND CONCLUSIONS

The following findings and conclusions on issues 1 and 2 are based on evidence presented at the hearing and the record thereof:

1. *The "dairy farmer for other markets" provision.* That portion of the producer definition commonly referred to as the "dairy farmer for other markets" provision should be modified. A cooperative association or a pool plant operator should be permitted to deliver to plants as other than producer milk under the Texas order up to one-third of the milk production of a dairy farmer during the period of September through November without causing that dairy farmer to be ineligible as a producer under the Texas order during the following months of February through July.

Presently, the "dairy farmer for other markets" provision excludes as a producer any person with respect to milk produced by him during the months of February through July that is caused to be delivered to a pool plant by a cooperative association or a pool plant operator if during the immediately preceding months of September through November any milk from the same farm was caused by such cooperative association or pool plant operator to be delivered to plants as other than producer milk. However, a dairy farmer does not lose his producer eligibility in those cases where such deliveries of nonproducer milk result from being diverted to a nonpool plant in excess of the diversion limitations or from a temporary loss of grade A approval. Also, the "dairy farmer for other markets" provision does not apply to the milk received from dairy farmers associated with a plant that was not a pool plant during any of the preceding months of September through November but which is regulated under the Texas order during any of the months of February through July. These three exceptions to the provision would not be changed by this decision.

A cooperative association proposed that the "dairy farmer for other markets" provision not apply unless 28 percent or more of the milk from a dairy farmer is caused by a cooperative association or pool plant operator to be delivered to plants as other than producer milk under the Texas order during the period of September through November. The cooperative's witness testified that this revision is needed because the present provision is too restrictive and has caused severe financial hardship upon the members of the cooperative association.

Proponent cooperative indicated that it needs greater flexibility in the marketing of milk for fluid use than is now permitted by the order. The witness for the cooperative testified that the cooperative supplies milk to a Texas distributing plant which bottles milk only 5 days per week. As a consequence, the cooperative is forced to find other outlets for the milk of its members on the 2 remaining days of the week. The cooperative's witness indicated that during September through November 1977 it was necessary for the cooperative to move approximately 16 percent of the milk of 138 of its members to fluid outlets in Mississippi and Louisiana because the cooperative had no manufacturing outlets in the Texas market available to it.

The witness pointed out that the proponent cooperative moved the milk to available fluid outlets in Mississippi and Louisiana where it was utilized in class I. Under the terms of the orders involved, such utilization resulted in the milk that was received in the other markets being treated as producer milk under the other orders. The witness indicated that by becoming producers under such other orders, the 138 producers were unable to market any of their milk as producer milk under the Texas order during the months of February–July.

The witness for the cooperative indicated that in order to fully supply all of the cooperative's fluid outlets in Texas during February–July, it was necessary for the cooperative to acquire a supply plant, pool it under the greater Louisiana order, and then supply the Texas market with other order milk. The witness claimed that the cooperative incurred much greater handling costs in marketing the milk of its members.

The cooperative claimed that the milk of the 138 producers which was not permitted to be pooled on the Texas market should have been considered as a reserve supply for the Texas market and pooled on that market.

As further indication of the restrictive nature of the current provision, the cooperative's witness cited an instance in which several producers who were normally supplying the Texas market lost their eligibility for producer status under the Texas order because their milk happened to be loaded on a truck delivering milk to pool plants regulated under another order.

The cooperative's proposal to amend the "dairy farmer for other markets" provision was supported by another cooperative association in the market. The witness for the latter cooperative described a situation where 60 of its producer-members became ineligible to be producers under the Texas order during the months of February through July 1976. This situation occurred because in November 1975 the cooperative's supply plant lost some class I sales in the Texas market. To assure that its Aurora, Mo., supply plant met the pool plant shipping percentage, the cooperative disassociated 60 producers from the Texas market for that month. As a result, these dairy farmer members were not eligible for producer status the following February–July period. The cooperative's witness, however, did not reveal for the record whether the milk of these 60 producers was needed for class I in Texas during the period when they were not eligible for producer status.

The cooperative association that represents the majority of the producers on the Texas market proposed that the "dairy farmer for other markets" provision be deleted from the order in its entirety. Its witness claimed that this provision:

1. It is not necessary to insure the integrity of the Texas order;
2. Is not conducive to the orderly marketing of milk;
3. Does not permit the flexibility needed in balancing milk supplies with the demands of handlers;
4. Makes it necessary to associate milk with the Texas market in excess of handlers' fluid requirements to insure that handlers have adequate milk supplies at all times;
5. Results in inequity between its members and other producers who do not perform the service of balancing the supply with market demand;
6. Results in producers under other Federal orders maintaining some of the reserve milk supplies for the Texas market; and
7. Prevents pooling the milk of producers in February through July who demonstrate, under reasonable pooling standards, an association with the Texas market during the fall months when their milk is needed.

The witness for the cooperative association testified further that the provision has caused the cooperative to market its members' milk on the Texas market in an uneconomical manner in order to assure that the dairy farmers maintain their producer status at all times during the months of September through November. The witness cited several examples where the weekend reserve milk supplies associated with certain Texas distributing plants were hauled long distances during the months of September through November in order to maintain the producer status of its members. He argued that the milk could have been delivered more conveniently and economically to nearby distribut-

ing plants regulated under another order.

Two cooperative associations and a handler on behalf of the nonmember producers supplying his plants opposed any change in the "dairy farmer for other markets" provision. Opponents stressed that any relaxation in the application of this provision would result in the addition of milk supplies to the market with a corresponding reduction in the blend price. One opponent expressed particular concern that any relaxation of this provision would allow the major cooperative association in the market to add to the Texas market the reserve milk supplies associated with its Class I sales in other markets in which this cooperative is the sole supplier.

The "dairy farmer for other markets" provision should be retained in the order but with some allowance for the limited shifting of supplies to other markets. Current marketing conditions do not warrant the deletion of this provision from the order.

The provision in question was included in the order to prevent cooperative associations and pool plant operators from pooling on the Texas market during the months of Feruary through July, when milk supplies are more than adequate, milk that could be reasonably considered as a reserve supply for another market. In the Assistant Secretary's May 2, 1975, decision (of which official notice was taken at the hearing) incorporating this provision in the Texas order, the following conclusions were set forth:

"If a handler causes the milk of a dairy farmer to be moved to another market as other than producer milk during the months when supplies are in greatest demand, producers regularly supplying the Texas market should not have the burden of sharing their pool proceeds with such other dairy farmers during the flush production months when the handler finds their milk to be surplus to the needs of the other market. A handler associating a dairy farmer with another market during the short-production season should not be able to have the dairy farmer qualify as a producer on the Texas market in other months when supplies are much more plentiful relative to demand. Permitting a handler to shift dairy farmers back and forth between markets in this manner would take supplies of milk away from the Texas market at a time when they are needed and then would reassociate such supplies at a time when they are not needed. This procedure would not be conducive to the orderly marketing of milk of producers regularly supplying the Texas market."

This record indicates that there continues to be both an opportunity and an incentive for the major cooperative in the market to pool on the Texas market milk that should be considered as a reserve supply for other markets.

In this regard, the major cooperative operates six plants that process the reserve milk supplies that are associated with over two-thirds of the fluid milk requirements of regulated handlers in 11 Southwestern Federal order markets. Three of the six plants are pool plants under the Texas order. Two of the plants are located in Texas—at Muenster and Sulphur Springs—while the third plant is located at Hillsboro, Kans. These three plants are manufacturing outlets not only for the Texas market but for other nearby markets as well. Of the remaining three plants, one is located at El Paso, Tex., and is pooled under the Rio Grande Valley order. The other two plants are located at Oklahoma City and Tulsa, Okla., and are pooled under the Oklahoma metropolitan order. Thus, it is evident that the cooperative has the potential to pool the reserve supplies of 8 of the 11 markets on the Texas, the Rio Grande Valley, or the Oklahoma metropolitan markets.

A witness for this cooperative testified that reserve milk associated with the cooperative's fluid milk sales in the Texas Panhandle market is delivered sometimes to its Texas order plant at Muenster for manufacturing. Thus, if the "dairy farmer for other markets" provision were deleted from the order, the cooperative could receive this milk at Muenster as a receipt of producer milk under the Texas order. Under this arrangement, the burden of bearing the reserve milk supplies for the Texas Panhandle market could be shifted from the Texas Panhandle market, which is supplied almost entirely by this cooperative, to producers supplying the Texas market. The shifting of the burden of carrying such reserve supplies to nonmembers of the cooperative is possible because the Texas market is supplied not only by this cooperative but by a substantial number of other producers as well. Thus, by receiving the milk at Muenster as producer milk under the Texas order, the Texas order producers who are not members of the major cooperative would be sharing the burden of the reserve milk supplies of the Texas Panhandle market that more appropriately should be borne by the producers supplying that market.

Although this record does not contain detailed information concerning the operations of the cooperative association's pool supply plant at Hillsboro, Kans., the cooperative's witness did state that milk associated with the Hillsboro plant is delivered to other orders as well as to Texas. The record does reveal that during the months of February through July 1977 nearly 55 million pounds of milk received at the Hillsboro plant for manufacture were ineligible to be producer milk under the Texas order. During the months of February through May 1978 nearly 24 million pounds of milk received at the Hillsboro plant represented receipts of dairy farmers for other markets. Presumably, some of this milk constituted the reserve supplies associated with the cooperative's class I sales to other nearby markets. Because several of these markets (i.e., Fort Smith, Ark.; central Arkansas; and Memphis, Tenn.) are supplied almost exclusively by this cooperative and the cooperative does not have any manufacturing facilities pooled on these markets, there would be an incentive in the absence of the "dairy farmer for other markets" provision to pool the reserve supplies of these markets at the Hillsboro plant as producer milk under the Texas order. This would result in Texas producers who are not members of this cooperative association sharing the burden of the reserve milk supplies of these three markets.

It was for similar reasons that the Assistant Secretary concluded in his May 2, 1975, decision that the "dairy farmer for other markets" provision was needed in the Texas order.

Although there is a continuing need for the "dairy farmer for other markets" provision in the Texas order, some relaxation of the current provision is warranted. This provision has caused some dairy farmers to lose their producer status during the months of February through July even though their milk had been delivered to a substantial extent to the Texas market for fluid use during the prior fall months.

Cooperative associations supply Texas pool plants with process and package fluid milk products 5 days per week. Consequently, the cooperatives must dispose of the remaining 2 days' milk production each week to other outlets. Unless a cooperative operates a manufacturing facility it must find other outlets to handle this weekly excess milk. In some instances, it is difficult for a cooperative to pool its reserve supplies on the Texas market due to the limited manufacturing outlets available to a cooperative that does not operate a manufacturing plant. Prior to October 1977, the proponent cooperative pooled some of its excess milk as producer milk on the Texas market by delivering its member milk to a manufacturing plant in Sulphur Springs, Tex. That outlet ceased operations in October 1977. The cooperative was unable to find outlets for this milk in Texas and instead found fluid milk plants in Louisiana and Mississippi that needed the milk. These plants were distributing

plants regulated under the Greater Louisiana (Order No. 96) or New Orleans-Mississippi (Order No. 94) Federal milk orders. Because Federal orders do not permit interorder diversions of producer milk for class I uses, the milk the cooperative diverted to these two markets became producer milk under the respective order. During the 3-month period of September through November 1977, the cooperative delivered 9 percent of the milk production of 138 producer-members to distributing plants regulated under the Greater Lousisiana order and 6.8 percent of New Orleans-Mississippi order plants. The remaining 84.2 percent of the milk was pooled under the Texas order.

These 138 dairy farmers, thus, were precluded from having their milk pooled under the Texas order during the months of February through June 1978 (the provision was suspended for the month of July) because of the application of the "dairy farmer for other markets" provision. Although the cooperative association had a fluid outlet in Texas for most of the milk of these dairy farmers during the February-July period, this provision forced it to pool this milk on the Greater Louisiana and New Orleans-Mississippi markets during February through June 1978.

Beginning in March, the cooperative association pooled some of the milk of the 138 members by renting a receiving station which it pooled as a supply plant on the Greater Louisiana market. The cooperative transferred the milk from its supply plant to the fluid outlet in Texas as "other order" milk. Through this procedure it was able to pool most of the milk of its members under a Federal order and, thus, derive the benefits of regulations. At the same time, the cooperative was able to supply its fluid outlet in the Texas market. The additional cost to the cooperative to market its milk in such manner was approximately $200,000 per month. Such additional cost was computed on the basis of the cooperative delivering its milk directly to the Texas pool distributing plant as producer milk as compared to shipping the milk through the supply plant.

It is also evident that since 85 percent of the milk of these 138 dairy farmers was pooled on the Texas market during the months of September through November 1977, the application of the current provision forced some of the reserve supplies associated with fluid milk sales in Texas in the months of February through June 1978 to be carried on other markets.

Another example of the restrictiveness of the provision concerns an instance in the fall of 1977 when two or three Texas dairy farmers had their milk pumped into a tank truck with a load of milk going to the Greater Louisiana market. As a consequence, these Texas dairy farmers were not eligible for producer status under the Texas order for the 5-month period of February through June 1978, even though there was a fluid outlet for their milk in Texas during these 5 months.

Counsel for a cooperative association in the Texas market that opposed any change in the "dairy farmer for other markets" provision stated in his posthearing brief that it is not necessary to disassociate large numbers of producers from the Texas order when making limited sales to a plant under another order. Also, he held that proponent cooperative could have avoided any significant problem by proper management of its sales.

Proponent cooperative was not faced with furnishing a daily supply for a handler in another market but, rather, was attempting to market the milk of a large number of producers which was surplus to the fluid milk requirements of Texas handlers. Hence, it was not able to disassociate only a few producers from the Texas market for an extended period of time as suggested in the proposed findings by counsel.

The record evidence indicates also that the current provision has caused uneconomical and unnecessary expenses in marketing the milk of producers to assure that such milk remains pooled each day during the months of September through November. The record reveals that cooperative associations have been forced to haul the milk of its members that is in excess of fluid needs several hundred miles at a substantial cost per hundredweight in order to assure that the milk remains pooled on the Texas market each day during the months of September through November. The extra costs associated with handling and hauling such milk ranged from 25 cents to 76 cents per hundredweight. The modification of the "dairy farmer for other markets" provision as proposed herein will eliminate to a large extent the costs associated with the extra handling necessitated by the current provision.

Counsel for the aforementioned opposing cooperative association stated in his brief that the diversion and balancing plant provisions of the order provide ample flexibility to keep producers pooled under the Texas order. Admittedly, these provisions do allow some flexibility in keeping producers pooled. However, the "dairy farmer for other markets" provision has resulted in uneconomic movements of milk simply for the purpose of keeping producers pooled on the Texas market each day during the months of September through November. It is not in the interest of producers to require them to bear the cost of transporting reserve milk additional distances merely to retain producer milk status for such milk.

A further reason for modifying the "dairy farmer for other markets" provision is to prevent the reserve milk supplies associated with the Texas market from being attached to other nearby order markets during the February-July period. The record indicates that 691 dairy farmers who delivered milk to Texas pool plants during September-November 1977 were ineligible for producer status under the Texas order during the months of February through June 1978. To the extent that the milk of these 691 dairy farmers was needed in Texas for fluid use during the September-November period of 1977, the current provision forced the reserve supplies associated with those deliveries to be pooled on other markets during the February-June period of 1978. It is recognized, on the other hand, that if all the milk produced by these dairy farmers during the months of February through July had been allowed to be pooled on the Texas market, then the reserve supply associated with their sales to other markets in September-November also would have been pooled on Texas rather than on the other markets. The provisions adopted herein are designed to assure that only those dairy farmers who are primarily associated with the Texas market during September-November may pool their entire production during February-July on the Texas market. This will retain the primary intent of the "dairy farmer for other markets" provision.

It is concluded that the proportion of a dairy farmer's milk that may be associated with another market should be established at a level slightly greater than was proposed by the proponent cooperative. The cooperative had suggested a percentage based on the proportion of the week that falls on a weekend. The selection of one-third as the appropriate proportion is based on this concept but recongized that some months contain five weekends. It is noted that the accounting for receipts and utilization of milk under the order is on a monthly basis.

The change adopted herein should permit cooperative associations and pool plant operators to utilize their weekend reserve milk supplies in the most economical manner available to them without jeopardizing their ability to qualify their dairy farmers as producers under the Texas order during the following months of February through July. The revised "dairy farmer for other markets" provision, however, would continue to inhibit cooperative associations and pool plant operators from pooling on the Texas

market during the months of February through July those dairy farmers who primarily had been supplying another market during the previous months of September through November.

Counsel for an opposing cooperative submitted a proposed finding that the reserve supplies are more than adequate to meet the needs of the Texas market without adding unneeded milk. The revisions adopted herein would allow some additional milk to be pooled under the Texas order during the months of February through July. It is appropriate that such supplies be pooled in the Texas market because the producers associated with such supplies will have delivered at least two-thirds of their milk production during September-November as producer milk under the Texas order. Under such circumstances, the additional milk supplies should be considered as reserve milk supplies for this market. The provision adopted herein will deter the shifting of dairy farmers to the Texas market during the heavy production months in those instances where such dairy farmers primarily were supplying another market during the previous short-production months.

The counsel for the opposing cooperative also claimed that the major cooperative in the market has historically engaged in predatory practices in the Texas market and asked that the Department make a finding to the effect. The record does not support such a finding.

2. *Diversions to nonpool plants.* (a) The producer milk definition should be revised to specify that during each of the months of September through January at least 15 percent of a dairy farmer's total deliveries of producer milk must be physically received at pool plants in order for any milk of such person to be eligible for diversion as producer milk to nonpool plants. If less than 15 percent of a producer's milk is received at pool plants, then only that part of his milk physicaly received at pool plants should be considered producer milk eligible for pooling. On the basis of every-other-day delivery, three deliveries by a producer normally would assure that such producer's milk is eligible for diversion during the months of September through January. If deliveries are made each day, a producer normally would need to make only five deliveries during the month to meet the 15-percent requirement.

Presently, the order provides that milk of a producer must be received at a pool plant before it is eligible to be diverted as producer milk. After the producer has established an association with the market via the one delivery, his milk may be diverted to nonpool plants continuously thereafter. A pool plant operator may divert to nonpool plants a quantity of milk equal to one-third of the producer milk that the operator received at his pool plants. In the case of a cooperative association, a quantity of milk equal to one-third of the producer milk it causes to be delivered to pool plants other than its pool "balancing plant" may be diverted to nonpool plants.

The cooperative association that represents a majority of the producers supplying the Texas market proposed that at least 15 percent of a producer's deliveries of milk each month be received at a pool plant in order for any milk of such producer to be eligible for diversion to a nonpool plant as producer milk. The cooperative's representative testified that such a requirement is necessary to assure that producer milk pooled on the Texas market is actually available for fluid use. He testified that a cooperative association with producers located in southwest Missouri delivered milk from such producers on a limited basis to a Texas pool plant and thereafter diverted the milk of these producers continuously to a manufacturing plant in Missouri. Such milk, he claimed, is not made available to supply the fluid requirements of Texas pool distributing plants under the current diversion provisions.

The cooperative association with the Missouri producers in question opposed this proposal because it would necessitate the delivery by the cooperative of milk of each of its producer-members in southeast Missouri to pool plants in Texas every month. This, the cooperative's witness claimed, would be an uneconomic movement of milk since the milk is not needed each month by Texas pool plants. In its posthearing brief, the cooperative association stated that if it is concluded that some minimum delivery to pool plants is necessary, such deliveries should not exceed 1 day per month during each of the months of September through November.

In its brief, another cooperative association in the Texas market also opposed the proposed 15-percent monthly delivery requirement because it would create inefficient movements of milk. Another cooperative with Missouri producers on the Texas market also opposed the 15-percent delivery requirement on the basis that it would require the cooperative to make uneconomic movements of milk to pool plants in Texas.

It is essential that milk associated with the Texas market be made available for fluid use. The record evidence indicates that the class I needs of handlers cannot be met during the months of seasonally short supply unless the milk of each producer is delivered to a pool plant at least once a week. It is evident from the 75- to 80-percent class I utilization of producer milk in the Texas market during the months of seasonally short supply that pool plants have been bottling each week on the average more than 5 days, production of each producer (the bottling of five-sevenths of the weekly milk production of producers would result in a class I utilization of 72 percent). In view of the present bottling schedule of handlers in the market (5 days per week or less), it can be seen that each producer would need to deliver more than 5 days' production to pool plants each week to meet the class I needs of handlers if the milk of all producers were delivered directly from the farm to pool distributing plants and utilized upon delivery. Because handlers do have some storage facilities available to them, they are in a position to utilize more than 5 days' production of certain producers. Thus, to supply the fluid requirements of handlers, it is not necessary to require that each producer deliver at least 5 days' production each week. It is apparent, also, that the adoption of a cooperative association's proposal requiring that the milk of a producer be delivered only once during each of the months of September through November would not furnish an adequate supply of milk to meet the fluid milk requirements of handlers. It is concluded, therefore, that the more stringent proposal requiring that at least 15 percent of each producer's milk be delivered to pool plants should be adopted. However, the provisions should apply only during the months of September through January. During these months, milk supplies are the shortest and the need for producer milk at pool plants is the greatest. As further evidence of the need for producer milk at pool plants during such period, it is noted that the months of September-January are the months in which pool supply plants must make shipments to pool distributing plants.

It is not necessary to require minimum deliveries of producer milk to pool plants during the remaining 7 months of the year. They are months of seasonally heavy milk production and demand tends to drop during the summer with the closing of schools. Requiring deliveries to pool plants during such months would cause unnecessary and uneconomical movements of milk merely to assure the pooling of producer milk that is diverted to nonpool plants.

(b) The order should be revised to allow a cooperative association to divert producer milk to nonpool plants from its pool "balancing" plant (a pool plant meeting the requirements of § 1126.7(e)). A provision that currently

excludes receipts of producer milk at a cooperative association's balancing plant in determining the total quantity of producer milk that the cooperative association may divert to nonpool plants would not be affected by this revision.

Presently, the order does not allow a cooperative association to divert producer milk from its balancing plant.

The cooperative association that operates the only balancing plants pooled under the order (at Muenster and Sulphur Springs, Tex.) proposed the change described above. Proponent's witness testified that the present provision has caused it to incur additional transportation costs to maintain producer milk status of its producers delivering to these balancing plants when their milk must be diverted to nonpool plants. On certain days the cooperative's balancing plants are filled to capacity, he stated, and the cooperative has no alternative but to divert milk from these balancing plants to nonpool plants. In such situation the cooperative attempts to receive the milk of these producers at a pool distributing plant and then divert the milk from the distributing plant. When this is not feasible, the cooperative diverts the milk directly from the balancing plants. As a consequence, the diverted milk loses producer milk status. During 1977 more than 2.7 million pounds of diverted milk from the cooperative's balancing plants were excluded from the pool.

A handler on behalf of nonmember producers delivering to his plant and two cooperative associations opposed the proposal. Opponents stated that the proposal would allow proponent cooperative to increase the quantity of milk associated with the market.

It is concluded that a cooperative association should be permitted to divert producer milk from its pool balancing plant to nonpool plants. The proposed change is needed to give a cooperative association additional flexibility in disposing of its reserve milk supplies. Contrary to the position taken by opponents, the change would not enable the cooperative to attach any additional supplies of milk to the order. The order would continue to base the quantity of producer milk that a cooperative could divert to nonpool plants on the deliveries of producer milk to pool plants other than its balancing plants. Thus, this revision would have virtually no impact upon the other producers who are supplying the market and should be adopted.

Rulings on Proposed Findings and Conclusions

Briefs and proposed findings and conclusions were filed on behalf of certain interested parties. These briefs, proposed findings and conclusions and the evidence in the record were considered in making the findings and conclusions set forth above. To the extent that the suggested findings and conclusions filed by interested parties are inconsistent with the findings and conclusions set forth herein, the requests to make such findings or reach such conclusions are denied for the reasons previously stated in this decision.

An objection was raised at the hearing and reiterated in his brief by counsel for a cooperative association that the administrative law judge erred in excluding the admission of three internal memorandum of the U.S. Department of Agriculture. The administrative law judge ruled that these documents should not be admitted as exhibits since they lacked relevancy and materiality and that the preparers of the memorandums were not available for cross-examination the hearing. His ruling has been reviewed in light of the arguments presented and is hereby affirmed.

General Findings

The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of the aforesaid order and of the previously issued amendments thereto; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) The tentative market agreement and the order, as hereby proposed to be amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(b) The parity prices of milk as determined pursuant to section 2 of the Act are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the marketing area, and the minimum prices specified in the tentative marketing agreement and the order, as hereby proposed to be amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(c) The tentative marketing agreement and the order, as hereby proposed to be amended, will regulate the handling of milk in the same manner as, and will be applicable only to persons in the respective classes of industrial and commercial activity specified in, a marketing agreement upon which a hearing has been held.

Recommended Marketing Agreement and Order Amending the Order

The recommended marketing agreement is not included in this decision because the regulatory provisions thereof would be the same as those contained in the order, as hereby proposed to be amended. The following order amending the order, as amended, regulating the handling of milk in the Texas marketing area is recommended as the detailed and appropriate means by which the foregoing conclusions may be carried our:

1. Section 1126.12(b)(5) is revised as follows:

§ 1126.12 Producer.

* * * * *

(b) * * *

(5) Any person with respect to milk produced by him during the months of February through July that is caused to be delivered to a pool plant by a cooperative association or a pool plant operator if during the immediately preceding period of September through November more than one-third of the milk from the same farm was caused by such cooperative association or pool plant operator to be delivered to plants as other than producer milk (except milk that is not producer milk as a result of a temporary loss of grade A approval or the application of § 1126.13(e) (4) and (5)), unless such pool plant was a nonpool plant during any of such immediately preceding months.

2. In § 1126.13, the introductory text of paragraph (e) immediately preceding subparagraph (1), and paragraph (e)(1) are revised as follows:

§ 1126.13 Producer milk.

* * * * *

(e) Diverted from a pool plant to a nonpool plant that is not a producer-handler plant for the account of the handler operating such pool plant or a handler described in § 1126.9(b), subject to the following conditions:

(1) Milk of a dairy farmer shall not be eligible for diversion during any month unless milk of such dairy farmer was physically received as producer milk at a pool plant and the dairy farmer has continuously retained producer status since that time and further, during each of the months of September through January not less than 15 percent of the milk of such dairy farmer is physically received as producer milk at a pool plant. If a dairy farmer loses his producer status under the order (except as a result of a temporary loss of grade A approval), his milk shall not be eligible for diversion until milk of such dairy farmer has been physically re-

ceived as producer milk at a pool plant;

* * * * *

(An impact analysis relative to this decision is available from the Agricultural Marketing Service.)

Signed at Washington, D.C., on August 4, 1978.

WILLIAM T. MANLEY,
Deputy Administrator,
Marketing Program Operations.

[FR Doc. 78-22143 Filed 8-7-8:45 am]

[3410-05]

Agricultural Stabilization and Conservation Service

[7 CFR Part 722]

1979 EXTRA LONG STAPLE COTTON PROGRAM

Proposed Determinations Regarding National Marketing Quota, National Acreage Allotment, and Other Related Operating Provisions for 1979

AGENCY: Agricultural Stabilization and Conservation Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Secretary of Agriculture proposes to make the following determinations with respect to the 1979 crop of extra long staple cotton (referred to as "ELS cotton"):

(1) National marketing quota.

(2) National acreage allotment.

(3) Apportionment of the national acreage allotment to States and counties.

(4) Date or period for conducting the national marketing quota referendum.

The above determinations are required to be made by the Secretary in accordance with provisions of the Agricultural Adjustment Act of 1938, as amended. The effect of these determinations is to determine the national marketing quota and national acreage allotment, apportionment of the national allotment to States and counties and set the date or period for the referendum in which farmers vote on marketing quotas.

This notice invites written comments on these proposed determinations.

DATES: Comments must be received on or before October 10, 1978.

ADDRESSES: Mail comments to Acting Director, Production Adjustment Division, ASCS, U.S. Department of Agriculture, Room 3630 South Building, P.O. Box 2415, Washington, D.C. 20013. Comments will be made available for public inspection at the office of the Acting Director during regular business hours, 8:15 to 4:45 p.m.

FOR FURTHER INFORMATION CONTACT:

Charles V. Cunningham (ASCS), 202-447-7873.

SUPPLEMENTARY INFORMATION: The following determinations with respect to the 1979 crop of ELS cotton are to be made pursuant to the Agricultural Adjustment Act of 1938, as amended (52 Stat. 31, 7 U.S.C. 1281) (hereafter referred to as the "act"):

(a) *National marketing quota.* Section 347(b)(1) of the act requires the Secretary to proclaim the amount of the national marketing quota for the 1979 crop of ELS cotton by October 15, 1978. Such marketing quota shall be the number of standard bales of ELS cotton equal to the sum of the estimated domestic consumption and estimated exports, less estimated imports, for the 1979-80 marketing year, which begins August 1, 1979, plus such additional number of bales, if any, as the Secretary determines necessary to assure adequate working stocks in trade channels until ELS cotton from the 1980 crop becomes readily available without resort to Commodity Credit Corporation stocks. The Secretary may reduce the quota so determined for the purpose of reducing surplus stocks, but not below the minimum quota of 82,481 standard bales prescribed under section 347 (b) (2) of the act.

(b) *National acreage allotment.* Pursuant to section 34(a), the national acreage allotment for the 1979 crop of ELS cotton shall be that acreage determined by multiplying the national marketing quota in bales by 480 pounds (net weight of a standard bale) and dividing the result by the national average yield per acre of ELS cotton for the 4 calendar years 1974, 1975, 1976, and 1977.

If favorable worldwide growing conditions exist throughout the 1978-1979 marketing year the carryover of ELS cotton as of August 1, 1979, the beginning of the 1979-80 marketing year, could be around 61,000 bales. If poor weather should prevail during the 1978-89 season, carryout on August 1, 1979, could fall to as low as 36,000 bales. A carryover of about 40,000 to 50,000 bales is generally considered desirable.

Based on these carryover projections, and tentative projections of domestic use, exports, and imports for the 1979-80 season, we estimate that the 1979 national marketing quota should be around 105,000 to 140,000 bales and the national allotment around 88,000 to 115,000 acres in order to maintain the desirable carryover level at the end of the 1979-80 marketing year.

(c) *Apportionment of the national acreage allotment to States and counties.* Sections 344 (b) and (e) provide that the national acreage allotment for the 1979 crop of ELS cotton shall be apportioned to States and counties on the basis of the acreage planted to ELS cotton, (including acreage regarded as having been planted) during the 5 calendar years, 1973, 1974, 1975, 1976, and 1977, adjusted for abnormal weather conditions during such period. Section 344(e) further provides that the State committee may reserve not to exceed 10 percent of its State allotment to adjust county allotments for trends in acreage, for counties adversely affected by abnormal conditions affecting plantings, or for small or new farms, or to correct inequities in farm allotments and to prevent hardship.

(d) *Date or period for conducting the national marketing quota referendum.* Section 343 requires the Secretary to conduct a referendum by secret ballot of the farmers engaged in the production of ELS cotton during 1978, by December 15, 1978, to determine whether such farmers are in favor of or opposed to the quota. If more than one-third of the farmers voting in the referendum oppose the national marketing quota, such quota shall become ineffective upon proclamation of the results of the referendum. Section 343 further requires the Secretary to proclaim the results of the referendum within 30 days after the date of such referendum.

Pursuant to section 343, the Secretary proposes that said referendum be held during the period December 4-8, 1978, inclusive.

Signed at Washington, D.C., on August 2, 1978.

RAY FITZGERALD,
Administration, Agricultural Stabilization and Conservation and Conservation Service.

[FR Doc. 78-21935 Filed 8-7-78; 8:45 am]

[3410-02]

Agricultural Marketing Service

[7 CFR Part 993]

HANDLING OF DRIED PRUNES PRODUCED IN CALIFORNIA

Proposed Amendment of Administrative Rules and Regulations

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposal, recommended by the Prune Administrative Committee, would amend § 993.149(c)(2) of the rules and regulations which currently requires the handler to have the inspection service issue a signed inspection certificate. It would eliminate the requirement that an inspector sign each certificate. All

of the computations on these certificates are made by the inspection service's computer firm, and requiring an inspector to sign each certificate serves no useful purpose.

DATES: Written comments on this proposal must be received by August 15, 1978.

ADDRESSES: Written comments should be submitted in duplicate to the Hearing Clerk, Room 1077, South Building, U.S. Department of Agriculture, Washington, D.C. 20250. All written submissions will be made available for public inspection at the office of the hearing clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT:

Charles R. Brader, 202-447-6393.

SUPPLEMENTARY INFORMATION: This proposal would amend paragraph (c)(2) of section 993.149 of Subpart — Administrative Rules and Regulations (7 CFR 993.101-993.174). The subpart is operative pursuant to the marketing agreement, as amended, and Order No. 993, as amended (7 CFR, part 993), regulating the handling of dried prunes produced in California. The amended marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674).

The proposal was recommended by the Prune Administrative Committee and would remove the requirement that the inspector sign each inspection certificate issued by the inspection service on each lot of prunes received by a handler from a grower or dehydrator. The D.F.A. of California is the inspection service designated to perform inspections under the order. All of the computations on these inspection certificates are made by the inspection service's computer firm, and then checked by the inspection service for obvious errors. Since these certificates are computerized print outs, the inspector's signature is unnecessary to attest to the certificate's accuracy.

The proposal is as follows:

§ 993.149 [Amended]

1. In the first sentence in § 993.149(c)(2), the word "signed" is deleted.

Dated: August 3, 1978.

CHARLES R. BRADER,
Deputy Director,
Fruit and Vegetable Division.

[FR Doc. 78-22102 Filed 8-7-78; 8:45 am]

[6750-01]

FEDERAL TRADE COMMISSION

[16 CFR Part 13]

[File No. 771 0034]

THE ADVERTISING CHECKING BUREAU, INC.

Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Provisional consent agreement.

SUMMARY: In settlement of alleged violations of Federal law prohibiting unfair acts and practices and unfair methods of competition, this provisionally accepted consent agreement, among other things, would require a New York City administrator and auditor of cooperative advertising programs to cease designing or implementing cooperative advertising programs for their clients which limit or restrict the rights of dealers to obtain cooperative advertising allowances for merchandise they have advertised or sold at other than regular or suggested retail prices.

DATE: Comments must be received on or before October 5, 1978.

ADDRESS: Comments should be directed to Office of the Secretary, Federal Trade Commission, 6th Street and Pennsylvania Avenue NW., Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT:

William A. Arbitman, Regional Director, Federal Trade Commission, 450 Golden Gate Avenue, San Francisco, Calif. 94102, 415-556-1270.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's rules of practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist and an explanation thereof, having been filed with and provisionally accepted by the Commission, has been placed on the public record, together with material submitted to the Commission that is not exempt from public disclosure under the Freedom of Information Act, for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(14) of the Commission's rules of practice (16 CFR 4.9(b)(4)).

[File No. 771 0034]

IN THE MATTER OF THE ADVERTISING CHECKING BUREAU, INC., A CORPORATION

AGREEMENT CONTAINING CONSENT ORDER TO CEASE AND DESIST

The Federal Trade Commission having initiated an investigation of certain acts and practices of the Advertising Checking Bureau, Inc., a corporation, and it now appearing that the Advertising Checking Bureau, Inc., a corporation, hereinafter sometimes referred to as proposed respondent, is willing to enter into an agreement containing an order to cease and desist from the use of the acts and practices being investigated,

It is hereby agreed by and between the Advertising Checking Bureau, Inc., by its duly authorized officer and its attorney, and counsel for the Federal Trade Commission that:

1. Proposed respondent the Advertising Checking Bureau, Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of New York, with its office and principal place of business located at 353 Park Avenue South, in the city of New York, State of New York. Proposed respondent is the parent corporation of four corporate subsidiaries which respectively maintain offices in Chicago, Ill.; San Francisco, Calif.; Memphis, Tenn.; and Columbus, Ohio.

2. Proposed respondent admits all of the jurisdictional facts set forth in the draft complaint here attached.

3. Proposed respondent waives:

(a) Any further procedural steps;

(b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and

(c) All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

4. This agreement shall not become a party of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission it, together with the draft of complaint contemplated thereby and related material pursuant to rule 2.34 will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft of complaint here attached.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's rules, the Commission may, without further notice to proposed respondent: (1) Issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to cease and desist in disposition of the proceeding, and (2) make information public in respect thereto. When so entered, the order

to cease and desist shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Mailing of the complaint and decision containing the agreed-to order to proposed respondent's address as stated in this agreement shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the proposed complaint and order contemplated hereby. It understands that once the order has been issued, it will be required to file one or more compliance reports showing that it has fully complied with the order, and that it may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

ORDER

For the purposes of this order, the following definitions shall apply:

"Client" is defined as any person, partnership, corporation, or firm which has retained the Advertising Checking Bureau, Inc., to conduct, administer, or audit, or to assist in the design or implementation of any cooperative advertising program or portion thereof.

"Dealer" is defined as any person, partnership, corporation, or firm which is eligible to participate in any client's cooperative advertising program.

I

It is ordered, That respondent, the Advertising Checking Bureau, Inc., a corporation, its successors, and assigns, and respondent's officers, agents, representatives, and employees, directly or indirectly, or through any corporation, subsidiary, division, or other device, in connection with the designing, implementing, conducting, administering, or auditing of any cooperative advertising program, or portion thereof, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, shall cease and desist from:

Designing, implementing, conducting, administering, or auditing any plan, program, or scheme, in whole or in part, in such manner as to restrict, condition, or limit the right of any dealer to obtain cooperative advertising credits or allowances because of any of the following:

a. Selling or advertising any product at other than the dealer's regular selling price.

b. Selling or advertising any product at a sale price, at a discount price, at a promotional price, at a reduced price, at an off-price, or at a markdown.

c. Selling or advertising any product at less than the suggested retail price, at less than the preticketed price, or at less than any minimum resale price.

d. Selling or advertising any product using comparative prices.

II

Any cooperative advertising plan or program which limits or restricts any dealer from obtaining cooperative advertising credits or allowances for the advertising of closeouts, irregulars, or seconds shall not be deemed to violate this order.

III

It is further ordered, That respondent shall:

1. Within thirty (30) days after service of this order, mail under separate cover a copy of this order and complaint to every client whose cooperative advertising program is designed, implemented, conducted, administered, or audited by respondent in such manner as to restrict, condition, or limit the right of any dealer to obtain cooperative advertising credits or allowances because of any of the restrictions or limitations contained in paragraph I hereinabove. An affidavit of mailing shall be sworn to by an official of respondent verifying that said mailing was performed.

2. Within sixty (60) days after service of this order, distribute a copy of this order to each of its operating divisions and subsidiaries and to all officers, sales personnel, and auditing personnel, and secure from each such entity or person a signed statement acknowledging receipt of said order.

IV

It is further ordered, That respondent notify the Commission at least thirty (30) days prior to any proposed changes in the corporate respondent such as dissolution, assignments or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation which may affect compliance obligations arising out of the order.

V

It is further ordered, That respondent shall, within sixty (60) days after service upon it of this order, file with the Commission a report in writing, setting forth in detail the manner and form in which it has complied with this order.

ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission has provisionally accepted an agreement to a proposed consent order from the Advertising Checking Bureau, Inc. ("ACB").

The proposed consent order, and material submitted by ACB to the Commission that is reasonably related to the merits of the order and is not exempt from disclosure under the Freedom of Information Act, have been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

The complaint in this matter alleges that:

(1) ACB administers or audits cooperative advertising programs for over 400 prominent manufacturers. It has also assisted in the design or implementation of such programs.

(2) Some of these programs limit or restrict the rights of dealers to obtain cooperative advertising allowances when they sell or advertise merchandise:

a. At other than the dealers' regular selling price;

b. At a sale price, at a discount price, at a promotional price, at a reduced price, at an off-price, or at a markdown;

c. At less than the suggested retail price, at less than the preticketed price, or at less than any minimum resale price; or

d. Using a price comparison.

(3) Programs containing any of the restrictions described in paragraph 2 hereinabove have the capacity, tendency, and effect of illegally influencing the resale prices of dealers, and of suppressing competition between or among dealers selling a manufacturer's products.

The proposed order prohibits ACB from:

Designing, implementing, conducting, administering, or auditing any plan, program, or scheme, in whole or in part in such manner as to restrict, condition, or limit the right of any dealer to obtain cooperative advertising credits for allowances because of any of the following:

a. Selling or advertising any product at other than the dealer's regular selling price.

b. Selling or advertising any product at a sale price, at a discount price, at a promotional price, at a reduced price, at an off-price, or at a markdown.

c. Selling or advertising any product at least than the suggested retail price, at less than the preticketed price, or at less than any minimum resale price.

d. Selling or advertising any product using comparative prices.

The proposed order does not prohibit ACB from administering any program which restricts dealers from obtaining cooperative advertising allowances for the advertising of closeouts, irregulars, or seconds.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

CAROL M. THOMAS,
Secretary.

[FR Doc. 78-21950 Filed 8-7-78; 8:45 am]

[1505-01]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 16, 10, and 812]

[Docket No. 76-N-0324]

MEDICAL DEVICES

Procedures for Investigational Device Exemptions

Corrections

In FR Doc. 78-12794 appearing at page 20726 in the issue for Friday, May 12, 1978, the following corrections should be made.

1. In the first line of the first full paragraph in the third column on page 20728, the section number should read, "§ 812.2(b)(6)"

2. In the fourteenth line of the second full paragraph in the middle column on page 20733, the word now reading, "fight" should read, "right".

3. In the eighteenth line of the middle paragraph in the third column on page 20738, "informal" should read, "informed".

4. The sixth line of the first full paragraph in the first column on page 20746 should read, "Stat. 565-574, 578 (21 U.S.C. 331, 351,"

5. The eighth line of paragraph number eight in the third column on page 20752 should read, "practices used in conducting the study"

6. On page 20753 the section heading now reading, "§ 182.35" should read, "§ 812.35"

7. On page 20755 the section heading now reading, "§ 112.43", should read "§ 812.43"

8. The first line of paragraph number four in the first column on page 20755 should read, "A statement as to whether any".

[4110-03]

[21 CFR Part 320]

[Docket No. 78N-0178]

PROCAINAMIDE HYDROCHLORIDE BIOEQUIVALENCE REQUIREMENTS

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This proposal would establish a bioequivalence requirement for procainamide hydrochloride oral drug products used in treatment and control of irregular hearbeat (cardiac arrhythmia). Available data suggests that a bioequivalence problem exists among the various brands of procainamide hydrochloride intended to be used for a comparable therapeutic effect. Under this proposed bioequivalence requirement, different brands of procainamide hydrochloride drug products intended to be used interchangeably in treatment of cardiac arrhythmia would all meet the same standards. Batch-to-batch uniformity of the same drug product by each manufacturer would also be ensured.

DATES: Comments by October 10, 1978. The Director of the Bureau of Drugs proposes that the final regulation based on this proposal be effective September 7, 1978.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

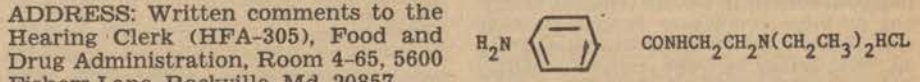
FOR FURTHER INFORMATION CONTACT:

Jerome P. Skelly, Bureau of Drugs (HFD-522), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4750.

SUPPLEMENTARY INFORMATION: Regulations in subpart C of part 320 (21 CFR Part 320), published in the FEDERAL REGISTER of January 7, 1977 (42 FR 1624), set forth procedures for the Commissioner of Food and Drugs, on his own intitiative or in response to a petition from an interested person, to propose and establish a bioequivalence requirement for drug products in the same dosage form that contain identical amounts of the same active drug ingredient and that are intended to be used interchangeably for the same therapeutic effect and for which there is a known or potential bioequivalence problem. This authority to issue, amend, or repeal regulations establishing bioequivalence requirements for drug products for human use is delegated to the Director and Deputy Director of the Bureau of Drugs of the Food and Drug Administration (FDA) by § 5.79 (21 CFR 5.79), which was published in the FEDERAL REGISTER of November 11, 1977 (42 FR 58738). Data available to FDA suggest that there is well-documented evidence of actual and potential bioequivalence differences among the currently marketed brands of oral formulations of procainamide hydrochloride produced by various manufacturers, based on the criteria set forth in § 320.52 (21 CFR 320.52). Therefore, the Director of the Bureau of Drugs, hereafter referred to as "the Director," on his own intitiative tentatively concludes that a bioequivalence requirement involving in vivo testing in humans and in vitro dissolution testing should be established for procainamide hydrochloride. The evidence on which the Director bases his tentative conclusion (Ref. 1) and the proposed bioequivalence requirement are discussed below.

BACKGROUND

Orally administered procainamide hydrochloride, the chemical name of which is *p* - amino - *N*(2 - diethylamino)ethyl) benzamide, is effective in suppressing irregular heartbeat by depressing the excitability and conductivity of both the atrium and the ventricles. The drug is depicted by the following structural formula:



Although some of the orally administered drug is metabolically cleared by the liver (Ref. 2), 60 percent is eliminated through the kidneys, involving, in part, renal tubular secretion (Refs. 3 and 4). Insignificant amounts are excreted in the bile (Refs. 2 and 5). The drug has a half-life of 3 to 4 hours.

EVIDENCE TO ESTABLISH A BIOEQUIVALENCE REQUIREMENT

The following criteria as set forth in § 320.52 were considered by the Director in determining that a bioequivalence requirement should be established:

1. *Evidence that the drug products exhibit a narrow therapeutic ratio, e.g., there is less than a twofold difference in median lethal dose (LD_{50}) and median effective dose (ED_{50}) values, or have less than a twofold difference in the minimum toxic concentrations and minimum effective concentrations in the blood, and safe and effective use of the drug products requires careful dosage titration and patient monitoring (§ 320.52(c)).*

Gey, Levy, Fisher, Pettet, and Bruce (Ref. 6) state that procainamide hydrochloride is effective at a plasma concentration of 4 to 8 micrograms per milliliter (mcg/ml), while Gelbrand and Rosen (Ref. 7) state that the effective range is 3 to 10 mcg/ml. Moe, Gordon, and Abildskov (Ref. 8) state that the drug is partially effective at a plasma concentration of 2 to 4 mcg/ml, usually effective at a concentration of 4 to 8 mcg/ml, and potentially toxic at plasma levels above 8 mcg/ml. Koch-Weser (Refs. 2, 10, and 11) shows that procainamide hydrochloride is usually effective at a plasma concentration of 4 to 8 mcg/ml, although in occasional patients 8 to 16 mcg/ml is more effective. He further states that toxic manifestations are

rare below 12 mcg/ml, common above it, and are the rule above 16 mcg/ml. He cites four patient deaths where the plasma values ranged from 17.6 to 25.2 mcg/ml (Ref. 11). Other observers, however, have reported toxicity in the 4 to 8 mcg/ml range (Ref. 12).

2. *Competent medical determination that a lack of bioequivalence would have a serious adverse effect in the treatment or prevention of a serious disease or condition (§ 320.52(d)).*

Procainamide hydrochloride, employed in the treatment of severe and often life-threatening cardiac arrhythmias, is titrated to the individual patient. Substitution of a poorly bioavailable drug product in the regimen of a patient controlled on a satisfactorily available drug product would result in failure to control life-threatening arrhythmias. On the other hand, a satisfactorily bioavailable drug product, if substituted in the regimen of a patient controlled on a poorly available drug product, would precipitate severe hypotensive responses and perhaps death.

3. *Pharmacokinetic evidence that: a. The degree of absorption of the active drug ingredient, therapeutic moiety, or its precursor is poor, e.g., less than 50 percent, ordinarily in comparison to an intravenous dose, even when it is administered in pure form, e.g., in solution (§ 320.52(f)(2)).*

Data from several studies show that 75 percent of orally administered procainamide hydrochloride is absorbed in most patients (Refs. 2, 9, and 10). However, in a significant portion (25 percent) of the patients studied, less than half of the orally administered form was absorbed (Refs. 2, 10, and 11).

b. *There is rapid metabolism of the therapeutic moiety in the intestinal wall or liver during the process of absorption (first-pass metabolism) so the thereapeutic effect and/or toxicity of such drug product is determined by the rate as well as the degree of absorption (§ 320.52(f)(3)).*

Orally administered procainamide hydrochloride gains access to the body's circulatory system via the liver. Data from several studies (Refs. 9 and 11) show that a significant amount of the drug, 21 percent, is metabolized by the liver during the first passage through the circulatory system. This phenomenon is generally referred to as the first-pass effect.

THE BIOEQUIVALENCE REQUIREMENT

On the basis of the above information, the Director tentatively concludes that the evidence meets one or more of the criteria set forth in § 320.52 and proposes to establish a bioequivalence requirement for single active ingredient oral drug products containing procainamide hydrochloride. The proposed bioequivalence requirement would be applicable to all manufacturers of such drug products and would require each manufacturer, except a manufacturer of a reference material or a manufacturer who has previously conducted in vivo bioavailability/bioequivalence studies fulfilling the requirements of this section, to (1) conduct an in vitro dissolution test comparing its drug product with a specified reference material, and (2) conduct an in vivo bioavailability study comparing the same lot of its drug product with a specified reference material. Under this proposed requirement, the test product would be considered to meet the bioequivalence requirement if (1) the in vitro data show that the dissolution rate for the test drug product is not less than 50 percent in 30 minutes and not less than 80 percent in 60 minutes, and (2) the in vivo data show that the test drug product meets the following conditions:

1. The test drug product and the reference material indicate no more than 20 percent difference in the comparison of measured parameters, e.g., concentration of the active drug ingredient in the plasma, peak plasma levels (Cmax), area under the plasma concentration-time curves (AUC), and time to obtain peak plasma levels (Tmax); and

2. The test product should be at least 75 percent as bioavailable as the administered reference material using the subjects as their own controls, that is, administering both the reference material and the test drug material to each subject.

3. Analytical and statistical techniques used are of sufficient sensitivity to detect those differences in rate and extent of absorption that are not attributable to subject variability.

The Director advises that further in vivo studies may be required where the data submitted in the application differ significantly from data involving valid studies reported in the literature or obtained by the agency using a validated protocol and method.

The Director further proposes that the manufacturer of the drug product selected by FDA as the reference material and the manufacturer of any drug product subject to the requirements of the section proposed below, who has already conducted in vivo tests in humans to demonstrate bioavailability/bioequivalence of its drug product in accordance with the provisions of the proposed section below, would be required, in addition, to conduct an in vitro dissolution test on three consecutive lots/batches of its drug product to demonstrate consistent dissolution performance. If the manufacturer of the reference material has not already conducted in vivo bioavailability/bioequivalence studies fulfilling the requirements of this section, the manufacturer shall conduct an in vivo bioavailability study comparing the reference material with a solution of an equivalent amount of the procainamide hydrochloride contained in the reference material.

Any manufacturer of a drug product subject to this proposed section who has conducted in vivo bioavailability/bioequivalence studies before the effective date of this section may request FDA to evaluate these studies to determine whether (1) the studies now fulfill the requirements under this proposed section or (2) the studies are adequate and conclusive to assure the bioequivalence of the drug product in light of current scientific knowledge and methodology. Each request is required to contain the new drug application number, the established (generic) name of the drug product, the dosage form and strength of the drug product, and the date(s) of submission of the pertinent study information contained in the new drug application.

To obtain data necessary to correlate in vivo data with in vitro data, the Director proposes that the same lot/batch of the test product and one of the three lots/batches of the reference material that were used in the in vitro tests also be used in the in vivo test, unless a manufacturer has conducted in vivo tests in humans to demonstrate bioavailability/bioequivalence before the effective date of the proposed section below.

General guidelines for conducting in vivo testing are set forth in § 320.25 (21 CFR 320.25). Specific guidlines for in vivo testing and for in vitro dissolution testing of procainamide hydrochloride oral drug products are on file in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, and are available on request. The reference material to be used in the in vivo and in vitro tests is specified in the "Guide for In Vivo Bioavailability Studies for Procainamide."

The Director proposes that the results of the required in vitro dissolution test be submitted to FDA on or before 60 days after the effective date of the final regulation and that the results of the required in vivo test be submitted to FDA on or before 180 days after the effective date of the final regulation. The proposed effective date of the final regulation is 30 days after its date of publication in the FEDERAL REGISTER. The Director believes this will be sufficient time for a manufacturer to conduct the required tests, evaluate the data, prepare the necessary reports, and submit them to FDA. The Director advises, however, that in meeting an in vivo bioavailability requirement for some

procainamide hydrochloride oral drug products the agency may require a manufacturer to conduct a pilot study before beginning the tests. The Director may grant an additional extension up to 180 days upon request from the manufacturer to allow sufficient time to conduct the pilot study and submit the data to FDA. In addition, FDA encourages the submission of protocols for conducting in vivo bioavailability studies. If a manufacturer submits a protocol for evaluation by FDA, the Director will grant an extension of time necessary for the initial review of the protocol.

The Director advises that a drug product subject to this proposal is regarded as a new drug as defined in section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)), requiring either an approved full or abbreviated new drug application as a condition to lawfully market the product. Such a drug product is to be marketed in accordance with the requirements of § 320.58 (21 CFR 320.58).

REFERENCES

Copies of all references cited below are on public display in the office of the Hearing Clerk (HFC-20), Food and Drug Administration.

1. Skelly, J. P., C. M. Ise, V. Shah, and S. V. Dighe in collaboration with V. Bharnagri and W. Barr, "Procainamide HCl Bioavailability Monograph."

2. Koch-Weser, J., and S. W. Klein, "Procainamide Dosage Schedules, Plasma Concentrations and Clinical Effects," *Journal of the American Medical Association*, 215:1454-1460, 1971.

3. "Physicians' Desk Reference," 31st Ed., Medical Economics Co., Oradell, NJ, pp. 1544-1545, 1977.

4. Rousteenoja, R., P. Torsti, and A. Sothmann, "Experiences on a Sustained-Release Procainamide Preparation," *Current Therapeutic Research*, 15:707-712, 1973.

5. Weily, H. S., and E. Genton, "Pharmacokinetics of Procainamide," *Archives of Internal Medicine*, 130:366-369, 1972.

6. Gey, G. O., R. H. Levy, L. Fischer, G. Pettet, and R. A. Bruce, "Plasma Concentration of Procainamide and Prevalence of Exertional Arrhythmias," *Annals of Internal Medicine*, 80:718-722, 1974.

7. Gelbrand, H., and M. R. Rosen, "pharmacologic Basis for the Treatment of Cardiac Arrhythmias," *Pediatrics*, 55:56-67, 1975.

8. Moe, Gordon K., and J. A. Abildskov, "Antiarrhythmic Drugs," *in* "The Pharmacological Basis of Therapeutics," 5th Ed., Edited by Goodman, L. S., and A. Gilman, The MacMillan Co., New York, pp. 694-696, 1975.

9. Atkinson, A. J., and J. M. Strong, "Application of Plasma Level Response Correlations to the Assessment of Drug and Drug Metabolite Potency," *Acta Pharmaceutica Suecica*, 11:69, 1975.

10. Koch-Weser, J., "Pharmacokinetics of Procainamide in Man," *Annals of the New York Academy of Science*, 179:370-382, 1971.

11. Koch-Weser, J., "Antiarrhythmic Prophylaxis in Ambulatory Patients with Coronary Heart Disease," *Archives of Internal Medicine*, 129:763-772, 1972.

12. Jelinek, M. V., L. Lohrbauer, and B. Town, "Antiarrhythmic Drug Therapy for Sporadic Ventricular Ectopic Arrhythmias," *Circulation*, XLIX:659, 1974.

The Director has determined that this document does not contain an agency action covered by § 25.1(b) (21 CFR 25.1(b)) and, therefore, consideration by the agency of the need for preparing an environmental impact statement is not required.

A proposal to amend part 320 by adding Subpart D—Bioequivalence Requirements for Specific Drug Products—was proposed in the FEDERAL REGISTER of August 5, 1977 (42 FR 39675). The section proposed below would be added to subpart D.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701(a), 52 Stat. 1041-1042, 1050-1053 as amended, 1055 (21 U.S.C. 321(p), 352, 355, 371(a))) and under authority redelegated to the Director of the Bureau of Drugs (21 CFR 5.79), it is proposed that part 320 be amended by adding § 320.108, to read as follows:

§ 320.108 Procainamide hydrochloride.

(a) *Applicability.* The requirements of this section apply to all single active ingredient oral dosage form drug products containing procainamide hydrochloride.

(b) *Bioequivalence requirement for in vitro testing.* (1) Each manufacturer of a drug product subject to this section, except as provided in paragraph (b)(3) of this section, shall conduct an in vitro dissolution test comparing its drug product with the reference material.

(2) The test drug product is considered to meet the bioequivalence requirement for in vitro testing if it dissolves not less than 50 percent in 30 minutes and not less than 80 percent in 60 minutes.

(3) Each manufacturer of a drug product subject to this section selected by the Food and Drug Administration as the reference material and each manufacturer of a drug product subject to this section who has already conducted in vivo tests in humans to demonstrate bioavailability/bioequivalence of its drug product in accordance with the provisions of this section shall conduct an in vitro dissolution test on three consecutive lots/batches of its drug product to demonstrate consistent dissolution performance.

(4) Each manufacturer of a drug product subject to this section shall submit the results of the required in vitro dissolution test to the Food and Drug Administration on or before (60 days after the effective date of this section).

(c) *Bioequivalence requirement for in vivo testing in humans.* (1) Each manufacturer of a drug product subject to this section, other than a manufacturer of the reference material, who has not conducted in vivo bioavailability/bioequivalence studies fulfilling the requirements of this section before the effective date of this section shall conduct an in vivo bioavailability study in humans comparing its drug product with the reference material.

(2) The test drug product is considered to meet the bioeqivalence requirement for in vivo testing in humans if the following conditions are met:

(i) The test drug product and the reference material do not differ by more than 20 percent as determined by comparing parameters, e.g., concentration of the active drug ingredient in the plasma, peak plasma levels (Cmax), area under the plasma concentration-time curves (AUC), and time to obtain peak plasma levels; and

(ii) The test product should be at least 75 percent as bioavailable as the administered reference material utilizing subjects as their own controls, that is, administering both the reference material and the test drug material to the same subject.

(iii) Analytical and statistical techniques used are of sufficient sensitivity to detect those differences in rate and extent of absorption that are not attributable to subject variability.

(3) Each manufacturer of a drug product subject to this section that is selected by the Food and Drug Administration as the reference material, who has not conducted in vivo bioavailability/bioequivalence studies fulfilling the requirements of this section before the effective date of this section, shall conduct an in vivo bioavailability study in humans comparing its product (i.e., the reference material) with a solution of an equivalent amount of the procainamide hydrochloride contained in the reference material.

(4) Each manufacturer of a drug product subject to this section shall submit the results of the required in vivo testing to the Food and Drug Administration on or before (180 days after the effective date of this section). The Food and Drug Administration may grant an extension of time up to 180 days upon request for the submission of the results of the required in vivo tests when pilot studies are required before starting such test. If a manufacturer submits a protocol for evaluation, the Food and Drug Administration shall grant an extension of time necessary for the initial review of the protocol.

(5) Any manufacturer of a drug product subject to this section who has conducted one or more in vivo bioavailabilty/bioequivalence studies before the effective date of this section may request an evaluation of these studies to determine whether (i)

the studies now fulfill the requirements under this section or (ii) the studies are adequate and conclusive to ensure the bioequivalence of the drug product in light of current scientific knowledge and methodology. Each request is required to contain the new drug application number, the established (generic) name of the drug product, the dosage form and strength of the drug product, and the date(s) of submission of the pertinent study information contained in the new drug application.

(6) Each manufacturer holding an approved or pending full new drug application for the drug product shall submit a request for an evaluation to the Division of Cardio-Renal Drug Products (HFD-110), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857. Each manufacturer holding an approved or pending abbreviated new drug application for the drug product shall submit a request for an evaluation to the Division of Generic Drug Monographs (HFD-530), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

(d) *Reference material and guidelines for testing.* (1) The reference material to be used in the in vivo and in vitro tests is specified in the "Guidelines for In Vivo Bioavailabiltiy Studies for Procainamide." For the in vivo test, the manufacturer shall use the same lot/batch of the test drug product and one of the three lots/batches of the reference material that were used in the in vitro test, unless the manufacturer has conducted in vivo tests in humans to demonstrate bioavailability/bioequvalence before the effective date of this section.

(2) Guidelines for the conduct of in vivo and in vitro tests of procainamide are on file in the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, and are available on request to that office.

Interested persons may, on or before October 10, 1978, submit written comments regarding this proposal to the Hearing Clerk, Food and Drug Administration. Four copies of all comments should be submitted, except that individuals may submit single copies of comments, and should be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

NOTE.—The Food and Drug Administration has determined that this proposal will not have a major economic impact as defined by Executive Order 11821 (amended by Executive Order 11949) and OMB Circular A-107. A copy of the economic impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Dated: July 31, 1978.

JEROME A. HALPERIN,
Acting Director,
Bureau of Drugs.

[FR Doc. 78-21943 Filed 8-7-78; 8:45 am]

[4110-03]

[21 CFR Part 558]

[Docket No. 77N-0318]

NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Animal Feeds Containing Penicillin and Tetracycline; Postponement of Final Action

AGENCY: Food and Drug Administration

ACTION: Postponement of final action on a proposed rule.

SUMMARY: The Food and Drug Administration announces postponement of final action on its proposal to limit the distribution of animal feed premixes and medicated feeds containing penicillin and tetracycline (chlortetracycline and oxytetracycline) because issues raised at public hearings on the proposal and comments submitted to the agency warrant resolution of certain related issues first. Final action on the proposal will be postponed until resolution of previously published administrative proceedings which propose to amend the regulations by deleting the provisions of use for pencillin in animal feeds and by revising the provisions for the subtherapeutic use of the tetracyclines in animal feeds which have not been shown to be safe.

FOR FURTHER INFORMATION CONTACT:

Gerald B. Guest, Bureau of Veterinary Medicine (HFV-101), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20587, 301-443-4313.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of August 30, 1977 (42 FR 43772), the Director of the Bureau of Veterinary Medicine issued a notice of opportunity for hearing proposing to withdraw approval of all new animal drug applications for penicillin-containing new animal drugs intended for use in animal feed principally because the evidence surrounding this use demonstrates that they have not been shown to be safe. The Director issued a similar notice of opportunity for hearing concerning certain subtherapeutic uses of tetracycline in animal feed in the FEDERAL REGISTER of October 21, 1977 (42 FR 56264).

In the FEDERAL REGISTER of January 20, 1978 (43 FR 3032), the Commissioner of Food and Drugs proposed to limit the distribution of animal feed premixes containing penicillin and tetracyclines (chlortetracycline and oxytetracycline) to feed mills holding approved medicated feed applications for manufacturing those medicated feeds. The proposal was based on the recommendations of the National Advisory Food and Drug Committee concerning evidence of the development and transfer of antibiotic resistance. The Commissioner also proposed to restrict further the distribution of those feeds to the order of a licensed veterinarian as part of the record maintenance requirements of the Federal Food, Drug, and Cosmetic Act. Interested persons were given until April 20, 1978 to file written comments on the proposal. The comment period was extended to June 19, 1978 in the FEDERAL REGISTER of April 21, 1978 (43 FR 16997).

In the FEDERAL REGISTER of February 7, 1978 (43 FR 5010), the Commissioner announced that public hearings would be held on March 23, 1978 in Ames, Iowa, on March 30, 1978 in Raleigh, N.C., and on April 6, 1978 in Dallas, Tex., to receive information and views from interested persons on the January 20, 1978 proposal.

Many concerns regarding the proposal were expressed at the public hearings and in submissions to the hearing clerk. One of the concerns was that implementing the proposal before the conclusion of notices offering opportunity for formal evidentiary hearings would constitute prejudgment of those administrative procedures. The Commissioner agrees that it is inappropriate to issue a final order implementing the proposal before the conclusion of these notices because all the proceedings rely on the same scientific basis. Among other concerns expressed by the public which the Commissioner will need to evaluate further are:

1. Contention that the number, distribution, and kinds of veterinarians available are not adequate to diagnose and write prescriptions under the proposed requirements.

a. Many producers testified that veterinarians treating livestock are not available within their farming territories. Some small producers stated that they would be at a severe economic disadvantage if they had to compete with the large farms and feedlot units to employ or retain veterinary services to meet the proposed requirements.

b. Producers stated that the proposal would be particularly disruptive to the poultry industry because there are few veterinarians trained or experienced in poultry diseases and management practices; and, often, veterinarians are associated with a university or the State and may not be licensed to

practice. Some poultry producers stated that they are monitored by service representatives who are not veterinarians but who are trained and experienced individuals, experts at diagnosing poultry health problems. Some large, integrated poultry producers with farms in many States stated that even if they employ a licensed veterinarian, the veterinarian's license to practice would not extend to all the firm's operations.

2. Testimony that the 2 grams per pound product intended for emergency use without the need for form FD-1800 approval is not a practical drug level.

3. Statements that State pharmacy laws will impact on the proposed veterinarian's procedure.

4. Allegations that the proposed restrictions will be circumvented by using pencillin and the tetracyclines in soluble powder dosage forms which are not subject to the proposal.

5. Assertions that the proposal will unnecessarily restrict the practice of veterinary medicine because it will eliminate flexibility in the dosage levels available to be prescribed. Additionally, veterinarians have not previously been required to indicate on their written orders the disease condition being treated. Some veterinarians have contended that this requirement would increase their liability.

6. Statements that the proposal may disrupt or interfere with the States' control over the feed industry. It was stated that all existing labels for feeds containing penicilllin or the tetracyclines will have to be revised which will require approval and registration by the State. Also, under certain State laws, e.g., Virginia Animal Remedy law, prescription items are exempt from State feed control; therefore, feeds subject to that law could no longer be regulated under the State feed control laws.

Because of these and other concerns submitted in response to the proposal, the Commissioner is considering whether the proposal should be withdrawn or revised to better address the public's concerns. The Commissioner has determined, however, that the agency will not finalize this or a revised proposal pertaining to the restriction of animal feed premixes containing penicillin or the tetracyclines (chlortetracycline and oxytetracycline) until substantive issues which may be identified pertaining to the notices offering an opportunity for formal evidentiary hearings on the subject drugs have been resolved.

Dated: August 1, 1978.

DONALD KENNEDY,
Commissioner of Food and Drugs.

[FR Doc. 78-21788 Filed 8-7-78; 8:45 am]

[4210-01]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Federal Insurance Administration

[24 CFR Part 1917]

[Docket No. FI-4344]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determination for the Township of Cedarville, Menominee County, Mich.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the Township of Cedarville, Menominee County, Mich. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the Township Hall, Hessel Road, Hessel, Mich. Send comments to: Mr. Albert Lindberg, township supervisor, Township of Cedarville, Township Hall, Hessel, Mich. 49745.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the township of Cedarville, Mich., in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Green Bay	Confluence with Deer Creek.	584
	Confluence with Olsen Creek.	584
Cedar River (backwater from Green Bay).	200 ft west from the junction of State Highway 35 and River Rd.	584

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 19, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21979 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4345]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determination for the City of Flushing, Genesee County, Mich.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the city of Flushing, Genesee County, Mich. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the na-

tional flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the City Hall, Flushing, Mich. Send comments to: The Honorable Russell M. Phillips, Mayor, City of Flushing, City Hall, 309 East Main Street, Flushing, Mich. 48433.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the city of Flushing, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Flint River	Northeast corporate limit.	667
	2,700 ft downstream of main St.	669
	At Main St	674
	2,650 ft upstream of Main St.	677
	7,600 ft upstream of Main St.	680
	5,300 ft downstream of east corporate limit.	684
	At east corporate limit	687
Cole Creek	20 ft downstream of Grand Trunk Western RR.	669
	80 ft upstream of Seymour Rd.	674
	360 ft upstream of Seymour Rd.	674
	1,430 ft upstream of Seymour Rd.	679
	1,630 ft upstream of Seymour Rd.	681
	120 ft downstream of Pierson Rd.	684
	50 ft upstream of Pierson Rd.	690
	540 ft upstream of Pierson Rd.	691
	730 ft upstream of Pierson Rd.	692
	200 ft downstream of Grand Trunk Western RR.	694
	50 ft downstream of Seymour Rd.	696
	50 ft upstream of Seymour Rd.	698
	550 ft upstream of Seymour Rd.	699
	At southwest corporate limit.	702
Mud Creek	At corporate limit downstream of Morrish Rd.	688
	50 ft downstream of Morrish Rd.	691
	50 ft upstream of Morrish Rd.	695
	450 ft upstream of Morrish Rd.	695

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 14, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21980 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4346]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determinations for the City of Gibraltar, Wayne County, Mich.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the city of Gibraltar, Wayne County, Mich. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the City Hall, Gibraltar, Mich. Send comments to: The Honorable James Taylor, Mayor, City of Gibraltar, 29450 Munro Avenue, Gibraltar, Mich. 48173.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the city of Gribraltar, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448)), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation in feet, International Great Lakes datum
Detroit River	North corporate limit	576
	South corporate limit	576
Frank and Poet drain.	South Gibraltar Rd	576
	Just downstream of McLouth Steel RR entry.	576
	Just upstream of McLouth Steel RR entry.	579
	Just downstream of Detroit & Toledo Shoreline RR.	579
	Just upstream of Detroit & Toledo Shoreline RR.	580
	Just upstream of ConRail.	581
	Just upstream of Vreeland Rd.	581
Brownstown Creek.	South Gibraltar Rd	576
	Just downstream of Middle Gibraltar Rd.	576
	700 ft upstream of Middle Gibraltar Rd.	577
	Just upstream of ConRail at Quarry Lake.	579
	Confluence with Marsh Creek.	580
	2,000 ft downstream of Fort St.	580
	Just downstream of Fort St.	583
Marsh Creek	Just downstream of ConRail.	580
	Just upstream of Conrail.	581
	Just downstream of Fort St.	583
Division A	Confluence with Brownstown Creek.	579
	Confluence with Frank and Poet drain.	580
Division B	Confluence with Brownstown Creek.	579
	350 ft upstream of from Brownstown Creek.	581
	Confluence with Frank and Poet drain.	581

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 26, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21981 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4347]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determinations for the City of Lapeer, Lapeer County, Mich.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the city of Lapeer, Lapeer County, Mich. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the City Hall, Lapeer, Mich. Send comments to: The Honorable Orin E. Connor, Mayor, City of Lapeer, City Hall, 576 Liberty Street, Lapeer, Mich. 48446.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the city of Lapeer in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448)), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
South branch Flint River.	At northern corporate limit.	812
	2,100 ft upstream of the corporate limits.	813
	Just downstream of Oregon St.	816
	Just downstream of ConRail, near Oregon St.	817
	Just upstream of ConRail, near Oregon St.	819
	At confluence of Farmers Creek.	820
	Just downstream of Grand Trunk Western RR.	822
	Just upstream of Grand Trunk Western RR.	823
	At eastern corporate limit.	823
Hunters Creek	At confluence with South Branch Flint River.	823
	Just downstream of ConRail.	823
	Just upstream of ConRail.	824
	Downstream of DeMille St.	826
	Just upstream of DeMille St.	830
	At southern corporate limit.	831
Farmers Creek	100 ft downstream of Main St.	822
	Just upstream of Main St.	826
	50 ft downstream of Grand Trunk Western RR.	826
	Just upstream of Grand Trunk Western RR.	830
	At Millville Rd	831

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 14, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21982 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4348]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determination for the City of Rockwood, Wayne County, Mich.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the city of Rockwood, Wayne County, Mich. These base (100-year) flood ele-

vations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the City Hall, Rockwood, Mich. Send comments to: The Honorable Walter Stiles, Mayor, City of Rockwood, 32409 Fourth Street, Rockwood, Mich. 48173.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the city of Rockwood, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Huron River	East corporate limit	579
	Just downstream Detroit & Toledo Shoreline RR.	582
	Just upstream of ConRail.	583
	Just downstream of Fort St..	584
	250 ft upstream of ConRail (at Fort St.).	585
	Just upstream of Interstate 75.	586
	West corporate limit	587
Smith Creek	East corporate limit	577
Silver Creek	East corporate limit	577
	At Huron River Dr	578
	Just upstream of railroad spur to Silica Mine.	580
	Just downstream of Detroit & Toledo Shoreline RR.	581
	Just downstream of Fort St.	582
	100 ft downstream of Interstate 75.	585
	West corporate limit	587

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 26, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21983 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4349]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determination for The City of Dearborn, Platte County, Mo.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the city of Dearborn, Platte County, Mo. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the City Hall, Dearborn, Mo. Send comments to: The Honorable Fred Gardner, Mayor, City of Dearborn, Dearborn Mo. 54439.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the City of Dearborn, Platte County, Mo. in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Bee Creek	Southwest corporate limit.	877
	200 ft upstream from Highway 371.	878
	Northern corporate limit.	878
Bee Creek Tributary.	At confluence with Bee Creek.	877
	70 ft upstream of Great Western RR.	878
	At southern corporate limit 100 ft upstream from Main St.	879

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development

Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001–4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 20, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21984 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4350]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determination for the City of Portageville, New Madrid County, Mo.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the city of Portageville, New Madrid County, Mo. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the City Hall, Portageville, Mo. Send comments to: Mr. George Vogel, City of Portageville, City Hall, Portageville, Mo. 63873.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the city of Portageville, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Main Ditch	Northeast corporate limit.	281
Portageville Open Bay.	West corporate limit	279
	At St. Louis & San Francisco RR.	281

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 28, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21985 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4351]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determinations for the City of Weston, Platte County, Mo.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the city of Weston, Platte County, Mo. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the City Hall, 526 Main, Weston, Mo. Send comments to: Mr. Larry Clemens, City Engineer, City of Weston, 1005 Nebraska, Weston, Mo. 64098.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the city of Weston, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Brills Creek	50 ft upstream of Washington St.	784
	150 ft upstream of State Highway 45.	803
Benner Branch	At Burlington Northern RR.	780

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
	Just upstream of Spring St.	782
	Upstream corporate limit.	795
Wells Branch.....	At Burlington Northern RR.	780
	At private road approximately 1,300 ft downstream of west corporate limit.	805
	Eastern corporate limit..	815

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 28, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21986 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4352]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determination for the City of Tracy, Platte County, Mo.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the city of Tracy, Platte County, Mo. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the home of Mayor Hartland, Andy Street, Tracy, Mo. Send comments to: The Honorable Ernest W. Hartland, Mayor, City of Tracy, Andy Street, Tracy, Mo. 64091.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the city of Tracy, Platte County, Mo., in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Platte River	500 ft downstream from Missouri Highway 92.	780
	Upstream side of Missouri Highway 92.	785
	Corporate limit 2,640 ft above Missouri Highway 92.	786
	Andy St. (extended).....	786

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 26, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21987 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4353]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determination for the City of Miles City, Custer County, Mont.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the city of Miles City, Custer County, Mont. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the City Hall, 2d and Custer, Miles City, Mont. Send comments to: The Honorable B. Dean Holmes, Mayor, City of Miles City, City Hall, drawer 910, Miles City, Mont. 59301.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the city of Miles City, Mont., in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more

stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation, feet, national geodetic vertical datum
Yellowstone River	Intersection of Daly Ave. and Edgewood St.	2,352
	7th St. between Levee and River St..	2,355
	State Highway 22 at centerline (west of Levee).	2,356
	Confluence with Tongue River.	2,359
Tongue River.....	Chicago, Milwaukee, St. Paul & Pacific Railroad at centerline.	2,359
	Pacific Ave. 150 ft upstream of centerline.	2,363
	Balsam Dr., 1,600 ft west of intersection with Strevell Ave.	*2,364

Source of flooding	Location	Depth in feet above ground
Tongue River.....	Area bounded by Front St., Pleasant St., 9th St., and Washington St.	*1

* Shallow flooding.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 17, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21988 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4354]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determination for the Town of Hooksett, Merrimack County, N.H.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the town of Hooksett, Merrimack County, N.H. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the Town Office, 16 Main Street, Hooksett, N.H. Send comments to: Mr. Raymond Langer, Chairman, Board of Selectmen, Town Office, 16 Main Street, Hooksett, N.H. 03106.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the town of Hooksett, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448) 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Merrimack River...	At southern corporate limit.	185
	4100 ft upstream of confluence of Peters Brook.	190
	Just downstream of Main St.	191
	Just upstream of Hooksett Dam.	194
	At northern corporate limit.	198
Dalton Brook.....	At confluence with Merrimack River.	187
	500 ft upstream of Boston & Maine RR.	188
	1,050 ft upstream of Boston & Maine RR.	218
	2,300 ft upstream of Boston & Maine RR.	236
	3,700 ft upstream of Boston & Maine RR.	249
	1,950 ft downstream of Benton Rd.	264
	300 ft downstream of Benton Rd.	273
	Just upstream of Benton Rd.	295
	Upstream end of U.S. Route 3 culvert.	298
	Downstream end of State Route 38 bypass.	299
	Just upstream of Route 28 bypass culvert.	302
Messer Brook.....	At confluence with Merrimack River.	186
	285 ft downstream of Martins Ferry Rd.	186
	85 ft downstream of Martins Ferry Rd.	189
	50 ft upstream of Martins Ferry Rd.	197
	2,600 ft upstream of Martins Ferry Rd.	221
	850 ft downstream of Trailor Park Rd.	225
	65 ft downstream of Trailor Park Rd.	234
	Just upstream of Trailor Park Rd.	239
	1,225 ft upstream of Trailor Park Rd.	244
	At downstream end of State Route 28 culvert.	265
Peters Brook.....	At confluence with Merrimack River.	189
	Just upstream of Boston & Maine RR.	195
	260 ft upstream of Boston & Maine RR.	195
	Just upstream of Gravel Pit Dam.	212
	80 ft downstream of Construction Products Rd.	214
	80 ft upstream of Construction Products Rd.	223
	1,080 ft upstream of Construction Products Rd.	230
	1,815 ft upstream of Construction Products Rd.	241
	140 ft downstream of Industrial Park Rd (southernmost crossing).	255
	Just upstream of Industrial Park Rd (southernmost crossing).	278
	Just upstream of Industrial Park Rd (northernmost crossing).	282
	60 ft downstream of U.S. Route 3.	289

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
	Just upstream of U.S. Route 3.	294
	Just upstream of Gravel Pit culvert C (3,350 ft upstream of Industrial Park North crossing).	304

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 26, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21989 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4355]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determination for the Township of Delanco, Burlington County, N.J.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the township of Delanco, Burlington County, N.J. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the Township Hall, Burlington Avenue, Burlington, N.J.. Send comments to: The Honorable W. S. Ryan, Mayor, Township of Delanco, Township Hall, Burlington Avenue, Burlington, N.J. 08075.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, 202-755-5581 or toll-free line 800-424-8872 room 5270, 451 Seventh Street SW., Washington, D.C. 20410.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the Township of Delanco, N.J., in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation, in feet, national geodetic vertical datum
Rancocas Creek.....	Confluence with Delaware River.	11
	Burlington Ave.	11
	ConRail	11
	Upstream corporate limits.	11
Delaware River.....	Downstream corporate limits.	11
	Upstream corporate limits.	11

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 19, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21990 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4356]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determination for the Township of Riverside, Burlington County, N.J.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the township of Riverside, Burlington County, N.J. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the Township Hall, Scott and Pavilion Avenues, Riverside, N.J. Send comments to: The Honorable John W. Van Scriver, Mayor, Township of Riverside, Township Hall, P.O. Box 188, Riverside, N.J. 08075.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the township of Riverside, N.J., in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed

to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation, in feet, national godetic vertical datum
Rancocas Creek.....	Pavilion Ave—30 ft*	11
	ConRail—30 ft*	11

* Upstream of centerline.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 26, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21991 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4357]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determinations for the Town of Colden, Erie County, N.Y.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the town of Colden, Erie County, N.Y. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the Colden Town Hall, Route 240, Colden, N.Y. 14033. Send comments to: Mr. William Miller, Town Supervisor of Colden, Colden Town Hall, Route 240, Colden, N.Y. 14033.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the Town of Colden, Erie County, N.Y. in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
West Branch Cazenovia Creek.	Downstream Town boundary.	942
	State Route 240—1st crossing upstream of town boundary.	944
	Burr Rd	969
	State Route 240—1st crossing downstream of Heath Rd.	1,055
	Heath Rd	1,059
	State Route 240—1st crossing upstream of Heath Rd.	1,077
	Chessie System Bridge...	1,083
	Farm bridge south of village of Colden.	1,121
	Murray Rd—upstream side.	1,169
	Upstream town boundary.	1,191

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 19, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21992 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4358]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determination for the Village of Lancaster, Erie County, N.Y.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the village of Lancaster, Erie County, N.Y. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the Department of Public Works, 5200 Broadway, Lancaster, N.Y. 14086. Send comments to: Hon. Burt T. Lyon, Mayor of Lancaster, 5423 Broadway, Lancaster, N.Y. 14086.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the village of Lancaster, Erie County, N.Y., in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Cayuga Creek	Penora St	649
	Aurora St	655
	Lake Ave	664
	Courd Park Dam	671
	Uptream corporate limits.	672
Plum Bottom Creek.	Confluence with Cayuga Creek.	653
	Central Ave	661
	Clark St	663
	Holland Ave	670
	Court St	677
	Upstream corporate limits.	680
Spring Creek	Confluence with Plum Bottom Creek.	662
	ConRail Bridge	676
	Court St	683
	Upstream corporate limits.	688

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 26, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21993 Filed 8-7-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4359]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determination for the Village of Valleyview, Franklin County, Ohio

AGENCY: Federal Insurance Administration, HUD.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the village of Valleyview, Franklin County, Ohio. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

DATE: The period for comment will be ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in the above-named community.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed base (100-year) flood elevations are available for review at the Village Hall, 432 North Richardson Avenue, Columbus, Ohio. Send comments to: The Honorable Clyde Keller, Mayor, Village of Valleyview, 2770 Valley View Drive, Columbus, Ohio 43204.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the proposed determinations of base (100-year) flood elevations for the village of Valleyview, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)).

These elevations, together with the flood plain management measures required by § 1910.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their flood plain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations for selected locations are:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Dry Run	At downstream corporate limit.	770
	1,000 ft upstream of the downstream corporate limit.	772
	800 ft downstream of Hague Ave.	776
	680 ft upstream of Hague Ave.	777
	60 ft downstream of Hague Ave.	779
	Just upstream of Hague Ave.	787
	Upstream of corporate limit.	788
North Branch Dry Run.	At confluence with Dry Run.	771
	Just upstream of Richardson Ave.	771
	Just downstream of Dibblee Ave.	775
	40 ft upstream of Dibblee Ave.	777
	340 ft upstream of Dibblee Ave.	780
	At upstream corporate limit.	781

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 26, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-21994 Filed 8-7-78; 8:45 am]

[3710-08]

DEPARTMENT OF DEFENSE

Department of the Army

[32 CFR Part 553]

ARMY NATIONAL CEMETERIES

Restrictions of Bicycles

AGENCY: Department of the Army.

ACTION: Proposed rule—extension of comment period.

SUMMARY: This notice is a follow-up to a proposed rule which appeared in

the FEDERAL REGISTER on July 13, 1978 (43 FR 30075) to restrict bicyclists to certain roads within Arlington National Cemetery.

DATES: The public comment period is extended to August 15, 1978.

ADDRESS: Comments must be submitted to HQDA(DAAG-PED) Washington, D.C. 20314

FOR FURTHER INFORMATION CONTACT:

Lt. Comdr. Ellsworth S. Clarke, 202-693-0882.

By authority of the the Secretary of the Army.

Dated: August 3, 1978.

W. J. WINTER, Jr.,
Colonel, U.S. Army, Director, Personal Affairs, TAGCEN.

[FR Doc. 21998 Filed 8-7-78; 8:45 am]

[4310-70]

DEPARTMENT OF THE INTERIOR

National Park Service

[36 CFR Part 7]

FIRE ISLAND NATIONAL SEASHORE, NEW YORK

Seaplane and Amphibious Aircraft Regulations

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

SUMMARY: The proposed regulation set forth below is necessary to control seaplane and amphibious aircraft operations within Fire Island National Seashore. Unregulated use of Seashore waters by seaplanes and amphibious aircraft has resulted in aircraft accidents, threats to boating safety, complaints of extremely low overflights and trespassing. It is the objective of this regulation to promote the safety of all users, minimize the conflicts among the various uses and to protect the resources of the Seashore.

DATES: Written comments, suggestions or objections will be accepted until September 7, 1978.

ADDRESSES: Comments should be directed to: Superintendent, Fire Island National Seashore, 120 Laurel Street, Patchogue, N.Y. 11772.

FOR FURTHER INFORMATION CONTACT:

Richard W. Marks, Superintendent, Fire Island National Seashore, telephone 516-289-4810.

SUPPLEMENTARY INFORMATION:

BACKGROUND

This regulation is being promulgated by the National Park Service in response to public concern for safety and protection of property and resources within Fire Island National Seashore. Complaints concerning seaplanes and amphibious aircraft operation have been received from homeowners and recreational boaters. These complaints involve aircraft taxiing, docking, take-offs, landings, extremely low overflights and trespassing.

The determination to regulate seaplanes and amphibious aircraft was based on the following considerations:

1. An analysis of past and present transportation modes.

2. An obligation by the National Park Service to be responsive to public concern for safety and orderly management.

3. The recognized responsibility of the National Park Service for visitor safety.

4. The legislative mandate that the National Park Service conserve and preserve Fire Island National Seashore for future generations.

Since boating has been and will continue to be the predominant means of access to the Seashore, it was deemed impractical to restrict boating at this time. Seaplanes and amphibious aircraft represent a valid means of transportation and a total restriction on their use is an unwanted and overly sever measure at this time. This regulation would reduce conflicting uses by requiring aircraft to land and take off at least 1,000 feet from shore and require that all aircraft taxiing be accomplished with due regard for public safety and only perpendicular to and from legal docking sites.

AUTHORITY

Section 3 of the Act of August 25, 1916, 39 Stat. 535, as amended (16 U.S.C. 3); 245 DM 1 (77 FR 16631); and National Park Service Order 77 (38 FR 7478).

DRAFTING INFORMATION

The following persons participated in the writing of this regulation: Richard W. Marks and William Schenk, Fire Island National Seashore; and Michael Finley, National Park Service, Washington, D.C.

IMPACT ANALYSIS

The National Park Service has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11821 and OMB Circular A-107; nor is it a major Federal action significantly affecting the quality of the human environment, which would require preparation of an environmental impact statement.

In consideration of the foregoing, it is proposed to amend § 7.20 of Title 36, Code of Federal Regulations by the addition of a new paragraph (b) as follows:

§ 7.20 Fire Island National Seashore.

* * * * *

(b) *Operation of seaplane and amphibious aircraft.* (1) Aircraft may be operated on the waters of the Great South Bay and the Atlantic Ocean within the boundaries of Fire Island National Seashore, except as restricted in § 2.2(a) of this chapter and by the provisions of paragraph (b)(2) of this section.

(2) The waters of the Great South Bay and the Atlantic Ocean within 1,000 feet of any shoreline are closed to takeoffs, landings and other aircraft operations, except that aircraft may taxi on routes perpendicular to the shoreline to and from legal docking at the following locations.

(i) *Kismet*—Located at approximate longitude 73°12½' and approximate latitude 40°38½'.

(ii) *Fair Harbor*—Located at approximate longitude 73°11' and approximate latitude 40°38½'.

(iii) *Ocean Bay Park*—Located at approximate longitude 73°09' and approximate latitude 40°39'.

(iv) *Cherry Grove*—Located at approximate longitude 73°05½' and approximate latitude 40°39½'.

(v) *Fire Island Pines*—Located at approximate longitude 73°04½' and approximate latitude 40°40'.

(vi) *Davis Park*—Located at approximate longitude 73°00' and approximate latitude 40°41'.

(3) Aircraft operation in the vicinity of marinas, boats, boat docks, floats, piers, ramps, bird nesting areas, or bathing beaches must be performed with due caution and regard for persons and property and in accordance with any posted signs or uniform waterway markers.

(4) Aircraft are prohibited from landing or taking off from any land surfaces, any estuary, lagoon, marsh, pond, tidal flat, paved surface, or any waters temporarily covering a beach; except with prior authorization of the Superintendent. Permission shall be based on the need for emergency service, resource protection, resource management or law enforcement.

(5) Aircraft operations shall comply with all Federal, State and county ordinances and rules for operations as may be indicated in available navigation charts or other aids to aviation

which are available for the Fire Island area.

RICHARD W. MARKS,
Superintendent,
Fire Island National Seashore.

JULY 17, 1978.

[FR Doc. 78-21963 Filed 8-7-78; 8:45 am]

[4310-70]

[36 CFR Part 21]

HOT SPRINGS NATIONAL PARK, ARKANSAS

Bathhouse Regulations

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

SUMMARY: This notice proposes a complete revision of 36 CFR Part 21, which contains regulations pertaining to the operation of bathhouses within Hot Springs National Park. The revisions deletes references to two advisory boards which were recently terminated, as well as regulations on subjects which are sufficiently covered in other ways, such as concession contract language, and need not be dealt with in these regulations. An addition to the regulations is being proposed that will allow management to expand the use of thermal water for other than traditional therapeutic tub bathing, thereby permitting recreational pool bathing in and out of the park in accordance with an approved Statement for Management. A penalty section would also be added to correct a deficiency in the current regulations.

DATES: Written comments on this proposal will be accpeted until September 7, 1978.

ADDRESS: Mail comments to Regional Director, Southwest Region, National Park Service, P.O. Box 728, Santa Fe, N. Mex. 87501.

FOR FURTHER INFORMATION CONTACT:

Richard Maeder, Superintendent, Hot Springs National Park. 501-624-3383.

SUPPLEMENTARY INFORMATION: The proposed regulations reduce the scope of part 21 from 30 existing sections to 12 revised sections. This reduction is due, in large part, to the termination of the park's two advisory boards by the Secretary of the Interior on June 30, 1977, as recommended by the Office of Management and Budget on December 7, 1976. These boards were the Hot Springs National Park Federal Registration Board and the Examining Board for Technicians. The termination of the boards makes it possible to eliminate all or portions of existing §§ 21.4 through 21.16 of part 21, as well as allowing the simplification of a number of other sections.

In reviewing the present regulations in order to remove material made obsolete by termination of the advisory boards, it was found that certain other material was no longer necessary. The language of present concession contracts and directives issued by the park adequately covers these subjects. Accordingly, these regulations would be deleted from the new part 21.

Existing regulations prohibit the use of the park's hot mineral waters for other than bathing or other therapeutic purposes. With the decline in therapeutic use of these waters which has taken place in recent years, it is no longer necessary to be as restrictive with their use. Therefore, the new regulations would merely limit use of the waters to those purposes authorized by the Superintendent.

One management objective of the park is "To make available opportunities for recreational and therapeutic bathing and associated activities in a manner that is appropriate to present day public interests and that insures high quality visitor experience." Another objective is "To encourage a broadened recreational bathing use concept as a future bathhouse service." The adoption of the proposed regulations will give the Superintendent authority to permit adaptive uses of the park's thermal water in accordance with the above stated management objectives which were approved on June 1, 1977.

The penalties which would be established by the new section 21.2 are authorized by the Act of April 20, 1904, chapter 1400, as amended (16 U.S.C. 374).

DRAFTING INFORMATION

The following persons are principally responsible for the preparation of these proposed regulations: Hugh L. Crenshaw, Bernard Goodman, and Benson Holmes, National Park Service.

Dated: August 2, 1978.

ROBERT STANTON,
Acting Associate Director,
National Park Service.

It is proposed that Part 21 of Title 36, Code of Federal Regulations, be revised in its entirety to read as follows:

PART 21—HOT SPRINGS NATIONAL PARK: BATHHOUSE REGULATIONS

Sec.

21.1 Definitions.
21.2 Penalties.
21.3 Use of thermal water.
21.4 Registration of physicians.
21.5 Therapeutic bathing requirements.
21.6 Use of therapeutic pools.
21.7 Health examinations
21.8 Employee certification.
21.9 Solicitation by employees.
21.10 Losses.
21.11 Redemption of tickets.
21.12 Lost tickets.

AUTHORITY: Sec. 3 of the Act of August 25, 1916, 39 Stat. 535, as amended (16 U.S.C. 3); sec. 3 of the Act of March 3, 1891, 26 Stat. 842, as amended (16 U.S.C. 363).

§ 21.1 Definitions.

When used in the regulations in this part:

(a) The term "Superintendent" means the Superintendent of Hot Springs National Park, Ark.

(b) The term "physician" means a doctor of medicine or osteopathy who is licensed to practice by a State or territory of the United States.

(c) The term "registered physician" means a physician registered at the office of the Superintendent as authorized to prescribe the waters of Hot Springs National Park.

(d) The term "employee" means any person licensed or certified by a State or territory of the United States in his or her specialty, or who is certified by the Superintendent to perform or render special services in a bathhouse.

(e) The term "bathhouse" means any facility which is operated by an individual, trustee, partnership, corporation, or business entity and which receives thermal water from Hot Springs National Park.

§ 21.2 Penalties.

Any person convicted of violating any provision of the regulations contained in this part, or as the same may be amended or supplemented, shall be punished by a fine not exceeding $100 and shall be adjudged to pay all costs of the proceedings.

§ 21.3 Use of thermal water.

(a) The use of the thermal waters of Hot Springs National Park, for purposes other than those authorized by the Superintendent, is prohibited.

(b) The heating, reheating, or otherwise increasing the temperature of the thermal waters of Hot Springs National Park is prohibited.

(c) The introduction of any substance, chemical, or other material or solution into the thermal waters of Hot Springs National Park, except as may be prescribed by a physician for a bather or as may be directed by the Superintendent, is prohibited.

§ 21.4 Registration of physicians.

Physicians desiring to prescribe the thermal waters of Hot Springs National Park must first be registered at the office of the Superintendent. Any physician may make application for registration to the Superintendent. To maintain registered status, reapplication is required triannually.

§ 21.5 Therapeutic bathing requirements.

Baths shall be administered to persons having a prescription from a registered physician with prescription

instructions given therein. Baths shall be administered to patrons who do not have prescriptions from registered physicians only if the bath is administered in accordance with the bath directions prescribed by the Superintendent, the violation of which is not subject to the penalty provisions of § 21.2.

§ 21.6 Use of therapeutic pools.

No person shall use the therapeutic pools except on presenting a prescription describing the treatment from a registered physician. Persons with acute or infectious diseases or discharges of the body, or who lack complete control of their bodily functions, are prohibited from using the therapeutic pools.

§ 21.7 Health examinations.

No employee who comes in direct personal contact with bathers or pool users will be permittted to enter duty without first undergoing a health examinations, or remain in such employment without undergoing periodic health examination, as required by the Superintendent, and being found free from any infectious or communicable diseases.

CROSS REFERENCE: For a list of communicable diseases included in the regulations of the U.S. Public Health Service, see 21 CFR 1240.54.

§ 21.8 Employees certification.

(a) Employee engaged as physical therapists must be licensed or certified by a State or territory of the United States to practice.

(b) Employees engaged as plysical therapy aids or physical therapy technicians will be certified by the Superintendent upon completion of an examination.

(c) Employees engaged as masseurs or masseuses must be licensed or certified by a State or territory of the United States, or be certified by the Superintendent upon completion of an examination.

(d) Employees engaged as bath attendants will be certified by the Superintendent upon completion of an apprenticeship and an examination.

§ 21.9 Solicitation by employees.

Soliciting by employees for any purpose, including soliciting for gratuities, commonly called "tips," is prohibited in all bathhouses.

§ 21.10 Losses.

A bathhouse receiving deposits of jewelry, money, or other valuables from patrons shall provide means for the safekeeping thereof, satisfactory to the Superintendent. It is understood, however, that the Government assumes no responsibility for such valuables kept on the premises. All losses must be reported promptly to the Superintendent by the bathhouse manager.

§ 21.11 Redemption of tickets.

Unused tickets may be redeemed by the purchaser within one year from the date of purchase, according to the redemption scale approved by the Superintendent.

§ 21.12 Lost tickets.

A patron who loses his ticket may continue to receive service, without additional charge, for the number of units remaining in the ticket. Records of lost tickets, and of service given thereunder, shall be maintained as required by the Superintendent. Lost tickets shall have no redemption value.

[FR Doc. 78-21974 Filed 8-7-78; 8:45 am]

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 52]

[FRL 940-7]

DISTRICT OF COLUMBIA IMPLEMENTATION PLAN

Proposed Revision—Withdrawal and Proposal

AGENCY: Environmental Protection Agency.

ACTION: Withdrawal of previously proposed rule and notice of proposed rule

SUMMARY: The District of Columbia has submitted an amendment to the District's air pollution control regulations and has requested that it be reviewed and processed as a revision of the District of Columbia implementation plan (SIP). The amendment revises the requirement for "no visible emissions," at any time to a requirement that would not permit any visible emissions except for up to 40-percent opacity for a period of 2 minutes in any 60-minute period and for an aggregate of 12 minutes in any 24-hour period during "startup," cleaning, soot blowing, adjustment of combustion controls of boilers and/or unavoidable malfunction of equipment. (The current Federal regulation prohibits visible emissions at any time.) This amendment supersedes a previous District amendment which permitted transient emissions of 20-percent opacity and which had been previously proposed but not approved as a SIP revision. In this notice, the Administrator withdraws the earlier proposal and proposes to approve this more recent amendment to the District's regulations.

DATE: Comments must be submitted on or before September 7, 1978.

ADDRESSES: All comments should be submitted to: Mr. Howard R. Heim (3AH10), Chief, Air Programs Branch, U.S. Environmental Protection Agency, Region III, Curtis Building, 10th Floor, Sixth and Walnut Streets, Philadelphia, Pa. 19106, Attn.: AH010bDC. Copies of the proposed SIP revision and accompanying support documentation are available for public inspection during normal business hours at the following offices:

U.S. Environmental Protection Agency, Region II, Air Programs Branch, Curtis Building, 10th Floor, Sixth and Walnut Streets, Philadelphia, Pa. 19106, Attn.: Mr. Harold A. Frankford (3AH12).

District of Columbia Department of Environmental Services, Bureau of Air and Water Quality, 5010 Overlook Avenue SW., Washington, D.C. 20032, Attn.: Mr. John V. Brink.

Public Information Reference Unit, Room 2922, EPA Library, U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:

Mr. Harold A. Frankford (3AH12) Air Programs Branch, U.S. Environmental Protection Agency, Curtis Building, 10th Floor, Sixth and Walnut Streets, Philadelphia, Pa. 19106, telephone 215-597-8392.

SUPPLEMENTARY INFORMATION:

1. BACKGROUND

On May 24, 1974, the District of Columbia submitted to the Regional Administrator, EPA Region III, an amendment to the District's air quality control regulations and requested that it be reviewed and processed as a revision of the District of Columbia's implementation plan (SIP). On March 3, 1977, the District of Columbia submitted to the Regional Administrator, EPA Region III, an additional amendment to the District's air quality control regulations and requested that it be reviewed and processed as a revision of the District of Columbia's implementation plan. In accordance with 40 CFR 51.4, the District certified that a public hearing had been held on May 25, 1976.

Both amendments consist of changes to section 8-2:713 (Visible Emissions) of the District's regulations. Following a prolonged period of discussion between EPA and the District of Columbia concerning the approvability of the amendments of SIP revisions, the District of Columbia has agreed to withdraw its request of May 24, 1974. Concurrently, the Regional Administrator, EPA Region III, agreed to recommend a proposed approval of the March 3, 1977, request for a SIP revi-

sion as is further discussed in this notice.

The amended regulation now being proposed as a SIP revision is applicable to all stationary sources within the District and, in part, reads as follows:

> * * * no person shall cause, suffer, or allow to be emitted into the outdoor atmosphere, visible emissions from stationary sources: *Provided*, That discharges not exceeding 40-percent opacity (or No. 2 on the Ringelmann Smoke Chart) shall be permitted for 2 minutes in any 60-minute period and for an aggregate of 12 minutes in any 24-hour period. These discharges shall be allowed only for startup, cleaning, soot blowing, adjustment of combustion controls of boilers, and/or unavoidable malfunction of equipment * * *.

The original section 8-2:713, as approved by the Administrator, permitted discharges for startup, cleaning, soot blowing, and/or adjusting combustion controls of boilers not exceeding 40-percent opacity (No. 2 on the Ringelmann Chart) for 4 minutes in any 60-minute period and for an aggregate of 24 minutes in any 24-hour period, until August 31, 1973. After that date, no visible discharges are permitted at any time.

II. Approvability of the Proposed Revision

A request for a revision of a SIP must be approved by the Administrator if the revision meets the requirements of section 110 and EPA's regulations, 40 CFR Part 51. In this case, the mass emission limitation contained in the plan is not being changed. Instead, the District has only requested that the SIP's visible emission requirements be modified to allow for periodic short-term visible emissions during startup, cleaning, soot blowing, adjustment of combustion controls of boilers, and/or unavoidable malfunction of equipment. Such emissions are a part of normal operation and maintenance functions of combustion sources. The basic substantive requirement for approval of this revision is that the revision will not interfere with attainment or maintenance of the national ambient air quality standards.

Where emissions from a flue are addressed by a mass emission limitation and a visible emission requirement, the mass emission limitation is controlling in any air-quality demonstration that may be needed to insure attainment and maintenance of the national standards. Where both visible and mass emission limitations are approved by the Administrator, both are properly a part of the SIP. At present, the District of Columbia SIP requires that a source may never have any visible emissions. However, the mass emission limitation contained in the SIP does not impose an absolute ban on the discharge of particulate matter. Instead, a finite quantity of particulate matter emissions is permissible under the applicable mass emission limitations. The Agency believes that the quantity of emissions permitted by the amendment to the District's regulations does not exceed those mass emission limitations, and therefore the "no visible emissions" requirement is more restrictive than necesssary to accomplish the objectives of sections 110(a)(2) and (a)(3) of the act.

Consequently, the Agency believes that the amendment to the District's regulations submitted on March 3, 1977, does not interfere with attainment or maintenance of the ambient standards for particulate matter and that approval may be granted. In this notice of proposed rulemaking, the Administrator hereby formally withdraws his proposal of July 11, 1974 (39 FR 25502), from any further consideration as a revision of the District of Columbia implementation plan.

The public is invited to submit comments on whether the amendment to section 8-2:713 on visible emission requirements should be approved as a revision of the District's SIP. All comments submitted on or before September 7, 1978, will be considered. All comments should be submitted to Mr. Howard R. Heim (3AH10), Chief, Air Programs Branch, U.S. Envirionmental Protection Agency, Region III, Curtis Building, 10th Floor, Sixth and Walnut Streets, Philadelphia, Pa. 19106, Attn: AHO10bDC.

The Administrator's decision to approve or disapprove the amendment to section 8-2:713 as a revision of the District's SIP will be based on a final determination as to whether it meets the requirements of section 110 of the Clean Air Act and 40 CFR Part 51, Requirements for Preparation, Adoption, and Submittal of Implementation Plans.

(42 U.S.C. 7401.)

Dated: August 3, 1978.

Douglas M. Costle,
Administrator.

[FR Doc. 78-22111 Filed 8-7-78; 8:45 am]

[4110-86]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

Center for Disease Control

[42 CFR Part 91]

GRANTS FOR THE PREVENTION OF LEAD-BASED PAINT POISONING

AGENCY: Center for Disease Control, PHS, HEW.

ACTION: Notice of proposed rulemaking.

SUMMARY: Under the proposed regulations, grants would be awarded to State and local government agencies and to private nonprofit organizations to assist them in meeting the costs of comprehensive lead-based paint poisoning prevention programs, and to State agencies for the purpose of establishing centralized laboratory services for analyzing lead specimens.

Federal funds are to be used for services which will provide an addition to or an improvement in services that would otherwise be provided. A 90-percent limitation on the Federal contribution over a 3-year period is set forth. The proposed rule would implement the Lead-Based Paint Poisoning Prevention Act, as amended.

DATE: Written comments must be received on or before September 7, 1978.

ADDRESSES: Written comments should be sent to the following address: Center for Disease Control, Attention: Director, Environmental Health Services Division, Bureau of State Services, Atlanta, Ga. 30333.

Comments received will be available for public inspection during regular business hours in Room 511, 255 East Paces Ferry Road NE., Atlanta, Ga. 30305.

FOR FURTHER INFORMATION CONTACT:

Mrs. Sara S. Owens, Regulations Officer, Center for Disease Control, Atlanta, Ga. 30333, 404-633-3311, ext. 6723.

SUPPLEMENTARY INFORMATION: This proposed rulemaking is to implement Pub. L. 94-317 and Pub. L. 93-151 which amend the Lead-Based Paint Poisoning Prevention Act.

Background

Children 1 to 5 years of age experience the maximum neurologic development. Lead absorbed in the body directly affects the development of the brain. Therefore, children in this age group are at the highest risk of permanent brain damage. This damage shows up in the later years as distinct behavioral changes such as attentional disorders, learning disabilities, or emotional disturbances. Accordingly, the regulations are focused on preventing lead poisoning in this age group.

The level of lead permitted in paint manufactured after June 22, 1977, has been set at 0.06 of 1 percent by the Consumer Product Safety Commission.

The attached regulations require the grantees to carry out an environmental investigation whenever a child is identified with undue lead absorption. In determining if a lead hazard exists in the child's environment, an X-ray fluorescence analyzer provides the most efficacious method of measuring

the content of lead in paint which has already been applied. This technique provides a minimum reading of 0.5 mg/cm^2 of lead content which is higher than the amount of lead permitted to be included in paint which is manufactured after June 22, 1977. No other method currently available would permit determinations of a lower lead level without damaging the surfaces being tested and requiring time-consuming and costly laboratory analysis.

Costs of eliminating lead hazards in a child's environment are generally borne by landlords or by State and local agencies. However, these regulations permit grant funds to be used for hazard elimination activities in emergency situations where: (1) The house is occupied by the owner; (2) the owner is determined by the grantee to be financially unable to pay for the needed improvements; and (3) other sources of funds cannot be identified. The applicable provisions in the regulations, although seldom used in practice, are necessary to insure that lead hazards are removed quickly in emergency situations.

Rules are set forth in the proposed regulations to govern the establishment of advisory boards for local screening programs under section 505(b) of the Act, as amended. These proposed rules on advisory boards were developed after consultation with the Secretary of Housing and Urban Development.

Other minor changes were made to the regulations for clarity and workability.

It is, therefore, proposed to revise 42 CFR Part 91 as set forth below.

NOTE.—The Department of Health, Education, and Welfare has determined that this document does not contain a major proposal requiring preparation of an economic impact statement under Executive Order 11821, as amended by Executive Order 11949, and OMB Circular A-107.

Dated: April 25, 1978.

J. B. RICHMOND,
Assistant Secretary for Health.

Approved: August 1, 1978.

JOSEPH A. CALIFANO, Jr.,
Secretary.

PART 91—GRANTS FOR THE PREVENTION OF LEAD-BASED PAINT POISONING

Sec.

91.1 Applicability.
91.2 Applicability of 45 CFR Part 74.
91.3 Definitions.
91.4 Eligibility.
91.5 Application—General.
91.6 Application—Grants for detection and reduction of lead-based paint poisoning.
91.7 Application—Grants for establishing centralized laboratory services.
91.8 Evaluation and grant award.
91.9 Grant payments.
91.10 Use of grant funds.
91.11 Grantee accountability.
91.12 Publications and copyright.
91.13 Records and reports.
91.14 Nondiscrimination.
91.15 Additional conditions.

AUTHORITY: The provisions of this part 91 are issued under sections 101, 504, and 505(b), 84 Stat. 2078, as amended, 42 U.S.C. 4801, 4844, and 4845.

§91.1 Applicability.

The regulations in this part apply to the award of grants under section 101(a) of the Lead-based Paint Poisoning Prevention Act (42 U.S.C. 4801) for the purpose of providing assistance in developing and carrying our local programs to detect and treat incidents of lead-based paint poisoning among children under 6 years of age and to eliminate lead-based paint hazards from surfaces in and around residential dwelling units or houses; and under section 101(e) of the Act (42 U.S.C. 4801) to establish centralized laboratory facilities for analyzing biological and environmental lead specimens obtained from local lead-based paint poisoning detection programs.

§ 91.2 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, which establish uniform administrative requirements and cost principles, apply to a grantee under this part as follows:

(a) To a State or local government as those terms are defined in subpart A of part 74.

(b) To other than a State or local government agency, relevant provisions of subparts A, B, C, D, F, G, K, L, M, O, and Q.

§ 91.3 Definitions.

As used in this part:

"Act" means the Lead-Based Paint Poisoning Prevention Act, Pub. L. 91-695, as amended by Pub. L. 93-151 and Pub. L. 94-317.

"Lead-based paint hazard" means a surface containing lead-based paint which is reachable by young children or which contains paint that is cracking, scaling, chipping, peeling, or loose.

"Confirmed blood lead level" means two or more tests which produce elevated results.

"Lead poisoning" is defined as existing whenever a child has any one or more of the following:

(a) Two successive blood lead levels equal to or greater than 70 μg/dl with or without symptoms.

(b) Erythrocyte protophorphyrin (EP) level equal to or greater than 250 μg/dl whole blood and a confirmed blood lead level equal to or greater than 50 μg/dl with or without symptoms.

(c) EP level greater than 109 μg/dl associated with a confirmed elevated blood lead level (>30 μg/dl) with compatible symptoms.

(d) Confirmed blood lead levels greater than 49 μg/dl with compatible symptoms and evidence of toxicity (e.g., abnormal EP, calcium disodium EDTA mobilization test, urinary aminolevulinic acid excretion or urinary coproporphyrin excretion).

"Private nonprofit organization" means an organization which is a corporation or an association no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

"Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department to whom authority under the Act has been delegated.

"State" means the several States, the District of Columbia, the Commonwealth of Puerto Rico, and the territories and possessions of the United States.

"Surfaces" means all surfaces in and around residential dwelling units or houses.

"Undue lead absorption" refers to excess led in the blood with evidence of biochemical derangement in the absence of clinical symptoms. It is defined by a confirmed blood lead level of 30 to 69 μg/dl associated with an EP level of 50 to 249 μg/dl whole blood.

"Units of general local government" means (a) any city, county, township, town, borough, parish, village, or other general purpose political subdivision of a State, (b) any combination of units of general local government in one or more States, (c) an Indian tribe, or (d) with respect to lead-based paint poisoning elimination activities in their urban areas, the territories and possessions of the United States.

§ 91.4 Eligibility.

(a) The following are eligible to apply for a grant under section 101(a) of the Act:

(1) A public agency of a unit of general local government.

(2) A private nonprofit organization.

(3) An agency of a State government where the State government provides direct services to citizens in a local community or where units of general local government within the State are prevented from implementing or receiving grants or from conducting programs consistent with the Act and these regulations.

(b) State agencies which provide centralized laboratory services to local health agencies or programs are eligible to apply for a grant under section 101(e) of the Act.

§ 91.5 Application—General.

(a) An application for a grant under this part shall be submitted to the Secretary in such form and manner

and at such times as the Secretary may prescribe.[1]

(b) The application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of any award, including the regulations of this part.

(c) The application shall contain evidence satisfactory to the Secretary that it has been reviewed, commented upon, or approved by the appropriate planning agency as may be required in regulations implementing the National Healh Planning and Resources Development Act (42 U.S.C. 300k-1, Pub. L. 93-641).

(d) An application for a grant under this part shall contain or describe the following:

(1) In a narrative plan, the manner in which the applicant proposes to conduct the program and carry out the requirements of this part.

(2) A detailed budget for the proposed program and a justification for the grant funds requested.

(3) The applicant's current legal authority and responsibility for the administration of the program or the applicant's plans to obtain legal authority not currently available to the applicant but necesary for the administration of the program.

(4) The current administrative organization, procedures, facilities, staff, and financial and other resources; and the applicant's plan for changes or development in this area, including additional staff necessary to carry out the program efficiently and effectively.

(5) The extent to which the services to be provided will either add to or be a significant improvement in the quality of services which would otherwise be provided, including the steps which will be taken to insure that services will be maintained after a reduction and termination of Federal support.

(6) An evaluation plan which will be used to measure progress in attaining program objectives.

§ 91.6 Application—Grants for detection and reduction of lead-based paint poisoning.

An application for a grant under section 101(a) of the Act shall meet the requirements in § 91.5 and shall also contain the following:

(a) A description of the nature, effects, and extent of the actual and potential local undue lead absorption problem and the methods used for making this determination.

(b) A description of the overall program objectives for reduction of the undue lead absorption problem identified in paragraph (a) of this section.

(c) A description of specific measures of a comprehensive program to be implemented to accomplish the objectives and a schedule for their accompliment. Specific objectives must be stated for screening, medical management, and hazard reduction activities. The program shall include all of the following elements:

(1) An orderly sequence of planning, implementation, and evaluation for both the developmental and operational phases of the program using specific dates wherever feasible.

(2) The development of a community education program to inform parents, educators, and local health personnel of the danger and prevalence of undue lead absorption among children and to generate community and individual action in addressing the problem.

(3) An intensive community screening program to detect evidence of undue lead absorption and lead poisoning in children. Emphasis shall be placed on door-to-door efforts designed to reach the greatest number of children at risk. These activities shall be conducted at hours of the day which minimize financial sacrifice or inconvenience to residents. Provision shall be made for testing the children who may have been missed during the hours of normal activities. In addition to, but not to replace door-to-door screening, the use of clinics shall be encouraged for "walk-in" testing.

(4) An intensive community followup program to insure that children with evidence of undue lead absorption are placed in a program of medical surveillance or treatment as indicated. Investigation shall be carried out to determine the source of lead, and steps shall be taken to insure against further exposure to lead-based paint hazards where there is a level greater than 0.5 mg/cm^2 of lead on the surfaces of walls as measured by an X-ray fluorescence analyzer or any other method approved by the Secretary. A plan for eliminating a lead-based paint hazard must include the following minimal actions:

(i) Thoroughly cleaning the surfaces identified as a hazard by washing, sanding, scraping, using a wire brush, or otherwise cleaning to remove all paint that is cracking, scaling, peeling, chipping, loose, or within reach of children.

(ii) When the integrity of the surface cannot be maintained, completely removing the paint or recovering the surface with a suitable material (e.g., hardboard, plywood, drywall, or plaster) before repainting.

(5) The use of a laboratory which demonstrates its proficiency in a program of proficiency testing or performance review which is acceptable to the Secretary.

(6) Promotion, development, improvement, adoption, and enforcement of effective ordinances and codes which may help prevent childhood lead-based paint poisoning.

(7) Employment opportunities for the residents of the areas affected by the lead problem. Describe methods and procedures that will be used to inform residents of job opportunities in the program as well as the provisions made for appropriate training and education.

(8) Coordination and integration of program activities with other community programs related to health and environmental improvement, such as early and periodic screening, diagnosis, and treatment programs, in the delivery of screening, treatment, and followup services.

(9) Identification and use of resources from the public and private sectors of the community.

(10) Each grantee assisted under section 101(a) of the Act shall establish a community advisory board. Two-thirds of the board members must live in the neighborhoods affected by lead-based paint poisoning. At the time of appointment, a majority of the members shall have at least one child under 6 years of age. The board will advise the grantee on the operation of the program, particularly in the areas of public education and public action related to the prevention of undue lead absorption. The application shall contain a description of the duties and responsibiities of the board. The board shall meet at least once a year but not more frequently than once a quarter. A member shall be reimbursed only for expenses incurred in the performance of duties as a member of the board. Expenses of the board members not paid from Federal grant funds are acceptable for meeting requirements for matching funds from non-Federal sources.

§ 91.7 Application—Grants for establishing centralized laboratory services.

An application for a grant under section 101(e) of the Act shall meet the requirements in § 91.5 and shall also contain the following:

(a) A description of the laboratory services now available to serve current and proposed local and State programs, including those for early and periodic screening, diagnosis, and treatment, and an analysis of these laboratory services in terms of accuracy, capacity, and cost.

(b) A description of the immediate and long-range objectives of the State under this grant to meet needs identified in paragraph (a) of this section.

(c) A description of the methods to be employed in meeting the objectives.

[1] Applications and instructions may be obtained from the Regional Health Administrator of the Regional Office of the Department of Health, Education, and Welfare for the region in which the project is to be conducted.

(d) A description of the steps to be taken to insure that laboratory services provided under the grant meet and continue to meet high standards and the steps to be taken to insure outside review of laboratory performance.

§ 91.8 Evaluation and grant award.

(a) Within the limits of the funds available for this purpose, the Secretary may award a grant for a project which will best promote the purposes of the Act. Special consideration will be given to the following factors:

(1) The magnitude of the problem and the resources needed to adequately address the problem.

(2) The approach taken in the program plan to deal with the problem in the community.

(3) The identification of additional funding and other resources to insure that the program will continue beyond the termination of Federal grant support.

(4) The provision for coordination of program activities with other community health services programs.

(5) The provision of assurances, satisfactory to the Secretary, that the services to be provided will constitute an addition to, or a significant improvement in, quality of services that would otherwise be provided.

(b) The amount of any award shall be based upon the Secretary's estimate of the sum necessary for all or a designated portion of direct costs plus an additional amount for indirect costs, if any.

However, a grant under § 91.6 shall not exceed 90 percent of the total cost of developing and carrying out an approved program over a 3-year period. Costs borne by other Federal grants or costs used to match other Federal grants may not be included except as may be otherwise provided by law.

(c) All grant awards shall be in writing and shall set forth the amount of funds granted and the period for which support is recommended.

(d) The approval of a grant application shall not obligate the United States to make any additional, supplemental, continuation, or other award to any approved program. The grantee must apply separately for continuing support.

§ 91.9 Grant payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award. These payments may be made either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the program. The payments shall be made as the Secretary determines necessary to promote initiation and advancement of the approved program.

§ 91.10 Use of grant funds.

(a) The grantee shall provide assurances, satisfactory to the Secretary, that Federal funds will be used to supplement and not replace State, local, and other non-Federal funds that would, in the absence of Federal funds, be made available to the program. The grantee shall use Federal funds to the extent practical to increase the level of expenditures for the program.

(b) Grant funds may be used solely for the purposes for which the funds were granted, subject to the following limitations:

(1) With respect to medical care or treatment, only when such care or treatment is required for emergency purposes and only when the grantee finds and demonstrates to the satisfaction of the Secretary that no other funds are available for this purpose.

(2) With respect to the elimination of a hazard of lead-based paint in and around a residential dwelling unit, only under the following conditions:

(i) When the grantee finds that a hazard at a residential dwelling unit presents an imminent danger to at least one child with undue lead absorption. Priority of action shall be given to the residence of a child with lead poisoning.

(ii) When the grantee finds and demonstrates to the satisfaction of the Secretary that an owner-occupant of a dwelling which houses a child with diagnosed lead poisoning is financially unable to eliminate the hazard and that no other funds are reasonably available for the reduction of the hazard.

§ 91.11 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved program, the grantee shall account for the total of all amounts paid out by presenting or otherwise making available evidence, satisfactory to the Secretary, of expenditures for direct and indirect costs meeting the requirements of this part. However, when the amount awarded for indirect cost was based on a predetermined fixed percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) *Accounting for grant related income—Interest.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political subdivisions of the State. All grantees other than a State, as defined in this subsection, must return all interest earned on grant funds to the Federal Government.

(c) *Grant closeout*—(1) *Date of final accounting.* A grantee shall provide to the Secretary, within 120 days from the termination of the grant, a full accounting of funds spent under the grant.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section;

(ii) Any credits for earned interest pursuant to paragraph (b) of this section;

(iii) Any other amounts due pursuant to subparts F, M, and O of 45 CFR 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assignees by setoff or other action as provided by law.

§ 91.12 Publications and copyright.

Unless otherwise provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films, or similar materials resulting from a grant under these regulations. This authorization is subject to a royalty-free, nonexclusive, and irrevocable right in the Government to reproduce, translate, publish, use, disseminate, and dispose of the materials and to authorize others to do so.

§ 91.13 Records and reports.

The grantee shall maintain such progress and fiscal records and file with the Secretary such progress, fiscal, and other reports relating to the conduct and results of grant activities as the Secretary may find necessary to carry out the purposes of this part.

§ 91.14 Nondiscrimination.

Recipients of grants under this part are advised that in addition to complying with the terms and conditions of these regulations, the following laws and regulations are applicable:

(a) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.) and

its implementing regulation, 45 CFR Part 86 (prohibiting discrimination in federally assisted programs on the ground of race, color, or national origin).

(b) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and its implementing regulation, 45 CFR Part 84 (prohibiting discrimination in federally assisted programs on the basis of handicap).

§ 91.15 Additional conditions.

The Secretary may impose additional conditions when in his judgment they are necessary to advance the approved program, the interest of the public health, or the conservation of grant funds.

[FR Doc. 78-21914 Filed 8-7-78; 8:45 am]

[4110-35]

Health Care Financing Administration

[42 CFR Part 448]

MEDICAL ASSISTANCE PROGRAMS

State Residence Requirements

AGENCY: Health Care Financing Administration (HCFA), HEW.

ACTION: Proposed rule.

SUMMARY: This regulation would establish new criteria for determining State residency of applicants and recipients under Medicaid programs (title XIX of the Social Security Act). Clearer rules are needed to resolve situations which have not been adequately and equitably resolved under the procedures currently used by the State Medicaid agencies.

DATES: Closing date for receipt of comments: October 10, 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-140-P. Agencies and organizations are requested to submit comments in duplicate. Beginning two weeks from today, the public may review the comments on Monday through Friday of each week, from 8:30 a.m. to 5 p.m.: Department of Health, Education, and Welfare, Health Care Financing Administration, Room 5231, 330 C Street SW., Washington, D.C., 202-245-0950.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Barnes, 202-245-0596.

SUPPLEMENTARY INFORMATION: The current regulation governing the determination of a Medicaid applicant's and recipient's State of residence (42 CFR 448.40) has not been uniformly applied by the State Medicaid agencies. Moreover, it does not adequately address the full range of situations which arise. Consequently, there have been instances, particularly involving persons who are institutionalized, in which Medicaid services have been denied because two or more States refused to recognize an individual as a resident. The individual, in effect, "falls between the cracks" and is unable to establish any State residency. The proposed regulation is designed to insure, as far as practicable, that eligible persons are not denied Medicaid coverage because of disagreement among States and, in particular, because their placement in long-term care makes it difficult to determine their proper State of residence.

WHO IS A STATE RESIDENT

The current regulation defines a resident as "* * * on who is living in the State voluntarily with the intention of making his home there and not for a temporary purpose." Some States have interpreted the reference to "making his home" to require that the person have the ability to undertake homemaking, which obviously rules out persons in nursing homes. Some States have also denied eligibility to migrant farm workers and other people in the State for the purpose of employment, based on the "temporary purpose" provision of the current regulation. The proposed regulation addresses both of these problems, as explained more fully below, by rephrasing the general rule regarding the person's intent to remain in the State and adding a specific provision regarding presence in the State for purposes of employment.

The current regulations also states: "Residency may not depend upon the reason for which the individual entered the State, except insofar as it may bear upon whether he is there voluntarily or for a temporary purpose." Some States have interpreted this exception to mean that presence in a nursing home is involuntarily and for a temporary purpose, thus denying medical care to otherwise eligible individuals. We did not intend the current regulation to have this result and, therefore, propose deleting this sentence.

1. GENERAL RULE FOR DETERMINING RESIDENCY

The proposed regulation specifies that a person is a resident of a State if he is living there with the intention to remain permanently or for an indefinate period. This phrasing is more consistent with the long standing case law dealing with questions of residency than the current regulation. (See "Stifel v. Hopkins," 497 F. 2d 1116 (1973) and "Hadnott v. Amos," 320 F. Supp. 107 (1970).) It should resolve most of the difficulties which have arisen under the current regulation concerning the residency of a person in a nursing home. It would be the governing rule for the vast majority of Medicaid applicants and recipients. The State would have discretion in determining what verification, if any, will be used to substantiate a person's indication of intent.

2. PERSON LIVING IN THE STATE FOR PURPOSES OF EMPLOYMENT

The proposed rule also specifies that a person is a resident of a State if he is living there for purposes of employment. This is intended to deal with the specific problem that has arisen when highly mobile workers move from State to State and are denied Medicaid eligibility by each State to which they apply, on the grounds they are in a State only for a temporary purpose. The prime example is the migrant farm worker who is denied eligibility all along the migrant stream.

Under the proposed rule, a person who would otherwise be eligible for Medicaid cannot be denied eligibility, as long as he is living in the State and is employed or seeking employment, on the grounds that the employment is short term and the person is likely to move to another State to seek employment. The rationale for the proposed rule is that the State which is receiving the economic benefit of the person's employment should take responsibility for providing Medicaid services.

The proposed regulation preserves the principle that a person can only be a resident of one State and can only be eligible for Medicaid in one State. We have redrafted the current regulation which specifies that a resident retains his Medicaid eligibility while he is temporarily absent from the State if he intends to return. (See 42 CFR 448.40(b)(2)). The proposed regulation provides an exception to this rule when another State determines that the person has established residence in that other State. For example, if a migrant farm worker had established a permanent residence in one State he would retain that residence until a second State finds that he is a resident there based on the employment provision of this proposed regulation.

INDIVIDUALS UNDER AGE 21

The current rule for determining a "child's" State of residence would be replaced by new rules governing individuals under age 21.

For individuals under 21 whose Medicaid eligibility is determined wholly or partly under the rules of the Aid to Families with Dependent Children (AFDC) program, the residency criteria of that program will apply. This in-

cludes AFDC cash recipients, AFDC-related individuals who are not receiving cash, and needy individuals who meet the AFDC income test but are not dependent children as defined in section 406 of the Social Security Act. The AFDC residency criteria would also apply to individuals under 21 in those groups who are financially eligible as medically needy. Use of the AFDC rules will allow States to use the regular AFDC eligibility process for these individuals and preclude any need for separate residency determinations.

For individuals under 21 whose Medicaid eligibility is based on blindness or disability, the proposed regulation would establish criteria based primarily on the concept of parental responsibility:

(a) The natural or adoptive parents' State of residency shall be considered the individual's State of residency.

(b) If the parents reside in separate States, the State of residence of the parent who is applying for Medicaid eligibility on behalf of the individual shall be the individual's State of residency.

(c) If the parents reside outside the United States, cannot be located or are deceased, or if a legal guardian is appointed for the individual, the State in which the individual is physically present, not for a temporary purpose, shall be the State of residence.

Criteria (a) and (b) are more equitable than basing residency on physical presence within a State. If residency of institutionalized children were based solely on physical presence, States with high-facilities would have a significant increase in program costs because of placements from other States. Also, other States may not be motivated to provide sufficient, high-quality care if the residency criteria shifted the costs for such care to the States with more attractive existing facilities. However, (c) is the only logical approach to determine residency when the individual's parents are deceased, living outside of the United States or cannot be located.

Criteria for Determining Residence of Adults Incapable of Indicating Intent

New criteria are proposed for detrimining residence of individuals who are age 21 or older but who are incapable of indicating intent on residence. These criteria are necessary because the existing lack of rules on this point has caused controversy between States and coverage problems for inidviduals.

In order to insure program consistency, criteria to determine whether an individual is capable of stating intent are similar to those used under the Supplemental Security Income (SSI) program for determining whether an individual can manage SSI cash benefits. An individual shall be considered incapable of stating intent if his I.Q. is 49 or less or if he has a mental age of 7 or less, or if he has been judged legally incompetent. In all other instances, such as when an individual is in a coma, medical documentation or other documentation acceptable to the State is required to establish the individual's incapacity.

The regulation would provide different rules for adults who became incapable of indicating intent before reaching age 21 and those who became incapable at or after 21. Age 21 is being use for purposes of this regulation because, although State laws vary, most States confer adult status at age 21.

The Department believes it is equitable to place responsibility primarily on the parents of persons who are now adults but who became incapable before 21. Thus, the criteria proposed for adults who became incapable before reaching 21 are the same as those specified for blind or disabled individuals who are under 21 when the residency determination is made.

Individuals who became incapable at or after age 21 are considered to have become emancipated at 21, and are thus no longer their parents' responsibility. The proposed rule applicable to them is:

> "For any individual who became incapable of stating intent at or after age 21, the State of residence will be the State in which the individual most recently established residence prior to becoming incapable of indicating intent."

For example, an 80-year-old woman who cannot state intent and has lived in Virginia for several years is placed by her husband in a Maryland skilled nursing home. In this situation, Virginia remains her State of residence. While an individual who intentionally seeks long-term institutional care in a new State could become a resident of that State if he so chose, persons unable to state intent who are placed in out-of-State facilities by others (e.g., by the family or a guardian) cannot be assumed to have intentionally changed their State of residence.

Placements by States to Out-of-State Institutions

When a State arranges for an individual to be placed in an out-of-State facility, the need for this action generally results from the first State's lack of a sufficient number of appropriate facilities. Consequently, the regulation would place responsibility for providing Medicaid on the State making the placement, irrespective of the individual's expressed intent or ability to express intent.

Prohibited Residency Criteria

The regulation proposes specific prohibitions on State residency criteria:

(1) *Durational residence requirements.* Individuals should not be penalized because they have exercised their right to move freely within the country. Consequently, States may not deny Medicaid eligibility because the individual has not resided in the State for a specified period. This prohibition is based on the Supreme Court decision in the case of "Shapiro v. Thompson" (April 29, 1969), which declared the durational residence requirements of several State assistance programs to be unconstitutional.

(2) *Institutions as places of residence.* Some States have denied Medicaid to an institutionalized individual because he did not previously have an "ordinary," or non-institutional, place of residence in the State. This leads to an unacceptable limitation on eligibility. Therefore, the regulation would prohibit States from denying Medicaid to an individual solely because he did not establish a residence in the State before entering the institution.

(3) *Temporary absence from State, with intent to return.* The proposed rule would retain the present rule that, once a person has established a residence, he retains that residence until he established a new one in a different State. Thus, if a resident leaves his State of residence temporarily, but intends to return, he retains his residence and may not be denied Medicaid eligibility. The State may deny or terminate a resident's eligibility only if the person changes his residence to another State or if another State determines that person is a resident there for purposes of Medicaid eligibility.

Interstate Agreements

The regulation would allow States to enter into interstate agreements for resolving cases of disputed residency. The agreements need not be consistent with the residency criteria specified in the proposed regulation, i.e., different rules and procedures may be adopted through interstate agreements. However, the agreements must not establish residency criteria that are specifically prohibited in the regulation (e.g., durational residency requirements that result in denial by both States). Also, the agreements must include procedures for providing Medicaid coverage pending resolution of the dispute.

Interstate agreements may be general (dealing with all cases in dispute between the States) or they may be developed as necessary (on a case-by-case basis).

Since it is virtually impossible for Federal regulations to anticipate or cover every residency problem that

may arise, we feel that allowing alternate approaches to handling disputed cases through interstate agreements will contribute to resolution of nearly all residency problems of Medicaid applicants and recipients.

CODIFICATION

Current residency regulations were originally codified under 45 CFR 248.40. Recodification changes, effective October 1, 1977, established a new chapter IV in title 42 of the Code of Federal Regulations for the Health Care Financing Administration. Subchapter C of chapter IV contains medicaid regulations. Therefore, the proposed amendments to the regulation are codified as 42 CFR 448.40 and 448.41.

Section 448.40 specifies circumstances under which medical care and services must be provided to an eligible individual who is temporarily absent from and in need of care outside his State of residence. It contains no change from the existing regulation, but has merely been rewritten in simpler language.

A new § 448.41 defines criteria for determining State of residency as explained above.

OPERATION COMMON SENSE

In drafting this proposed rule, we have followed the objectives of Operation Common Sense (see 42 FR 59555, November 18, 1977). To assist a user in understanding the proposed rule, we have also prepared an appendix, illustrating how any individual situation would be resolved (in the absence of an interstate agreement) by answering a series of questions.

42 CFR Part 448 is amended as follows:

1. Section 448.40 is revised to read as set forth below:

§ 448.40 Payments for services furnished out-of-State.

(a) *Purpose.* This section implements section 1902(a)(16) of the Social Security Act, which authorizes the Secretary to promulgate State plan requirements for the furnishing of medical assistance to State residents who are absent from the State.

(b) *Payment for services.* A State Medicaid plan must provide that the State will make Medicaid payments for medical services furnished to an eligible resident of the State while that resident is in another State, to the same extent those medical services are reimbursed under the State plan for residents in the State, when:

(1) The services are needed because of a medical emergency;

(2) The services are needed because the individual's health would be endangered if he were required to travel to his State of residence or to postpone obtaining services until his return to his State of residence;

(3) The State determines, on the basis of the attending physician's medical advice, that the medical services (or necessary supplementary resources) are more readily available in the other State; or

(4) It is the general practice for residents of a particular locality to use medical resources in an adjacent State.

(c) *Cooperation among States.* The State Medicaid plan must provide that the State will establish procedures to facilities the furnishing of medical services to individuals who are present in the State and are eligible for Medicaid under another State's plan.

2. A new § 448.41 is added to read as follows:

§ 448.41 Determinations of State residence.

(a) *Purpose.* This section specifies rules for implementing section 1902(b) of the Social Security Act, which prohibits States from applying any residence requirement that results in denial of medical assistance to any individual residing in the State.

(b) *Condition for plan approval.* A State Medicaid plan may not impose any residence requirement which excludes any individual who is a resident of the State under the terms of this section.

(c) *Who is a State resident.* Except as provided in an interstate agreement under paragraph (h) of this section, a resident of a State is any individual who:

(1) Is living in the State with the intention to remain there permanently or for an indefinite period;

(2) Is living in the State for purposes of employment;

(3) Meets the conditions in paragraphs (d), (e), or (f) of this section.

(d) *Rules applicable to individuals under age 21.* (1) The State of residence of any individual under age 21, except those whose Medicaid eligibility is based on blindness or disability, shall be determined in accordance with 45 CFR 233.40, the rules governing residence under the Aid to Families with Dependent Children program.

(2) The State of residence for any individual under age 21 whose Medicaid eligibility is based on blindness or disability shall be the parent's State of residence, except:

(i) If the parents reside in separate States, the State of residence of the parent who is applying for Medicaid eligibility on behalf of the individual shall be the individual's State of residence; or

(ii) If the parents reside outside the United States, cannot be located or are deceased, or if a legal guardian is appointed for the individual, the State in which the individual is physically present, not for a temporary purpose, shall be the individual's State of residence.

(e) *Rules applicable to individuals over age 21 who are incapable of indicating intent.* (1) An individual shall be considered incapable of indicating intent if:

(i) His I.Q. is 49 or less or he has a mental age of 7 or less;

(ii) He is judged legally incomplete; or

(iii) Medical documentation, or other documentation acceptable to the State, supports a finding that he is incapable of stating intent.

(2) For an individual who became incapable of indicating intent before age 21, the State of residence shall be determined in accordance with paragraph (d)(2) of this section.

(3) For an individual who became incapable of indicating intent at or after age 21, the State of residence shall be the State in which the individual most recently established residence before becoming incapable of indicating intent.

(f) *Placement by States in an out-of-State institution.* If a State arranges for an individual to be placed in an institution located in another State, the State making the placement shall be the individual's State of residence, irrespective of the individual's indicated intent or ability to indicate intent.

(g) *Specific prohibitions.* (1) A State may not deny Medicaid eligibility because an individual has not resided in the State for a specified period.

(2) A State may not deny Medicaid eligibility to an individual in an institution, who satisfies the residency rules set forth in this section, on the grounds that the individual did not establish residence in the State before entering the institution.

(3) A State may not deny or terminate a resident's Medicaid eligibility because of that person's temporary absence from the State if the person intends to return when the purpose of the absence has been accomplished, unless another State has determined that the person is a resident there for purposes of Medicaid.

(h) *Interstate agreements.* A State may have a written agreement with another State setting forth rules and procedures resolving cases of disputed residency. These agreements may establish criteria other than those specified in paragraphs (b) through (f) of this section: *Provided,* That those criteria are not prohibited under paragraph (g) of this section. The agreements must contain a procedure for providing Medicaid to individuals whose residence is in dispute pending resolution of the case.

(Sec. 1102, Social Security Act, 49 Stat. 647 (42 U.S.C. 1302))

(Catalog of Federal domestic assistance program No. 13.714, medical assistance program.)

Dated: March 17, 1978.

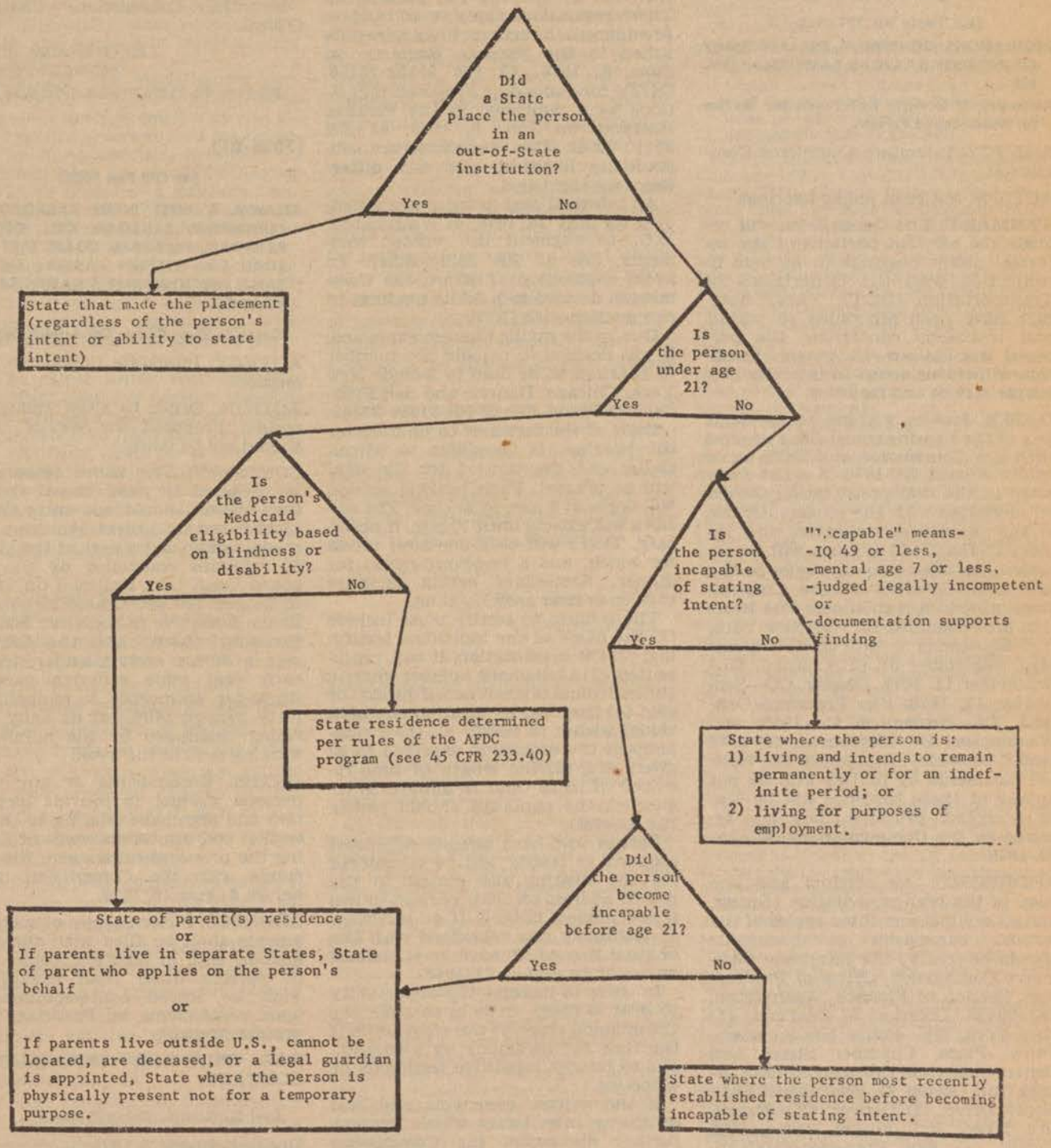
WILLIAM D. FULLERTON,
Acting Administrator,
Health Care Financing
Administration.

Approved: July 24, 1978.

HALE CHAMPION,
Acting Secretary.

MEDICAID: STATE RESIDENCE REQUIREMENTS

Unless interstate agreements specify other rules, these questions and answers determine State residence of Medicaid eligible persons:



PROHIBITED RESIDENCE CRITERIA: No State may deny Medicaid to an eligible person because that person-

- has not lived in the State for a specified period,
- did not live in the State before entering an institution, or
- is temporarily out of the State but plans to return.

[FR Doc. 78-21715 Filed 8-7-78; 8:45 am]

[7035-01]

INTERSTATE COMMERCE COMMISSION

[49 CFR Part 1124]

[Ex. Parte No. 227 (Sub-1)]

REGULATIONS GOVERNING THE ADEQUACY OF INTERCITY RAILROAD PASSENGER SERVICE

Adequacy of Intercity Rail Passenger Service for Handicapped Persons

AGENCY: Interstate Commerce Commission.

ACTION: Notice of public hearings.

SUMMARY: The Commission will cochair the relevant portions of the informal public hearings to be held in conjuction with the Department of Transportation (DOT). These hearings have been scheduled to permit oral testimony concerning the proposed regulations to insure handicapped persons access to intercity passenger service and facilities.

DATES: Parties wishing to speak at any of the hearings must file a request with the Commission and DOT on or before August 23, 1978. A short summary of the oral presentation should be submitted with the request. Copies of the summaries presented with respect to the DOT sections will be accepted, provided they also refer to the appropriate section of the Commission's proposed regulations. The hearings are scheduled for: (1) New York, NY—September 7, 1978 (and, if necessary, September 8); (2) Chicago, IL—September 11, 1978; Denver, CO—September 13, 1978; San Francisco/Oakland, CA—September 15, 1978; and Washington, DC—September 19, 1978 (and if necessary, September 20). Written comments by parties who do not appear at these hearings will be also be accepted, provided they are received by the Commission by October 20, 1978.

ADDRESSES: An original and one copy of the oral presentation request, and an original and three copies of the written summaries or comments should be sent to the Interstate Commerce Commission, Office of Proceedings, Section of Finance, Washington, DC 20423. Location of hearings: (1) New York, NY—Police Headquarters, Police Plaza, Chamber Street and Center Street; (2) Chicago, IL—McCormick Inn (Room 7), 2300 South Lake Shore Drive; (3) Denver, CO—Executive Tower Inn, Forum Room, 1405 Curtis; (4) San Francisco/Oakland, CA—Claremont Hotel Empire Room, Ashby and Domingo Avenues; (5) Washington, DC—Department of Health, Education, and Welfare, North Building Auditorium, 330 Independence Avenue SW.

SUPPLEMENTARY INFORMATION: The Commission has drafted proposed regulations to insure adequate services and facilities for handicapped persons traveling as intercity rail passengers. These regulations apply to all carriers providing such services. They were published in the FEDERAL REGISTER on June 9, 1978, 43 FR 25152-25156. DOT's corresponding proposed regulations were published in the FEDERAL REGISTER on June 8, 1978, 43 FR 25016-25066. The regulations are substantially identical, and any differences are identified.

An informal oral hearing was scheduled for July 26, 1978, in Washington, D.C., to augment the written comments. See 43 FR 28216-28217. To avoid duplication of effort, the Commission decided to hold its hearings in conjunction with DOT.

Due to the public interest expressed, it was decided to expand the number of hearings to be held to include New York, Chicago, Denver, and San Francisco/Oakland. See 49 FR 31364-31365.

Each of the facilities to be used for the hearings is accessible to wheelchairs and interpreters for the deaf will be present. Each hearing seesion will begin at 9 a.m. local time. The sessions will extend until 10 p.m. if necessary. There will be a one-hour recess for lunch, and a one-hour recess for dinner. Accessibler eating facilities exist in or near each building.

The request to testify must include (1) the name of the individual testifying; (2) the organization, if any, represented; (3) a telephone number wherein the individual can be reached during the day; (4) the hearing location the individual wishes to testify at; (5) a summary of the testimony expected to be given; and (6) the length of time required (if more than 10 minutes is requested, the applicant should justify the request).

Parties who have already submitted requests to testify will be considered for the hearing site closest to the return address on their request unless a new request is filed. If no summary of testimony was submitted with the original request, it must be submitted on or before August 23, 1978.

In order to increase the opportunity to hear as many views as possible, the Commission reserves the right to limit the time for testimony by witnesses,. and to restrict repetitive testimony or witnesses.

If the written comments and oral testimony raise issues which warrant further discussion, the Commission may schedule further hearings at a later date.

The written comments and summaries will be available for public inspection at the offices of the Interstate Commerce Commissionn, 12th Street and Constitution Avenue NW., Washington, D.C., during regular business hours.

Decided: August 3, 1978.

By the Commission, Chairman O'Neal.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-22270 Filed 8-7-78; 9:22 am]

[7035-01]

[49 CFR Part 1033]

ATLANTA & WEST POINT RAILROAD CO., CLINCHFIELD RAILROAD CO., GEORGIA RAILROAD, SEABOARD COAST LINE RAILROAD CO., WESTERN RAILWAY OF ALABAMA AND LOUISVILLE & NASHVILLE RAILROAD CO.

Order To Show Cause; Car Service Orders

AGENCY: Interstate Commerce Commission.

ACTION: Order to show cause why certain proposed car service orders should not be issued.

SUMMARY: The above respondents are ordered to show cause why the Commission should not enter the attached service orders requiring railroads, comprising a part of the system of railroads controlled by the Seaboard Coast Line Railroad Co. (SCL), to deliver 100 serviceable locomotives to the Louisville & Nashville Railroad Company (L&N) and the L&N to supply during each calendar week to each coal mine ordering cars for single-car shipments a minimum of forty percent (40%) of its daily mine rating multiplied by the number of working days in the week.

DATES: Respondents or any other persons wishing to provide information and argument relating to the necessity and appropriateness of entering the proposed orders may file comments with the Commission on or before August 18, 1978.

ADDRESS: Fifteen copies of such documents shall be filed with the Commission and, in addition, copies filed by persons other than respondents shall be served contemporaneously upon respondents by first-class mail, postage prepaid.

FOR FURTHER INFORMATION CONTACT:

Joel E. Burns, 202-275-7849.

Decided: August 3, 1978.

It appears to the Commission that good cause may exist for entering the attached service orders requiring railroads, comprising a part of the system of railroads controlled by the Seaboard Coast Line Railroad Co. (SCL),

to deliver 100 serviceable locomotives to the Louisville & Nashville Railroad Co. (L&N) and the L&N to supply during each calendar week to each coal mine ordering cars for single-car shipments a minimum of forty percent (40%) of its daily mine rating multiplied by the number of working days in the week.

Accordingly, the above-named parties to whom this order is addressed are ordered to show cause why the attached service orders should not be entered by filing with the Secretary of the Commission on or before August 18, 1978, 15 copies of a document setting forth all facts within their knowledge and legal arguments which might tend to show that entry of the contemplated orders is unnecessary or would be inappropriate. More specifically, the Commission is interested in obtaining specific information with regard to the following areas of inquiry.

1. The effect which requiring railroads other than the L&N in the SCL system to supply the specified number of locomotives to L&N will have upon those railroads' ability to provide adequate service to their shippers.

2. The effect which obtaining use of additional locomotives will have upon improving L&N's ability to provide more adequate service to coal mines on its lines.

3. The effect which requiring L&N to supply cars equal to 40% of daily mine rating to single-car coal shippers will have upon L&N's ability to adequately serve its other shippers.

4. Any other information which respondents believe would be helpful to the Commission in determining the necessity and appropriateness of entering the proposed orders. In this connection, respondent L & N is specifically requested to supply to the Commission the following:

a. A listing of all coal mines on the L & N system including the rating assigned to each mine.

b. A listing showing the scheduled frequency of service to each mine and an explanation detailing actual service to each mine. The explanation shall distinguish between mines tendering unit train shipments and less than unit train shipments.

c. A full explanation, including appropriate documentation, describing the percentage of cars furnished unit train shippers of coal against the number of cars ordered since January 1, 1978.

d. A full explanation, including appropriate documentation, describing the percentage of cars furnished single car shippers of coal against the number of car orders since January 1, 1978.

A copy of this order shall be served upon the Washington agent for each of the named railroad respondents. Notice shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by publication in the FEDERAL REGISTER.

Any interested person may file comments or provide information and argument relating to the necessity and appropriateness of entering the proposed orders within the time allowed for respondents to show cause (August 18, 1978) by filing 15 copies with the Secretary of the Commission. Copies of any materials so filed shall also be served contemporaneously upon respondents by first-class mail, postage prepaid.

Oral argument is not presently contemplated by the Commission. However, if the commission subsequently determines that an oral argument would be helpful, notice of the time and place for such argument will be published in the FEDERAL REGISTER.

By the Commission.

H.G. HOMME, Jr.,
Acting Secretary.

[Service Order No. ——]

REGULATIONS FOR THE USE OF LOCOMOTIVES

ATLANTA AND WEST POINT RAILROAD CO., CLINCHFIELD RAILROAD CO., GEORGIA RAILROAD, SEABOARD COAST LINE RAILROAD CO., AND WESTERN RAILWAY OF ALABAMA TO DELIVER LOCOMOTIVES TO LOUISVILLE AND NASHVILLE RAILROAD CO.

An acute shortage of locomotives for transporting shipments of coal exists on the Louisville and Nashville Railroad Co. (LN). This company is a part of a system of railroads controlled by the Seaboard Coast Line Railroad Co. (SCL), which comprise the lines of the Atlanta and West Point Railroad Co., Clinchfield Railroad Co., Georgia Railroad, LN, SCL and Western Railway of Alabama. The LN has leased locomotives from unaffiliated railroads but has been unsuccessful in obtaining sufficient locomotives to move cars promptly over its lines. The effects of these shortages are highly concentrated in the movement of coal from mines served by the LN and have contributed to the critical car shortages at coal mines served by the LN. These car shortages have resulted in great economic loss and reduced employment in those coal mines.

It is the opinion of the Commission that present regulations and practices with respect to the use, supply, control, movement, distribution, exchange, interchange, and return of locomotives are ineffective and that an emergency exists requiring immediate action to promote car service in the interest of the public and the commerce of the people. Accordingly, the Commission finds that notice and public procedure are impractical and contrary to the public interest, and that good cause exists for making this order effective on less than thirty (30) days' notice.

It is ordered,

§ 1033. . . . Atlanta and West Point Railroad Company, Clinchfield Railroad Company, Georgia Railroad, Seaboard Coast Line Railroad Company and Western Railway of Alabama to Deliver Locomotives to Louisville and Nashville Railroad Company.

(a) The Atlanta and West Point Railroad Company (AWP), Clinchfield Railroad Company (CRR), Georgia Railroad (Ga), Seaboard Coast Line Railroad Company (SCL) and Western Railway of Alabama (WA) shall collectively deliver to the Louisville and Nashville Railroad Company (LN) a total of one hundred (100) serviceable locomotive units suitable for road freight movements. This delivery shall be accomplished within 21 days after the effective date of this order.

Locomotives delivered under this order shall be under the control of the LN and shall be used in the normal course of transporting traffic thereon.

AWP, CRR, Ga, SCL, and WA locomotives in use on and under the control of the LN on the effective date of this order may be deducted from the one hundred (100) locomotives SCL is required to deliver under this order, and contractural agreements for the use of locomotives delivered prior to the effective date of this order shall not be affected by this order. AWP, CRR, Ga, SCL, and WA locomotives on the LN in "run-through" services in which these railroads and the LN have each agreed to permit the other's locomotives run through an interchange connection to a destination terminal subject to an equalization agreement may not be considered as locomotives furnished to the LN under this order.

(b) The LN shall not return to railroads other than the AWP, CRR, Ga, SCL, and WA locomotives which it has leased unless such locomotives are recalled by the owner or unless such locomotives become unserviceable.

(c) Locomotives furnished to the LN by any railroad subject to this order which become unserviceable and which cannot be restored to service by the LN within seven (7) days shall be replaced by the owner with a serviceable locomotive unit.

(d) *SCL responsible.* Inasmuch as the AWP, CRR, Ga, LN, SCL, and WA comprise a single system of railroads controlled by the SCL, after the quota of locomotives to be furnished by the AWP, CRR, Ga, and WA has been determined, the SCL shall furnish sufficient of its own locomotives to enable the entire group of carriers to deliver the required one hundred (100) locomotives to the LN.

(e) *Compensation to be paid.* The rates of compensation to be paid by the LN for the use of locomotives furnished by the AWP, CRR, Ga, SCL, and WA shall be those voluntarily agreed upon among the carriers, or, in the event they are unable to agree, those determined by the Commission at the request of any of the carriers named in this order.

(f) *Locomotive defined.* The term locomotive units, as used in this order, means diesel electric locomotive power units, of 1500

horsepower or more each, capable of being used in road freight train service.

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

Expiration date. This order shall expire at 11:59 p.m., ——, 1978, unless otherwise modified, changed, or suspended by order of the Commission.

(49 U.S.C. 1(10-17).)

It is further ordered, That a copy of this order and direction shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association; and that notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[Service Order No. ——]

REGULATIONS FOR THE DISTRIBUTION OF HOPPER CARS

There is an acute shortage of hopper cars for shipments of coal originating at stations on the Louisville and Nashville Railroad Company. This acute shortage of hopper cars is depriving single car shippers of sufficient cars to allow them to maintain operations, thus creating great economic loss and reduced employment.

Present regulations and practices with respect to the use, supply, control, movement, distribution, exchange, interchange, and return of hopper cars are ineffective. It is the opinion of the Commission that an emergency exists, requiring immediate action to promote car service in the interest of the public and the commerce of the people. Accordingly, the Commission finds that notice and public procedure are impractical and contrary to the public interest, and that good cause exists for making this order effective upon less than thirty days' notice.

It is ordered,

§ 1033. . . . Regulations for the distribution of hopper cars.

(a) *Cars Required To Be Furnished.* During each calendar week the Louisville and Nashville Railroad Company (LN) shall supply to each mine ordering cars for single car shipments a minimum of forty percent (40%) of its daily mine rating multiplied by the number of working days in the week.

(b) *Reports required.* The LN shall report in writing the following information no later than the twenty-fifth and tenth day of each month. Reports to be furnished on the twenty-fifth day of the month shall include all required data for the first fifteen days of the month. Reports to be furnished on the tenth day of each month shall include all required data for the period commencing on the 16th day of the immediately preceeding month and ending on the last day. Reports shall be submitted to Joel E. Burns, Director, Bureau of Operations, Interstate Commerce Commission, Washington, D.C. 20423:

(1) The name of each operating mine making single car shipments.

(2) The rating given each such mine.

(3) The number of cars ordered by each such mine for each day of the period.

(4) The number of cars furnished to each such mine for each day of the period.

(5) The total number of cars ordered for the period.

(6) The total number of cars furnished for the period.

(7) The percent of cars furnished to cars ordered for the period.

(8) The percent of cars furnished to the cumulative mine rating for the period.

(c) *Limitations on car supply.* No mine shall be furnished more cars during any period than it has ordered for loading during such period.

(d) *Definitions:* 1. *Mine rating.* The number of cars a mine can load in one day as determined by the mine rating rules of the LN.

2. *Single-car shipments.* Any shipment of less than 4500 tons of coal tendered to the LN for transportation.

(e) *Exceptions.* Exceptions or modifications to this order may be issued to the LN by the Director or Assistant Director, Bureau of Operations, Interstate Commerce Commission, Washington, D.C. 20423. Requests for modifications must be in writing, or confirmed in writing, and must clearly state the reasons for such modification and the effect upon shippers dependent upon the LN for their car supplies for transporting shipments of coal and other commodities shipped in open hopper cars.

(f) The provisions of this order shall apply to intrastate, interstate or foreign commerce.

(g) *Effective date.* The provisions of this order shall become effective at 11:59 p.m., ——, 1978.

(h) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., ——, 1978, unless otherwise modified, changed, or suspended by order of this Commission.

(49 U.S.C. 1(10-17).)

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

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-22269 Filed 8-7-78; 9:19 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.

[3410-16]

DEPARTMENT OF AGRICULTURE

Office of the Secretary

PRIVACY ACT OF 1974

Notice of Systems of Records

AGENCY: Department of Agriculture.

ACTION: Notice of proposed new system of records.

SUMMARY: The Agricultural Stabilization and Conservation Service (ASCS) proposes to establish a new system of records, USDA/ASCS-33, Peanut allotment and quota file in accordance with the Privacy Act of 1974, 5 U.S.C. 552a(e) (4) and (11). The new system will be an automated data file containing information on all producers participating in the ASCS peanut allotment and quota system. The information will be obtained primarily from documents originating in county ASCS offices and from information submitted by peanut producers and peanut associations to the county ASCS office(s).

DATES: Comments must be received by September 7, 1978.

ADDRESS: Send comments to: Director, Research and Operations Division, Office of the General Counsel, U.S. Department of Agriculture, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT:

Wayne L. Wang, Acting Director, Management Services Division, ASCS/USDA, P.O. Box 2415, Washington, D.C. 20013. Phone 202-447-2717.

PROPOSED EFFECTIVE DATE: This additional system of records will be adopted without further publication as set forth below on September 7, 1978, unless modified by a subsequent notice to incorporate comments received from the public.

Dated: August 3, 1978.

BOB BERGLAND,
Secretary.

USDA/ASCS-33

System name:

Peanut Allotment and Quots File, USDA/ASCS.

System location:

Management Field Office, USDA/ASCS, 8930 Ward Parkway, Kansas City, Mo. 64114.

Categories of individuals covered by the system:

All producers who participate in the peanut allotment and quota program as set forth by the Food and Agriculture Act of 1977. (Effective 1978 through 1981 peanut crop year.)

Categories of records in the system:

This file contains data such as farm number, producer name, address, State and county in which peanut farming is conducted, acreage allotments, quotas and marketing data.

Authority for maintenance of the system:

7 U.S.C. 1358, 1359, 1373, 1377 and 1441.

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

Furnished to Cooperative Marketing Associations for price support and marketing data; and referral to the appropriate agency, whether Federal, State, local or foreign, charged with the responsibility of investigating or prosecuting a violation of law, or of enforcing or implementing the statute, rule, regulation or order issued pursuant thereto, of any record within this system when information available indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or by rule, regulation or order issued pursuant thereto; referral to a court, magistrate or administrative tribunal, or to opposing counsel in a proceeding before any of the above, of any record within the system which constitutes evidence in that proceeding, or which is sought in the course of discovery. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual. Disclosure may be made to Federal State Inspection Service, Cooperative Peanut Associations and Peanut Board.

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

Storage:

Magnetic tapes and disks at the Kansas City Computer Center, 8930 Ward Parkway, Kansas City, Mo. 64114.

Retrievability:

Records are indexed by State, county and farm number.

Safeguards:

Records maintained on magnetic tapes and disks are kept in a limited access secured Federal Government facility.

Retention and disposal:

Maintained on a currently updated basis for the 1978-1981 crop years of peanuts.

System manager and address:

Deputy Administrator, Management, USDA/ASCS, Washington, D.C. 20250.

Notification procedure:

Any peanut producer may request information on this system of records or information as to whether or not the system contains records pertaining to the named producer from: Director, Management Field Office, USDA/ASCS, 8930 Ward Parkway, Kansas City, Mo. 64114, telephone 816-926-6502. However, all data concerning the producer is available in the appropriate county ASCS office, as well as similar peanut allotment and quota information about other peanut producers in the county. Thus the county office would be the most help in servicing a Privacy Act request for personal data from the peanut producer. A request for information pertaining to an individual, as a minimum, must contain name, address and ASCS county office(s) where peanut farm records are maintained.

Record access procedures:

Same as notification procedure.

Contesting record procedures:

Same as notification procedure.

Record source categories:

Information in this system comes primarily from documents origination in county ASCS offices and from information submitted by peanut producers and peanut associations to the county ASCS office(s).

[FR Doc. 78-22190 Filed 8-7-78; 8:45 am]

[3410-16]

Soil Conservation Service

BRUSHY-PEACEABLE CREEK WATERSHED PROJECT, OKLAHOMA

Intent Not To Prepare an Environmental Impact Statement

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the Council on Environmental Quality guidelines (40 CFR Part 1500), and the Soil Conservation Service guidelines (7 CFR Part 650), the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the remaining work in the Brushy-Peaceable Creek watershed project, Pittsburg County, Okla.

The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional or national impacts on the environment. As a result of these findings, Mr. Roland R. Willis, State Conservationist, has determined that the preparation and review of an environmental impact statement is not needed for this project.

The project concerns a plan for watershed protection and flood prevention. The planned works of improvement include 35 single-purpose floodwater retarding structures and two multiple-purpose water storage structures.

The notice of intent not to prepare an environmental impact statement has been forwarded to the Environmental Protection Agency. The basic data developed during the environmental assessment is on file and may be reviewed by interested parties at the Soil Conservation Service, Agricultural Center Building, Farm Road and Brumley Street, Stillwater, Okla. 74074, 405-624-4360. An environmental impact appraisal has been prepared and sent to various Federal, State, and local agencies and interested parties. A limited number of copies of the environmental impact appraisal is available to fill single copy request.

No administrative action on implementation of the proposal will be taken until September 7, 1978.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention Program—Pub. L. 83-566, 16 U.S.C. 1001-1008.)

Dated: July 28, 1978.

JOSEPH W. HAAS,
Assistant Administrator for Water Resources, Soil Conservation Service, U.S. Department of Agriculture.

[FR Doc. 78-21916 Filed 8-7-78; 8:45 am]

[3410-16]

JACKSON COUNTY ROADSIDE CRITICAL AREA TREATMENT R.C. & D. MEASURE, OHIO

Intent Not To Prepare an Environmental Impact Statement

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality guidelines (40 CFR Part 1500); and the Soil Conservation Service guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Jackson County roadside critical area treatment R.C. & D. measure, Jackson County, Ohio.

The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Mr. Robert E. Quilliam, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

The measure concerns a plan for critical area treatment. The planned works of improvement will include seeding approximately 18 acres of county and township roadbanks.

The notice of intent not to prepare an environmental impact statement has been forwarded to the Environmental Protection Agency. The basic data developed during the environmental assessment are on file and may be reviewed by contacting Mr. Robert E. Quilliam, State Conservationist, Soil Conservation Service, Federal Building, Room 522, 200 North High Street, Columbus, Ohio 43215, telephone 614-469-6962. An environmental impact appraisal has been prepared and sent to various Federal, State, and local agencies and interested parties. A limited number of copies of the environmental impact appraisal are available to fill single copy requests at the above address.

No administrative action on implementation of the proposal will be taken until September 7, 1978.

(Catalog of Federal Domestic Assistance Program No. 10.901, Resource Conservation and Development Program—Pub. L. 87-703, 16 U.S.C. 590 a-f, q.)

Dated: August 1, 1978.

EDWARD E. THOMAS,
Assistant Administrator for Land Resources Soil Conservation Service.

[FR Doc. 78-21921 Filed 8-7-78; 8:45 am]

[3410-16]

LAKE WASHINGTON CRITICAL AREA TREATMENT R.C. & D. MEASURE, MISSISSIPPI

Intent Not To Prepare an Environmental Impact Statement

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality guidelines (40 CFR Part 1500); and the Soil Conservation Service guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Lake Washington critical area treatment R.C. & D. measure, Washington County, Miss.

The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Mr. Chester F. Bellard, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

The measure concerns a plan for critical lake bank stabilization. The planned works of improvement include the stabilization of approximately 5,460 feet of eroding shoreline on the eastern and western banks of Lake Washington.

The notice of intent not to prepare an environmental impact statement has been forwarded to the Environmental Protection Agency. The basic data developed during the environmental assessment are on file and may be reviewed by contacting Mr. Chester F. Bellard, State Conservationist, Soil Conservation Service, P.O. Box 610, 210 South Lamar, Jackson, Miss. 39205, telephone 601-969-4335. An environmental impact appraisal has been prepared and sent to various Federal, State, and local agencies and interested parties. A limited number of copies of the environmental impact appraisal are available to fill single copy requests at the above address.

No administrative action on implementation of the proposal will be taken until September 7, 1978.

(Catalog of Federal Domestic Assistance Program No. 10.901, Resource Conservation and Development Program—Pub. L. 87-703, 16 U.S.C. 590 a-f, q.)

Dated: August 1, 1978.

EDWARD E. THOMAS,
Assistant Administrator for Land Resources, Soil Conservation Service.

[FR Doc. 78-21919 Filed 8-7-78; 8:45 am]

[3410-16]

LOWER MIDDLE FABIUS WATERSHED, MISSOURI

Intent To Prepare an Environmental Impact Statement

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality guidelines (40 CFR part 1500); and the Soil Conservation Service guidelines (7 CFR part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is being prepared for the Lower Middle Fabius Watershed, Knox and Lewis Counties, Mo.

The environmental assessment of this federally assisted action indicates that the project may cause significant local, regional, or national impacts on the environment. As a result of these findings, Mr. Kenneth G. McManus, State Conservationist, has determined that the preparation and review of an environmental impact statement is needed for this project.

The project concerns a plan for flood prevention and watershed protection. The planned works of improvement may include accelerated land treatment and selected environmental quality measures.

A draft environmental impact statement will be prepared and circulated for review by agencies and the public. The SCS invites participation of agencies and individuals with expertise or interest in the preparation of the draft environmental impact statement. The draft environmental impact statement will be developed by Mr. Kenneth G. McManus, State Conservationist, Soil Conservation Service, 555 Vandiver Drive, Columbia, Mo. 65201, 314-442-2271, extension 3155.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention Program—Pub. L. 83-566, 16 U.S.C. 1001-1008.)

Dated: July 28, 1978.

JOSEPH W. HAAS,
Assistant Administrator for Water Resources, Soil Conservation Service, U.S. Department of Agriculture.

[FR Doc. 78-21917 Filed 8-7-78; 8:45 am]

[3410-16]

PYMATUNING STATE PARK CRITICAL AREA TREATMENT R.C. & D. MEASURE, PENNSYLVANIA

Intent Not To Prepare an Environmental Impact Statement

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality guidelines (40 CFR Part 1500); and the Soil Conservation Service guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Pymatuning State Park critical area treatment R.C. & D. measure, Crawford County, Pa.

The environmental assessment of this federally assisted action indicates that the measure will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Mr. Graham T. Munkittrick, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this measure.

The measure concerns a plan for critical area treatment. The planned works of improvement include riprap, blanket revetment, bulkheads, and vegetation.

The notice of intent not to prepare an environmental impact statement has been forwarded to the Environmental protection Agency. The basic data developed during the environmental assessment are on file and may be reviewed by contacting Mr. Graham T. Munkittrick, State Conservationist, Soil Conservation Service, Federal Building, 228 Walnut Street, Harrisburg, Pa. 17108, telephone 717-782-2297. An environmental impact appraisal has been prepared and sent to various Federal, State, and local agencies and interested parties. A limited number of copies of the environmental impact appraisal are available to fill single copy requests at the above address.

No administrative action on implementation of the proposal will be taken until September 7, 1978.

(Catalog of Federal Domestic Assistance Program No. 10.901, Resource Conservation and Development Program—Pub. L. 87-703, 16 U.S.C. 590 a-f, q.)

Dated: August 1, 1978.

EDWARD E. THOMAS,
Assistant Administrator for Land Resources, Soil Conservation Service.

[FR Doc. 78-21928 Filed 8-7-78; 8:45 am]

[3410-16]

SENECAVILLE LAKE RECREATION R.C. & D. MEASURE, OHIO

Intent Not To Prepare an Environmental Impact Statement

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the Council on Environmental Quality guidelines (40 CFR Part 1500), and the Soil Conservation Service guidelines (7 CFR Part 650), the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Senecaville Lake recreation R.C. & D. measure, Noble County, Ohio.

The environmental assessment of this federally assisted action indicates that the project will not cause significant adverse local, regional, or national impacts on the environment. As a result of these findings, Mr. Robert E. Quilliam, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

The measure concerns a plan for public water-based recreation. The planned works of improvement are to install 150 new campsites and upgrade 150 existing campsites. A sewage treatment plant will be installed to serve the camping, picnicking, and beach areas. A new boat-launching facility will be constructed in the camping area and the entire construction area landscaped.

The notice of intent not to prepare an environmental impact statement has been forwarded to the Environmental Protection Agency. The basic data developed during the environmental assessment are on file and may be reviewed by contacting Mr. Robert E. Quilliam, State Conservationist, Soil Conservation Service, Federal Building, Room 522, 200 North High Street, Columbus, Ohio 43215, telephone 614-469-6962. An environmental impact appraisal has been prepared and sent to various Federal, State, and local agencies and interested parties. A limited number of copies of the environmental impact appraisal is available to fill single copy requests at the above address.

No administrative action on implementation of the proposal will be taken until September 7, 1978.

(Catalog of Federal Domestic Assistance Program No. 10.901, Resource Conservation and Development Program—Pub. L. 87-703, 16 U.S.C. 590 a-f, q.)

Dated: August 1, 1978.

EDWARD E. THOMAS,
Assistant Administrator for Land Resources, Soil Conservation Service.

[FR Doc. 78-21920 Filed 8-7-78; 8:45 am]

[3410-16]

UPPER MIDDLE FABIUS WATERSHED, MISSOURI

Intent To Prepare an Environmental Impact Statement

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality guidelines (40 CFR Part 1500);

and the Soil Conservation Service guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is being prepared for the Upper Middle Fabius watershed, Adair, Know, Schuyler, and Scotland Counties, Mo.

The environmental assessment of this federally assisted action indicates that the project may cause significant local, regional, or national impacts on the environment. As a result of these findings, Mr. Kenneth G. McManus, State Conservationist, has determined that the preparation and review of an environmental impact statement is needed for this project.

The project concerns a plan for flood prevention and watershed protection. The planned works of improvement may include accelerated land treatment, environmental quality measures, and a system of flood prevention structures.

A draft environmental impact statement will be prepared and circulated for review by agencies and the public. The SCS invites participation of agencies and individuals with expertise or interest in the preparation of the draft environmental impact statement. The draft environmental impact statement will be developed by Mr. Kenneth G. McManus, State Conservationist, Soil Conservation Service, 555 Vandiver Drive, Columbia, Mo. 65201, 314-442-2271, extension 3155.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention Program—Pub. L. 83-566, 16 U.S.C. 1001-1008.)

Dated: July 28, 1978.

JOSEPH W. HAAS,
Assistant Administrator for Water Resources, Soil Conservation Service, U.S. Department of Agriculture.

[FR Doc. 78-21918 Filed 8-7-78; 8:45 am]

[6330-01]

CIVIL AERONAUTICS BOARD

[Order 78-7-128; Dockets 31680, 31917, and 33091]

FLORIDA SERVICE CASE ET AL.

Order Instituting Proceeding

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 25th day of July 1978.

In the matter of *Florida Service* case, docket 33091; application of, Southern Airways for Atlanta-Florida and intra-Florida authority, docket 31680; and application of Coastal Airlines for New Orleans/Mobile-Florida and intra-Florida authority, docket 31917.

Southern Airways has applied in docket 31680 for a new Atlanta-Pensacola-Tallahassee-Jacksonville-Gainesville-Tampa/St. Petersburg/Clearwater-Orlando-Melbourne-West Palm Beach-Miami/Fort Lauderdale segment and moved that the Board set its application for hearing. Civic parties from Gainesville, Melbourne, Tampa, West Palm Beach, Pensacola, Fort Lauderdale, and Tallahassee support the motion.[1] Northwest Airlines opposes inclusion of the Atlanta-Tampa/Miami/Fort Lauderdale and Tampa-Miami/Fort Lauderdale markets in any hearing on Southern's application,[2] and Delta Air Lines similarly opposes inclusion of the Atlanta-Jacksonville/Orlando/Tampa/Miami/Fort Lauderdale/West Palm Beach markets. While Delta does not oppose a hearing on the Atlanta-Pensacola/Gainesville/Melbourne markets and the intra-Florida markets in Southern's application, it argues that the Board should not hear the former until completion of the *Florida-Atlanta* case and should not accord the latter priority treatment. Eastern Air Lines opposes the entire motion for hearing.

The basic arguments of the carriers opposing a hearing on all or part of Southern's application are that the markets are well served and need no additional service and/or that the markets do not warrant priority treatment on the Board's hearing calendar. Eastern also complains about the revenue diversion from it which would result from approval of Southern's application.

The Jacksonville parties[3] also filed a motion for hearing on Southern's application, as well as a petition to intervene. Southern and Melbourne support Jacksonville's motion, Eastern opposes, and Delta takes the same position as it did in response to Southern's motion.

Coastal Airlines, a Florida corporation, has filed an application in docket 31917 for New Orleans-Mobile-Pensacola-Panama City-Tallahassee-Gainesville-Jacksonville authority. Later, in its pleading objecting to finalization of Order 78-4-67, which proposed to make National Airlines' Tallahassee authority permissive and to give Southern unrestricted authority in the Tallahassee-Mobile/New Orleans markets, Coastal also moved that the Board set its application in docket 31917 for hearing.

Coastal argues that, because of the limited traffic in many of the markets it wants to serve, a comprehensive service pattern will depend on larger nonstop markets for support, and that if Southern is granted improved authority before Coastal, it may prevent Coastal from providing needed service.

In answer, the Bay County Chamber of Commerce (the Chamber), located in Panama City, requests consolidated consideration of Coastal's application, Southern's application in docket 31680, parts of Southern's application in docket 32060, and National's Tallahassee and Panama City suspension and deletion applications, dockets 31436, 31437, 32287, and 32288. The Chamber argues that the Board should not take a piecemeal approach to solving Florida's air service problems, particularly since service in some markets affects service in other markets.

We have decided to institute the *Florida Service Case*, docket 33091, in which new authority between and among all cities in Southern's and Coastal's applications will be in issue.[4] We will not, however, consolidate dockets 31436, 31437, 32287, 32288, and 32060 with this proceeding, or defer action on those applications and related matters pending the outcome of this case. The focus of the case is new Florida authority. While we can understand the desire of communities to avoid gaps in service, we believe that it would be an unnecessary burden on National to continue to provide service at Panama City and Tallahassee until the conclusion of this proceeding.[5]

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[1] City of Gainesville and Gainesville Area Chamber of Commerce; city of Melbourne Airport Authority and Melbourne Area Chamber of Commerce; counties of Hillsborough and Pinellas, Greater Tampa Chamber of Commerce, and city of Tampa; county of Palm Beach and West Palm Beach Chamber of Commerce; city of Pensacola and Pensacola Area Chamber of Commerce; Broward County; and city of Tallahassee and Tallahassee Chamber of Commerce.

The Tallahassee parties preferred inclusion of Southern's application in the *Florida-Atlanta Competitive Nonstop Service* case, docket 30679, and the Gainesville, Melbourne, Tampa, and West Palm Beach parties requested either a separate hearing or inclusion of the application in docket 30679. By Order 77-7-144, July 28, 1977, we decided not to expand the *Florida-Atlanta* case since, at that time, our hearing resources were more limited and we wanted to reserve them for applications promising the greatest public benefits.

[2] Northwest also opposed expansion of the *Florida-Atlanta* case to include Southern's application in docket 31680.

[3] City of Jacksonville, Jacksonville Port Authority and Jacksonville Area Chamber of Commerce.

[4] Thus, the case will consider new authority between and among Ft. Lauderdale, Gainesville, Jacksonville, Melbourne, Miami, Orlando, Panama City, Pensacola, Tallahassee, Tampa-St. Petersburg-Clearwater, West Palm Beach, Atlanta, Mobile, and New Orleans. We recognize that this puts in issue more authority than Southern and coastal are seeking, as well as some authority at issue in other cases, and will result in a very large proceeding; but, we wish to take a broad look at Florida's service needs.

[5] By Order 78-7-131, adopted July 25, 1978, we proposed to make permissive its

Footnotes continued on next page

Similarly, the new Tallahassee authority proposed for Southern in Order 78-4-67, which conforms to the route-realignment minor-market guidelines, and any new authority proposed in connection with Southern's route-realignment application in docket 32060 should be considered independently. By their very nature, route realignments do not result in significant new authority, but are designed to increase carrier flexibility. These benefits should not and need not be dependent on a formal proceeding.[6]

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 promises.

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.[7] Further, although low fares naturally will continue to be relected 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.[8]

Accordingly, *it is ordered*, That: 1. the *Florida Service Case*, docket 33091, be instituted and set for hearing at a time and place to be designated later;

2. This proceeding shall consider whether the public convenience and necessity require new or improved authority between and among Fort Lauderdale, Gainesville, Jacksonville, Melbourne, Miami, Orlando, Panama City, Pensacola, Tallahassee, Tampa-St. Petersburg-Clearwater, West Palm Beach, Atlanta, Mobile, and New Orleans; if so, which carrier or carriers should be authorized to provide such service; whether restrictions should be imposed on new or existing authority, and whether Coastal Airlines is fit, willing, and able to provide the service it proposes;

3. The applications of Southern Airways in docket 31680 and Coastal Airlines in docket 31917 be consolidated into the proceeding instituted by paragraph 1;

4. To the extent granted above, the motions for hearing of Southern Airways and the Jacksonville Parties in docket 31680 and Coastal Airlines in docket 31917 be granted; otherwise they be denied;

5. The petition to intervene of the Jacksonville Parties in docket 31680 be granted;

6. The following be made parties to the proceeding instituted by paragraph 1: Southern Airways, Coastal Airlines, Delta Air Lines, Eastern Air Lines, Northwest Airlines, the Jacksonville parties, the Bay County Chamber of Commerce, and the civic parties from Gainesville, Melbourne, Tampa, West Palm Beach, Pensacola, Broward County, and Tallahassee who filed answers to Southern's motion in docket 31680.

7. Applications, amended applications, and motions to consolidate conforming to the scope of the proceeding instituted by paragraph 1,[9] and petitions for reconsideration of this order shall be filed no later than August 22, 1978, and answers shall be filed no later than September 1, 1978; and

8. All applicants who have not done so shall file environmental evaluations conforming to the scope of their applications or amended applications within 30 days of the date of service of this order.

This order shall be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board.[10]

PHYLLIS T. KAYLOR,
Secretary.

O'MELIA, MEMBER, CONCURRING IN PART AND DISSENTING IN PART

I concur in the Board's decision to institute the *Florida Service Case*, and its action on applications and motions related thereto. However, on further reflection I have come to the conclusion that I cannot agree to the language and novel direction that is being included in this order on the question of evidentiary burdens which traditional carrier-selection issues entail. I must dissent, therefore, to the drastic departure from estab-

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Footnotes continued from last page

Panama City authority. By Order 78-7-90, we made final our proposal to make the same change in its Tallahassee authority.

[6] We reject any *Ashbacker* argument that Coastal may be making. We see no need to protect authority in minor markets; as a result, Southern's new authority granted by Order 78-7-90 and any additional authority to be granted in response to its realignment application will not preclude Coastal from obtaining the same authority. We also refuse to freeze market conditions so no one will get a headstart on Coastal. If Coastal's service best meets the needs of the traveling public, it should be able to compete effectively whether it receives authority in the Tallahassee-Mobile/New Orleans markets at the same time as Southern, or later.

[7] 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.

[8] We confess to some confusion about the import of our colleague's dissenting and concurring statement. Our so-called "boilerplate" language, and our invitation to the parties and the judge to consider the desirability of multiple permissive awards, clearly leave ultimate control over the evidence and subissues to the presiding judge—hardly the "drastic departure from established practice and procedure" Member O'Melia alleges. If the import of his statement is that in this and future cases the parties will be less likely to pursue their interests, or that the judge will be disinclined to offer us his independent judgment on the issues, we disagree.

[9] We delegate to the presiding administrative law judge the authority to consolidate by order any applications which conform to the scope of the proceeding.

[10] All Members concurred except Member O'Melia who concurred in part and dissented in part and filed the attached partial concurrence and dissent.

lished practice and procedure that the new Board provisions on exhibits and materials maps out for the future. The language I refer to, in particular the text appearing in Footnote 7 of the Board's instant order, has been referred to in the Board's discussions as the "boilerplate" language, because it is intended that these same views, and exhortations to the parties and the administrative law judge, are to be grafted on to other pending or future cases. I indicated during the Board's public deliberations on this issue that I had reservations on the desirability of the "boilerplate" language. The comments I offer below with respect to the "boilerplate" language in this order, I would similarly apply to other cases in which the Board's latest procedural streamlining would be imposed.

First, I would re-affirm, although I recognize that this re-affirmation should not be necessary, that I wholeheartedly support the Board's efforts to reduce regulatory burdens and to expedite our proceedings. Moreover, I would note that the de-emphasis of the "buy a route" approach in Board route certification proceedings merely re-establishes what has been the balance before. However, this de-emphasis neither dictates nor requires any change in our administration of the Federal Aviation Act. To the extent that the new "boilerplate" language rectifies what I believe was an unwarranted weighting of one criteria to the detriment of others, I concur. Moreover, if it is made clear that, as the Bureau would have it, "the Board does not require detailed justification of price offers in arriving at decisions in route cases," and hence is not concerned with whether these offers are realistic, or feasible, or based on costs, then simple route cases will indeed remain simple. Among other things, we will be able to avoid legal questions arising from the problem of assuring that the *quid pro quo* of a route award will be paid.

Unfortunately, however, adopting the new "boilerplate" language essentially prejudges a large number of economic issues—the resolution of which is necessary to determine the public convenience and necessity. The rather strident tone and direction of the new language cannot help but chill the efforts of parties to make their best case and certainly must be read by any observer as being an attempt to limit the ability of the parties and the agency to explore relevant material and data. While I support streamlining of the procedures so as to reduce the burdens on all parties, I cannot support language which seeks to inhibit the parties, and ultimately the agency, from making important determinations in individual cases.

Further, the probable non-participation of the Bureau of Pricing and Domestic Aviation in most of the Board's route cases should not be enshrined by the use of language which encourages the Bureau's unwillingness to put on witnesses to support its novel theories. The continued exhortation in the "boilerplate" language about reducing the staff's burdens has little validity in the absence of the Bureau's participating in making a complete record. As I have already noted, the Bureau should not be given *carte blanche* to determine when it will participate in cases. But as long as the Board gives the Bureau that authority, it is less than desirable that the Board *ex cathedra* tell the remaining parties how to run their case. This should be left to the presiding officer and the parties.

I recognize, of course, that the Board's order, after making abundantly clear that traditional evidentiary materials relating to carrier-selection issues will be given diminishing attention in the Board's determinations, accepts that ultimately the resolution of these matters is left to the administrative law judge. I feel strongly that we must carefully review the implementation and consequences of the "boilerplate" language to ensure that it does not cripple the necessary prerogatives of the administrative law judges nor undermine the due process requirements of our administrative proceedings.

RICHARD J. O'MELIA.

[FR Doc. 78-22009 Filed 8-7-78; 8:45 am]

[6320-01]

[Docket 32126]

TWIN CITIES-KANSAS CITY-OKLAHOMA-TEXAS ROUTE PROCEEDING

Reassignment of Proceeding

This proceeding has been reassigned from Administrative Law Judge William H. Dapper to Administrative Law Judge Alexander N. Argerakis. Future communications should be addressed to Judge Argerakis.

Dated at Washington, D.C., August 3, 1978.

NAHUM LITT,
Chief Administrative Law Judge.

[FR Doc. 78-22008 Filed 8-7-78; 8:45 am]

[6335-01]

CIVIL RIGHTS COMMISSION

NEBRASKA 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 Nebraska Advisory Committee (SAC) of the Commission will convene at 10 a.m. and will end at 1:30 p.m. on August 28, 1978, Community Plaza for Human Resources Building, 4601 North 36th Street, Second Level Board Meeting Room, Omaha, Nebr. 68111.

Persons wishing to attend this open meeting should contact the committee chairperson, or the Central States Regional Office of the Commission, 911 Walnut Street, Room 3103, Kansas City, Missouri 64106.

The purpose of this meeting is to plan and discuss the upcoming consultation on health care problems in Nebraska update the SAC on the private sector employment study and review the follow-up activity on the State Government affirmative action in mid-America report.

This meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, D.C., August 1, 1978.

JOHN I. BINKLEY,
Advisory Committee Management Officer.

[FR Doc. 78-22096 Filed 8-7-78; 8:45 am]

[6335-01]

VERMONT 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 Vermont Advisory Committee (SAC) of the Commission will convene at 7:30 p.m. and will end at 9 p.m. on August 22, 1978, in the Brown Derby Motor Inn, Montpelier, Vt.

Persons wishing to attend this open meeting should contact the committee chairperson, or the Northeastern Regional Office of the Commission, 26 Federal Plaza, Room 1639, New York, N.Y. 10007.

The purpose of this meeting is to discuss program planning.

This meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, D.C., August 10, 1978.

JOHN I. BINKLEY,
Advisory Committee Management Officer.

[FR Doc. 78-22007 Filed 8-7-78; 8:45 am]

[3510-22]

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

NORTH PACIFIC FISHERY MANAGEMENT COUNCIL

Meeting

AGENCY: National Marine Fisheries Service, NOAA.

ACTION: Notice of public meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C., appendix I, notice is hereby given of a joint meeting of the North Pacific Fishery Management Council, established by section 302, and its Scientific and Statistical Committee (SSC), and its Advisory Panel (AP), established by section 302(g), of the Fishery Conservation and Management Act of 1976 (Pub. L. 94-265), and separate meetings of the SSC and AP.

DATES: The SSC and AP will meet separately on September 27, 1978. The

SSC will meet at 10 a.m. The AP will meet at 9:30 a.m. Both meetings will be held in individual meeting rooms. The Council and its SSC and AP will meet jointly on September 28-29, 1978; convening at 8:30 a.m., and adjourning at approximately 5 p.m. on both days. The meetings may be extended or shortened depending upon progress on the agenda.

ADDRESS: On September 27, 1978, the AP will meet at the Centennial Building in the small meeting room. On September 28-29, 1978, the SSC and AP will meet jointly at the Centennial Building in the large meeting room. The Centennial Building is located downtown Sitka, Alaska.

FOR FURTHER INFORMATION CONTACT:

Mr. Jim H. Branson, Executive Director, North Pacific Fishery Management Council, P.O. Box 3136DT, Anchorage, Alaska 99510, telephone 907-274-4563.

SUPPLEMENTARY INFORMATION: All Council, SSC, and AP meetings will be open to the public. For information on seating arrangements, changes to the agenda, and/or written comments, contact the Executive Director.

Proposed agenda:

SEPTEMBER 28, 1978

(1) Executive Director's report and other Council administrative business; (2) reports from the Scientific and Statistical Committee and Advisory Panel; (3) progress report and update from the Council's drafting management planning teams; (4) period for public comment; (5) review of foreign fishing activities.

SEPTEMBER 29, 1978

(1) Discussions of management plans: High seas salmon fishery off the coast of Alaska east of 175° E. longitude; Bering Sea clam fishery; king crab; Bering Sea groundfish fishery; tanner crab off Alaska, 1978; Gulf of Alaska groundfish fishery during 1978; Bering Sea shrimp fishery; halibut; (2) and other Council business.

Dated: August 2, 1978.

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

[FR Doc. 78-21953 Filed 8-7-78; 8:45 am]

[3510-17]

Office of the Secretary

ECONOMIC ADVISORY BOARD

NOTICE OF MEETING

Pursuant to the provisions of section 10(a)(2) of the Federal Advisory Committee Act, as amended, 5 U.S.C. App. (1976), notice is hereby given that the meeting of the Department of Commerce Economic Advisory Board will be held on Tuesday, September 26, 1978, from 9:30 a.m. to 4 p.m. in Room 4832, Main Commerce Building, 14th Street and Constitution Avenue NW., Washington, D.C.

The Board was established by the Secretary of Commerce on January 13, 1967. The purpose of the Board is to advise the Secretary of Commerce on economic policy issues. The intended agenda for this meeting is as follows:

A review of the economic outlook by major sector.

A discussion of the outlook for prices and employment and of strategies for sustaining economic growth and dealing with inflation.

A limited number of seats will be available to the public on a first come, first served basis. Public participation will be limited to requests for clarification of items under discussion. Additional statements or inquiries may be submitted to the Chair before or after the meeting.

Copies of the minutes will be available on request 30 days after the meeting.

Additional information concerning this meeting may be obtained by contacting Ms. Virginia Marketti, Office of the Chief Economist for the Department of Commerce, Room 4848, Department of Commerce, Washington, D.C. 20230, 202-377-3523.

Dated: August 1, 1978.

COURTENAY M. SLATER,
Chief Economist
for the Department of Commerce.

[FR Doc. 78-21941 Filed 8-7-78; 8:45 am]

[3710-08]

DEPARTMENT OF DEFENSE

Department of the Army

SHORELINE EROSION ADVISORY PANEL

Rechartered

In accordance with the provisions of Pub. L. 92-463, Federal Advisory Committee Act, notice is hereby given that the Shoreline Erosion Advisory Panel which was established by Pub. L. 93-251 is being rechartered.

The nature and purpose of the Shoreline Erosion Advisory Panel is to provide advice to the Chief of Engineers on the general conduct of the shoreline erosion control demonstration program established by section 54, Pub. L. 93-251; to recommend criteria for the selection and development of demonstration sites; to recommend alternative institutional, legal, and financial arrangements necessary to effect agreements with non-Federal sponsors of erosion control demonstration project sites; to make periodic reviews of the program's progress; to recommend means by which the knowledge obtained from the program may be readily available to the public; and to perform such functions as the Chief of Engineers may designate.

The criteria provided under section 54(d) of Pub. L. 93-251 for constituting the Panel will be continued in maintaining its balanced membership. The Panel is required by law to meet at least once every 6 months. The panel operates in accordance with the provisions of the Federal Advisory Committee Act, Pub. L. 92-463, E.O. 12024 and implementing directives.

Dated: August 3, 1978.

MAURICE W. ROCHE,
Directorate for Correspondence
and Directives, Washington
Headquarters Services.

[FR Doc. 78-22012 Filed 8-7-78; 8:45 am]

[3810-70]

DEPARTMENT OF DEFENSE

Office of the Secretary

DEFENSE SCIENCE BOARD TASK FORCE ON ICBM's/MX

Advisory Committee Meeting

The Defense Science Board Task Force on ICBM's/MX will meet in closed session at Lawrence Livermore Laboratory, Livermore, Calif., on August 30-31, 1978.

The mission of the Defense Science Board is to advise the Secretary of Defense and the Under Secretary of Defense for Research and Engineering on overall research and engineering policy and to provide long-range guidance to the Department of Defense in these areas.

The task force will evaluate alternative basing modes for U.S. land-based ICBM's. Concepts will be examined against survivability, cost, and SALT verification considerations.

In accordance with section 10(d) of appendix I, title 5, United States Code, it has been determined that this task force meeting concerns matters listed in section 552b(c) of title 5 of the United States Code, specifically subparagraph (1) thereof, and that accordingly this meeting will be closed to the public.

Dated: August 3, 1978.

MAURICE W. ROCHE,
Director, Correspondence and
Directives, DOD/WHS.

[FR Doc. 78-21954 Filed 8-7-78; 8:45 am]

[6740-02]

Federal Energy Regulatory Commission

[Project No. 82]

ALABAMA POWER CO.

Application for Approval of Recreation Master Plan

AUGUST 1, 1978.

Take notice that an application was filed on November 24, 1976, and supplemented on September 30, 1977, under the Federal Power Act, 16 U.S.C. § 791a-825r, by the Alabama Power Co., (Licensee) (Correspondence to Mr. F. L. Clayton, Jr., senior vice president, Alabama Power Co., P.O. Box 2641, Birmingham, Ala. 35291), for approval of a comprehensive recreation master plan at the Mitchell Project No. 82. The project is located on the Coosa River in Chilton and Coosa Counties, Ala.

The Licensee seeks approval of its Recreation Master Plan filed pursuant to Article 46 of the license issued for Project No. 82 on November 26, 1975. The purpose of the recreation plan is to develop a management program for the protection of the Mitchell reservoir and its shoreline.

The Master Plan delineates existing developed shoreline areas (approximately 30 percent of the shoreline) and proposes future land use classifications on undeveloped lands around the Mitchell Reservoir. These land use classifications are (1) general public recreation areas, (2) residential subdivisions, and (3) natural areas.

Under the plan, certain areas leased to the State as a game preserve are designated as existing residential or as proposed residential areas. The remaining leased game preserve areas are designated as either public recreation or natural areas.

The Licensee also proposes that those areas which have been, or would be, developed into cottage or residential subdivisions be removed from the project boundary. The shoreline of the Mitchell Project is about 147 miles long. Approximately 30 percent of the total shoreline is developed of this time. The Licensee owns about 44 percent, or 65.2 miles, of the total shoreline, and 23.2 miles of this land are developed. The remaining 81.8 miles, or 56 percent, of the total shoreline not owned by the Licensee also have been considered in the Master Plan. However, the Licensee does not plan to enter into agreements with the owners of the undeveloped shoreline to make the proposed classifications effective on those lands.

Generally, those areas near the center of the Mitchell Reservoir have been classified residential while areas near the upper ends of the reservoir are classified as natural and public recreation areas.

Under Article 41 of the license the Commission reserves the right to require the Licensee to include within the project such lands as may be necessary to make effective the purposes of the license. The Licensee does not propose to include any additional shoreline property within the project boundary.

Any person desiring to be heard or to make any protest with reference to this application should on or before September 15, 1978, file with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure, 18 C.F.R. § 1.8 or § 1.10 (1977). The Commission will consider all protests filed with it in determining the appropriate action to be taken, but protests will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any hearing in this proceeding must file a petition to intervene in accordance with the Commission's Rules.

The application is on file with the Commission and is available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-22079 Filed 8-7-78; 8:45 am]

[6740-02]

[Docket Nos. RP72-150, (Rate Design), et al.]

EL PASO NATURAL GAS CO.

Filing Report of Refund Acknowledgment

AUGUST 1, 1978.

On July 21, 1978, El Paso Natural Gas Co. (El Paso) filed with the Commission a report that it had received acknowledgment of receipt of refunds from all its jurisdictional customers in this docket.

Any person desiring to be heard or to protest said filing should file comments with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, on or before August 21, 1978. Comments will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-22080 Filed 8-7-78; 8:45 am]

[6740-02]

[Docket No. RP76-59]

EL PASO NATURAL GAS CO.

Filing Report of Refund Acknowledgement

AUGUST 1, 1978.

On July 21, 1978, El Paso Natural Gas Co. (El Paso) filed with the Commission a report that it had received acknowledgment of receipt of refunds from all its jurisdictional customers in this docket.

Any person desiring to be heard or to protest said filing should file comments with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, on or before August 21, 1978. Comments will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-22081 Filed 8-7-78; 8:45 am]

[6740-02]

EL PASO NATURAL GAS

[Docket No. RP77-18]

Filing Report of Refund Acknowledgment

AUGUST 1, 1978.

On July 21, 1978, El Paso Natural Gas Co. (El Paso) filed with the Commission a report that it had received acknowledgment or receipt of refunds from all its jurisdictional customers in this docket.

Any person desiring to be heard or to protest said filing should file comments with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, on or before August 21, 1978. Comments will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-22082 Filed 8-7-78; 8:45 am]

[6740-02]

FLORIDA POWER & LIGHT CO.

[Docket No. ER78-508]

Notice of Filing

AUGUST 1, 1978.

Take notice that Florida Power & Light Co. (FPL), on July 25, 1978, tendered for filing as an "Agreement To Provide Specified Transmission Service Between Florida Power & Light Co. and Tampa Electric Co." FPL states that under the Agreement, FPL will transmit power and energy for the Tampa Electric Co. (TECO) as is required by TECO in the implementation of its interchange agreements with the Orlando Utilities Commission, the Lake Worth Utilities Authority, and the city of Homestead. A certificate of concurrence by TECO was filed with the Agreement.

FP&L requests an effective date for this Agreement of no later than 30 days after the date of filing. According to FPL copies of this filing were served on the senior vice president of TECO.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before August 11, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspections.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-22083 Filed 8-7-78; 8:45 am]

[6740-02]

MARY C. HEATHER

[Project No. 2801]

Application for Minor License

AUGUST 1, 1978.

Public notice is hereby given that an application for minor license was filed on July 6, 1977, and revised on June 12, 1978, under the Federal Power Act, 16 U.S.C. §§ 791a-825r, by Mrs. Mary C. Heather (Applicant) (Correspondence to: Mrs. Mary C. Heather, Housatonic Energy Conservation Association, Stockbridge, Mass. 01260) for the Glendale Project No. 2801. The project is located on the Housatonic River in the town of Stockbridge, Berkshire County, Mass.

The project consists of: (1) A reinforced concrete dam 30 feet high and 180 feet long; (2) a reservoir with a surface area of 40 acres at a normal water surface elevation of 850 feet msl; (3) a 1,500-foot long, 40-foot wide unlined canal with a mean water depth of 5 feet; (4) an intake structure leading to; (5) a 250-foot long, 12-foot diameter steel penstock; (6) a powerhouse with a concrete foundation and quarry rock walls containing; (7) a waterwheel connected to a single belt-driven 360 kW generator; and (8) appurtenant facilities. The project would be run-of-river operation. The project is to be restored to operating condition as it existed in the early 20th century and would use generating equipment patented in 1909. The restoration would include clearing of vegetation, repair of headgate machinery, reconstruction of a gatehouse destroyed by fire, and repairs to the powerhouse structure and machinery.

The Applicant proposes to sell 90 percent of the power to the Massachusetts Electric Co. and the remaining 10 percent would be used for powerplant lighting and other station uses.

On October 1, 1977, pursuant to the provisions of the Department of Energy Organization Act (DOE Act), Public Law 95-91, 91 Stat. 565 (August 4, 1977), and Executuve Order No. 12009, 43 Fed. Reg. 46267 (September 15, 1977), the Federal Power Commission (FPC) ceased to exist and its functions and regulatory responsibilities were transferred to the Secretary of Energy and the Federal Energy Regulatory Commission (FERC) which, as an independent Commission within the Department of Energy, was activated on October 1, 1977. The functions which are the subject of the proceeding were specifically transferred to the FERC by section 402(a)(1) or 402(a)(2) of the DOE Act.

Any person desiring to be heard or to make any protest with reference to said application should on or before October 2, 1978, file with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of Practice and Procedure, 18 CFR § 1.8 or § 1.10 (1977). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

The application is on file with the Commission and is available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-22085 Filed 8-7-78; 8:45 am]

[6740-02]

MID-LOUISIANA GAS CO.

[Docket No. RP73-43; PGA78-4]

Order Accepting for Filing, Suspending, and Setting for Hearing PGA Rate Increases

JULY 31, 1978.

On June 16, 1978, Mid-Louisiana ("Mid-La") filed an alternate 30th revised sheet No. 3a to FERC gas tariff, first revised volume No. 1. This filing includes costs attributable to two emergency purchases from Louisiana Intrastate Gas Co. at rates in excess of the appropriate nationwide rate. There is insufficient evidence to show that the prices paid by Mid-La were at rates a reasonably prudent pipeline would pay for gas under the same circumstances. We will therefore institute hearing procedures for the purpose of resolving this issue.

On June 16, 1978, Mid-La also filed a 30th revised sheet No. 3a to FERC gas tariff, first revised volume No. 1 which included the same emergency purchases and a 1.61 cents per Mcf transportation cost tracker. This alternate appears to be based on Mid-La's proposed settlement rates and provisions in docket No. RP77-58. Mid-La's settlement in RP77-58 has not been approved by the Commission. Both filings propose an August 1 effective date. Both filings are also based in part on rates from United Gas Pipe Line Co. which were accepted subject to downward revisions.

We will suspend the effectiveness of rates contained in alternate 30th revised sheet No. 3a for 1 day, until August 2, 1978, at which time they may be made effective subject to refund. We will also make the acceptance of rates contained in this sheet subject to the filing of a revised tariff sheet reflecting the proper rates of United and will reject Mid-La's 30th revised sheet No. 3a inasmuch as its filing is premature at this time.

The Commission orders: (A) Mid-La's alternate 30th revised sheet No. 3a to FERC gas tariff first revised volume No. 1 filed on June 16, 1978, is hereby accepted for filing, suspended for 1 day until August 2, 1978, at which time it may be made effective subject to refund.

(B) A presiding administrative law judge to be designated by the chief administrative law judge (18 CFR 3.5 (d)) shall convene a settlement conference in this proceeding to be held within 10 days after the service of Staff's top

sheets in a hearing room of the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426. The presiding administrative law judge is authorized to establish such further procedural dates as may be necessary and to rule on all motions (except motions to sever, consolidate, or dismiss) as provided for in the rules of practice and procedure.

(C) Staff shall serve its statement of position on or before September 25, 1978.

(D) Mid-La shall file its case in chief in support of the prudency of its emergency purchases included in this filing on or before August 23,1978.

(E) Acceptance of Mid-La's alternate 30th revised sheet No. 3a is further conditioned upon the company's filing of a revised sheet reflecting proper supplier rates.

(F) The 30th revised sheet No. 3a is hereby rejected.

(G) The Secretary shall cause prompt publication of this order in the FEDERAL REGISTER.

By the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-22084 Filed 8-7-78; 8:45 am]

[6740-02]

[Docket No. CP78-419]

NATURAL GAS PIPELINE CO. OF AMERICA

Notice of Application

AUGUST 1, 1978.

Take notice that on July 12, 1978, Natural Gas Pipeline Co. of America (applicant), 122 South Michigan Avenue, Chicago, Ill. 60603, filed in docket No. CP78-419 an application pursuant to section 7 of the Natural Gas Act and section 157.7(g) of the Commission's regulations under the Natural Gas Act (18 CFR 157.7(g)), for a certificate of public convenience and necessity authorizing the construction and for permission for and approval of the abandonment, during the 12-month period commencing October 1, 1978, and operation of field gas compression and related metering and appurtenant facilities, all as more fully set forth in the application file with the Commission and open to public inspection.

The stated purpose of this budget-type application is to augment applicant's ability to act with reasonable dispatch in the construction, relocation, and operation and abandoment of facilities which will not result in changing applicant's system saleable capacity or service from that authorized prior to the filing of the instant application.

Applicant states that the total cost of the proposed construction and abandonment of facilities would not exceed $3,000,000, and that the cost of any single project would not exceed $500,000. Applicant states that it would finance these costs with funds on hand.

Any person desiring to be heard or to make any protest with reference to said application should on or before August 24, 1978, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.70). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal 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 this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate and permission and approval for the proposed abandonment are required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-22086 Filed 8-7-78; 8:45 am]

[6740-02]

[Docket No. CP78-434]

NORTHWEST PIPELINE CORP.

Notice of Application

AUGUST 1, 1978.

Take notice that on July 19, 1978, Northwest Pipeline Corp. (applicant), P.O. Box 1526, Salt Lake City, Utah 84110, filed in docket No. CP78-434 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the sale of natural gas to and the exchange of natural gas with, Mountain Fuel Supply Co. (Mountain Fuel), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is stated that applicant has entered into a gas purchase contract dated May 30, 1978, with Chevron U.S.A., Inc. (Chevron) covering an area in the Yellow Creek Unit in Uintah County, Wyo., which is remote from applicant's existing transmission system. In order to make available the volumes of natural gas to be purchased from the Yellow Creek Unit at the least possible investment, applicant states that it has entered into a gas purchase, transportation, and exchange agreement which provides for the exchange of up to 1,000 Mcf of natural gas per day and gives Mountain Fuel the right to purchase up to 25 percent of the volumes of gas received for exchange.

Pursuant to said agreement with Mountain Fuel, applicant states, applicant would deliver to Mountain Fuel, for exchange, all volumes of gas purchased by applicant in the Yellow Creek Unit at a point on Mountain Fuel's gathering facilities located in Uintah County, Wyo., where the Amoco-Gulf No. 1 well is located and/or at such other points as may be mutually agreed upon. Applicant further states that Mountain Fuel would redeliver equivalent volumes, subject to Mountain Fuel's option to purchase 25 percent of the volumes received for exchange, at an existing point of interconnection between the facilities of applicant and itself, where applicant is currently authorized to sell and deliver volumes of natural gas to Mountain Fuel, located in Sweetwater County, Wyo.

Applicant estimates that the initial volumes of gas to be delivered to Mountain Fuel would be 100 Mcf per day; Mountain Fuel would thus have an option to purchase approximately 25 Mcf per day initially, it is stated. Said option would have to be exercised in writing prior to initial delivery, the application continues, and the subsequent purchase would be on the same terms and conditions as applicant's purchase in all respects, if Mountain Fuel so elects.

The price to be paid to Mountain Fuel by applicant for the transportation service is said to be 8.0 cents per Mcf for all gas which is delivered to Mountain Fuel and which Mountain Fuel does not purchase.

Applicant does not propose the construction of any facilities to effectuate this proposal since delivery to Mountain Fuel's gathering system will be at the wellhead, it is stated.

Any person desiring to be heard or to make any protest with reference to said application should on or before August 24, 1978, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to 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 this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-22087 Filed 8-7-78; 8:45 am]

[6740-02]

[Docket No. RP73-36; PGA78-3; DCA78-2]

PANHANDLE EASTERN PIPE LINE CO.

Order Accepting for Filing, Suspending, and Setting for Hearing Proposed Purchased Gas Adjustment Rate Increase

JULY 31, 1978.

On June 15, 1978, Panhandle Eastern Pipe Line Co. ("Panhandle") filed a PGA rate increase of 4.73 cents per Mcf. The filing also contains a revised lower demand charge adjustment surcharge. Our review of the filing indicates that the PGA includes a December 1977 purchase from Oklahoma Natural Gas Exploration, Inc., of 5,496,527 Mcf and a purchase from Colorado Interstate Gas Co. at rates in excess of the appropriate nationwide rates. There is insufficient evidence for the Commission to find the prices paid for these "emergency" purchases were at rates that a prudent pipeline would have paid under similar circumstances. We will suspend the effectiveness of the filing 1 day until August 2, 1978, at which time the filing may be made effective subject to refund. We will also set for hearing the sole questions of the prudence of these purchases.

Public notice of Panhandle's filing was issued on July 21, 1978, with protests and petitions to intervene due on or before August 4, 1978.

The Commission orders: (A) The effectiveness of the 25th revised sheet No. 3-A and second revised sheet No. 3-B to Panhandle Eastern Pipe Line's FERC gas tariff, original volume No. 1 is hereby suspended for 1 day, until August 2, 1978, at which time it may be made effective subject to refund.

(B) Panhandle Eastern's case-in-chief in support of the prudence of the above referenced purchases shall be filed with this Commission no later than August 23, 1978.

(C) Staff's statement of position shall be filed on or before September 25, 1978.

(D) A presiding administrative law judge to be designated by the chief administrative law judge (18 CFR 3.5(d)) shall convene a settlement conference in this proceeding to be held within 10 days after the service of Staff's top sheets in a hearing room of the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426. The presiding administrative law judge is authorized to establish such further procedural dates as may be necessary and to rule on all motions (except motions to sever, consolidate or dismiss) as provided for in the rules of practice and procedure.

(E) The Secretary shall cause prompt publication of this order in the FEDERAL REGISTER.

By the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-22088 Filed 8-7-78; 8:45 am]

[6740-02]

[Docket No. CP78-426]

UNITED GAS PIPE LINE CO.

Notice of Application

AUGUST 1, 1978.

Take notice that on July 17, 1978, United Gas Pipe Line Co. (applicant), P.O. Box 1478, Houston, Tex. 77001, filed in docket No. CP78-426 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the replacement of two segments of 8-inch pipeline totaling approximately 3.44 miles with 12-inch diameter pipe on its Longview-Huntsville pipeline in Gregg County, Tex., all as more fully set forth in the application on file with the Commission and open to public inspection.

It is indicated that the portions of the 8-inch line which applicant proposes to replace were constructed in 1928 and are now in need of repair and replacement to insure dependable natural gas service to the customers of applicant and to continue compliance with industry and governmental safety standards. It is further indicated that during colder than normal days in recent winter periods, applicant has experienced significant capacity problems on this line, particularly on the laterals serving the towns of Rusk and Henderson, Tex. Applicant states that in order to alleviate these capacity problems, it has elected to replace the affected segments of the 8-inch line with 12-inch diameter pipe. Such replacement will increase the capacity on the subject line by approximately 2,000 Mcf per day, which increase does not represent and increase in service to the referenced customers, but rather is necessitated in order to fulfil present service obligations, it is said. It is stated that the cost of such replacement is estimated to be $449,110.

Any person desiring to be heard or to make any protest with reference to said application should on or before August 24, 1978, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to 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 this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is

timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-22089 Filed 8-7-78; 8:45 am]

[6740-02]

[Docket No. CP78-427]

UNITED GAS PIPE LINE CO.

Notice of Application

AUGUST 1, 1978.

Take notice that on July 17, 1978, United Gas Pipe Line Co. (applicant), P.O. Box 1478, Houston, Tex. 77001, filed an application in docket No. CP78-427 pursuant to section 7(c) of the Natural Gas Act requesting authorization to transport on a best efforts basis up to 1,000 Mcf of natural gas per day for Texas Gas Transmission Corp. (Texas Gas), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant proposes to receive volumes of natural gas for the account of Texas Gas at a point of receipt on applicant's existing pipeline located in Judice Field, Lafayette Parish, La., pursuant to an agreement between applicant and Texas Gas dated June 8, 1978. Texas Gas, it is said, would construct or cause to be constructed the required measuring and regulating station to be located at the above-described point. Applicant would redeliver, the application states, equal volumes, less an allowance for fuel and company-used gas, to Texas Gas at the outlet side of applicant's existing authorized measuring and regulating stations at points of interconnection between the systems of applicant and Texas Gas at one or more of the following locations:

(i) Branch, Acadia Parish, La., and/or

(ii) Lonewa, Ouachita Parish, La., and/or

(iii) At any other mutually agreeable point.

Said transportation agreement between applicant and Texas Gas shall be in full force and effect for a term of one year, beginning on the date on which deliveries of gas commence and would continue from year to year thereafter, it is stated.

It is further stated that Texas Gas has agreed to pay an amount per Mcf equal to applicant's average jurisdictional transmission cost of service in effect from time to time in applicant's northern and/or southern rate zones, as applicable, depending on location of the redelivery point, as such may be determined by applicant based on rate filings made from time to time with the Commission, less any amount included in such average jurisdictional transmission cost of service which is attributable to gas consumed in the operation of Applicant's pipeline system. It is added that the northern rate zone would be the applicable rate if the redelivery point is located in the northern rate zone; otherwise the southern rate zone would be applicable.

The current average jurisdictional transmission costs of service, exclusive of cost of gas consumed in applicant's operation is 18.84 cents per Mcf in its southern rate zone and 24.46 cents per Mcf in its northern rate zone, it is asserted.

Applicant asserts that the subject gas would be purchased from production in the Judice Field area, Lafayette Parish, La., attributable to the interest of Superior Oil Co. It is asserted that the proposed arrangement would enable Texas Gas to receive the subject gas into its system.

Any person desiring to be heard or to make any protest with reference to said application should on or before August 24, 1978, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to 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 this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB
Secretary.

[FR Doc 78-22090 Filed 8-7-78; 8:45 am]

[6740-02]

[Docket No. ER78-506]

WISCONSIN PUBLIC SERVICE CORP.

Proposed Tariff Change

AUGUST 1, 1978.

Take notice that Wisconsin Public Service Corp. (Company), on July 25, 1978, tendered for filing proposed changes in its FERC electric service tariff Nos. 3, 6, 7, 9, 13, 22, 24, 25, 27, 31, and 36. Company indicates that the proposed changes would increase revenues from jurisdictional sales and service by $1,056,936 based on the 12-month period ending June 30, 1979.

Wisconsin Public Service Corp. states that the proposed rate increase is necessary to meet rising financial and operating costs. The proposed effective date of the rates contained in the filing is August 28, 1975.

Copies of the filing were served upon the public utility's jurisdictional customers, the Public Service Commission of Wisconsin and the Michigan Public Service Commission.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before August 11, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any persons wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB
Secretary.

[FR Doc. 78-22091 Filed 8-7-78; 8:45 am]

[6740-02]

[Docket No. CI75-604]

McCULLOCH OIL CORP.

Applications for Certificates, Abandonment of Service and Petitions to Amend Certificates [1]

AUGUST 1, 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.

It appears reasonable and consistent with the public interest in this case to prescribe a period shorter than 10 days for the filing of protests and petitions to intervene. Therefore, any person desiring to be heard or to make any protest with reference to said application should on or before August 10, 1978, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a part to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in 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 ft [3]	Pressure base
CI75-604 C, Oct. 28, 1976	McCulloch Oil Corp., 10880 Wilshire Blvd., Suite 1500, Los Angeles, Calif. 90024.	Montana-Dakota Utilities Co., Federal oil and gas lease, (M23843-A), sec. 2, township 1 south, range 49 east, Powder River County, Mont.	(2)	14.73

[2] Applicant is willing to accept a certificate at the applicable national rate pursuant to opinion No. 770, as amended.

[3] Filing code: A—Initial Service; B—Abandonment; C—Amendment to add acreage; D—Amendment to delete acreage; E—Total Succession; and F—Partial Succession.

[FR Doc. 78-22098 Filed 8-7-78; 8:45 am]

[3128-01]

DEPARTMENT OF ENERGY

NOTICE OF CASES FILED WITH THE OFFICE OF HEARINGS AND APPEALS

Week of July 14 Through July 21, 1978

Notice is hereby given that during the week of July 14 through July 21, 1978, the appeals and applications for exception or other relief listed in the appendix to this notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under the DOE's procedural regulations, 10 CFR Part 205, any person who will be aggrieved by the DOE action sought in such cases may file with the DOE written comments on the application within 10 days of service of notice, as prescribed in the procedural regulations. For purposes of those regulations, the date of service of notice shall be deemed to be the date of publication of this notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20461.

RICHARD T. TEDROW,
Acting Director, Office of Hearings and Appeals.

JULY 27, 1978.

APPENDIX.—*List of cases received by the Office of Hearings and Appeals*

[Week of July 14 through July 21, 1978]

Date	Name and location of applicant	Case No.	Type of submission
July 14, 1978	Bassett Oil & Equipment Co. Bassett, Va.	DRX-0096	Supplemental order. If granted: DOE region II would be granted an extension of 30 days in which to issue a revised remedial order to Basset Oil & Equipment Co.
Do	Consumers Power Co., Washington, D.C.	DED-0180	Motion for discovery. If granted: Consumers Power Co. would be permitted to serve interrogatories on DOE personnel within the Office of Fuels Regulation in connection with appeal proceedings relating to the Mar. 31, 1978 assignment order issued by the DOE Economic Regulatory Administration.
Do	Exxon Co., U.S.A., Houston, Tex.	DMR-0028	Modification of relief granted in *TOSCO Corporation*, 1 DOE Par.—(June 14, 1978). If granted: The DOE's June 14, 1978 decision and order would be modified with respect to the determinations reached regarding TOSCO Corp.'s entitlement purchase obligations.
Do	Good Hope Industries, Inc., Springfield, Mass.	DPI-0015	Exception from base fee requirements. If granted: Good Hope Industries, Inc. Would be permitted to import naphtha on a fee-exempt basis from May 1, 1978 through Apr. 30, 1979.

APPENDIX.—*List of cases received by the Office of Hearings and Appeals*—Continued

Date	Name and location of applicant	Case No.	Type of submission
July 14, 1978	United Petroleum, Inc., Tampa, Fla	DRS-0090	Stay request. If granted: The proceedings involving the statement of objections submitted by United Petroleum, Inc. in response to the Jan. 10, 1978 proposed remedial order issued to the firm would be stayed pending a final determination on a Freedom of Information request which it has filed.
July 17, 1978	Commonwealth Oil Refining Co., Inc., San Antonio, Tex.	DEN-1369	Request for an interim order. If granted: Certain portions of a proposed decision and order issued to Commonwealth Oil Refining Co. on June 30, 1978 (case No. DEE-1369) would be made effective on an interim basis prior to the issuance of a final determination in that proceeding.
Do	Mid-America Refining Co., Inc., Washington, D.C.	DES-1421	Stay request. If granted: Mid-America Refining Co. would be granted a stay of its obligation to purchase entitlements under the provisions of 10 CFR 211.67 pending a determination of an application for exception which the firm intends to file.
Do	Mountain States Energy Corp., Englewood, Colo.	DEE-1423	Allocation exception (sec. 212.145). If granted: Mountain States Energy Corp. would be assigned a supplier of JP-4 jet fuel and would be substituted for that firm as a supplier of that product to the Department of Defense during the period October 1978 through September 1979.
Do	Peerless Petrochemicals, Inc., Roslyn, N.Y.	DEE-1422	Exception from the entitlements program. If granted: Peerless Petrochemicals, Inc. would be granted and exception from the provisions of 10 CFR 211.67 applicable to the firm's imports of crude oil.
Do	Peerless Petrochemicals, Inc., Roslyn, N.Y.	DPI-0016	Exception from base fee requirements. If granted: Peerless Petrochemicals, Inc. would be permitted to import crude oil on a fee-exempt basis from May 1, 1978 through Apr. 30, 1979.
July 18, 1978	Belco Petroleum Corp., Houston, Tex	DEE-1426	Price exception (sec. 212.73). If granted: Belco Petroleum Corp. would be permitted to sell the crude oil produced from the White River unit, located in Unitah County, Utah, at upper tier ceiling prices.
Do	Monsanto Co., Houston, Tex	DXE-1424 and DXE-1425.	Extension of relief granted in *Monsanto Company*, 1 DOE Par. —— (May 15, 1978). If granted: Monsanto Co. would be permitted to sell the crude oil produced from the Milo No. 1 well located in Williams County, N. Dak., and the State 16 No. 1 well located in Sheridan County, Mont. at upper tier ceiling prices.
July 19, 1978	Koch Exploration Co., Wichita, Kans	DXE-1427 and DXE-1428.	Extension of relief granted in *Koch Exploration Company*, 1 DOE Par. 81,010 (November 4, 1977). If granted: Koch Exploration Co. would be permitted to sell the crude oil produced from the Sink Draw No. 1 and Cedar Rim No. 3 leases located in Duchesne County, Utah at upper tier ceiling prices.
Do	Whitco, Inc., Dallas, Tex	DES-0091	Stay request. If granted: Whitco, Inc. would be granted a stay of the provisions of 10 CFR 211.25 with respect to the base period supply obligation of Sun Oil Co. to the firm pending a final determination on Whitco's request for an extension of exception relief previously granted to the firm (case No. DEX-0055).
July 20, 1978	C. K. Smith & Co., Inc., Boston, Mass	DRH-0061	Request for evidentiary hearing. If granted: An evidentiary hearing would be convened in connection with a statement of objections submitted by C. K. Smith & Co., Inc. in response to a proposed remedial order issued to the firm (case No. DRO-0060).
Do	C. K. Smith & Co., Inc., Boston, Mass	DRD-0061	Motion for discovery. If granted: C. K. Smith & Co., Inc. would be granted discovery with respect to its objections to a proposed remedial order issued to the firm by DOE region I on May 25, 1978.
Do	Coastal States Gas Corp., Houston, Tex	DXE-1431	Price exception (sec. 212.165). If granted: Coastal States Gas Corp. would be permitted to increase its prices to reflect nonproduct cost increases in excess of $0.005 per gallon for natural gas liquid products produced at the Almeda plant.
Do	Husky Oil Co. of Delaware, Denver, Colo	DEE-1433 through DEE-1444.	Price exception (sec. 212.73). If granted: Husky Oil Co. of Delaware would be permitted to sell the crude oil produced from the Acquistapace, Bonetti, Edmonston, Fleisher, Goodwin, Lakeview, Los Flores, Nicholson, Nicholson No. 4, Nicholson No. 5, standard Nicholson and Victory leases located in Santa Barbara County, Calif., at upper tier ceiling prices.
Do	LaSalle National Bank, Chicago, Ill	DSG-0025 and DES-0092.	Request for special redress and stay request. If granted: The Office of Hearings and Appeals would review the Economic Regulatory Administration's denial of the application to quash a subpena submitted by LaSalle National Bank, and compliance with the subpena would be stayed pending a determination on the firm's petition for special redress.
Do	Monterrey Producing Co., Seminole, Okla	DRH-0080	Request for evidentiary hearing. If granted: Monterrey Producing Co. would be granted en evidentiary hearing in connection with objections which it has raised in response to the proposed decision and order issued to the firm on June 16, 1978.
Do	Natural Resources Defense Council, Inc., Palo Alto, Calif.	DFA-0199	Appeal of an information request denial. If granted: The DOE's June 16, 1978 information request denial would be rescinded and Natural Resources Defense Council, Inc. would be granted access to DOE data concerning the Bonneville Power Plant located in Portland, Oreg.
Do	Ozona Gas Processing Plant, Dallas, Tex	DEH-1237	Request for evidentiary hearing. If granted: An evidentiary hearing would be convened in connection with the DOE's consideration of objections raised by the Ozona Gas Processing Plant regarding the June 28, 1978 Proposed decision and order issued to the firm (case No. DXE-1237).
Do	Pierremont Petroleum Corp., Shreveport, La.	DEE-1429	Price relief (sec. 212.73). If granted: Pierremont Petroleum Corp. would be permitted to sell the crude oil produced from the C. G. Henderson 17-8 No. 1 well located in Scott County, Miss., at upper tier ceiling prices.

Notices of Objection Received

Date	Name and location of applicant	Case No.
July 17, 1978	Placid Oil Co., Dallas, Tex	DEE-0156
July 18, 1978	Arizona Fuels Corp., Salt Lake City, Utah	DXE-1046
July 19, 1978	Giant Industries, Inc., Phoenix, Ariz	DEE-0060
July 20, 1978	Pennzoil Producing Co., Houston, Tex	DEE-0085
Do	Ozona Gas Processing Plant, Washington, D.C	DXE-1237

Proposed Remedial Orders

July 17, 1978	Ashland Oil, Inc., Ashland, Ky	DRO-0084
July 20, 1978	Mornes, Inc., Washington, D.C	DRO-0085

[FR Doc. 78-21803 Filed 8-8-78; 8:45 am]

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 940-5; OPP-66045]

PESTICIDE PROGRAMS

Intent To Cancel Registrations of Certain Pesticide Products

Pursuant to section 6(a)(1) 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.), firms listed below have requested that the Environmental Protection Agency (EPA) cancel the registrations of several pesticide products. Such cancellation shall be effective September 7, 1978, unless the registrant or an interested person with the concurrence of the registrant, requests that the registration be continued in effect.

The Agency has determined that the distribution and sale of stocks of these products which were produced on or before the effective date of cancellation would not be inconsistent with the purposes of FIFRA and would not have an unreasonable adverse effect on the environment. Therefore, the distribution and sale of existing stocks of these products shall be permitted until the supply is exhausted or for 1 year after the effective date of cancellation, whichever occurs earlier, provided that these products shall be used only in a manner consistent with the label and labeling registered with EPA. Production of these products after the effective date of cancellation will be considered a violation of FIFRA.

Requests that the registration of these products be continued may be submitted to the Product Control Branch, Registration Division (WH-567), Office of Pesticide Programs, EPA, 401 M Street SW., Washington, D.C. 20460. Any comments filed regarding this notice of intended cancellation will be available for public inspection in the office of the Product Control Branch from 8:30 a.m. to 4 p.m. Monday through Friday.

The registrants concerned and the products affected by this action are listed below.

Dated: August 1, 1978.

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

EPA Reg. No.:	Product name	Registrant
239-1158	Ortho Phosdrin 2 Dust	Chevron Chemical Co., 940 Hensley St., Richmond, Calif. 94804.
264-92	Benzac 1281	Amchem Products, Inc., Ambler, Pa. 19002.
264-220	Amchem Brushkiller 155	Do.
802-317	Miller's Endrin 1.6E	The Chas. H. Lilly Co., 7737 NE. Killingsworth, Portland, Oreg. 97218.
806-6	Avon Moth Proofer	Avon Products, Inc., 9 West 57th St., New York, N.Y. 10019.
806-7	Avon Klean Air Surface Disinfectant & Deodorizer.	Do.
1007-45	Pfizer Lindane Compound	Pfizer Inc., 235 East 42d St., New York, N.Y. 10017.
2596-33	Hartz Mountain 90-Day Brand Bird Perch.	Hartz Mountain Corp., 700 South 4th St., Harrison, N.J. 07029.
2800-38	Humco Cresol Solution N.F. (Saponated).	Humco Laboratory, Inc., 1008 Whitaker St., Texarkana, Tex. 75501.
2800-61	Humco Chloroform and Benzene Mixture.	Do.
2800-62	Humco Screw Worm Smear 62	Do.
2829-3	Cunilate #2174-XY	Ventron Corp., Chemicals Division, Congress St., Beverly, Mass. 01915.
2829-38	Cuniphen #6114	Do.
6720-147	SHCP Tetra-Fumigant	Southern Mill Creek Products Co., Inc., P.O. Box 1096, Tampa, Fla. 33601.
9779-214	Riverside BHC-1	Riverside Chemical Co., P.O. Box 171376, Memphis, Tenn. 38117.
9859-34	B & G Fumi-Ban	Landia Chemical Co., P.O. Box 366, Lakeland, Fla. 33801.
12472-9339	Acritet 34-66	M. F. Canle & Co., 4511 North St. Vincent St., Tampa, Fla. 33614.

[FR Doc. 78-21912 Filed 8-7-78; 8:45 am]

[6210-01]

FEDERAL RESERVE SYSTEM

FEDERAL OPEN MARKET COMMITTEE

Longer Run Ranges for Monetary Aggregates

On July 18, 1977, the Federal Open Market Committee adopted the following ranges for rates of growth in monetary aggregates for the period from the second quarter of 1978 to the second quarter of 1979: M-1, 4 to 6½ to 9 percent; M-2, 6½ percent; and M-3, 7½ to 10 percent. The associated range for bank credit is 8½ to 11½ percent.

By order of the Federal Open Market Committee, July 28, 1978.

ARTHUR L. BROIDA,
Secretary.

[FR Doc. 78-21923 Filed 8-7-78; 8:45 am]

[6210-01]

FIRST AMERICAN BANK CORP.

Acquisition of Bank

First American Bank Corp., Kalamazoo, Mich., has applied for the Board's approval under § 3(a)(3) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(3)) to acquire 100 percent (less directors' qualifying shares) of the voting shares of the successor by merger to Van Buren State Bank, Hartford, Mich. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than August 21, 1978.

Board of Governors of the Federal Reserve System, August 3, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 78-21924 Filed 8-7-78; 8:45 am]

[6210-01]

FIRST RAILROAD & BANKING CO. OF GEORGIA

Acquisition of Bank

First Railroad & Banking Co. of Georgia, Augusta, Ga., has applied for the Board's approval under § 3(a)(3) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(3)) to acquire 80 percent of the voting shares of First Georgia Bank, Atlanta, Ga. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Atlanta. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than August 25, 1978.

Board of Governors of the Federal Reserve System, July 26, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 78-21925 Filed 8-7-78; 8:45 am]

[6210-01]

NORTHWEST BANCORP.

Acquisition of Bank

JULY 28, 1978.

Northwest Bancorp., Minneapolis, Minn., has applied for the Board's approval under § 3(a)(3) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(3)) to acquire 80 percent or more of the voting shares of the First National Bank of Marion, Marion, Iowa. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Minneapolis. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than August 28, 1978.

Board of Governors of the Federal Reserve System, July 28, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 78-21926 Filed 8-7-78; 8:45 am]

[6210-01]

QUAIL CREEK BANCSHARES, INC.

Formation of Bank Holding Company

Quail Creek Bancshares, Inc., Oklahoma City, Okla., has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 80 percent or more of the voting shares of Quail Creek Bank, N.A., Oklahoma City, Okla. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received no later than August 30, 1978.

Board of Governors of the Federal Reserve System, July 31, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 78-21927 Filed 8-7-78; 8:45 am]

[6210-01]

[Reg. C; Docket No. R-0058]

ORDER ANNULLING ILLINOIS EXEMPTION UNDER THE HOME MORTGAGE DISCLOSURE ACT

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Order.

SUMMARY: Based upon the decision of the Illinois Supreme Court that the Illinois Financial Institutions Disclosure Act is unconstitutional and void in its entirety, the exemption under the Federal Home Mortgage Disclosure Act granted to Illinois-chartered depository institutions is annulled. Those insititutions must begin complying with the Federal act and the Board's regulation C, which implements the act, within 90 days.

DATE: The Board's order is effective immediately.

FOR FURTHER INFORMATION CONTACT:

Robert C. Plows, Section Chief, Division of Consumer Affairs, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 202-452-3667.

SUPPLEMENTARY INFORMATION: In response to applications by the State of Illinois and the Illinois Savings and Loan League, the Board granted, on December 21, 1976 (41 FR 55582), an exemption from the disclosure requirements of the Home Mortgage Disclosure Act of 1975, as implemented by regulation C, to Illinois-chartered depository institutions subject to the Illinois Financial Institutions Disclosure Act. The exemption was based on the requirements of that act and the implementing directives of the Illinois Department of Financial Institutions, which the Board determined to be substantially similar to the requirements imposed under the Federal Home Mortgage Disclosure Act.

At the time that the exemption was granted, the Illinois Financial Institutions Disclosure Act had been challenged in State court in the case of *Glen Ellyn Savings and Loan Association, et al.* v. *Tsoumas.* Thus, the continuation of the exemption, as initially granted, was expressly conditioned upon developments in that litigation. The Illinois Supreme Court decided *Glen Ellyn* on May 26, 1978, striking down the Illinois financial Institutions Disclosure Act in its entirety.

Since the Illinois Supreme Court's decision renders the Illinois statute void, there no longer is a State law basis for the Illinois exemption. Accordingly, the Board issues the following order pursuant to § 306(b) of the

Home Mortgage Disclosure Act (12 U.S.C. 2805(b)).

ORDER

The Supreme Court of Illinois has declared the Illinois Financial Institutions Disclosue Act (95 Ill. Rev. Stat. 201-208 unconstitutional and void in its entirety. The court's decision has now become final. Therefore, all Illinois-chartered depository institutions previously exempted on the basis of compliance with the Illinois act from the data compilation and disclosure requirements of the Federal Home Mortgage Disclosure Act of 1975 (12 U.S.C. 2801-2809), as implemented by regulation C (12 CFR 203), henceforth shall comply with the Federal act and regulation.

Each previously exempted Illinois-chartered depository institution that is now subject by virtue of this order to the Home Mortgage Disclosure Act shall prepare and make available to the public, within 90 days from the date of this order, the report required by the act and regulation C for its last full fiscal year ending prior to the date of this order.

However, since the requirements of the Illinois Financial Institutions Disclosure Act had been deemed by the Board to be substantially similar to the provisions of the Home Mortgage Disclosure Act, if an institution has already prepared and made publicly available a report for any portion of its last fiscal year ending prior to the date of this order in compliance with the Illinois act, the institution shall be deemed to be in compliance with the data compilation and disclosure requirements of the Federal act and regulation for the period covered by the State report. For any portion of its last fiscal year ending prior to the date of this order not covered by a State disclosure report and for each fiscal year thereafter, the institution shall compile and disclose the relevant information in accordance with the Home Mortgage Disclosure Act and regulation C.

By order of the Board of Governors, July 26, 1978.

THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 78-21922 Filed 8-7-78; 8:45 am]

[6210-01]

ELSE INVESTMENT CO.

Formation of Bank Holding Company

AUGUST 2, 1978.

Else Investment Co., Fairbury, Nebr., has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring an additional 53 percent or more of the voting shares of the Fairbury State Bank, Fairbury, Nebr. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than August 31, 1978.

Board of Governors of the Federal Reserve System, August 2, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 78-21946 Filed 8-7-78; 8:45 am]

[6210-01]

FAYETTE BANCORP.

Formation of Bank Holding Company

AUGUST 2, 1978.

Fayette Bancorp., Marion, Iowa, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 percent or more of the voting shares of Citizens Savings Bank, Hawkeye, Iowa. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received no later than August 31, 1978.

Board of Governors of the Federal Reserve System, August 1, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 78-21945 Filed 8-7-78; 8:45 am]

[6210-01]

FIRST NATIONAL HOLDING CORP.

Acquisition of Bank

AUGUST 1, 1978.

First National Holding Corp., Atlanta, Ga., has applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire up to 100 percent of the voting shares of the proposed successor by merger to Gwinnett Bank & Trust Co., Norcross, Ga. The factors that are considered in acting on the application are set forth in section 3(c) of the act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Atlanta. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than August 31, 1978.

Board of Governors of the Federal Reserve System, August 1, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 78-21947 Filed 8-7-78; 8:45 am]

[6210-01]

FEDERAL RESERVE SYSTEM

CHEROKEE INVESTMENT CO., INC.

Formation of Bank Holding Company

AUGUST 4, 1978.

Cherokee Investment Co., Inc., Baxter Springs, Kans., has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 100 percent (less directors' qualifying shares), of the voting shares of Citizens State Bank, Galena, Kans. The factors that are considered in acting on the application are set forth in § 3(c) of the act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than August 23, 1978.

Board of Governors of the Federal Reserve System, August 4, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 78-22227 Filed 8-7-78; 8:45 am]

[6820-28]

GENERAL SERVICES ADMINISTRATION

Federal Preparedness Agency

[GSA Order FPA 1095.1]

ENVIRONMENTAL IMPACT STATEMENTS

Preparation Procedures

Notice is hereby given that the General Services Administration, in accordance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.), is proposing the procedures to be followed by the Federal

Preparedness Agency (FPA) in preparing environmental impact statements which implement the GSA order, environmental considerations in decisionmaking (ADM 1095.1A). Any person who wishes to submit written comments pertaining to the proposed procedures may do so by filing them in triplicate with the General Services Administration (EE), Washington, D.C. 20405, on or before September 24, 1978.

Dated: July 17, 1978.

JOSEPH A. MITCHELL,
Director,
Federal Preparedness Agency.

ENVIRONMENTAL CONSIDERATIONS IN DECISIONMAKING

1. *Purpose.* This order prescribes the uniform procedures to be followed in implementing the laws, Executive orders, and directives concerning all major Federal Preparedness Agency (FPA) actions that may affect significantly the quality of the human environment, consistent with the basic statutory responsibilities governing FPA program operations. This order is applicable to all FPA programs.

2. *Background.* a. The laws, Executive orders, and directives implemented by this order include the following:

(1) GSA order, environmental considerations in decisionmaking (ADM 1095.1A);

(2) The National Environmental Policy Act of 1969 (42 U.S.C. 4321, et seq.), hereinafter referred to as NEPA;

(3) Executive Order 11514, of March 5, 1970, as amended, entitled "Protection and Enhancement of Environmental Quality";

(4) Section 106 of the National Historic Preservation Act of 1966 (16 U.S.C. 470f);

(5) Executive Order 11593, of May 13, 1971, entitled "Protection and Enhancement of the Cultural Environment";

(6) Executive Order 11752, of December 17, 1973, as amended, entitled "Prevention, Control, and Abatement of Environmental Pollution at Federal Facilities";

(7) Executive Order 11988, of May 24, 1977, entitled "Floodplain Management";

(8) Executive Order 11990, of May 24, 1977, entitled "Protection of Wetlands"; and

(9) The revised guidelines issued by the Council on Environmental Quality (CEQ) for preparing environmental impact statements, hereinafter referred to as the guidelines, published in the FEDERAL REGISTER on August 1, 1973, 38 FR 20550, and amended in the FEDERAL REGISTER on August 7, 1973, 38 FR 21265.

b. Section 102 of NEPA directs all Federal agencies to apply the following to the fullest extent possible.

(1) Use a systematic, interdisciplinary approach which will insure the integrated use of the natural and social sciences and the environmental design arts in planning and decisionmaking which may have an impact on man's environment.

(2) Identify and develop methods and procedures which will insure that presently unquantified environmental amenities and values may be given appropriate consideration in decisionmaking along with economic and technical considerations.

(3) Include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment a detailed statement by the responsible official which includes:

(a) The environmental impact of the proposed action;

(b) Any adverse environmental effects which cannot be avoided should the proposal be implemented;

(c) Alternatives to the proposed action;

(d) The relationship betwen local short-term uses of man's environment and the maintenance and enhancement of long-term productivity; and

(e) Any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

3. *Role of the environmental impact statement process.* The environmental impact statement process is a means of coordinating active consideration of environmental concerns throughout the FPA planning, action development, and review processes. Through serious consideration of all reasonable alternatives, adverse environmental effects are to be avoided or minimized to the fullest extent possible. The process shall be used to reassess ongoing actions because NEPA applies to those actions approved prior to January 1, 1970, and to assess future actions to avoid or minimize adverse effects.

4. *Officials responsible for determining the course of environmental action.* The Assistant Directors, FPA, have the initial responsiblity for determining whether an action is "a major Federal action significantly affecting the quality of the human environment," for preparing environmental assessments, and for submitting negative declarations or draft and final environmental impact statements.

a. *The Executive Director, Federal Preparedness Agency.* The Executive Director (EE) is responsible for the overall direction of environmental protection within FPA for all policy and procedure programs and shall:

(1) Provide professional and technical guidance to the Director, FPA; Assistant Directors, FPA; and Regional Directors, FPA;

(2) Review, evaluate, and process negative declarations, draft, and final environmental impact statements for review and comment by the Office of General Counsel (L), the Environmental Affairs Division (PRE), and for final approval by the Director, FPA.

(3) Consult with the Environmental Affairs Division (PRE) and the Office of General Counsel (L) on matters pertaining to environmental protection in FPA; and

(4) Develop and coordinate orders and guidance on FPA environmental programs.

b. *The Assistant Directors for Civil Crisis Preparedness; Conflict Preparedness; Research, Development, and Program Coordination; and Stockpile Disposal, FPA.* These officials are responsible for direction and execution of environmental protection for their programs and shall:

(1) Maintain a continuing review of activities which potentially have significant environmental impacts as outlined in this order;

(2) Make initial decision on the necessity for preparing a negative declaration or an environmental impact statement following preparation and review of the environmental assessment;

(3) Determine the need and the adequacy of an environmental assessment and justify the writing and processing of a negative declaration through EE for final clearance with the Environmental Affairs Division (PRE) and the office of General Counsel (L) in a timely manner;

(4) Prepare and process, through EE, draft and final environmental impact statements for review and comment by the Office of General Counsel (L), Environmental Affairs Division (PRE), and for the signature of the Director, FPA; and

(5) Conduct public hearings and meetings, issue press announcements, and maintain files for public review.

5. *Procedures.* Environmental assessments and negative declarations prepared by the Assistant Directors are submitted to the Executive Director, FPA, to insure full compliance with all applicable acts, orders, and guidelines related to environmental planning. The Executive Director, FPA, is responsible for approving the draft environmental impact statement or negative declaration and transmitting the document to the Environmental Affairs Division (PRE) and the Office of General Counsel (L) for review and comment. After review and comment by the Office of General Counsel (L) and the Environmental Affairs Division (PRE), the draft and final envi-

ronmental impact statements shall be approved by the Director, FPA, for submission to the Environmental Protection Agency (EPA), heads of Federal agencies, the Governor and Members of Congress from the affected State, and other interested entities, groups, or individuals. The draft environmental impact statement or negative declaration shall be prepared by the responsible official with the full cooperation and coordination of all FPA officials as necessary. The draft and final environmental impact statement must be circulated as prescribed in GSA order ADM 1095.1A. After all comments on the draft statement are received, the initiating FPA office shall prepare a final environmental impact statement which takes into consideration all substantive comments.

6. *Reports.* Reports control symbol PB-123 has been assigned to the report required by this order.

ATTACHMENT

1. *Preparation of the environmental assessment.* An assessment of any major FPA action that may significantly affect environmental quality shall be prepared which will address the requirements of section 102(2)(C) of NEPA to the fullest extent possible. (See subpt. 2b(3)). From this assessment a determination can be made to develop an environmental impact statement or a negative declaration. Those FPA actions and activities which are covered by NEPA include, but are not limited to:

a. Major actions which would result from recommendations or favorable reports on legislation, including requests for apprpriations originating both within and outside the Agency when FPA has primary responsibility for implementing the legislation;

b. Major actions which would result from establishment or modification of rules, regulations and procedures, and policies;

c. Major new and continuing actions by FPA, including stockpile actions; and

d. Major actions which would result from new technology, research, and development, on the basis of the size of FPA's investment, likelihood of widespread application, potential environmental impacts, and degree that continued investment will foreclose alternatives.

2. *Decision to prepare an environmental impact statement.* Following an environmental assessment, if there is doubt whether a statement should be prepared or if the proposed action is likely to be environmentally controversial, a statement shall be prepared. Many Federal decisions seem of limited environmental consequence when viewed individually but are of significant consequence when viewed collectively. When FPA is responsible for the cumulative impact of decisions, an FPA statement shall be filed covering the entire complex of decisions and actions.

3. *Specific criteria.* As required by section 1500.6(c) of the guidelines, the typical classes of actions likely to require environmental statements and those actions likely not to require environmental statements are as follows:

a. *Category I projects which will almost always require environmental impact statements (EIS).* Category I consists of all FPA projects where the assessment process identifies known or potentially significant environmental impacts. These projects include but are not limited to stockpile actions which result in—

(1) Opening of new mines (green field sites);

(2) Reopening of abandoned mines; and

(3) Placing of a commodity which would create public health, safety and environmental problems into a floodplain or wetland.

b. *Category II projects which may require EIS or further assessments.* These projects include:

(1) Expansion of special facilities; and

(2) Stockpile actions for—

(i) Rotation or upgrading of current inventories;

(ii) Disposal of hazardous materials or materials that have become contaminated or unstable while in storage;

(iii) Relocation of materials to mitigate environmental damage; or

(iv) Legislative authorization of stockpile acquisitions or disposals.

c. *Category III projects not requiring EIS (may require assessment and negative declaration).* These projects include but are not limited to those concerning which the Commissioner, Public Buildings Service (P), upon petition by the Director, FPA, through Environmental Affairs Division (PRE), has determined, following consultation with EPA, that a public or Government exigency is present. This would be restricted to projects where a limited environmental impact has been identified, but action is not irreversible or irretrievable.

4. *Classified environmental impact statements.* If a proposed action is of a classified nature, the proponent of the action still must comply with the requirements of this directive. Environmental impact statements, both draft and final, containing classified information shall be prepared, safeguarded, and disseminated in accordance with the requirements of the GSA handbook, Document Secureity (ADM P 1025.2). When feasible, these statements shall be organized to include classified portions as appendixes, so that the unclassified portions can be made available to the public.

5. *Negative declaration.* A negative declaration must state that an analysis and review of all environmental factors have been completed and the determination has been made that the proposed action is not considered a major Federal action significantly affecting the quality of the human environment and consequently does not require the preparation of an environmental impact statement. The decision is a report of findings developed to include a brief assessment of environmental considerations analyzed and documented as an environmental assessment. The negative declaration with accompanying assessment is submitted for review and comment to the Director, Environmental Affairs Division (PRE), the Office of General Counsel (L), and for approval by the Director, FPA.

6. *Environmental assessments.* The environmental assessment is the basis for judgment by the responsible official in the official's analysis of the proposed action and can be entered as evidence in hearings and court actions. The assessment is a full disclosure document, presenting a description of existing and projected environmental conditions related to the proposed action and an evaluation of possible adverse or beneficial impacts. The assessment shall be prepared using inerdisciplinary expertise to insure complete assessment and full consideration of the range of environmental factors in the development of the action to make certain that:

a. Commitments are not made to courses of action that will unnecessarily complicate reconciliation with environmental factors;

b. Environmentally desirable alternatives are not inadvertently foreclosed; and

c. Negative environmental impacts are minimized. Actions will be reviewed to determine both their individual and cumulative impacts because the environmental effect of many decisions may be individually limited but cumulatively significant.

7. *Draft environmental impact statement.* Each statement shall reflect that the particular economic and technical benefits of its proposed action have been assessed and weighed against the environmental costs. In the early stages of preparation of the draft environmental impact statement, the office preparing the statement shall solicit information and opinions from Federal, State, and local agencies possessing expertise on the potential impacts of a proposed action. This will assist in providing the necessary data and guidance for the analyses required

to be included in environmental impact statements as described below:

a. *Coordination process in accordance with OMB Circular A-95, Revised.* (1) When the A-95 review process for a proposed project or when the consultation with the clearinghouse takes place prior to the filing of a draft environmental impact statement or negative declaration, the comments received represent inputs to the statement or declaration. (2) Federal agency comments received prior to filing the statement shall be included in copies of the statement being sent to the agency submitting the substantive comments. The statements being sent to clearinghouses shall include a listing of all agencies from which comments have been received.

b. *Technical content of draft statement.* The EIS shall include:

1. A description of the proposed action including the technical data adequate to permit a careful assessment of the environmental impact of the proposed action by commenting parties.

(2) The probable impact of the proposed action on the environment, including impact on ecological systems. Consequences of direct and indirect impacts on the environment shall be included in the analysis.

(3) Any probable adverse environmental effects that cannot be avoided, such as water, air, or noise pollution, undesirable land-use patterns, damage to life systems, threats to health or other consequences adverse to the environmental goals set out in section 101(b) of NEPA.

(4) A rigorous exploration and objective evaluation of possible alternative actions which, if chosen instead of the proposed action, might avoid some or all of the adverse environmental effects, including alternatives outside of FPA's authority to implement. Section 102(2)(D) of NEPA requires the responsible agency to "study, develop, and describe appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources." Sufficient analysis of alternatives, their costs, and their impact on the environment shall accompany the proposed action through the agency review process so as not to foreclose prematurely considerateion of options which might have less detrimental effects.

(5) The relationship between local short-term uses of the environment and maintenance and enhancement of long-term productivity. Include a brief discussion of the extent to which the proposed action involves tradeoffs between short-term gains at the expense of long-term losses, or vice versa, and a discussion of the extent to which the proposed action forecloses future options. This, in essence, requires assessment of the action from the perspective that each generation is trustee of the environment for succeeding generations.

(6) Any irreversible or irretrievable commitments of resources, for example, land, work hours, costs, natural resources, and cultural resources, which would be involved in the proposed action should it be implemented. Identify from the survey of unavoidable adverse impacts the extent to which the action curtails the range of beneficial uses of the environment.

(7) The economic costs and benefits of the proposed action compared with the environmental costs and benefits. Alternate courses of action must be discussed as to their effect upon this cost and benefit balance. If a formal cost-benefit analysis on the proposed action is prepared, it shall be submitted with the environmental impact statement.

8. *List of draft environmental impact statements and negative declarations.* a. To provide timely public notice and understanding of projects and actions that may have an environmental impact and to obtain the views of interested parties, Assistant Directors, FPA, shall establish an early notice system for informing the public of the decision to prepare a draft environmental impact statement on proposed projects or actions. A list will be maintained of all projects or actions for which environmental impact statements will be prepared. This list shall be updated monthly and available for public inspection. Assistant Directors, FPA, Shall submit early warning lists to the Executive Director, FPA, for compilation and forwarding to the Environmental Affairs Division (PRE) as a basis for agencywide quarterly reporting to EPA as required by ADM 1095.1A, ch. 2, par. 15. Reports control symbol PB-123 has been assigned to this report.

b. If it is decided that an EIS is not necessary for a proposed project or action: (1) Which normally requires the preparation of a statement, (2) which is similar to actions for which a significant number of statements have been prepared, (3) which has previously been announced would be the subject of a statement, or (4) for which a negative declaration has been made pursuant to section 1500.11(f) of the guidelines, the responsible Assistant Director, FPA, shall prepare a publicly available record briefly setting forth the decision and the reasons for the declaration.

c. The list of such negative declarations shall be prepared and made available to the public on request in the same manner as provided for lists of statements under preparation as required by a. above.

9. *Public meetings.* a. Each major Federal action having a possible adverse effect on the environment will be evaluated to determine whether a public meeting should be held. Consideration will be given to the following elements in deciding whether a public meeting is appropriate:

(1) The magnitude of the proposal in terms of economic costs, the geographic area involved, and the uniqueness of size of commitments of the resources involved;

(2) the degree of interest or probable composition of controversial items in the proposal, as evidenced by requests from the public and from Federal, State, and local authorities that a meeting be held;

(3) The complexity of the issue and the likelihood that information will be presented at the meeting which will be of assistance to the agency in fulfilling its responsibilities under NEPA; and

(4) The extent to which public involvement already has been achieved through other means such as earlier public meetings, meetings with citizen representatives, and/or written comments on the proposed action.

b. Draft environmental impact statements will be made available to the public at least 15 calendar days prior to the time of public meetings, unless the meetings are held prior to issuance of the statement.

10. *Submission and distribution of draft environmental impact statements.* Initially, draft environmental impact statements shall be processed as follows:

a. Three copies of the preliminary draft environmental impact statement for FPA projects shall be transmitted to the Executive Director (EE),

b. After determining that the statement is satisfactory, the Executive Director (EE) shall forward the preliminary draft statement to the Office of General Counsel (L) and the Environmental Affairs Division (PRE) for review and comment. All review periods shall run concurrently for a period of 15 workdays from the date of receipt. Any requests for additional review time, information, or revision shall be directed to the Executive Director (EE), FPA, who shall have authority to extend the 15-workday period. All comments shall be forwarded to the Executive Director (EE). The Commissioner, PBS, shall reconcile any differences concerning the need for additional information or revision that may arise between the office responsible for the proposed action and other reviewing offices, except the final approval for legal sufficiency shall be the responsibility of the Office of General Counsel. Unless otherwise notified within the review period, the Executive Director (EE), shall assume the statement is ade-

quate, or the statement shall be revised according to comments received from reviewing offices. After comments are reviewed, the draft EIS is transmitted to the Office of General Counsel (L), the Environmental Affairs Division (PRE), and to the Director, FPA, for approval. The Director, FPA, will sign the transmittal letters soliciting comments on the draft environmental impact statement to:

(1) The Governor and Senators from the affected State, the Representative from the affected district, and other appropriate State officials;

(2) The EPA Central Office, which will receive five copies of the draft EIS and the appropriate EPA regional offices, which will also receive five copies;

(3) The relevant A-95 clearinghouse, appropriate elected officials, and all State and local agencies that would be interested in the action;

(4) Federal agencies directly related to the specific action;

(5) All other Federal agencies competent to comment owing to legal jurisdiction or special expertise (for reference, see appendix II of the guidelines);

(6) Any group or individual that requests a copy of the environmental statement; and

(7) Any entity, group, or individual that the Director, FPA, decides should be included.

c. The Director, FPA, shall determine the extent of newspaper coverage which would most adequately inform the reading public in the area that an FPA draft environmental impact statement has been prepared. Notice shall be published at least once and should include how and where copies of the statement may be obtained.

d. The Environmental Protection Agency publishes in the notices section of the FEDERAL REGISTER lists of environmental statements received during the preceding week that are available for public comment. The date establishing the minimum period of review (not less than 45 days) and advance availability of the draft EIS will be calculated from the date of publication in the FEDERAL REGISTER, which can be expected to be the second Friday following the filing of the statement with EPA. Draft environmental impact statements shall be made available to the public without charge to the extent practicable or at a fee which is not more than the cost of reproduction. Environmental impact statements will also be made available to the public for review at the FPA Central Office during normal working hours.

11. *Consideration of comments and preparation of final environmental impact statements.* The initiating Assistant Director, FPA, shall carefully reconsider the action in relation to the relevant and substantive comments received on the draft environmental impact statement and, to the fullest extent possible but consistent with basic statutory responsibilities governing its program operations, shall make every attempt to reconcile its action with respect to any divergent recommendations by:

a. Altering its current plan of action;

b. Working with the commenting entities to develop mutually acceptable plans or workable compromises; and

c. Working with any additional entities or private groups to initiate additional projects or programs designed to mitigate environmental impacts.

The final environmental impact statement shall incorporate FPA responses to all substantive comments submitted by other Federal agencies, State and local officials, individuals, and groups. The sections of the statement where change has occurred will be marked by a vertical line in the margin of the statement unless the final differs substantially from the draft. All substantive comments received on the draft (or summaries thereof where comment has been exceptionally voluminous) should be attached to the final statement. The Executive Director, FPA, will coordinate compilation of comments for forwarding to EPA.

12. *Submission and distribution of final environmental impact statements.* a. Following Central Office approval of the final EIS (procedure is similar to that in subpt. 10b), the initiating FPA office shall transmit the original and three copies of the final environmental impact statement as soon as practicable to the Executive Director, FPA. The original copy of the final EIS shall include the original copy of all comments and exhibits received on the draft environmental statement. After review and approval, copies of the final environmental impact statement and comments received shall be sent to the Office of General counsel (L) and the Environmental Affairs Division (PRE). Upon review and comment, the final statement will be sent to the Director, FPA, for submission to EPA and appropriate officials.

b. Copies of final statements, with comments attached, shall be sent to interested Federal, State, local agencies, private organizations, clearinghouses, and individuals that made substantive comments on the draft statement and to individuals or organizations that requested a copy of the final statement. Ten copies of the final statements shall in all cases be sent to the Environmental Protection Agency to assist in carrying out its responsibilities under section 309 of the Clean Air Act. Where the number of comments on a draft statement is such that distribution of the final statement to all commenting entities appears impracticable, the Executive Director, FPA, will notify PRE and request that EPA be consulted concerning an alternative arrangement for distribution of the statement.

13. *Time requirements for review of draft and final environmental statements.* a. During the 90-calendar-day review period for the draft EIS, the action under review shall be held in abeyance, nor shall action be taken for 30 calendar days after EPA has announced in the FEDERAL REGISTER that the statement is available.

b. A time limit of 45 days is provided for comment on the draft statement. If no reply is received from those consulted, it will be presumed that the agency or party consulted has no comment to make. If an agency or party requests an extension of time in which to comment, an extension of the commenting period of up to 15 calendar days may be granted if time permits.

c. If the final text of an environmental impact statement is filed at least 60 calendar days after the notice of the draft is published by EPA in the FEDERAL REGISTER, the 30-day period and 90-day period may run concurrently to the extent that they overlap.

d. If emergency circumstances make it necessary to take a major Federal action with significant environmental impact without observing the provisions of the guidelines concerning minimum periods for agency review, the executive Director, FPA, will advise PRE of the nature of the action and the need for requesting an exception to standard procedures. PRE shall consult with EPA concerning alternative arrangements. Similarly, if there are overriding considerations of expense to the Government or impaired program effectiveness, the Executive Director, FPA, will advise PRE, and PRE will consult with EPA concerning appropriate modification of the minimum periods.

14. *Amendment of draft or final environmental statement.* Assistant Directors, FPA, shall keep abreast of any substantial changes in the proposed action or environmental developments which may result in significant impacts on the proposed action. Supplements or amendments to draft statements subsequent to review by PRE and L will be issued pursuant to subpt. 10b of this Attachment and the final statements will be issued pursuant to subpt. 12b of this Attachment. Notice of these circumstances will be given to PRE by the Executive Director, FPA. PRE shall consult with EPA with respect to the desirability of recirculation of the statement for the appropriate period.

15. *Responsibility for draft and final environmental impact statement preparation in multiagency action.* When FPA and one or more agencies directly sponsor an action or are directly involved in a group of actions directly related to each other because of their functional interdependence and geographical proximity, a "lead agency" shall be designated to assume supervisory responsibility for preparation of the statement. Factors relevant in determining the appropriate "lead agency" include the time sequence in which the agencies become involved, the magnitude of their involvement, and their relative expertise with respect to the environmental effects of the action. Where there is a question as to the primary responsibility for statement preparation, the matter shall be referred to the Environmental Affairs Division (PRE) for referral to EPA for resolution. In a case where FPA is the "lead agency" and one or more agencies have partial responsibility for the action, the other agencies shall be requested to provide to the responsible FPA official such information as may be necessary to prepare a suitable and complete environmental impact statement. If another agency is designated to be the "lead agency" the criteria for statement preparation by that agency shall apply.

16. *Format requirements.* a. The statement number shall be assigned by the Executive Director, FPA, in accordance with FPA Information System procedures.

b. A summary sheet shall be prepared in accordance with the format prescribed in appendix I of the guidelines, and it will be attached to the environmental impact statement as the second page.

c. A cover sheet shall be prepared for each environmental statement in accordance with ADM 1095.1A, ch. 2, par. 17, figure 2-5.

[FR Doc. 78-22000 Filed 8-7-78; 8:45 am]

[6820-22]

REPORT ON ENVIRONMENTAL ACTIONS

Real Property Disposal Actions and for Facility Planning Actions

Pursuant to the provisions of the National Environmental Policy Act of 1969 (42 U.S.C. 4321, et. seq.), and section 1500.6(e) of the Council on Environmental Quality Guidelines for the preparation of environmental impact statements (38 FR 20550) the following is a list of administrative actions for which environmental impact statements were under preparation by the General Services Administration from March 1, 1978 through May 31, 1978, for real property disposal actions and for facility planning actions. Also listed are administrative actions for which environmental impact statements are planned in the future and actions for which environmental assessments were completed with negative declarations.

Dated: July 18, 1978.

JAMES B. SHEA, Jr.,
Commissioner,
Public Buildings Service.

FACILITY PLANNING ACTIONS

ENVIRONMENTAL IMPACT STATEMENTS/ NEGATIVE DECLARATIONS

REGION 1

A. *EIS's in preparation.*

Fort Kent, Maine.—Final EIS for construction of a new Border Station.

Springfield, Mass.—Final EIS for construction of a new Courthouse-Federal Office Building and Parking Facility.

Boston, Mass.—Final EIS for construction of a new Federal Office Building.

Providence, R.I.—Final EIS for leased construction of a new Federal Office Building.

B. *EIS's planned.*

Boston, Mass.—Preliminary draft EIS for lease construction of a new Veterans Administration Clinic Building.

Houlton, Maine.—Preliminary draft EIS for construction of new Border Station.

C. *Environmental assessments completed with negative declarations.*

None.

REGION 2

A. *EIS's in preparation.*

New York, N.Y. 201 Varick Street.—Draft EIS for repair and alteration project to include a detention facility for illegal aliens (temporarily deferred).

B. *EIS's planned.*

None.

C. *Environmental assessments completed with negative declarations.*

None.

REGION 3

A. *EIS's in Preparation.*

Suitland, Md.—Draft EIS for the Suitland Federal Center Master Plan—Southern portion including Smithsonian Institution Museum Support Center.

Washington, D.C.—Draft EIS for the relocation and consolidation and new construction of the Nuclear Regulatory Commission.

Washington, D.C.—Draft EIS for new construction for the University of the District of Columbia.

Washington, D.C.—Final EIS for the repair and alteration of the West Heating Plant.

Washington, D.C.—Final EIS for lease 1900 Half Street (Buzzard Point).

Washington, D.C.—Final EIS for the restoration and modernization of the Old Post Office.

Wilkes-Barre, Pa.—Draft EIS for lease construction of Federal Office Building.

B. *EIS's planned.*

None.

C. *Environmental assessments completed with negative declarations.*

None.

REGION 4

A. *EIS's in preparation.*

Savannah, Ga.—Final EIS for new construction of a Federal Building and Parking Facility.

Knoxville, Tenn.—Draft EIS for new construction of a Federal Building (temporarily deferred).

Birmingham, Ala.—Draft EIS for new construction of Federal Building-Courthouse and Parking Facility.

Nashville, Tenn.—Draft EIS for renovation of Union Station.

B. *EIS's planned.*

None.

C. *Environmental assessments completed with negative declarations.*

Miami, Fla.—New construction of leased building for the Immigration and Naturalization Service.

REGION 5

A. *EIS's in preparation.*

East St. Louis, Ill.—Final EIS for construction of a Federal Building and Courthouse (temporarily deferred).

Detroit, Mich.—Final EIS for acquisition, repair and alteration of a Secondary Truck Inspection Facility for the U.S. Customs Service.

Milwaukee, Wis.—Draft EIS for lease construction of a Federal Building and Parking Facility.

B. *EIS's planned.*

None.

C. *Environmental assessments completed with negative declarations.*

None.

REGION 6

A. *EIS's in preparation.*

Omaha, Nebr.—Draft EIS for construction of a Federal Office Building.

Kansas City, Mo.—Draft EIS for the repair and alteration of Union Station.

B. *EIS's planned.*

Kansas City, Kans./Kansas City, Mo. (standard metropolitan statistical areas).—Preliminary draft EIS for Internal Revenue Service-Midwest Service Center.

C. *Environmental assessments completed with negative declarations.*

None.

REGION 7

A. *EIS's in preparation.*

El Paso, Tex.—Draft EIS for construction of Federal Building and Parking Facility and the repair and alteration of Courthouse Federal Building Conversion.

Roma, Tex.—Draft EIS for lease of a Border Station.

B. *EIS's planned.*

None.

C. *Environmental assessments completed with negative declarations.*

Little Rock, Ark.—Federal construction and repair and alteration of Post Office-Courthouse extension.

REGION 8

A. *EIS's in preparation.*

Denver Federal Center, Jefferson County, Colo.—Draft Master Plan/Draft Environmental Impact Statement.

B. *EIS's planned.*

None.

C. *Environmental assessments completed with negative declarations.*

None.

REGION 9

A. *EIS's in preparation.*

Los Angeles, Calif.—Final EIS for construction of a Parking Facility.

Santa Barbara, Calif.—Draft EIS for lease construction of Veterans Administration Outpatient Clinic.

West Los Angeles, Calif.—Draft EIS for construction of a Federal Bureau of Investigation Parking Facility.

B. *EIS's planned.*

San Francisco, Calif.—Preliminary draft EIS for construction of Federal Building.

C. *Environmental assessments completed with negative declarations.*

None.

REGION 10

A. *EIS's in preparation.*

Anchorage, Alaska—Federal Building.—Supplement to the final EIS.

B. *EIS's planned.*

None.

C. *Environmental assessments completed with negative declarations Alaska Highway Border Station.*—Construction of housing for Border Station personnel.

Cougar, Wash.—Lease space for the Forest Service.

REAL PROPERTY DISPOSAL ACTIONS

ENVIRONMENTAL IMPACT STATEMENTS/ NEGATIVE DECLARATION

REGION 1

A. *EIS's in preparation.*

Charlestown, R.I.—Draft EIS regarding disposal of approximately 604 acres of the former Naval Auxiliary Landing Field, published 4-28-78; public comment and review period through 6-27-78.

Newport, North Kingstown, Middletown, and Portsmouth, R.I.—Draft EIS regarding disposal of approximately 3,200 acres of the former Quonset Point Naval Air Station, Construction Battalion Center, and U.S. Naval Base, published 4-28-78; public comment and review period through 6-27-78.

B. *EIS's planned.*

None.

C. *Environmental assessments completed with negative declarations.*

South Addison, Maine—Nash Island Light Station.—Conveyance through the Department of Health, Education, and Welfare, for transfer to the Washington County Cooperative Board for Vocational Education, region No. 6, for educational purposes.

Middletown, Conn.—Public sale using competitive sealed bid procedures subject to historic preservation covenants to be incorporated in the deed of conveyance.

REGION 2

A. *EIS's in preparation.*

None.

B. *EIS's planned.*

None.

C. *Environmental Assessments Completed with Negative Declarations.*

Hornell, N.Y.—Public sale of 0.18 of an acre being a portion of the Hornell Channel Improvement Project by competitive bid.

San Juan, P.R.—Negotiated sale of 91.93 acres of Fort Buchanan Military Reservation to the Commonwealth of Puerto Rico for municipal use.

Township of Oldmans, N.J.—Negotiated sale of 5.82 acres being a portion of the Pedricktown Disposal Area to the County of Salom for municipal use.

Fishers Island, N.Y.—Public sale of 0.22 of an acre of the Coast Guard Station by competitive bid and 1 acre to Fishers Island School District for educational purposes.

Rochester, N.Y.—Negotiated sale of 0.463 of an acre being a portion of the Light Station to ConRail for railroad use and 1.342 acres to Holy Cross Church for educational purposes.

New Windsor, N.Y.—Public sale of 1.4 acres of the former Naval Reserve Center by competitive bid.

Aguadilla, P.R.—Negotiated sale of approximately 286 acres, 1,498.48 acres for airport use, approximately 750 acres for park and recreational use, 1,166.26 acres for educational use, 13.29 acres together with water and sanitary sewer lines for health use to the Commonwealth of Puerto Rico, 12.00 acres to Inter American University for educational use and 6.7 acres to the children's medical Relief International for health use being a portion of Ramey Air Force Base, Aguadilla, Puerto Rico and satellite areas.

Jersey City, N.J.—Public sale of 12.1 acres being a portion of the U.S. Army Reserve Center by competitive bid.

REGION 3

A. *EIS's in preparation.*

None.

B. *EIS's planned.*

Draft EIS regarding the disposal of 109.77 acres and improvements of the Frankford Arsenal, Philadelphia, Pa.

C. *Environmental assessment completed with negative declarations.*

Anne Arundel County, Md.—Negotiated sale of the GSA-Curtis Bay Storage Depot to Anne Arundel County for an industrial complex.

Cheltenham, Md.—Assignment of the Naval Communications Unit to the Historic Conservation and Recreation Service for Prince Georges County for public park and recreational purposes.

Gainesville, Va.—Proposed assignment of Portion, Vint Hill Farms Station to Department of Transportation for Virginia Highway Commission.

REGION 4

A. *EIS's in preparation.*

None.

B. *EIS's planned.*

None.

C. *Environmental assessments completed with negative declarations.*

Fort Rucker, Ala.—Public sale of 40 acres (Perimeter Lands) of the Fort Rucker Military Reservation by competitive bid.

Selma, Ala.—Airport conveyance of a protion of the Craig AFB to the Craig Field Airport and Industrial Authority, Selma, Alabama, for airport purposes; negotiated sale of the electrical and gas distribution lines, as well as the telephone system, to the Craig Field Airport and Industrial Authority and/or servicing companies for continued use as utility systems; assignment of portions of the utility systems to the Department of Health, Education, and Welfare for subsequent conveyance to the appropriate public body for public health purposes; assignment of approximately 99 acres to the Department of Health, Education, and Welfare for subsequent conveyance to the Alabama Department of Public Safety, George C. Wallace Community College, Dallas County Board of Education, and Selma-Dallas County Public Library for various educational purposes; assignment of a 2.08-acre portion to the Department of Health, Education, and Welfare for subsequent conveyance to the Dallas County Health Department for public health purposes; assignment of 344.90-acre portion to the Heritage Conservation and Recreation Service for subsequent conveyance to the City of Selma/Dallas County for park and recreational purposes; negotiated sale of approximately 50.32 acres to the Craig Field Airport and Industrial Authority for controlled development purposes; negotiated sale of approximately 132.54 acres to the Selma Housing Authority for public housing or by public sale by competitive bid.

Cecil Field, Fla.—Public sale of Building No. 39 at the Naval Air Station by competitive bid for offsite removal.

Florida City, Fla.—Public sale of 1.07 acres of the ILS Outer Marker (KYVP) by competitive bid.

Orlando, Fla.—Airport conveyance of a portion of the U.S. Army Reserve Center No. 3 at the former McCoy AFB and the Alert Facility Complex at McCoy AFB to the City of Orlando for airport purposes.

Mammoth Cave, Ky.—Public sale of Building No. 193 at the Mammoth Cave National Park by competitive bid for offsite removal.

Natchez, Miss.—Public sale of Feltus House No. 2 at the Natchez Trace Parkway by competitive bid for offsite removal.

Jacksonville, N.C.—Negotiated sale of a portion of the Camp Lejeune Marine Corps Base (Hubert by-pass area) to Onslow County, N.C., for the construction of a volunteer fire department.

Chattanooga, Tenn.—Assignment of a portion of the Volunteer Army Ammunition Plant, Parcel "C" to the Heritage Conservation and Recreation Service for subsequent conveyance to Hamilton County, Tenn., for park and recreational purposes.

REGION 5

A. *EIS's in preparation.*

None.

B. *EIS's planned.*

None.

C. *Environmental assessments completed with negative declarations.*

Jacksonville, Ill.—Former U.S. Post Office, 301 E. State Street. Property consists of a single story masonry building, with basement, on a 0.59 acre site of fee-owned land. Proposed disposal by negotiated sale to Morgan County.

Grosse Ile, Mich.—Former U.S. Post Office Site. Property consists of a rectangular site measuring 150 feet of frontage on Macomb Street with a depth of 327 feet. The site is unimproved. Proposed disposal by sealed bid sale to the general public.

Matinsville, Ind.—Government-owned machinery and equipment. Property consists of 30 items of metal cutting equipment and metal testing items located in a contractor-owned plant. Proposed disposal by sale to Twigg Corporation, the operating contractor, by negotiated sale.

Pontiac, Mich.—Former Federal Building, Huron and Perry Streets. Property consists of a 0.63 acre square tract improved with a two-story masonry, stone and steel-sash Federal Building, with full basement. The building occupies about three quarters of the site. Proposed disposal by conveyance through Heritage Conservation and Recrea-

tion Service to city of Pontiac for recreation and cultural purposes.

Kokomo, Ind.—Former U.S. Post Office, Mulberry and Union Streets. Property consists of a 0.84 acre lot measuring 132 feet by 280 feet improved with a one-story and partial two-story post office building. Proposed disposal by negotiated sale to Howard County.

Chicago, Ill.—Chicago Administration Center, 1819 W. Pershing Road. Property consists of 10.6 acres of fee-owned land, 0.98 acre of easements, and is improved with five buildings containing 1.8 million square feet, railroad tracks, paved driveways and parking areas, and fencing. Proposed disposal by sealed bid sale as a unit or in 3 parcels, each parcel to consist of one major building and the land to the rear of the building.

REGION 6

A. *EIS's in preparation.*
None.

B. *EIS's planned.*
None.

C. *Environmental assessments completed with negative declarations.*

Geary County, Kans.—Assignment of 119.5 acre portion of Milford Lake to the Department of Health, Education, and Welfare for conveyance to the Kansas State University for research.

Salina, Kans.—Negotiated sale to the city of Salina, Kans., or a public sale of Schilling Manor Housing Area containing approximately 284.13 acres.

Festus, Mo.—Public sale of 0.467 acre improved with a Post Office building by competitive bid.

Geary County, Kans.—Public sale of 8.71 acre portion of Milford Lake by competitive bid.

REGION 7

A. *EIS's in preparation.*

Jonesboro, Ark.—Negotiated sale of 0.6 acre of land with Federal building and Courthouse located thereon to City of Jonesboro and County of Craighead, Ark., to be used as office space for parks department, building inspector's department, police department and courtrooms.

B. *EIS's Planned*
None.

C. *Environmental assessments completed with negative declarations.*

Castner Range, Fort Bliss, Tex.—Negotiated sale of 14.118 acres of land with city of El Paso, Tex. for use as a detention basin to accommodate storm water runoff.

Fort Bliss, El Paso, Tex.—Propose transfer of 1,296.256 acres of land in El Paso County, Tex. to Department of the Army for continued use as a training area by Fort Bliss, Tex.

Cimmaron County, Okla.—Sealed bid sale of house at Keyes Helium Plant, Okla. for off-site removal.

REGION 8

A. *EIS's in preparation.*
None.

B. *EIS's planned.*
None.

C. *Environmental assessments completed with negative declarations.*

Denver, Colo.—Federal transfer of 0.46-acre fee and 187.71 acre easement at Lowry Air Force Base to Federal Aviation Administration.

Glacier National Park, Mont.—Public sale of the former National Park Service Log Building by competitive bid.

Watertown, S. Dak.—Public sale of the former Postal Service unimproved lot by competitive bid.

Arlington, S. Dak.—Public sale of the former Bureau of Reclamation Radio Tower Site by competitive bid.

REGION 9

A. *EIS's in preparation.*
Negative.

B. *EIS's planned.*

Novato, Calif.—Draft EIS regarding disposal of approximately 1,745 acres of the former Hamilton Air Force Base.

C. *Environmental assessments completed with negative declaration.*

Tonopah, Nev.—Transfer to the Department of Agriculture approximately 0.60 acre improved with four one-story duplexes. The property was formerly a portion of the AEC Housing Complex and will be used for housing for Forest Service employees who will be responsible for administering the Youth Conservation Corps and Young Adult Conservation Corps programs.

Merced County, Calif.—Convey to California State Department of Fish and Game approximately 114.98 acres of a portion of the Central Valley Project, San Luis Canal Right of Way for conservation of wildlife.

San Pedro, Calif.—Transfer approximately 6.40 acres of land improved with seventeen buildings to the Department of Health, Education, and Welfare. Identified as the Hospital Area at Fort MacArthur, the property will be used as an Indian Health Service Ambulatory Care Center.

Oakland, Calif.—Amendment to previous determination on the U.S. Naval Hospital, San Leandro Annex revises the proposed disposal action to a sealed bid sale of approximately 28.52 acres of land.

Boron, Calif.—Transfer approximately 1.72 acres fee and 9.40 acres easements and improvements of Boron Air Force Station to the Federal Aviation Administration for continued use of the long range radar facility; convey approximately 640 acres to the State of California Department of Fish and Game for wildlife conservation; public sale of approximately 174 acres fee, 23.64 acres easements and improvements by competitive bid.

Long Beach, Calif.—Negotiated sale of 20.56 acres of the U.S. Naval Station, Lexington Defense Housing Area to the city of Long Beach.

REGION 10

A. *EIS's in preparation.*
None.

B. EIS's planned.
None.

C. *Environmental assessments completed with negative declaration.*

Washington County, Oreg.—Public sale of approximately 0.507 acre together with a single-story building located in the city of Hillsboro.

Deschutes County, Oreg.—Negotiated sale of approximately 1.15 acres being a portion of Block 21, Davidson's Addition to the city of Sisters.

Snohomish County, Wash.—Public sale of approximately 24.82 acres of unimproved land located near the city of Everett.

[FR Doc. 78-21999 Filed 8-7-78; 8:45 am]

[1505-01]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food And Drug Administration

[Docket No. 78-N-0124]

UPJOHN CO.; DEPO-PROVERA STERILE AQUEOUS SUSPENSION

Opportunity for Hearing on Proposal To Refuse To Approve Supplemental New Drug Application

Correction

In FR Doc. 78-17860 appearing at page 28555 in the issue of Friday, June 30, 1978, the following corrections should be made.

1. In the last full paragraph of the middle column on page 28555 the full address for the Food and Drug Administration should read "5600 Fishers Lane, Rockville, Md. 20857."

2. The second line of the third paragraph in the third column on page 28555 should read "(NDA 12-541/S-004)".

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. 77N-0152]

SUBTHERAPEUTIC ANTIBACTERIAL AGENTS IN ANIMAL FEEDS

Availability of Draft Environmental Impact Statement

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The agency announces the availability of a draft environmental impact statement prepared by the Bureau of Veterinary Medicine. The statement addresses the environmental impact of several proposals to restrict the subtherapeutic use of certain antibacterials in animal feeds.

DATE: Comments on the draft statement by October 10, 1978.

ADDRESSES: Copies of the draft statement are available from the Hearing Clerk (HFA-305), Food and Drug Administration, 4-65, 5600 Fishers Lane, Rockville, Md. 20857, or the Office of the Associate Commissioner for Public Affairs, Food and Drug Administration, 15B-42, 5600 Fishers Lane, Rockville, Md. 20857; written comments on the statement to the Hearing Clerk (HFA-305) at the above address.

FOR FURTHER INFORMATION CONTACT:

Susan E. Feinman, Bureau of Veterinary Medicine (HFV—130), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-1414.

SUPPLEMENTARY INFORMATION: The agency's notice of intent to propose rules was published in the FEDERAL REGISTER of May 27, 1977 (42 FR 27264). The notice called for the submission of environmental impact data for a series of proposals, to be published, which would restrict the subtherapeutic use of penicillin and tetracycline (chlortetracycline and oxytetracycline) in animal feeds.

Subsequently, the Bureau of Veterinary Medicine proposed to withdraw the use of penicillin with streptomycin on June 10, 1977 (42 FR 29928), and penicillin on August 30, 1977 (42 FR 43770), and proposed to restrict the subtherapeutic use of the tetracyclines (chlortetracycline and oxytetracyline) on October 21, 1977 (42 FR 56254). Additionally, the agency proposed to restrict the distribution of animal feeds containing penicillin and the tetracyclines on January 20, 1978 (43 FR 3032).

Notice is hereby given that the Bureau of Veterinary Medicine has prepared a document entitled, "Draft Environmental Impact Statement—Subtherapeutic Antibacterial Agents in Animal Feeds," which addresses the environmental impact of the proposals to limit the subtherapeutic use of penicillin and the tetracyclines in animal feeds. Copies of the statement are available from the Office of the Associate Commissioner for Public Affairs or from the Hearing Clerk at the above addresses.

All interested persons are requested to submit five copies of comments on this draft statement to the Hearing Clerk at the above address on or before October 10, 1978. All comments received shall be available for public examination at the office of the Hearing Clerk at the above address, from 9 a.m. to 4 p.m., Monday through Friday.

The statement is issued under the National Environmental Policy Act of 1969, Pub. L. 91-190 (sec. 102(2)(C), 83 Stat. 853 (42 U.S.C. 4332)), the Council on Environmental Quality guidelines published in the FEDERAL REGISTER of August 1, 1973 (38 FR 20550), Executive Order 11514 of March 7, 1970 (35 FR 4247), and the Food and Drug Administration's environmental regulations (21 CFR Part 25).

Dated: July 31, 1978.

C. D. VAN HOUWELING,
Director, Bureau of Veterinary Medicine.

[FR Doc. 78-21792 Filed 8-7-78; 8:45 am]

[4110-08]

National Institutes of Health

BOARD OF SCIENTIFIC COUNSELORS, NIDR

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Institute of Dental Research, National Institutes of Health, Bethesda, Md., on September 13-14, 1978, in Building 30, Conference Room 117. This meeting will be open to the public on September 13, from 1:30 p.m. to adjournment, and September 14, from 9 a.m. to adjournment, to discuss the research direction and activities of the Laboratories of the National Institute of Dental Research. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in section 552(b)(6), Title 5, U.S. Code and Section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on September 13 from 9 a.m. to 1:30 p.m., for the review, discussion and evaluation of individual programs and projects conducted by the National Institute of Dental Research, National Institutes of Health, including consideration of individual intramural programs, personnel qualifications and performance, the competence of individual investigators, and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Marie U. Nylen, Director of Intramual Research, National Institute of Dental Research, National Institutes of Health, Building 30, Room 132, Bethesda, Md. 20014, telephone 301-496-1483 will provide summaries of meetings, rosters of committee members, and substantive program information.

Dated: July 24, 1978.

SUZANNE L. FREMEAU,
Committee Management Officer, National Institutes of Health.

[FR Doc. 78-22025 Filed 8-7-78; 8:45 am]

[4110-08]

BOARD OF SCIENTIFIC COUNSELORS DIVISION OF CANCER TREATMENT

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Board of Scientific Counselors, DCT, National Cancer Institute, October 16-17, 1978, Building 31, 6th floor, "C" wing, Conference Room 10, National Institutes of Health. This meeting will be open to the public on October 16, 1978, from 8:30 a.m. to 5 p.m., and again on October 17, 1978, from 8:30 a.m. to 4:30 p.m. to review program plans, budget and management of NCI reorganization incorporating treatment grants into the DCT program. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Section 552b(c)(6), Title 5, U.S. Code and Section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on October 16, 1978, from 6:30 p.m. to 9:30 p.m., for the review, discussion, and evaluation of individual programs and projects conducted by the National Institutes of Health, including consideration of personnel qualifications and performance, the competence of individual investigators, and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Vincent T. DeVita, Director, Division of Cancer Treatment, National Cancer Institute, Building 31, Room 3A-52, National Institutes of Health, Bethesda, Md. 20014 301-496-4291, will furnish summaries of meetings, rosters of committee members, and substantive program information.

Dated: July 24, 1978.

SUZANNE L. FREMEAU,
Committee Management Officer, National Institutes of Health.

[FR Doc. 78-22033 Filed 8-7-78; 8:45 am]

[4110-08]

CLINICAL APPLICATIONS AND PREVENTION ADVISORY COMMITTEE

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Clinical Applications and Prevention Advisory Committee, Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute, September 12, 1978, Federal Building, Conference Room 6C01, Bethesda, Md.

This meeting will be open to the public on September 12 from 9 a.m. to adjournment, when the Committee will discuss the status of new initiatives and review the programs in the Epidemiology, Clinical Trials and Preventive Cardiology Branches. Attendance by the public will be limited to space available.

Mr. York Onnen, Chief, Public Inquiries and Reports Branch, National Heart, Lung, and Blood Institute, Building 31, Room 5A03, National Institutes of Health, Bethesda, Md. 20014, phone 301-496-4236, will provide summaries of the meeting and rosters of the Committee members.

Dr. William J. Zukel, Executive Secretary of the Committee, Federal Building, Room 4C10, Bethesda, Md. 20014, phone 301-496-2533, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13.837, National Institutes of Health.)

Dated: July 20, 1978.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 78-22024 Filed 8-7-78; 8:45 am]

[4110-08]

NATIONAL ADVISORY ENVIRONMENTAL HEALTH SCIENCES COUNCIL

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Advisory Environmental Health Sciences Council, National Institute of Environmental Health Sciences, September 18-19, 1978, in Building 18 Conference Room, National Institute of Environmental Health Sciences, Research Triangle Park, N.C.

This meeting will be open to the public on September 18, 1978, from 9 a.m. to approximately 12 noon to discuss program policies and issues, recent legislation, interagency activities, program planning and other items of interest. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S. Code and Section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on September 18, 1978, from 1 p.m. to adjournment on September 19, 1978, for the review, discussion and evaluation of individual grant applications.

Leota B. Staff, Committee Management Officer, NIEHS, Westwood Building, Room 340, Bethesda, Md. 20014, 301-496-7483, will provide summaries of the meeting and rosters of Council members.

Dr. Wilford L. Nusser, Associate Director for Extramural Program, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, North Carolina 27709, 919-755-4015, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.872, 13.873, 13.874, 13.875, National Institutes of Health)

Dated: August 2, 1978.

THOMAS E. MALONE,
Deputy Director,
National Institutes of Health.

[FR Doc. 78-22027 Filed 8-7-78; 8:45 am]

[4110-08]

NATIONAL ADVISORY EYE COUNCIL

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Advisory Eye Council, National Eye Institute, September 20, 21, and 22, 1978, Building 31, Conference Room No. 7, National Institutes of Health, Bethesda, Md.

This meeting will convene each day at 9 a.m. and will be open to the public from 9 a.m. until noon on September 20 for opening remarks by the Director, National Eye Institute, discussion of procedural matters, and presentations by the extramural staff of the National Eye Institute. Attendance by the public will be limited to space available.

In accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public from 1 p.m. until adjournment on Wednesday, September 20, and the entire day on Thursday and Friday, September 21 and 22, until adjournment for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications.

Mr. Julian Morris, Chief, Office of Scientific Reports and Program Planning, National Eye Institute, Building 31, Room 6A-25, AC 301-496-5248, will provide summaries of meetings and rosters of committee members.

Dr. Ronald G. Geller, Acting Associate Director for Extramural and Collaborative Programs, National Eye Institute, Building 31, Room 6A-04, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.867, 13.868, 13.869, 13.870, and 13.871, National Institutes of Health)

Dated: July 24, 1978.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 78-22028 Filed 8-7-78; 8:45 am]

[4110-08]

NATIONAL ADVISORY GENERAL MEDICAL SCIENCES COUNCIL

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Advisory General Medical Sciences Council, National Institute of General Medical Sciences, National Institutes of Health, September 8-9, 1978, building 31, conference room 10.

This meeting will be open to the public on September 8, 1978, from 9 a.m. to 12 noon for opening remarks; report of the Director, NIGMS; and other business of the Council. Attendance by the public will be limited to space available.

In accordance with provisions set forth in title 5, United States Code 552b(c)(4) and 552b(c)(6), the meeting will be closed to the public on September 8, 1978, from 12 noon to 5 p.m. and on September 9, 1978, from 9 a.m. to adjournment for the review, discussion, and evaluation of individual grant applications. These applications could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications.

Mr. Paul Deming, Public Information Officer, National Institute of General Medical Sciences, National Institutes of Health, Room 9A05, Westwood Building, Bethesda, Md. 20014, telephone 301-496-7301, will provide a summary of the meeting and a roster of council members.

Dr. Ruth L. Krischstein, Executive Secretary, NAGMS Council, National Institutes of Health, Building 31, Room 4A52, Bethesda, Md. 20014, telephone 301-946-5231 will provide substantive program information.

(Catalog of Federal domestic assistance programs Nos. 13-859, 13-860, 13-861, 13-862, 13-863, National Institutes of Health.)

Dated: July 24, 1978.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 78-22023 Filed 8-7-78; 8:45 am]

[4110-08]

NATIONAL HEART, LUNG, AND BLOOD ADVISORY COUNCIL AND ITS MANPOWER SUBCOMMITTEE AND RESEARCH SUBCOMMITTEE

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Heart, Lung, and Blood Advisory Council, National Heart, Lung, and Blood Institute, September 21, 22, and 23, 1978, National Institutes of Health, building 31, conference room 10, at 9 a.m.

This meeting will be open to the public on September 21 from 9 a.m. to approximately 3:30 p.m., to discuss program policies and issues. Attendance by the public is limited to space available. In addition, meetings of the Manpower Subcommittee and the Research Subcommittee of the above Council will be held September 20,

1978, at 8 p.m. in building 31, conference rooms 9 and 10 respectively.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, United States Code, and section 10(d) of Pub. L. 92-463, the meeting of the Council will be closed to the public on September 21 from 3:30 p.m. until recess, and on September 22 from 9 a.m. to adjournment on September 23 for the review, discussion, and evaluation of individual grant applications. The Manpower Subcommittee and the Research Subcommittee of the above Council will be closed from 8 p.m. to adjournment on September 20, also for the review, discussion, and evaulation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications.

Mr. York Onnen, Chief, Public Inquiries and Reports Branch, National Heart, Lung, and Blood Institute, Building 31, Room 5A03, National Institutes of Health, Bethesda, Md. 20014, 301-496-4236, will provide summaries of the meetings and rosters of the Council members.

Dr. Jerome G. Green, Director of Extramural Affairs, NHLBI, Westwood Building, Room 7A17, 301-496-7416, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.837, 13.838, and 13.839, National Institutes of Health.)

Dated: July 24, 1978.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 78-22030 Filed 8-7-78; 8:45 am]

[4110-08]

MAMMALIAN CELL LINES COMMITTEE

Meeting

Pursuant to Pub. L. 93-463, notice is hereby given of the meeting of the Mammalian Cell Lines Committee, National Institute of General Medical Sciences on September 28, 1978, 9 a.m., Room 910 Westwood Building, 5333 Westbard Avenue, Bethesda, Md.

This meeting will be open to the public on September 28, from 9 a.m. to 12 noon for opening remarks and discussion of procedural matters and issues relevant to the committee's responsiblities. Attendance by the public will be limited to space available.

In accordance with provisions set forth in title 5, U.S. Code 552b(c)(6), the meeting will be closed to the public on September 28 from 12 noon until adjournment, for the review, discussion, and evaluation of institutional training grant applications in genetics. These applications could disclose information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Mr. Paul Deming, Research Reports Officer, NIGMS, Westwood Building, Room 9A05, Bethesda, Md. 20014, Telephone 301-496-7301, will furnish summary minutes of the meeting and a roster of committee members.

Dr. John Dalton, Acting Executive Secretary, Mammalian Cell Lines Committee, Westwood Building, Room 949, Telephone 301-496-7061, will furnish substantive program information.

(Catalog of Federal domestic assistance program 13-862, General Medical Sciences Genetics Program.)

Dated: August 2, 1978.

THOMAS E. MALONE,
Deputy Director,
National Institutes of Health.

[FR Doc. 78-22031 Filed 8-7-78; 8:45 am]

[4110-08]

NATIONAL ADVISORY NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE COUNCIL

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Advisory Neurological and Communicative Disorders and Stroke Council, National Institutes of Health, October 5, 6, and 7, 1978, at 9 a.m. in Building 31-C, Conference Room 6, Bethesda, Md. 20014. The meeting will be open to the public from 9 a.m. until 11:30 a.m. on October 5, 1978, to discuss program planning and program accomplishments. Attendance by the public will be limited to space available. In accordance with the provisions set forth in sections 552b(c)(4), and 552b(c)(6) of Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public from 11:30 a.m. on October 5, 1978, until the conclusion of the meeting that day, and from 8:30 a.m. until 6 p.m. on October 6 and 7, 1978, for review, discussion and evaluation of research grant applications and applications for teacher-investigator awards, research career development awards, individual national research service awards and institutional national research service awards. These applications and the discussion could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications.

The Chief, Office of Scientific and Health Reports, Miss Sylvia Shaffer, Building 31, Room 8A06, NIH, NINCDS, Bethesda, Md., telephone 301-496-5751, will furnish summaries of the meeting and rosters of committee members.

Dr. J. Buckminster Ranney, Executive Secretary, Federal Building, Room 1016, Bethesda, Md. 20014, telephone 301-496-9248, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.851, 13.852, 13.853, 13.854, National Institutes of Health.)

Dated: July 28, 1978.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 78-22032 Filed 8-7-78; 8:45 am]

[4110-08]

NATIONAL ADVISORY NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE COUNCIL PLANNING SUBCOMMITTEE

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Advisory Neurological and Communicative Disorders and Stroke Council Planning Subcommittee, September 21, 1978, at 8:30 a.m., in the Lobby Room, The Holiday Inn, 5520 Wisconsin Avenue, Bethesda, Md. The meeting will be open to the public from 8:30 a.m. to 10:30 a.m. on September 21, 1978, to discuss program planning and program accomplishments. Attendance by the public will be limited to space available. In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6) of Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public from 10:30 a.m. on September 21, 1978, to adjournment on September 21, 1978. The portion of the meeting being closed involves the review, discussion, and evaluation of individual grant applications. These applications and the discussion could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications.

The Chief, Office of Scientific and Health Reports, Miss Sylvia Shaffer, Building 31, Room 8A06, NIH, NINCDS, Bethesda, Md., telephone, 301-496-5751, will furnish summaries of the meeting and rosters of committee members.

Dr. O. Malcolm Ray, Executive Secretary of the Committee, Room 1020C, Federal Building, NIH, NINCDS, Bethesda, Md., telephone, 301-496-9234, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.851, 13.852, 13.853, 13.854, National Institutes of Health.)

Dated: July 28, 1978.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 78-22029 Filed 8-7-78; 8:45 am]

[4110-08]

STATE-OF-THE-ART CONFERENCE ON LUNG CANCER

Meeting

Notice is hereby given of a State-of-the-Art Conference on Lung Cancer Screening to be sponsored by the Division of Cancer Control and Rehabilitation, National Cancer Institute to be held in the Sheraton Hotel, Reston, Va., on September 18-20, 1978.

The meeting will be open to the public from 9 a.m. to 5 p.m. on September 18-19, 1978 and from 9 a.m. to adjournment on September 20, 1978 to discuss and review the scientific basis of methods for early detection of lung cancer, and to estimate the results to be expected from their use. Attendance by the public will be limited to space available.

Dr. Margaret H. Sloan, Special Assistant for Liaison, 8300 Colesville Road, Blair Building, Room 722, Silver Spring, Md. 20910, 301-427-7298 will provide additional information.

Dated: August 1, 1978.

THOMAS E. MALONE,
Deputy Director,
National Institutes of Health.

[FR Doc. 78-22026 Filed 8-7-78; 8:45 am]

[4110-08]

BLADDER AND PROSTATIC CANCER REVIEW COMMITTEE, SUBCOMMITTEE FOR PROSTATIC CANCER

Meeting

Pursuant to Pub L. 92-463, notice is hereby given of the meeting of the Subcommittee for Prostatic Cancer, National Cancer Institute, September 6, 1978, Roswell Park Research Study Center, 666 Elm Street, Roswell Park Memorial Institute, Buffalo, N.Y.

The entire meeting will be open to the public from 8:30 a.m. to adjournment to review the national prostatic project. Attendance by the public will be limited to space available.

Mrs. Marjorie F. Early, Committee Management Officer, National Cancer Institute, Building 31, Room 4B43, National Institutes of Health Bethesda, Md. 20014, 301-496-5708, will furnish a summary of the meeting and rosters of members, upon request.

Dr. Andrew Chiarodo, Executive Secretary, Westwood Building, Room 853, National Cancer Institute, Bethesda, Md., 20014, 301-496-7194, will provide substantive program information.

Dated: July 31, 1978.

THOMAS E. MALONE,
Deputy Director,
National Institutes of Health.

[FR Doc. 78-22021 Filed 8-7-78; 8:45 am]

[4110-08]

CHEMICAL SELECTION SUBGROUP OF THE CLEARINGHOUSE ON ENVIRONMENTAL CARCINOGENS

Meeting

Notice is hereby given to change the meeting date of the Chemical Selection Subgroup of the Clearinghouse on Environmental Carcinogens, National Cancer Institute, National Institutes of Health, from August 29, 1978, to August 30, 1978, which was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28562).

Dated: July 27, 1978.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 78-22019 Filed 8-7-78; 8:45 am]

[4110-08]

CONTRACT PROPOSALS AND GRANT APPLICATIONS

Meetings for Review

Pursuant to Pub. L. 92-463, notice is hereby given of the meetings of committees advisory to the National Cancer Institute.

These meetings will be open to the public to discuss administrative details or other issues relating to committee business as indicated in the notice. Attendance by the public will be limited to space available.

These meetings will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, United States Code, and section 10(d) of Pub. L. 92-463, for the review, discussion, and evaluation of individual contract proposals and grant applications, as indicated. These proposals and applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposals and the applications.

Mrs. Marjorie F. Early, Committee Management Officer, NCI, Building 31, Room 4B43, National Institutes of Health, Bethesda, Md. 20014, 301-496-5708, will furnish summaries of the meetings and rosters of committee members, upon request. Other information pertaining to the meeting can be obtained from the executive secretary indicated. Meetings will be held at the National Institutes of Health, 9000 Rockville Pike, Bethesda, Md. 20014, unless otherwise stated.

Name of committee: Large Bowel and Pancreatic Cancer Review Committee (Large Bowel Subcommittee).
Dates: September 7-8, 1978; 7:30 p.m.
Place: Prudential Building, 10th floor, 1100 Holcombe Boulevard, Houston, Tex. 77025.
Times: Open—September 7, 7:30 p.m.-10:30 p.m. Closed—September 8, 9 a.m.-adjournment.
Closure reason: To review research grant applications.
Executive secretary: Dr. Andrew Chiarodo, Westwood Building, Room 853, National Institutes of Health, 301-496-7194.

(Catalog of Federal Domestic Assistance Nos. 13.393, 13.394, 13.395, National Institutes of Health.)

Name of Committee: Cancer and Nutrition Scientific Review Committee.
Dates: September 11, 1978; 8:30 a.m.
Place: Building 31C, Conference Room 8, National Institutes of Health.
Times: Open—September 11, 8:30 a.m.-9 a.m. Closed—September 11, 9 a.m.-5 p.m.
Closure reason: To review research contract proposals.
Executive secretary: Dr. Gio B. Gori, Building 31, Room 11A03, National Institutes of Health, 301-496-6616.

(Catalog of Federal Domestic Assistance No. 13.393, National Institutes of Health.)

Name of committee: Biometry and Epidemiology Contract Review Committee.
Dates: September 11-13, 1978; 8 p.m.
Place: Landow Building, Room C419, 7910 Woodmont Avenue, Bethesda, Md. 20014.
Times: Open—September 11, 8 p.m.-11 p.m. Closed—September 12, 9 a.m.-5 p.m. Closed—September 13, 8:30 a.m.-adjournment.
Closure reason: To review research contract proposals.
Executive secretary: Mr. Harvey Geller, Landow Building, Room 5C19, National Institutes of Health, 301-496-6014.

(Catalog of Federal domestic Assistance No. 13.393, National Institutes of Health.)

Name of committee: Virus Cancer Program Scientific Review Committee.
Dates: September 18, 1978; 9 a.m.
Place: Landow Building, Room C418, 7910 Woodmont Avenue, Bethesda, Md. 20014.
Times: Open—September 18, 9 a.m.-9:30 a.m. Closed—September 18, 9:30 a.m.-adjournment.
Closure reason: To review research contract proposals.
Executive secretary: Dr. Clarice E. Gaylord, Landow Building, Room 9A12, National Institutes of Health, 301-496-6085.

(Catalog of Federal domestic Assistance No. 13.393, National Institutes of Health.)

Name of committee: Bladder and Prostatic Cancer Review Committee (Bladder Subcommittee).
Dates: September 21, 1978; 8:30 a.m.
Place: Logan Airport Hilton, Logan International Airport, Boston, Mass.
Times: Open—September 21, 8:30 a.m.-9:30 a.m. Closed—September 21, 9:30 a.m.-adjournment.

Closure reason: To review research grant applications.

Executive secretary: Dr. William Straile, Westwood Building, Room 853, National Institutes of Health, 301-496-7194.

(Catalog of Federal Domestic Assistance Nos. 13.393, 13.394, 13.395, National Institutes of Health.)

Dated: August 2, 1978.

THOMAS E. MALONE,
Deputy Director.
National Institutes of Health.

[FR Doc.-22022 Filed 8-7-78; 8:45 am]

[4110-08]

EXPERIMENTAL DESIGN SUBGROUP OF THE CLEARINGHOUSE ON ENVIRONMENTAL CARCINOGENS

Cancellation of Metting

Notice is hereby given of the cancellation of the meeting of the Experimental Design Subgroup of the Clearinghouse on Environmental Carcinogens, National Cancer Institute, National Institutes of Health, August 30, 1978, which was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28562).

Dated: July 27, 1978.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 78-22018 Filed 8-7-78; 8:45 am]

[4110-08]

NATIONAL ADVISORY RESEARCH RESOURCES COUNCIL

Meeting of the Planning and Agenda Work Group

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Planning and Agenda Work Group of the National Advisory Research Resources Council, Division of Research Resources (DRR), September 5, 1978, Room 5B03, Building 31, National Institutes of Health, Bethesda, Md. 20014, from 9 a.m. to adjournment. The entire meeting will be open to the public. The Planning and Agenda Work Group will discuss the development of Council agenda for the September 18-19 meeting of the National Advisory Research Resources Council. Attendance by the public will be limited to space available.

Mr. James Augustine, Information Officer, Division of Research Resources, National Institutes of Health, Room 5B13, Building 31, Bethesda, Md. 20014, 301-496-5545, will provide summaries of the meeting and rosters of the members of the Work Group. Dr. James F. O'Donnell, Deputy Director, Division of Research Resources, National Institutes of Health, Room 5B03, Building 31, Bethesda, Md. 20014, 301-496-6023, will furnish substantive program information and will receive any comments pertaining to this announcement.

(Catalog of Federal Domestic Assistance Program Nos. 13.306, 13.333, 13.337, 13.371, 13.375, National Institutes of Health.)

Dated: July 28, 1978.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 78-22020 Filed 8-7-78; 8:45 am]

[4110-08]

NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES

Amended Notice of Meeting

Notice is hereby given of a location change in one of the three National Commission on Digestive Diseases meetings published in the FEDERAL REGISTER on May 5, 1978 (43 FR 19465.)

The third of the three meetings was to have convened August 17-19, 1978, Minary Conference Center, Dartmouth College, Hanover, N.H., but has been changed to the Sheraton-Reston Hotel, Reston, Va., for the purpose of reviewing the second draft of the long range plan. The meeting will be open to the public. Attendance by the public will be limited to space available. No input will be requested from the audience.

Messrs. James N. Fordham or Irving Shapiro, Office of Scientific and Technical Reports, NIAMDD, National Institutes of Health, Building 31, Room 9A04, Bethesda, Md. 20014, telephone 301-496-3583, will provide summaries of the meeting.

(Catalog of Federal Domestic Assistance Program No. 13.484, National Institutes of Health.)

Dated: August 2, 1978.

THOMAS E. MALONE,
Deputy Director,
National Institutes of Health.

[FR Doc. 78-22017 Filed 8-7-78; 8:45 am]

[4110-08]

Office of the Assistant Secretary for Health

NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

Meeting

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research will hold its final meeting on September 8, 1978, in Conference Room 6, C Wing, Building 31, National Institutes of Health, 9000 Rockville Pike, Bethesda, Md. The meeting will convene at 9 a.m. and will be open to the public, subject to the limitations of available space. Topics identified in the mandate to the Commission under the National Research Act (Pub. L. 93-348), as amended, will be the agenda for this meeting.

Written comments of any length may be submitted to the Commission at any time. Requests for information should be directed to Ms. Barbara Mishkin, Assistant Staff Director, 301-496-7526, Westwood Building, Room 125, 5333 Westbard Avenue, Bethesda, Md. 20016.

Dated: July 28, 1978.

MICHAEL S. YESLEY,
Staff Director, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

[FR Doc. 78-22099 Filed 8-7-78; 8:45 am]

[4110-07]

Office of the Secretary

SOCIAL SECURITY ADMINISTRATION

Statement of Organization, Functions, and Delegations of Authority

Part S (formerly part 4) of the statement of organization, functions, and delegations of authority for the Department of Health, Education, and Welfare contains the statement of organization, functions, and delegations of authority for the Social Security Administration (SSA). Sections SX.00 through SX.20 of the SSA statement (formerly included in section 4-04-00 through 4-04-20 of 40 FR 55888-89, dated December 2, 1975) describe the mission, organization, order of succession, and functions for SSA's Office of External Affairs (OEA). Sections SX.10 G and SX.20 G of the OEA statement are hereby modified and expanded to reflect the establishment of four divisions within OEA's Office of Public Inquiries (OPI). These changes do not constitute functional changes; they are being made to bring the organizational titles of existing OPI components into conformity with those used by other comparable organizational entities within SSA. This additional material reads as follows:

SECTION SX.10 *Office of External Affairs*—(Organization).

G. Office of Public Inquiries.
1. Division of Correspondence Appraisal and Policy.
2. Division of Special Inquiries.
3. Division of Inquiries.
4. Division of Services.

SECTION SX.20 *Office of External Affairs*—(Functions).

G. *Office of Public Inquiries.* Establishes, promulgates, and assesses SSA policy for processing public, congres-

sional, and other sensitive inquiries. Receives, analyzes, and controls high priority written and telephone inquiries; replies to most and refers those requiring specialized knowledge to the appropriate SSA component for input and/or response. Studies correspondence practices in use throughout SSA; performs an ongoing quality appraisal of written responses prepared throughout SSA; develops recommendations designed to improve the effectiveness of SSA's correspondence program and to enhance its consistency and accuracy. Conducts training programs in SSA field and headquarters components to improve correspondence to the public. Provides advice and assistance to SSA officials and liaison with HEW on public correspondence matters. The Office consists of the following components:

1. *Division of Correspondence Appraisal and Policy.* Develops SSA correspondence program objectives, and SSA-wide policy and procedures necessary to implement these objectives. Reviews correspondence practices in use throught SSA, assessing adequacy of and adherence to established policy and procedures. Conducts an ongoing appraisal and special studies to evaluate the quality of correspondence produced SSA-wide, identifying problem areas and making recommendations for corrective action. Conducts training programs in SSA field and headquarters components to improve the quality of SSA correspondence. Plans for effective and coordinated use throughout SSA of the SSA automated correspondence system to control, track, file, and retrieve inquiries and replies throughout SSA central office.

2. *Division of Special Inquiries.* Prepares and/or coordinates the preparation of written replies to particularly sensitive, high level, and complex inquiries concerning all aspects of SSA program administration. Receives and responds to sensitive, complex telephone calls from Members of Congress and their staffs and the public on general and technical matters concerning all SSA programs. Serves as liaison between executive level office/bureau officials and the Office of the Commissioner in solving technical problems arising in the area of sensitive correspondence. Prepares and/or coordinates preparation of SSA replies to inquires controlled by the Office of the Secretary.

3. *Division of Inquiries.* Receives, controls, and replies to incoming correspondence. Performs necessary preresponse technical and general research on inquiries dealing with all areas of social security jurisdiction. Prepares a written response to the majority of these inquiries and the necessary acknowledgement, referral, and transfer letters for those requiring the specialized knowledge of other components. Determines, from correspondence received, significant trends which may point up programmatic or procedural difficulties and possible public relations problems and brings these developments to the attention of appropriate SSA components.

4. *Division of Services.* Provides the clerical support needed to receive, file, track, followup, and furnish information on the status of high priority inquiries and responses processed in SSA. Files and retrieves SSA correspondence and replies controlled in the SSA automated correspondence system; operates the terminals for this system. Provides typing services for responses prepared in OPI.

Dated: July 27, 1978.

LEONARD D. SCHAEFFER,
Assistant Secretary for Management and Budget.

[FR Doc. 78-22100 Filed 8-7-78; 8:45 am]

[4310-84]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM 33831, 33833, 33983]

NEW MEXICO

Applications

JULY 28, 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 five 4½-inch natural gas pipelines rights-of-way across the following lands:

NEW MEXICO PRINCIPAL MERIDIAN, N. MEX.

T. 22 S., R. 22 E.,
Sec. 11, SE¼SW¼, SW¼SE¼;
Sec. 14, E½NW¼, SW¼NW¼, and NW¼SW¼.
T. 18 S., R. 25 E.,
Sec. 9, W½SE¼.
T. 9 S., R. 30 E.,
Sec. 31, NE¼NE¼.

These pipelines will convey natural gas across 1.613 miles of public lands in Chaves and Eddy 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.

FRED E. PADILLA,
Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-22002 Filed 8-7-78; 8:45 am]

[4310-84]

[U-40398]

UTAH

Application

JULY 28, 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 Northwest Pipeline Corp. has applied for an 8⅝-inch natural gas pipeline right-of-way across the following lands:

SALT LAKE MERIDIAN, UTAH

T. 16 S., R. 24 E.,
Secs. 13, 24, 25, 26, and 35.
T. 17 S., R. 24 E.,
Secs. 3, 10, 15, 21, 28, and 29.

The needed right-of-way is a portion of applicant's gas gathering system located in Grand County, Utah.

The purpose of this notice is to inform the public that the Bureau will be proceeding with the preparation of environmental and other analyses necessary for determining whether the application should be approved, and if so, under what terms and conditions.

Interested persons should express their interest and views to the Moab District Manager, Bureau of Land Management, P.O. Box 970, Moab, Utah 84532.

WARREN D. BROUGH,
Acting State Director.

[FR Doc. 78-22004 Filed 8-7-78; 8:45 am]

[4310-84]

[U-40533]

UTAH

Application

JULY 31, 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 Northwest Pipeline Corp. has applied for a 4½-inch natural gas pipeline right-of-way across the following lands:

SALT LAKE MERIDIAN, UTAH

T. 16 S., R. 24 E.,
Secs. 12 and 13.

The needed right-of-way is a portion of applicant's gas gathering system located in Grand County, Utah.

The purpose of this notice is to inform the public that the Bureau will be proceeding with the preparation of

environmental and other analyses necessary for determining whether the application should be approved, and if so, under what terms and conditions.

Interested persons should express their interest and views to the Moab District Manager, Bureau of Land Management, P.O. 970, Moab, Utah 84532.

ROBERT E. ANDERSON,
Acting State Director.

[FR Doc. 78-22006 Filed 8-7-78; 8:45 am]

[4310-84]

[U-40534]

UTAH

Application

JULY 28, 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 Northwest Pipeline Corp. has applied for a 4½ inch natural gas pipeline right-of-way across the following lands:

SALT LAKE MERIDIAN, UTAH

T. 16 S., R. 24 E.,
Secs. 11, 12 and 13.

The needed right-of-way is a portion of applicant's gas gathering system located in Grand County, Utah.

The purpose of this notice is to inform the public that the Bureau will be proceeding with the preparation of environmental and other analyses necessary for determining whether the application should be approved, and if so, under what terms and conditions.

Interested persons should express their interest and views to the Moab District Manager, Bureau of Land Management, P.O. Box 970, Moab, Utah 84532.

ROBERT E. ANDERSON,
Acting State Director.

[FR Doc. 78-22005 Filed 8-7-78; 8:45 am]

[4310-84]

[U-40544]

UTAH

Application

JULY 31, 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 Shenandoah Oil Corp. has applied for 3½-inch natural gas pipeline right-of-way across the following lands:

SALT LAKE MERIDIAN, UTAH

T. 16 S., R. 24 E.,
Secs. 17 and 18.

The needed right-of-way is for production of Shenandoah Well No. 33-18.

The purpose of this notice is to inform the public that the Bureau will be proceeding with the preparation of environmental and other analyses necessary for determining whether the application should be approved, and if so, under what terms and conditions.

Interested persons should express their interest and views to the Moab District Manager, Bureau of Land Management, P.O. Box 970, Moab, Utah 84532.

ROBERT E. ANDERSON,
Acting State Director.

[FR Doc. 78-22003 Filed 8-7-78; 8:45 am]

[4310-84]

SHOSHONE DISTRICT GRAZING ADVISORY BOARD

Meeting

Notice is hereby given that the Shoshone District Grazing Advisory Board of the Bureau of Land Management will meet on September 19, 1978, at 9 a.m., in the conference room of the district office, 400 West F Street, Shoshone, Idaho. The purpose of the meeting is a tour of the Sun Valley ES area which will include inventory procedures in preparation for the Sun Valley management framework plan and grazing environmental statement. The meeting will also include review and recommendation of range betterment funds allocated for fiscal year 1979 (Oct. 1, 1978 to Sept. 30, 1979).

The public is invited to attend the tour and meeting and make written or oral statements which should not exceed 15 minutes in length. Requests for these statements should be made to the official listed below at least 5 days prior to the meeting. Individuals who intend to take part in the tour must provide their own transportation and lunch arrangements.

Further information concerning this meeting may be obtained from the Shoshone District Manager, Bureau of Land Management, P.O. Box 2B, Shoshone, Idaho 83352, telephone 208-886-2208. Minutes of the meeting will be available for public inspection and copying 3 weeks after the meeting at the Shoshone District Office, Shoshone, Idaho.

Dated: July 31, 1978.

CHARLES J. HASZIER,
District Manager.

[FR Doc. 78-22001 Filed 8-7-78; 8:45 am]

[4310-03]

Heritage Conservation and Recreation Service

NATIONAL REGISTER OF HISTORIC PLACES

Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the Heritage Conservation and Recreation Service before July 28, 1978. Pursuant to section 60.13(a) of 36 CFR part 60, published in final form on January 9, 1976, written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the Keeper of the National Register, Office of Archeology and Historic Preservation, U.S. Department of the Interior, Washington, D.C. 20240. Written comments or a request for additional time to prepare comments should be submitted by August 18, 1978.

WILLIAM J. MURTAGH,
Keeper of the National Register.

CALIFORNIA

Santa Clara County

Coyote vicinity, *Rancho del Refugio de la Laguna Seca Stone Building*, NE of Coyote off U.S. 101.

DELAWARE

New Castle County

Port Penn, *Port Penn Historic District*, DE 9.

Port Penn vicinity, *Nelson, John B., House*, W of port Penn off U.S. 13.

INDIANA

Dubois County

Jasper, *Gramelspacher-Gutzweiler House*, 7th and Main Sts.

KANSAS

Linn County

Mound City, *Old Linn County Jail*, 312 Main St.

Marion County

Marion, *Elgin Hotel*, 3rd and Santa Fe Sts.

KENTUCKY

Scott County

Oxford vicinity, *Miller's Run Historic District*, roughly bounded by Old Oxford Pike, KY 922, U.S. 460, and Miller's Run.

MARYLAND

Carroll County

New Windsor vicinity, *Avalon*, E of New Windsor off MD 31.

Dorchester County

East New Market vicinity, *Fletcher, K. B., Mill*, N of East New Market.

Talbot County

Claiborne vicinity, *Wades Point*, SW of Claiborne.
Neavitt vicinity, *Long Point*, S of Neavitt.

MASSACHUSETTS

Suffolk County

Boston, *Fenway Studios Building*, 30 Ipswich St.

Worcester County

Worcester, *Day Building*, 300-310 Main St.
Worcester, *Worcester Five Cents Savings Bank*, 316 Main St.

MINNESOTA

Carver County

Carver County Historic Resources, SE Minnesota.

Wright County

Annandale, *Annandale Hotel*, 60 Elm St. W.

MISSOURI

Carter County

Grandin, *Missouri Lumber and Mining Company Historic Resources*, MO 21.

NEBRASKA

Adams County

Hastings, *Brach, William, House*, 823 N. Lincoln Ave.

Cedar County

Wynot vicinity, *Bow Valley Mills*, N of Wynot.

Douglas County

Omaha, *Zabriskie, Edgar, House*, 3524 Hawthorne Ave.

Fillmore County

Geneva, *Fillmore County Courthouse*, 9th and G Sts.

NEW JERSEY

Gloucester County

Harrisonville vicinity, *Horner Farm*, N of Harrisonville.
Mullica Hill vicinity, *Jessup Farm*, W of Mullica Hill on High St.
Mullica Hill vicinity, *Sherwin Farm*, E of Mullica Hill on U.S. 322.
Richwood, *Richwood Methodist Church*, Elmer Rd.
Swedesboro vicinity, *Butler Farm*, E of Swedesboro.

Middlesex County

Perth Amboy, *Perth Amboy Ferry Slip*, Smith St.

OKLAHOMA

Cherokee County

Tahlequah, *Loeser, Dr. Irwin D., Log Cabin*, 121 E. Smith St.

Grady County

Chickasha vicinity, *Horn Site No. 1*, N of Chickasha.

McCurtain County

Idabel, *Barnes-Stevenson House*, 3 SE. Adams St.

McIntosh County

Texanna vicinity, *Slippery Moss Shelter*, N of Texanna.
Warner vicinity, *Johnson Lake Shelters*, W of Warner.

Muskogee County

Warner vicinity, *Sheltered Shelter*, W of Warner.

Oklahoma County

Luther vicinity, *Booher Site*, S of Luther.
Midwest City vicinity, *Quilin Site*, N of Midwest City.
Oklahoma City, *Sinopoulo, John, House*, 4000 N. Kelley St.
Spencer vicinity, *Nagle Site*, N of Spencer.

Pawnee County

Pawnee, *Arkansas Valley National Bank*, 547 6th St.

Roger Mills County

Hammon vicinity, *Linville Site*, S of Hammon.
Hammon vicinity, *Trent, Lon, Site*, SW of Hammon.

Wagoner County

Okay vicinity, *Posey Site*, S of Okay.

PENNSYLVANIA

Jefferson County

Brookville, *Jefferson County Courthouse and Jail*, Main and Pickering Sts.

TENNESSEE

Hamilton County

Chattanooga, *Ochs Building (Times Building)*, Georgia Ave.

Shelby County

Memphis, *Sterick Building*, 8 N. 3rd St.

VERMONT

Rutland County

Rutland, *Baxter, H. H., Memorial Library*, 96 Grove St.

[FR Doc. 78-21511 Filed 8-7-78; 8:45 am]

[4310-84]

[AA-6697-A through AA-6697-E]

ALASKA NATIVE CLAIMS SELECTION

On September 17, October 30, and December 17, 1974, Tanadgusix Corp. for the Native village of St. Paul, filed selection applications AA-6697-A through AA-6697-E, as amended, under the provisions of section 12 of the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 688, 701; 43 U.S.C. 1601, 1611 (Supp. V, 1975)), for the surface estate of certain lands in the Pribilof-Aleutian Island area.

The State of Alaska filed general purposes grant selection application AA-12884 on April 1, 1977, pursuant to section 6(b) of the Alaska Statehood Act of July 7, 1958 (72 Stat. 339, 340; 48 U.S.C. ch. 2, sec. 6(b) (1970)), for lands on Unalaska Island within T. 73 S., R. 122 W., Seward Meridian. Tanadgusix Corp. properly selected sec. 36, T. 73 S., R. 122 W., Seward Meridian, in village selection application AA-6697-B on October 30, 1974. Section 6(b) of the Alaska Statehood Act of July 7, 1958, provides that the State may select vacant, unappropriated and unreserved public lands in Alaska.

Therefore, in view of the above, State selection application AA-12884 is hereby rejected as to the following described lands:

SEWARD MERIDIAN, ALASKA (UNSURVEYED)

T. 73 S., R. 122 W.
Sec. 36 (fractional), all.
Containing approximately 350 acres.

Further action on State selection application AA-12884 as to those lands not rejected herein will be taken at a later date.

In accordance with section 3(e)(1) of the Alaska Native Claims Settlement Act, the tracts of land mutually identified in the Cooperative Agreement and Memorandum of Understanding dated December 22, 1976, by the Department of Commerce and the village corporations of St. George Tanaq and Tanadgusix, have been determined to be the smallest practicable tracts used by the Department of Commerce in its administration of lands on St. Paul and St. George Islands. The tracts of land are described in case file AA-8452.

As to the lands described below, the applications submitted by Tanadgusix Corp., as amended, are properly filed and meet the requirements of the Alaska Native Claims Settlement Act and of the regulations issued pursuant thereto. These lands do not include any lawful entry perfected under or being maintained in compliance with Federal laws leading to acquisition of title.

In view of the foregoing, the surface estate of the following described lands, selected pursuant to section 12(a), aggregating approximately 113,321.43 acres, is considered proper for acquisition by Tanadgusix Corp. and is hereby approved for conveyance pursuant to section 14(a) of the Alaska Native Claims Settlement Act:

Blocks 1, 1A, 2, 3, 4, 5, 8, 8A; lots 4 and 5 of Block 9; Blocks 10 thorugh 16; lots 1 through 8 of Block 17; lots 1, 2, and 3 of Block 18; Block 19; lots 1, 2, 3, 6, 7, 8, and 9 of Block 20; Block 21; lot 2 of Block 22; lot 1 of Block 24; Blocks 25, 26, 27; lots 2 through 12 of Block 28; Blocks 29 through 33 of Tract A and Tracts B through G of land embraced in U.S. Survey No. 4943, Alaska, located on St. Paul Island, Pribilof Islands. Containing 465.43 acres.

Lots 1 and 2 of Block 6; Block 7; lots 13, 14, and 15 of Block 17; lot 6 of Block 18; lot

1 of Block 22; Block 23; lot 2 of Block 24; lot 1 of Block 28 of Tract A, excluding ANCSA section 3(e) determination AA-8452 of land embraced in U.S. Survey No. 4943, Alaska, located on St. Paul Island, Pribilof Islands. Containing approximately 77 acres.

SEWARD MERIDIAN, ALASKA (UNSURVEYED)

T. 53 S., R. 81 W.
Secs. 26, 27, and 28 (fractional), all;
Sec. 29, all;
Secs. 31, 32, and 33, all;
Sec. 34 (fractional), all.
Containing approximately 4,054 acres.
T. 54 S., R. 81 W.
Secs. 3, 4, and 5 (fractional), all;
Secs. 6 and 7, all
Secs. 8 to 11 (fractional), inclusive, all;
Secs. 14 to 17 (fractional), inclusive, all;
Secs. 20 and 21 (fractional), all;
Sec. 28 (fractional), all;
Secs. 29 to 32, inclusive, all;
Sec. 33 (fractional), all.
Containing approximately 7,317 acres.
T. 55 S., R. 81 W.
Sec. 4 (fractional), all;
Secs. 5 and 6, all.
Containing approximately 1,414 acres.
T. 35 S., R. 129 W.
Sec. 6 (fractional), all.
Containing approximately 30 acres.
T. 34 S., R. 131 W.
Sec. 13 (fractional), excluding ANCSA Sec. 3(e) determination AA-8452 and U.S. Survey 4943 Tract D;
Secs. 21, 22, and 23 (fractional), all;
Sec. 24 (fractional), excluding ANSCA Sec. 3(e) determination AA-8452;
Sec. 26 (fractional), all;
Sec. 27, all;
Secs. 28, 29, and 30 (fractional), all;
Secs. 31, 32, and 33, all;
Sec. 34, excluding ANSCA Sec. 3(e) determination AA-8452 and U.S. Survey 4943 Tract C;
Sec. 35 (fractional), excluding ANCSA Sec. 3(e) determination AA-8452 and U.S. Survey 4943 Tract C.
Containing approximately 5,860 acres.
T. 35 S., R. 131 W.
Secs. 3 and 4, excluding ANSCA Sec. 3(e) determination AA-8452;
Secs. 5 and 6, excluding U.S. Survey 4943 Tract B;
Sec. 7, all;
Secs. 8 and 9, excluding ANSCA Sec. 3(e) determination AA-8452;
Sec. 10 (fractional), excluding ANSCA Sec. 3(e) determination AA-8452;
Secs. 15, 16, and 17 (fractional), excluding ANSCA Sec. 3(e) determination AA-8452;
Sec. 18, excluding ANSCA Sec. 3(e) determination AA-8452;
Sec. 19 (fractional), excluding ANSCA Sec. 3(e) determination AA-8452;
Sec. 20 (fractional), all;
Sec. 30 (fractional), excluding ANSCA Sec. 3(e) determination AA-8452 and U.S. Survey 4943 Tract A.
Containing approximately 6,392 acres.
T. 34 S., R. 132 W.
Secs. 23 and 24 (fractional), all;
Sec. 25 (fractional), excluding U.S. Survey 4943 Tract E;
Secs. 26, 27, and 28 (fractional), all;
Sec. 29 (fractional), excluding U.S. Survey 4943 Tract G;
Sec. 31 (fractional), all;
Sec. 32 (fractional), excluding U.S. Survey 4943 Tract G;
Sec. 33 (fractional), all;
Secs. 34, 35, and 36, all.
Containing approximately 4,560 acres.
T. 35 S., R. 132 W.
Secs. 1 to 5, inclusive, all;
Sec. 6 (fractional), all;
Sec. 7 (fractional), excluding U.S. Survey 4943 Tract F;
Sec. 8 (fractional), all;
Secs. 9 to 12, inclusive, all;
Secs. 13 to 16 (fractional), excluding ANSCA Sec. 3(e) determination AA-8452;
Sec. 17 (fractional), all;
Sec. 24 (fractional), excluding ANSCA Sec. 3(e) determination AA-8452;
Sec. 25 (fractional), excluding ANSCA Sec. 3(e) determination AA-8452 U.S. Survey 4943 Tract A and U.S. Survey 4800 lots 1 and 2;
Sec. 36 (fractional), excluding ANSCA Sec. 3(e) determination AA-8452 and U.S. Survey 4943 Tract A.
Containing approximately 8,450 acres.
T. 36 S., R. 132 W.
Secs. 19, 20, 29, and 30 (fractional), all.
Containing approximately 155 acres.
Portions of land on Unalaska Island within the following protracted description:
T. 73 S., R. 121 W.
Sec. 31.
Containing approximately 560 acres.
T. 74 S., R. 121 W.
Secs. 1 and 3;
Secs. 5 to 14, inclusive
Sec. 15, excluding U.S. Survey 810 Tracts A and B;
Secs. 16, 17, and 18;
Secs. 20, 21, and 24.
Containing approximately 7,510 acres.
T. 73 S., R. 122 W.
Sec. 36.
Containing approximately 350 acres.
T. 74 S., R. 122 W.
Secs. 1, 2, and 12.
Containing 420 acres.
T. 78 S., R. 125 W.
Secs. 13 and 14;
Sec. 19;
Secs. 23 and 24;
Secs. 26 to 34, inclusive.
Containing approximately 8,104 acres.
T. 78 S., R. 126 W.
Sec. 13;
Sec. 14, excluding ANSCA Sec. 3(e) application AA-12852;
Secs. 15, 21, and 22;
Sec. 23, excluding U.S. Survey 807 Tract A;
Sec. 24, excluding U.S. Survey 807 Tracts A and B and U.S. Survey 5520 lot 2;
Sec. 25;
Secs. 26, excluding U.S. Survey 520 lot 1;
Secs. 27 to 30, inclusive;
Secs. 32 to 36, inclusive.
Containing approximately 5,469 acres.
Portions of land on Umnak Island within the following protracted description:
T. 77 S., R. 127 W.
Secs. 7, 18, 19, and 30.
Containing approximately 330 acres.
T. 76 S., R. 128 W.
Secs. 26, 27, and 18;
Secs. 30 to 36, inclusive.
Containing approximately 3,485 acres.
T. 77 S., R. 128 W.
Secs. 7 and 8, excluding Quitclaim Deed AA-5459;
Secs. 9 to 16, inclusive;
Secs. 17 to 20 inclusive, excluding Quitclaim Deed AA-5459;
Secs. 21 to 29, inclusive;
Sec. 30, excluding Quitclaim Deed AA-5459;
Secs. 31 to 36, inclusive.
Containing approximately 13,949 acres.
T. 76 S., R. 129 W.
Sec. 25;
Secs. 33 to 36, inclusive.
Containing approximately 855 acres.
T. 77 S., R. 129 W.
Secs. 1 to 30, inclusive;
Secs. 33 to 36, inclusive.
Containing approximately 21,056 acres.
T. 77 S., R. 130 W.
Secs. 1 to 8, inclusive;
Secs. 10 and 11;
Sec. 18.
Containing approximately 5,893 acres.
T. 78 S., R. 131 W.
Secs. 12, 13, and 14;
Secs. 21, 22, and 23;
Secs. 27 to 32, inclusive.
Containing approximately 4,145 acres.
T. 78 S., R. 131 W.
Secs. 6 to 9, inclusive.
Containing approximately 2,421 acres.
Aggregating approximately 113,321.43 acres.

The conveyance issued for the surface estate of the lands described above shall contain the following reservations to the United States:

1. That right-of-way A-053685 and all appurtenances thereto, constructed by the United States through, over or upon Secs. 16 and 17, T. 35 S., R. 131 W., Seward Meridian and the right of the United States, its agents or employees to maintain, operate, repair, or improve the same so long as needed or used for or by the United States.

2. The subsurface estate therein and all rights, privileges, immunities and appurtenances, of whatsoever nature, accruing unto said estate pursuant to the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 688, 704; 43 U.S.C. 1601, 1613(f) (Supp. V, 1975)); and

3. Pursuant to section 17(b) of the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 688, 708; 43 U.S.C. 1601, 1616(b) (Supp. V, 1975)), the following public easements, referenced by easement identification number (EIN) on the easement maps in case file AA-6697-EE, are reserved to the United States and subject to further regulation thereby:

a. (EIN 1 C4) A continuous linear easement twenty-five (25) feet in width upland of and parallel to the mean high tide line in order to provide access to and along the marine coastline and use of such shore for purposes such as the beaching of watercraft or aircraft, travel along the shore, recreation, and other similar uses. Deviations from the waterline are permitted when specific conditions so require, e.g., impassable topography or waterfront obstruction. This easement is subject to the right of the owner of the servient estate to build upon such easement a facility for public or private purposes, such right to be exercised reasonably and without undue or unnecessary interference with or obstruction of the easement. When access along the marine coastline easement is to be obstructed, the owner of the servient estate will be obligated to convey to the United States an acceptable alternate access route, at no cost to the United States, prior to the creation of such obstruction.

b. (EIN 2 C4) An easement for a proposed access trail twenty-five (25) feet in width

from Makushin Bay in Sec. 15, T. 74 S., R. 121 W., Seward Meridian, continuing along the right bank of Makushin Creed northerly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

c. (EIN 3a C4) An easement twenty-five (25) feet in width for an existing access trail from Mailboat cove in Sec. 26, T. 78 S., R. 126 W., Seward Meridian, westerly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

d. (EIN 3a C4) An easement twenty-five (25) feet in width for an existing access trail from Mailboat cove in Sec. 26, T. 78 S., R. 126 W., Seward Meridian, southeasterly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

e. (EIN 3c C4) An easement twenty-five (25) feet in width for an existing access trail from Mailboat Cove in Sec. 26, T. 78 S., R. 126W., Seward Meridian, around Chernofski Harbor to Mutton Cove, and easterly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

f. (EIN 3d C4) An easement twenty-five (25) feet in width for an existing access trail from trail easement EIN 3c C4 in Sec. 31, T. 78 S., R. 125W., Seward Meridian, easterly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

g. (EIN 4a C4) An easement sixty (60) feet in width for an existing road from an old military airstrip in Sec. 18, T. 77 S., R. 128W., Seward Meridian, southwesterly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

h. (EIN 4b C4) An easement sixty (60) feet in width for an existing road from an old military airstrip in Sec. 18, T. 77 S., R. 128W., Seward Meridian, southerly towards Fort Glenn to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

i. (EIN 4c C4) An easement sixty (60) feet in width for an existing road from road easement EIN 4a C4 in Sec. 7, T. 77 S., R. 128W., Seward Meridian, westerly roughly paralleling the coast toward Ashiskik Point for access to public lands and waters. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

j. (EIN 5 C4) An easement twenty-five (25) feet in width for an existing access trail beginning at the end of road easement EIN 4c C4 in Sec. 35, T. 76 S., R. 129 W., Seward Meridian, southerly to public lands. The usage of roads and trails will be controlled by applicable State or Federal laws or regulation.

k. (EIN 7 C4) An easement twenty-five (25) feet in width for a proposed trail from Aguliuk Point in Sec. 29, T. 77 S., R. 131 W., Seward Meridian, southeasterly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

l. (EIN 8 C4) Easements to serve public facilities on St. Paul Island referenced by the Memorandum of Understanding dated December 22, 1976, between the United States Department of Commerce, National Marine Fisheries Service, National Oceanic and Atmosphere Administration, and the village corporations of St. George Tanaq and Tanadgusix.

LIST OF RESERVED EASEMENTS

UTILITIES

A. Fresh waterline—pumphouse to village.
B. Fuel and powerline—Coast Guard to Weather Service.
C. Fuel line—beach to Coast Guard Station.
D. Proposed waterline—NMFS pumphouse to Weather Service.
E. Waterline to warehousing/staff quarters area.
F. Proposed power intertie—NMFS-CG-NWS.
G. Powerline to navigation beacon.
J. Power intertie
a. Diesel fuel line.
b. Gasoline fuel line.
g. Powerline to treatment plant.
i. Proposed NWS waterline and pump station.

ROADS

K. Lukanin Rookery Road.
L. Reef Road.
M. NE Point Road.
N. SE Point Road.
O. Polovina Pit Road.
P. Sanitary Fill Road.
Q. Telegraph Pit Road.
R. Pump Road.
S. Lake Hill Pit Road.
Z. Airport Road.
c. Polovina Rookery Access Road 1.
d. Polovina Rookery Access Road 2.
e. Polovina Rookery Access Road 3.
k. Zapadni Rookery Access Road 1.
l. Zapadni Rookery Access Road 2.
m. Zapadni Rookery Access Road 3.
n. Tolstoi Rookery Access Road.

OTHER

f. West Shoreline, joint use area.
j. Free area 600 radius of balloon launching site.
p. Lake Hills Borrow Pit.
q. Polovina vehicle boneyard.

The road easements are to be controlled by applicable State or Federal law or regulation.

m. (EIN 9C) The right of the United States to enter upon the lands hereinabove granted for cadastral, geodetic, or other survey purposes is reserved, together with the right to do all things necessary in connection therewith.

These reservations have not been conformed to the Departmental easement policy announced March 3, 1978. Conformance is contingent upon resolution of the litigation "Calista, et al. v. Andrus" and implementation of the Secretary's new easement policy.

The grant of lands shall be subject to:

1. Issuance of a patent confirming the boundary description of the lands hereinabove granted after approval and filing by the Bureau of Land Management of the official plat of survey covering such lands;

2. Valid existing rights therein, if any, including but not limited to those created by any lease (including a lease issued under section 6(g) of the Alaska Statehood Act of July 7, 1958 (72 Stat. 339, 341; 48 U.S.C. Ch. 2, Sec. 6(g) (1970))), contract, permit, right-of-way or easement and the right of the lessee, contractee, permittee, or grantee to the complete enjoyment of all rights, privileges, and benefits thereby granted to him;

3. The naval airspace reservation of Executive Order No. 8680, dated February 14, 1941.

4. Grazing lease A-060872 to Milton and Beverly Holmes on Unalaska Island within T. 78 S., Rs. 125 and 126 W., Seward Meridian, under the act of March 4, 1927 (44 Stat. 1452; 48 U.S.C. 471, 471a, and 471o);

5. The terms and conditions of the Cooperative Agreement and the Memorandum of Understanding between the United States Department of Commerce, National Oceanic and Atmospheric Administration, National Marine Fisheries Service and the village corporations of St. George Tanaq and Tanadgusix, dated December 22, 1976. A copy of the Cooperative Agreement and the Memorandum of Understanding shall be attached to and become a part of the conveyance document and shall be recorded therewith. A copy of the Cooperative Agreement and Memorandum of Understanding is located in Bureau of Land Management easement case file for Tanadgusix Corp., serialized AA-6697-EE. Any person wishing to examine these documents may do so at the Bureau of Land Management, Alaska State Office, 555 Cordova Street, Pouch 7-512, Anchorage, Alaska 99510.

6. Requirements of section 14(c) of the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 688, 703; 43 U.S.C. 1601, 1613(c) (Supp. V, (1975)), that the grantee hereunder convey those portions, if any, of the lands hereinabove granted, as are prescribed in said section; and

7. The terms and conditions of the agreement dated January 18, 1977, between the Secretary of the Interior, The Aleut Corp., Tanadqusix Corp., and other Aleut village corporations. A copy of the agreement shall be attached to and become a part of the conveyance document and shall be recorded therewith. A copy of the agreement is located in the Bureau of Land Management easement case file for Tanadgusix Corp., serialized AA-6697-EE. Any person wishing to examine this agreement may do so at the Bureau of Land Management, Alaska State Office, 555 Cordova Street, Pouch 7-512, Anchorage, Alaska 99510.

Tanadgusix Corp. is entitled to conveyance of 138,240 acres of land selected pursuant to section 12(a) of the Alaska Native Claims Settlement Act. Upon this initial conveyance of 113,321.43 acres described herein, a total of 24,918.57 acres will remain to be conveyed to the corporation before the village reaches full 12(a) entitle-

ment. The remaining entitlement will be conveyed at a later date.

Pursuant to section 14(f) of the Alaska Native Claims Settlement Act, conveyance of the subsurface estate of the lands described above shall be granted to the Aleut Corp. when conveyance is granted to Tanadgusix Corp., for the surface estate, and shall be subject to the same conditions as the surface conveyance.

There are no inland water bodies considered to be navigable within the lands described.

In accordance with Departmental regulation 43 CFR 2650.7(d), notice of this decision is being published once in the FEDERAL REGISTER and once a week for four (4) consecutive weeks, in the Anchorage Times. Any party claiming a property interest in land affected by this decision may appeal the decision to the Alaska Native Claims Appeal Board, P.O. Box 2433, Anchorage, Alaska 99510, with a copy served upon both the Bureau of Land Management, Alaska State Office, 555 Cordova Street, Pouch 7-512, Anchorage, Alaska 99510 and the Regional Solicitor, Office of the Solicitor, 510 L Street, Suite 408, Anchorage, Alaska 99501, also:

1. Any party receiving service of this decision shall have 30 days from the receipt of this decision to file an appeal.

2. Any unknown parties, any parties unable to be located after reasonable efforts have been expended to locate, and any parties who failed or refused to sign the return receipt shall have until September 7, 1978, to file an appeal.

3. Any party known or unknown who may claim a property interest which is adversely affected by this decision shall be deemed to have waived those rights which were adversely affected unless an appeal is timely filed with the Alaska Native Claims Appeal Board.

4. If Tanadgusix Corp. or the Aleut Corp. objects to any easement which is identified herein for reservation in the Conveyance, which is subject to the descretion of the State Director and not reserved pursuant to an express Secretarial directive, a petition for reconsideration must be filed within 30 days from receipt of service with the State Director, Bureau of Land Management, 555 Cordova Street, Pouch 7-512, Anchorage, Alaska 99510. A copy of the petition should be served upon the Regional Solicitor, Office of the Solicitor, 510 L Street, Suite 408, Anchorage, Alaska 99501. If a petition for reconsideration is not filed, it will be deemed that the right to contest any such easement has been waived.

To avoid summary dismissal of the appeal there must be strict compliance with the regulations governing such appeals. Further information on the manner of and requirements for filing an appeal may be obtained from the Bureau of Land Management, 555 Cordova Street, Pouch 7-512, Anchorage, Alaska 99510.

If an appeal is taken, the adverse parties to be served are:

State of Alaska, Division of Lands, 323 East Fourth Avenue, Anchorage, Alaska 99501.
Tanadgusix Corp. St. Paul Island, Alaska 99660.
The Aleut Corp. 833 Gambell Street Anchorage, Alaska 99501.

SUE A. WOLF,
Chief, Branch of Adjudication.

[FR Doc. 78-21977 Filed 8-7-78; 8:45 am]

[4310-70]

[Order No. 6]

ADMINISTRATIVE OFFICER, ET AL., GULF ISLANDS NATIONAL SEASHORE, FLORIDA AND MISSISSIPPI DISTRICTS

Delegation of Authority

SECTION 1. *Administrative Officer.* The Administrative Officer may execute, approve, and administer contracts not in excess of $100,000 for supplies, equipment, or services in conformity with applicable regulations and statutory authority and subject to the availability of appropriated funds.

SEC. 2. *Assistant Superintendent.* The Assistant Superintendent may execute, approve, and administer contracts not in excess of $100,000 for supplies, equipment, or services in conformity with applicable regulations and statutory authority and subject to the availability of appropriated funds.

SEC. 3. *Supply Technician.* The Supply Technican may execute, approve, and administer contracts not in excess of $10,000 for supplies, equipment, or services in conformity with applicable regulations and statutory authority and subject to the availability of appropriated funds.

SEC. 4. *Administrative Service Assistant.* The Administative Service Assistant may execute, approve, and administer contracts not in excess of $10,000 for supplies, equipment, or services in conformity with applicable regulations and statutory authority and subject to the availability of appropriated funds.

SEC. 5. *YACC Camp Director, Administrative Technician, Supply Clerk, Program Officers, and Supervisory Work Coordinator.* The YACC Camp Director, Administrative Technician, Supply Clerk, Program Officers, and Supervisory Work Coordinator of the Gulf Isalnds National Seashore, Young Adult Conservation Corps may issue purchase orders (10-131) and field purchase orders (SF-44) not in excess of $500 for supplies, equipment, or services in conformity with applicable regulations and statutory authority and subject to the availability of appropriated funds.

SEC. 6. *Revocation.* This order supersedes order No. 5, dated June 7, 1977 and published in 42 FR 40052 on August 8, 1977.

(National Park Service order No. 77 (38 FR 7478), as amended; Southeast Region order No. 6 (42 FR 59428).)

Dated: April 21, 1978.

FRANKLIN D. PRIDEMORE,
Superintendent,
Gulf Islands National Seashore.

[FR Doc. 78-21971 Filed 8-7-78; 8:45 am]

[4310-70]

[Order No. 2]

ADMINISTRATIVE OFFICER, ET AL., BUFFALO NATIONAL RIVER

Delegation of Authority

SECTION 1. *Administrative Officer.* The Administrative Officer may issue contracts not in excess of $25,000 for equipment, supplies or services in conformity with applicable regulations and statutory authority and subject to availability of appropriated funds.

SEC. 2. *Supply Technician.* The Supply Technician may issue contracts not in the excess of $500 for equipment, supplies, and services in conformity with applicable regulations and statutory authority and subject to the availability of appropriated funds.

SEC. 3. *Young Adult Conservation Corps Camp Director.* The Camp Director may issue contracts not in excess of $2,000 for supplies, equipment or services in conformity with applicable regulations and statutory authority and subject to availability of appropriated funds.

SEC. 4. *Young Adult Conservation Corps Administrative Technician.* The Administrative Technician may issue contracts not in excess of $500 for equipment, supplies, and services in conformity with applicable regulations and statutory authority and subject to the availability of appropriated funds.

SEC. 5. *Revocation.* This order supersedes order No. 1, Buffalo National River, and published Tuesday, January 28, 1975 (FR vol. 40 No. 19 page 4169, January 28, 1975).

(National Park Service order No. 77, 38 FR 7478, as amended, Southwest Region order No. 5, 37 FR 7722 as amended.)

Dated: May 26, 1978.

L. LORRAINE MINTZMYER,
Superintendent,
Buffalo National River.

[FR Doc. 78-21976 Filed 8-7-78; 8:45 am]

[4310-70]

ASSATEAGUE ISLAND NATIONAL SEASHORE

Announcement of Public Meetings to Review Assessment of Alternatives

The National Park Service, U.S. Fish and Wildlife Service, and the Maryland Park Service invite all those interested in the future of Assateague Island to attend a public meeting during the week of August 14. A series of these meetings will be held that week in Lancaster, Pa., Riverdale, Md., Worcester County, Md., and Chincoteague, Va. to review the "Assessment of Alternatives" for Assateague Island.

This document presents three alternative courses of action for the island. The public's review of this document is solicited and a forum for this review will be the public meetings. Limited numbers of the "Assessment of Alternatives" will be available on or about July 1, 1978. Those people not already on the mailing list can obtain copies by contacting one of the offices listed below.

Written comments are invited and will be accepted until September 1, 1978.

Further information can be obtained from:

Superintendent, Assateague Island National Seashore, Route 2, Box 294, Berlin, Md. 21811.

Manager, Chincoteague National Wildlife Refuge, P.O. Box 62, Chincoteague, Va. 23336.

Superintendent, Assateague State Park, Route 2, Box 293, Berlin, Md. 21811.

Dated: June 15, 1978.

RICHARD L. STANTON,
Regional Director,
Mid-Atlantic Region.

[FR Doc. 78-21966 Filed 8-7-78; 8:45 am]

[4310-70]

CARL SANDBURG HOME NATIONAL HISTORIC SITE, NORTH CAROLINA

Availability of Environmental Review on Environmental Assessment for Development Concept Plan

In February 1978 the National Park Service completed and placed on public review an environmental assessment on the development concept plan for Carl Sandburg Home National Historic Site. Public meetings were held in the vicinity of the park in February 1978.

After making an environmental review of the alternatives presented in the assessment and after public comment thereon, the National Park Service determined that this proposal would not have a significant effect on the human environment; therefore, an environmental impact statement will not be prepared.

Anyone needing additional information should contact the Regional Director, Southeast Regional Office, National Park Service, 1895 Phoenix Boulevard, Atlanta, Ga. 30349 or the Superintendent, Carl Sandburg Home National Historic Site, P.O. Box 395, Flat Rock, N.C. 28731. Copies of the environmental review may be obtained from the above locations.

Projects under this plan will begin in 30 days.

Dated: July 6, 1978.

NEAL G. GUSE, Jr.,
Acting Regional Director,
Southeast Region.

[FR Doc. 78-21970 Filed 8-7-78; 8:45 am]

[4310-70]

CHICKASAW NATIONAL RECREATION AREA, OKLAHOMA

Concurrent Jurisdiction Accepted

Notice is hereby given that effective August 8, 1978, concurrent legislative jurisdiction between the United States and the State of Oklahoma is established over all lands and waters within Chickasaw National Recreation Area. The retrocession of exclusive jurisdiction was authorized by the act of October 7, 1976 (Pub. L. 94-458; 90 Stat. 1939). The acceptance of jurisdiction was authorized by the act of February 1, 1940 (54 Stat. 19, as amended; 40 U.S.C. 255).

The Chickasaw National Recreational Area, created by the act of Congress of March 17, 1976, known as Pub. L. 94-235 (90 Stat. 235) is composed of lands formerly known as Platt National Park and the Arbuckle Dam and Reservoir. The legislative jurisdiction over Platt was the subject of section 7 of the act of June 16, 1906, (34 Stat. 272, 16 U.S.C. 153). The Arbuckle Dam and Reservoir was constructed by the Bureau of Reclamation under the act of August 24, 1962 (76 Stat. 395, 43 U.S.C. 616(k), et seq.). Prior to the creation of the Chickasaw Recreation Area, Platt was under the exclusive legislative jurisdiction of the United States, while Arbuckle was under the proprietary jurisdiction of the United States and legislative jurisdiction of the State.

Exclusive jurisdiction was retroceded and concurrent jurisdiction was accepted for the United states by letter dated April 18, 1978, from the Director of the National Park Service to the Governor of the State of Oklahoma, receipt of which was acknowledged by the Governor on June 15, 1978.

The establishment of concurrent jurisdiction will allow the National Park Service and the State of Oklahoma to jointly exercise responsibility for public health and safety and to otherwise administer this area more effectively.

Done at the City of Washington, D.C., this 14th day of July 1978.

WILLIAM J. WHALEN,
Director,
National Park Service.

[FR Doc. 78-21972 Filed 8-7-78; 8:45 am]

[4310-70]

FLOYD E. CATE

Intention to Negotiate Concession Contract

Pursuant to the provisions of section 5 of the act of October 9, 1965 (79 Stat. 969; 16 U.S.C. 20), public notice is hereby given that on or before September 7, 1978, the Department of the Interior, through the Director of the National Park Service, proposes to negotiate concession contract with Floyd E. Cate, authorizing him to continue to provide concession facilities and services for the public at Great Smoky Mountains National Park for a period of five (5) years from January 1, 1979, through December 31, 1983.

An analysis of the environmental impact of this proposed action has been made and it has been determined that it will not significantly affect the quality of the environment, and that it is not a major Federal action having a significant impact on the environment under the National Environmental Policy Act of 1969. The environmental analysis may be reviewed in the Southeast Regional Office, National Park Service, 1895 Phoenix Boulevard, Atlanta, Ga. 30349.

The foregoing concessioner has performed his obligations to the satisfaction of the Secretary under an existing contract which expires by limitation of time on December 31, 1978, and therefore, pursuant to the act of October 9, 1965, as cited above, is entitled to be given preference in the renewal of the contract and in the negotiation of a new contract. This provision, in effect, grants Floyd E. Cate, as the present satisfactory concessioner, the right to meet the terms of responsive proposals for the proposed new contract and a preference in the award of the contract, if, thereafter, the proposal of Mr. Cate is substantially equal to others received. In the event a responsive proposal superior to that of Floyd E. Cate (as determined by the Secretary) is submitted, Floyd E. Cate will be given the opportunity to meet the terms and conditions of the superior proposal the Secretary considers desirable, and, if he does so, the new contract will be negotiated with Mr. Cate. The Secretary will consider and evaluate all proposals received as a result of this notice. Any proposal including that of the existing concessioner, must be submitted on or before September

7, 1978, to be considered and evaluated.

Interested parties should contact the Chief, Concessions Management Division, National Park Service, Washington, D.C. 20240, for information as to the requirements of the proposed contract.

Dated: August 2, 1978.

ROBERT STANTON,
Acting Associate Director,
National Park Service.

[FR Doc. 78-21975 Filed 8-7-78; 8:45 am]

[4310-70]

PANTHER JUNCTION AREA, BIG BEND NATIONAL PARK, TEX.

Proposed Development Concept Plan Availability of Environmental Review/Negative Declaration

An environmental assessment which examined alternatives for a development concept plan at the Panther Junction (headquarters) area of Big Bend National Park, Brewster County, Tex., was distributed November 3, 1977 and was made available by publication in the FEDERAL REGISTER of December 16, 1977.

An environmental review has now been completed and alternatives selected. Based on 27 letters received and on management judgments, the review selected a location for additional concessioner and park housing and for a visitor center/administration building expansion.

Copies of the review are available at the following locations: Southwest Regional Office, National Park Service, 1100 Old Santa Fe Trail, Post Office Box 728, Santa Fe, N. Mex. 87501; Big Bend National Park, Tex. 79834; and National Park Service, Room 10-G-3, Fritz G. Lanham Federal Center, 819 Taylor Street, Fort Worth, Tex. 76102.

It is the conclusion of the National Park Service that the selected plan is not a major Federal action that will significantly affect the human evironment. Comprehensive design plans and specifications will be prepared and the plan implemented. No environmental impact statement will be prepared.

Dated: May 26, 1978.

JOHN E. COOK,
Regional Director, Southwest
Region National Park Service.

[FR Doc. 21964 Filed 8-7-78; 8:45 am]

[4310-70]

[Order No. 1]

PIPESTONE NATIONAL MONUMENT, MINN.

Delegation of Authority Regarding Purchasing Authority

SEC. 1. *Administrative technician.* The administrative technician may issue purchase orders not in excess of $500 for supplies, equipment, or services in conformity with applicable regulations and statutory authority and subject to availability of appropriate funds.

(National Park Service Order No. 77, 38 FR 7478, published March 22, 1978, as amended.)

Dated: May 4, 1978.

DAVID L. LANE,
Superintendent,
Pipestone National Monument.

[FR Doc. 78-21968 Filed 8-7-78; 8:45 am]

[4310-70]

VIRGIN ISLANDS NATIONAL PARK

Availability of Assessment of Alternatives Solid Waste Study

An assessment considering alternative solutions for the collection and disposal of solid wastes in the Virgin Islands National Park and all of St. John Island, including the national park, is available for inspection at the Southeast Regional Office of the National Park Service, 1895 Phoenix Boulevard, Atlanta, Ga. 30349, or the Office of the Superintendent, Virgin Islands National Park, P.O. Box 806, Charlotte Amalie, St. Thomas, V.I. 00801.

In addition to the alternatives, the assessment considers the nature of the resource, impacts of the various alternatives, mitigating measures to soften the effects of an alternative on the human environment and adverse effects that cannot be avoided should an alternative be implemented.

Public comments on the assessment and its alternatives are solicited. Written comments will be received at the offices listed above for a period of 45 days.

Dated: June 5, 1978.

JAMES L. BAINBRIDGE,
Acting Regional Director
Southeast Region.

[FR Doc. 78-21965 Filed 8-7-78; 8:45 am]

[4310-70]

PROPOSED SALINAS NATIONAL MONUMENT, NEW MEXICO

Negative Declaration

A general management plan assessment with a recommended proposal and four alternatives thereto involving a potential Salinas National Monument in Socorro and Torrance Counties, N. Mex., was made available February 14, 1978. A public workshop was held in Mountainair, N. Mex., on March 22, 1978.

As a result of the workshop and letters received commenting upon the proposal/assessment, an environmental review has been completed and the monument boundaries have been modified. Recommended actions now include the establishment of a Salinas National Mounument consisting of the existing Gran Quivira National Mounument and two State Mouments, Abo and Quarai, with a central administrative/interpretive facility in the town of Mountainair, N. Mex. The proposal as narrated in the assessment document and as presented at the public workshop has been modified by decreasing by 95 acres the lands proposed for acquisition surrounding the Abo unit.

The National Park Service will not prepare any further environmental documents on the general management plan for the Salinas National Monument.

Copies of the environmental review are on file and available upon request at the following locations: Southwest Regional Office, National Park Service, 1100 Old Sante Fe Trail, P.O. Box 728, Sante Fe, N. Mex. 87501; Gran Quivira National Monument, Route 1, Mountainair, N. Mex. 87036; and the Chaco Center, Arithropology Building, Room 240, University of New Mexico, P.O. Box 26176, Albuquerque, N. Mex. 87125.

The National Park Service will await congressional and executive action on the establishment legislation and proceed as directed if and when such legislation is enacted.

Dated: June 29, 1978.

JOHN E. COOK,
Regional Director, Southwest
Region National Park Service.

[FR Doc. 78-21973 Filed 8-7-78; 8:45 am]

[4310-70]

SAN JUAN ISLAND NATIONAL HISTORICAL

Availability of Draft General Management Plan and Negative Declaration

Alternatives for the general management plan for San Juan Island National Historical Park have been presented in an environmental assessment which was distributed to the public. On October 12, 1977, a public workshop was held to discuss alternatives for the general management plan, and comments were accepted until November 11.

The National Park Service has now prepared a plan for final public com-

ment which takes into consideration all previous public involvement as an integral part of a sound planning process. The plan includes measures that will serve both long- and short-term needs to protect the cultural and natural resources of the park while also providing for visitor use and enjoyment.

Copies of the plan will be sent to all persons, agencies and organizations commenting on the environmental assessment. It is also available upon request at the Regional Office, National Park Service, Fourth and Pike Building, Seattle, Wash. 98101, and at the Superintendent's office, San Juan Island National Historical Park, Box 549, Friday Harbor, Wash. 98250. Comments on the draft plan should be sent to the Regional Director at the above address on or before September 7, 1978.

It is the conclusion of the National Park Service that the plan is not a major Federal action that will significantly affect the environment. Therefore, no environmental statement will be prepared.

Dated: June 16, 1978.

RUSSELL E. DICKENSON,
Regional Director, Pacific Northwest Region, National Park Service.

[FR Doc. 78-21967 Filed 8-7-78; 8:45 am]

[4310-70]

[Order No. 2]

SLEEPING BEAR DUNES NATIONAL LAKESHORE, MICH.

Delegation of Authority Regarding Purchasing Authority

SEC. 1. *Purchasing Agent.* The Purchasing Agent may issue Purchase Orders not in excess of $1,000 for supplies, equipment or services in conformity with applicable regulations and statutory authority and subject to availability of appropriate funds.

(National Park Service Order No. 77, 38 FR 7478 published March 22, 1973, as amended)

Dated: May 9, 1978.

DONALD R. BROWN,
Superintendent, Sleeping Bear Dunes National Lakeshore.

[FR Doc. 78-21969 Filed 8-7-78; 8:45 am]

[7020-02]

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-ta-51]

CERTAIN CIGARETTE HOLDERS

Continuance of Prehearing Conference and Notice of Hearing

Notice is hereby given that the prehearing conference in this matter, previously scheduled for August 15, 1978, is continued until 9 a.m. on August 23, 1978, in Room 610, Bicentennial Building, 600 E Street NW., Washington, D.C. The purpose of this prehearing conference is to review the prehearing statements of the parties, complete the exchange of exhibits, and resolve any other matters in preparation for the hearing. The hearing will commence immediately after the prehearing conference.

On or before August 15, 1978, each party shall file an original and 19 copies of a prehearing statement with the Secretary of this Commission, and serve a copy on the other parties. Prehearing statements shall include:

1. Notice of intent to attend the prehearing conference and hearing.

2. Notice of any additional motions pertaining to the scope of the hearing or the proposed joinder of persons not presently named as parties.

3. A statement of the issues to be considered at the hearing, with a statement which sets forth with particularity a party's contentions on each of the proposed issues, and a citation to legal authorities in support thereof.

4. The names of all known witnesses, their addresses, and a statement summarizing the contents of their testimony. An estimate of trial time should be included.

5. A list of all exhibits which the parties will seek to introduce at the hearing, with provision made that an exchange of exhibits take place in timely fashion prior to the hearing. The parties shall provide 10 copies of such exhibits to the presiding officer at the time they are sought to be introduced into evidence.

The Secretary shall serve a copy of this notice on all parties of record, and shall publish it in the FEDERAL REGISTER.

Issued August 1, 1978.

JANET D. SAXON,
Administrative Law Judge.

[FR Doc. 78-21913 Filed 8-7-78; 8:45 am]

[7020-02]

RAYON STAPLE FIBER FROM BELGIUM

New Investigation (AA1921-186); Termination of Prior Investigation (AA1921-181)

An investigation (AA1921-181) was commenced on May 19, 1978 (43 FR 21740). The Secretary of the Treasury on July 28, 1978 (43 FR 32915) reconsidered the basis for his fair value comparisons in the antidumping investigation involving viscose rayon staple fiber from Belgium that is being, or is likely to be, sold at less than fair value, and, as a result of his reconsideration, he has modified his determination of May 1, 1978 (43 FR 18619) such that the weighted average margin with respect to the class or kind of articles that are the subject of the above investigation is increased from 6.7 percent to 57.6 percent.

Having received new and substantially different advice from the Secretary of the Treasury with regard to the importation of rayon staple fiber from Belgium, it is obvious that for the Commission to make a determination based upon the original advice of the Secretary would be or might be a mistake of fact. There is not enough time before this investigation would run against the statutory time limit to give intereted persons an opportunity to comment upon the change, which is not only a right guaranteed to them by the Antidumping Act itself, but perhaps also by considerations of due process. We must therefore afford interested parties opportunity to comment, notwithstanding the statutory time limits. Moreover, the Secretary appears to have given us a new determination that effectively vacates all or at least a portion of his prior advice to the Commission, justifying a termination of the present investigation and instituting a new investigation. We determine therefore, that our investigation into injury to the domestic industry based upon the margin reported on May 1, 1978, is now moot.

The Commission held a hearing in the investigation No. AA1921-181 on June 20, 1978, and received evidence from and the views of the domestic producers, the importer, and the Belgian producer. Inasmuch as the new determination of the Treasury involves solely a change in the weighted average margin, the Commission is particularly interested that written comments address this matter. The written statements and transcript of the hearing from the prior investigation will remain relevant to the Commission's determination in the new investigation.

The U.S. International Trade Commission, therefore, on August 25, 1978:

1. Terminated investigation No. AA1921-181, instituted on May 19,

1978 (43 FR 21740), under section 2012(a) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)), without any determination because of the intervening advice from the Secretary;

2. Instituted a new investigation (AA1921-186) to determine whether an industry in the United States is being, or is likely to be, injured, or is prevented from being established, by reason of the importation into the United States from Belgium of rayon staple fiber. The title of the new investigation will be the same as the investigation No. AA1921-181; and,

3. Determined that there does not at this time appear to be good and sufficient reason to hold a new public hearing in the investigation; however, in accordance with 19 CFR 208.4, any interested party who believes that a public hearing should be held, may, within ten days after the date of publication of this notice, submit a request in writing to the Secretary of the Commission and the reason for such request.

The Commission intends to expedite the investigation in this case, and to complete the investigation and make its determination within 30 days after the date this notice is published in the FEDERAL REGISTER. Parties wishing to submit written statements should therefore submit them in a timely manner, at the latest August 22, 1978.

Issued: August 3, 1978.
By order of the Commission.

KENNETH R. MASON,
Secretary.

[FR Doc. 78-22120 Filed 8-7-78; 8:45 am]

[4410-01]

DEPARTMENT OF JUSTICE

CIRCUIT JUDGE NOMINATING COMMISSION; SIXTH CIRCUIT PANEL

Meetings; Correction

The Sixth Circuit Panel of the U.S. Circuit Judge Nominating Commission has been activated to nominate candidates to fill one vacancy on the Sixth Circuit Court of Appeals. The Panel's schedule of meetings is as follows:

(1) The first meeting will be held on August 1, 1978, at 11 a.m., on the 28th floor of Citizens Plaza, Fifth and Jefferson Streets, Louisville, Ky. The morning session will be open to the public. The afternoon session will be devoted to discussion of candidates and will be closed to the public pursuant to Pub. L. 92-463, section 10(D) as amended. (CF 5 U.S.C. 552b(c)(6).)

(2) The second meeting will be held on August 22, 1978, at 9 a.m., in room 501 of the U.S. Post Office and Federal Building, Cincinnati, Ohio. The purpose of this meeting is to interview candidates and the meeting will be closed to the public pursuant to Pub. L. 92-463, section 10(D) as amended. (CF 5 U.S.C. 552b(c)(6).) If necessary, the meeting will be continued through August 23, 1978.

JULY 24, 1978.

JOSEPH A. SANCHES,
Advisory Committee Management Officer.

[FR Doc. 78-21867 Filed 8-7-78; 8:45 am]

[4410-09]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

IMPORTATION OF CONTROLLED SUBSTANCES

Application

Pursuant to Section 1008 of the Controlled Substance Import and Export Act (21 U.S.C. 958(h)), the Attorney General shall, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore in accordance with § 1311.42 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on June 9, 1978, Applied Science Laboratories, Inc., Brush Valley Road, Oak Hall, Pa. 16827, made application to the Drug Enforcement Administration to be registered as an importer of tetrahydro- cannabinol, organic (7371), a basic class of controlled substance in schedule I, which, if imported, will be supplied exclusively for authorized research or as chemical analysis standards.

As to the basic class of controlled substance listed above for which application for registration has been made, any other applicant therefor, and any existing bulk manufacturer registered therefor, may file written comments on or objections to the issuance of such registration and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.54 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Administrator, Drug Enforcement Administration, U.S. Department of Justice, 1405 I Street NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative (Room 1203), and must be filed no later than September 11, 1978.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1311.42 (b), (c), (d), (e) and (f). As noted in a previous notice at 40 FR 43745-46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in schedule I or II are and will continue to be required to demonstrate to the Administrator of the Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.42 (a), (b), (c), (d), (e) and (f) are satisfied.

Dated: July 28, 1978.

PETER B. BENSINGER,
Administrator, Drug Enforcement Administration.

[FR Doc. 78-22095 Filed 8-7-78; 8:45 am]

[4410-09]

IMPORTATION OF CONTROLLED SUBSTANCES

Notice of Application

Pursuant to Section 1008 of the Controlled Substance Import and Export Act (21 U.S.C. 958(h)), the Attorney General shall, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore in accordance with § 1311.42 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on June 14, 1978, Research Technology Branch, Div. of Research, NIDA, Room 9-42, 5600 Fishers Lane, Rockville, Md. 20857, made application to the Drug Enforcement Administration to be registered as an importer of the basic classes of controlled substances listed below:

Drug:	*Schedule*
Lysergic acid diethylamide (7315)	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
Buprenorphine (9064)	II

As to the basic classes of controlled substances listed above for which application for registration has been made, any other applicant therefor, and any existing bulk manufacturer registered therefor, may file written comments on or objections to the issuance of such registration and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.54 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Administrator, Drug Enforcement Administration, U.S. Department of Justice, 1405 I Street NW., Washington, D.C. 20537, Atten-

tion: DEA Federal Register Representative (Room 1203), and must be filed no later than September 11, 1978.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1311.42(b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745-46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in schedule I or II are and will continue to be required to demonstrate to the Administrator of the Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.42(a), (b), (c), (d), (e) and (f) are satisfied.

Dated: July 28, 1978.

PETER B. BENSINGER,
Administrator,
Drug Enforcement Administration.

[FR Doc. 78-22094 Filed 8-7-78; 8:45 am]

[4410-09]

MANUFACTURE OF CONTROLLED SUBSTANCES

Notice of Application

Pursuant to 21 U.S.C. 823(a) (1), and Section 1301.43(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on June 9, 1978, Applied Science Labs., Inc., Brush Valley Road, Oak Hall, Pa. 16827, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic class of controlled substances listed below:

Drug:	*Schedule*
Mescaline (7381)	I
D-Lysergic acid methylpropylamide (7328)	I
Morphine-N-oxide (9307)	I

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the above application and may also file a written request for a hearing thereon in accordance with 21 CFR 1301.54 and in the form prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Administrator, Drug Enforcement Administration, U.S. Department of Justice, 1405 I Street, NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative (Room 1203), and must be filed no later than September 11, 1978.

Dated: July 28, 1978.

PETER B. BENSINGER,
Administrator,
Drug Enforcement Administration.

[FR Doc. 78-22093 Filed 8-7-78; 8:45 am]

[4410-09]

MANUFACTURE OF CONTROLLED SUBSTANCES

Application

Pursuant to 21 U.S.C. 823(a)(1), and Section 1301.43(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on June 14, 1978, Abbott Labs., 14th & Sheridan Road, Attn: Customer Service D-345, North Chicago, Ill. 60064, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the schedule II controlled substance pentobarbital (2270).

Any other such applicant, and any person who is presently registered with DEA to manufacture such substance, may file comments or objections to the issuance of the above application and may also file a written request for a hearing thereon in accordance with 21 CFR 1301.54 and in the form prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Administrator, Drug Enforcement Administration, U.S. Department of Justice, 1405 I Street NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative (Room 1203), and must be filed no later than September 11, 1978.

Dated: August 2, 1978.

ARTHUR LEWIS,
Acting Administrator,
Drug Enforcement Administration.

[FR Doc. 78-22092 Filed 8-7-78; 8:45 am]

[4510-30]

DEPARTMENT OF LABOR

Employment and Training Administration

MIGRANT AND SEASONAL FARMWORKER PROGRAMS

Fiscal Year 1979 State Planning Estimates

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: Pursuant to 29 CFR 97.204 and 29 CFR 97.211, the Employment and Training Administration is required to announce State planning estimates of resources available to implement programs funded under title III, section 303 of the Comprehensive Employment and Training Act (CETA) of 1973, as amended.

FOR FURTHER INFORMATION CONTACT:

Harry Kranz, Acting Director, Office of Farmworker Programs, 601 D Street NW., Room 6308, Washington, D.C. 20213, phone 202-376-6128.

SUPPLEMENTARY INFORMATION:

1. Fiscal year 1979 State planning estimates. Planning estimates are announced for planning purposes only. They are subject to congressional action on the fiscal year 1979 appropriation for the Department of Labor, Employment and Training Administration, CETA. The total amount of planning estimates listed, $48,640,800, is 75 percent of 80 percent of the total amount planned for all section 303 purposes in fiscal year 1979. This amount is based on the notice in the July 14, 1978, FEDERAL REGISTER, volume 43, No. 136, page 30369, which alters the fiscal year funding cycle for CETA, title III, section 303. The funding cycle in 1979 for section 303 programs will be January 1 to September 30.

The amount required to fund section 303 programs for this 9-month period is $48,640,800. The apportionment of the planning estimates for 50 States and Puerto Rico is targeted toward each State's percentage of the Nation's farmworkers whose earnings fall below the poverty level and on each State's hold harmless level of 90 percent of the fiscal year 1978 estimates. The data source utilized for these estimates is Social Security records of those farmworkers whose annual earnings are less than $3,000. Eligible applicants should use the State planning estimates listed below in developing fiscal year 1979 funding requests:

Fiscal year 1979 State planning estimate

Alabama 649,800	Louisiana 758,850	Ohio 865,425
Alaska 4,725	Maine 422,100	Oklahoma 495,075
Arizona 635,550	Maryland 347,325	Oregon 736,875
Arkansas 867,975	Massachusetts 294,075	Pennsylvania 1,026,000
California 9,737,175	Michigan 939,075	Rhode Island 27,375
Colorado 545,400	Minnesota 1,188,375	South Carolina 763,425
Connecticut 218,175	Mississippi 1,057,650	South Dakota 401,250
Delaware 54,675	Missouri 788,400	Tennessee 544,725
Florida 2,513,700	Montana 469,575	Texas 3,349,950
Georgia 988,575	Nebraska 749,400	Utah 232,425
Hawaii 218,700	Nevada 90,075	Vermont 195,000
Idaho 744,675	New Hampshire 80,625	Virginia 871,725
Illinois 1,261,575	New Jersey 393,675	Washington 1,584,150
Indiana 811,650	New Mexico 442,875	West Virginia 335,550
Iowa 1,299,525	New York 1,025,550	Wisconsin 1,455,225
Kansas 849,000	North Carolina 2,619,450	Wyoming 232,425
Kentucky 745,800	North Dakota 417,375	Puerto Rico 1,293,075
		Total 48,640,800

The States and areas open to competition and competitive grant submission requirements will be announced on or about September 22 as described in the July 14 notice in the FEDERAL REGISTER.

Signed as Washington, D.C., this 2d day of August, 1978.

LAMOND GODWIN,
Administrator,
Office of National Programs.

[FR Doc. 78-22037 Filed 8-7-78; 8:45 am]

[4510-26]

Occupational Safety and Health Administration

OREGON STATE STANDARDS

Approval

1. *Background.* Part 1953 of title 29, Code of Federal Regulations prescribes procedures under section 18 of the Occupational Safety and Health Act of 1970 (hereinafter called the act) by which the Regional Administrator for Occupational Safety and Health (hereinafter called Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary) (29 CFR 1953.4) will review and approve standards promulgated pursuant to a State plan which has been approved in accordance with section 18(c) of the act and 29 CFR part 1902. On December 28, 1972, notice was published in the FEDERAL REGISTER (37 FR 28628) of the approval of the Oregon plan and the adoption of subpart D to part 1952 containing the decision. The notice of approval of revised developmental schedule was further published on April 1, 1974, in the FEDERAL REGISTER.

The Oregon plan provides for the adoption of State standards which are at least as effective as comparable Federal standards promulgated under section 6 of the act. Section 1953.20 provides that "where any alteration in the Federal program could have an adverse impact on the at least as effective as" status of the State program, a program change supplement to a State plan shall be required.

In response to Federal standards changes, the State has submitted by letter dated November 16, 1977, from Roy G. Green to James W. Lake and incorporated as part of the plan, State standards comparable to 29 CFR 1910.67 (b)(1) through (c)(5), amendments and additions to vehicle mounted elevating and rotating work platforms, as published in the FEDERAL REGISTER (40 CFR 13439) dated March 26, 1975.

These State standards, which are contained in OAR chapter 457, Oregon Occupational Safety and Health Code, Division 56, Vehicles, were promulgated after public hearings held on July 12, 1976, and amended September 15, 1977, with an opportunity for public comment.

2. *Decision.* Having reviewed the State submission in comparison with the Federal standards, it has been determined that the State standards are at least as effective as the comparable Federal standards and accordingly should be approved. The significant area of difference is the coverage of regulations dealing with work in proximity to overhead high-voltage lines and equipment under the electrical and telecommunication sections by reference. The detailed standards comparison document is available at the locations specified below.

3. *Location of supplement for inspection and copying.* A copy of the standards supplement, along with the approved plan, may be inspected and copied during normal business hours at the following locations: Office of the Regional Administrator, Occupational Safety and Health Administration, Room 6003, Federal Office Building, 909 First Avenue, Seattle, Wash. 98174; Workers' Compensation Board, Labor and Industries Building, Salem, Oreg. 97310; and the Technical Data Center, Room N2349R, Third and Constitution Avenue NW., Washington, D.C. 20210.

4. *Public participation.* Section 1953.2(c) of this chapter provides that where State standards are identical to or "at least as effective" as comparable Federal standards and have been promulgated in accordance with State law, approval may be effective upon publication without an opportunity for further public participation. As the standards under consideration are "at least as effective" as the Federal standards and have been promulgated in accordance with State law including an opportunity for public comment and/or a public hearing, they are approved without an opportunity for further public comment.

This decision is effective August 8, 1978.

(Sec. 18, Pub. L. 91-596, 84 Stat. 1602 (29 U.S.C. 667).)

Signed at Seattle, Wash., this 12th day of July 1978.

JAMES W. LAKE,
Regional Administrator, Occupational Safety and Health Administrator.

[FR Doc. 78-22038 Filed 8-7-78; 8:45 am]

[4510-28]

Office of the Secretary

[TA-W-999T]

AMERICAN MOTORS CORP.

Termination of Investigation

Pursuant to section 223(d) of the Trade Act of 1974 and 29 CFR 90.17, a termination investigation was initiated on October 21, 1977 to determine, with respect to the certification issued on October 28, 1976, whether total or partial separations from the Kenosha, Wisconsin plant of the American Motors Corp. are no longer attributable to the conditions specified in such certification.

Notice of Investigation Regarding Termination of Certification of Eligibility To Apply for Worker Adjustment Assistance was published in the FEDERAL REGISTER on November 15, 1977 (42 FR 59133). No public hearing was requested and none was held.

The existing certification will expire on October 28, 1978. Since workers newly separated, totally or partially, after October 28, 1978 would be ineligible to apply for adjustment assistance, termination of the certification by the Secretary of Labor within 90 days from statutory termination would serve no purpose; consequently the investigation has been terminated.

Signed at Washington, D.C. this 28th day of July 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-22039 Filed 8-7-78; 8:45 am]

[4510-28]

[TA-W-3253]

ANNETTA OF CALIFORNIA, INC.

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 in the results of TA-W-3253: 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 14, 1978, which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing women's coats at Annetta of California, Inc., Pico Rivera, Calif.

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 Annetta of California, 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 misses' and children's coats and jackets increased absolutely in 1976 compared to 1975, to 2,252 thousand dozen from 1,517 thousand dozen and increased in 1977 to 2,723 thousand dozen. Imports also increased relatively to 57.5 percent in 1976 from 38.9 percent in 1975.

Sales by the manufacturer for whom the subject firm worked, as well as contract work with the subject firm, declined in 1977 compared to 1976. A survey of retail customers of the manufacturer revealed that several customers decreased purchases of women's coats from the manufacturer in 1977 compared to 1976, while increasing purchases of imports of women's coats during the same period.

CONCLUSION

After careful review I conclude that increases of imports like or directly competitive with the women's coats produced by Annetta of California, Inc., Pico Rivera, Calif. contributed importantly 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 of Annetta of California, Inc., Pico Rivera, Calif. who became totally or partially separated from employment on or after February 9, 1977 but before August 27, 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 31st day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-22049 Filed 8-7-78; 8:45 am]

[4510-28]

[TA-W-3825]

CAR-MAL SPORTSWEAR, INC.

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-3825: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 12, 1978 in response to a worker petition received on June 7, 1978 which was filed on behalf of workers and former workers producing ladies' skirts at Car-Mal Sportswear, Inc., Boston, Mass.

The Notice of Investigation was published in the FEDERAL REGISTER on June 27, 1978 (43 FR 27925). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Car-Mal Sportswear, Inc., 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 sales or production, or both, of the firm or subdivision have decreased absolutely.

Car-Mal Sportswear is a contractor for ladies' skirts. Car-Mal produces based upon orders received and therefore sales equal production. Car-Mal increased production of ladies' skirts in 1977 compared to 1976 and in the first six months of 1978 compared to the same period in 1977.

CONCLUSION

After careful review, I determine that workers of Car-Mal Sportswear, Inc., Boston, 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 31st day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-22050 Filed 8-7-78; 8:45 am]

[4510-28]

[TA-W-3303]

DAVIS AND FURBER MACHINE CO.

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-3303: 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 27, 1978, which was filed by the United Steelworkers of America and a company official on behalf of workers and former workers producing textile machinery at Davis and Furber Machine Co., North Andover, Mass.

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 Davis and Furber Machine 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. It is concluded that all of the requirements have been met.

Imports of textile preparatory machinery increased from 1,735 units in 1975 to 2,211 units in 1976 and to 2,539 units in 1977.

Imports increased from 590 units in the first quarter of 1977 to 955 units in the same quarter of 1978. The ratio of imports to domestic production increased from 19.3 percent in 1976 to 38.4 percent in 1977.

Davis and Furber sells its equipment through competitive bidding. Major customers contacted during the investigation confirmed that Davis and Furber had lost substantial bids to foreign manufacturers of textile machinery 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 textile machinery, produced by Davis and Furber Machine Co., North Andover, Mass., contributed importantly to the decline in sales 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 at Davis and Furber Machine Co., North Andover, Mass., who became totally or partially separated from employment on or after February 20, 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 31st day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-22051 Filed 8-7-78; 8:45 am]

[4510-28]

[TA-W-2820]

H. MARGOLIN & CO., INC.

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-2820: 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 27, 1977, in response to a worker petition received on December 13, 1977, which was filed by the International Leather Goods, Plastics & Novelty Workers Union on behalf of workers and former workers producing ladies' handbags at the Fitchburg, Mass., plant of H. Margolin & Co., Inc.

The investigation was expanded to include workers and former workers producing ladies' handbags at the Brattleboro, Vt., and New York, N.Y., facilities of H. Margolin & Co., Inc.

The notice of investigation was published in the FEDERAL REGISTER on January 10, 1978 (43 FR 1555). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of H. Margolin & Co., Inc., its customers, the National Handbag Association, 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.

Imports of ladies' handbags increased yearly from 54.4 million units in 1974 to 92.8 million units in 1977 and rose from 22.1 million units in the first quarter of 1977 to 34.0 million units in the first quarter of 1978. The ratio of imports to domestic handbag production increased annually from 66.7 percent in 1974 to 116.6 percent in 1977.

Most of the customers of H. Margolin & Co. who were surveyed indicated that they purchased imported ladies' handbags either directly from foreign sources or indiretly through domestic suppliers. Some customers surveyed indicated that they reduced purchases of handbags from H. Margolin & Co. and increased purchases of imported handbags.

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' handbags produced at the Fitchburg, Mass.; Brattleboro, Vt.; and New York, N.Y., facilities of H. Margolin & Co., Inc., contributed importantly to the decline in sales or production and to the total or partial separations of workers at these plants. In accordance with the provisions of the act, I make the following certification:

All workers of the Fitchburg, Mass.; Brattleboro, Vt.; and New York, N.Y., facilities of H. Margolin & Co., Inc., who became totally or partially separated from employment on or after December 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 31st day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-22052 Filed 8-7-78; 8:45 am]

[4510-28]

[TA-W-2831]

HYDE ATHLETIC INDUSTRIES

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-2831: Investigation regarding certification of eligibility to apply for adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 3, 1978, in response to a worker petition received on December 12, 1977, which was filed on behalf of workers and former workers producing roller skates and ice hockey skates at the Cambridge, Mass., plant of Hyde Athletic Industries. The investigation revealed that workers at the Cambridge plant produce roller skate boots, ice hockey skates, and figure skates.

The notice of the investigation was published in the FEDERAL REGISTER on January 17, 1978 (43 FR 2459). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Hyde Athletic Industries, 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. The investigation revealed that all of the requirements have been met.

Imports of ice skates increased both absolutely and relative to domestic production in 1977 compared to 1976.

Imports of athletic footwear increased both absolutely and relative to domestic production in 1976 compared to 1975 and in 1977 compared to 1976. Imports of roller skate boots are included within the athletic footwear category.

A survey of customers who purchase ice skates from Hyde revealed that some customers increased their purchases of imported ice skates in 1977 compared to 1976. A survey of customers who purchase roller skate boots from Hyde revealed that some customers increased their purchases of im-

ported roller skate boots in 1977 compared to 1976.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with roller skate boots and ice skates produced at the Cambridge, Mass., plant of Hyde Athletic Industries contributed importantly to the total or partial separation of workers and to the decline in sales and production at that facility. In accordance with the provisions of the act, I make the following certification:

All workers at the Cambridge, Mass., plant of Hyde Athletic Industries who became totally or partially separated from employment on or after December 8, 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 31st day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-22053 Filed 8-7-78; 8:45 am]

[4510-28]

[TA-W-3033]

LEESONA CORP., TEXTILE MACHINERY DIVISION AND SALES AND SERVICE OFFICE TMD

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-3033: 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 30, 1978, which was filed by the International Association of Machinists & Aerospace Workers on behalf of workers and former workers producing heavy textile machinery at the Warwick, R.I., plant of Leesona Corp., Textile Machinery Division.

The investigation was expanded to include the sales and service personnel at the Textile Machinery Division sales and service office in Fort Mill, S.C.

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 Leesona Corp., the American Textile Machinery Association, 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. It is concluded that all of the requirements have been met.

The Department's investigation revealed that U.S. imports of textile winding machinery increased 48.8 percent in value in 1977 compared to 1976. The ratio of imports to domestic production increased from 32.8 percent in 1975 to 34.7 percent in 1976 and further increased to 81.4 percent in 1977. Although U.S. exports of textile winding machinery have also been substantial, 1977 was the first year since 1973 that the United States was a net importer of textile winding machinery.

Imports accounted for 44.2 percent of the value of apparent U.S. consumption of textile wining machinery in 1975. The percentage increased 47.5 percent in 1976 and further rose to 69.1 percent in 1977.

Leesona Corp. is a major U.S. producer of textile winding machinery. Its share of apparent U.S. consumption declined from 1975 to 1976 and decreased further from 1976 to 1977. As a result, the value of Leesona's sales of textile winding machinery to the U.S. domestic market dropped substantially in 1976 compared to 1975 and further declined in 1977 compared to 1976.

CONCLUSIONS

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with heavy textile winding machinery produced at the Warwick, R.I., facility of Leesona Corp., Textile Machinery Division, contributed importantly to the decline in sales and production and to the separation of workers at that plant and at the Fort Mill, S.C. sales and service office of Leesona Corp. In accordance with the provisions of the act, I make the following certification:

All workers of the Warwick, R.I., facility and the Fort Mill, S.C. sales and service office of Leesona Corp., Textile Machinery Division, who became totally or partially separated from employment on or after January 26, 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 31st day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Adminstration, and Planning.

[FR Doc. 78-22054 Filed 8-7-78; 8:45 am]

[4510-28]

[TA-W-3282]

MODFORM, INC.

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-3282: 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 22, 1978, which was filed on behalf of workers and former workers producing nuts, fasteners, and screw machines at the Cleveland, Ohio, plant of Modform, Inc. The investigation revealed that workers at the Cleveland plant produced specialty nuts only.

The notice of investigation was published in the FEDERAL REGISTER on March 14, 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 Modform, 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 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 or 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 and production.

U.S. imports of specialty nuts are not separately identifiable within TSUSA Classification 646.5600.

Industry sources estimate, however, that specialty nuts represent a very small portion of the category. Specialty nuts are generally produced domestically to guarantee some onsite quality control and minimum time lags for delivery. Furthermore, foreign producers have expressed little interest in the U.S. market for specialty nuts. For

these reasons, U.S. imports of specialty nuts are negligible.

Modform customers who were surveyed indicated that they do not purchase imported specialty nuts such as those purchased from Modform, Inc.

CONCLUSION

After careful review, I determine that workers of the Cleveland, Ohio, plant of Modform, Inc., are denied eligiblity to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 31st day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-22055 Filed 8-7-78; 8:45 am]

[4510-28]

[TA-W-2736]

PARRY FOOTWEAR, INC.

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-2736: 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 7, 1977, in response to a worker petition received on November 28, 1977, which was filed on behalf of workers and former workers producing men's and boys' house slippers at Parry Footwear, Inc., Cambridge, Mass.

The notice of investigation was published in the FEDERAL REGISTER on December 30, 1977 (42 FR 65308). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Parry Footwear, 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 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.

U.S. imports of house slippers increased from 23.9 million pairs in 1975 to 28.0 million pairs in 1976 and then decreased to 27.8 million pairs in 1977. The ratio of imports to domestic production increased from 43.1 percent in 1976 to 43.6 percent in 1977.

A survey by the Department of Parry Footwear's customers indicates that imports of slippers have not significantly influenced the company's operations. Most customers responding to the survey indicated either that they do not purchase imported men's and boys' slippers or that their purchases of imported men's and boys' slippers decreased in 1977 compared to 1976. Fifty percent of these customers reported increased purchases from Parry Footwear in 1977 compared to 1976 and aggregated survey data show that customer purchases from Parry Footwear increased 7.7 percent in 1977 compared to 1976.

The survey's results are supported by other data obtained during the investigation. This data reveals that sales, production, and employment at Parry Footwear increased in 1977 compared to 1976.

CONCLUSION

After careful review, I determine that all workers of Parry Footwear, Inc., Cambridge, 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 31st day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-22056 Filed 8-7-78; 8:45 am]

[4510-28]

[TA-W-2486]

TIMEX CORP.

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-2486: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on October 19, 1977, in response to a worker petition received on October 7, 1977, which was filed on behalf of workers and former workers producing watch components for LED and LCD watches at the Middlebury, Conn. plant of the Timex Corp. During the course of the investigation it was established that solid state watch modules were assembled and then inserted into cases at the Middlebury, Conn. plant and that these operations were performed by workers who comprised the Electronics Group at that plant.

The notice of investigation was published in the FEDERAL REGISTER on November 4, 1977 (42 FR 57775) no public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Timex 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. It is concluded that all of the requirements have been met.

Imports of nonconventional watches increased from 1.6 million units in 1975 to 5.2 million units in 1976 and increased to 8.7 million units in 1977. The ratio of imports to domestic production increased from 55.9 percent in 1976 to 84.5 percent in 1977. Imports of nonconventional watch modules increased from 327 thousand in 1975 to 4,182 thousand in 1976 and increased to 5,683 thousand in 1977. The ratio of imports to domestic production increased from 65.7 percent in 1976 to 98.7 percent in 1977.

Evidence developed during the course of the investigation revealed that solid state watch modules were assembled and put into cases by the Electronics Group in order to meet additional volume requirements and to some extent as part of a piloting program to develop the manufacturing process and test market solid state watches. The high level of imports of nonconventional watches made continuation of the production at Middlebury plant economically unfeasible. All solid state watch production was terminated at Middlebury in July 1977. All employees were separated when the Electronics Group was discontinued in January 1978.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with the solid state watch modules and watchheads produced by the Electronics Group of the Middlebury, Conn. plant of the Timex Corp. contributed importantly to the decline in production and to the total or partial separation of workers of that group. In accordance with the provisions of the Act, I make the following certification.

All workers of the Electronics Group of the Middlebury, Conn. plant of the Timex Corp. who became totally or partially separated from employment on or after Decem-

ber 26, 1976, and before January 31, 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 31st day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-22057 Filed 8-7-78; 8:45 am]

[4510-28]

[TA-W-2519]

TIMEX CORP.

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-2519: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on October 27, 1977, in response to a worker petition received on October 25, 1977, which was filed on behalf of workers and former workers assembling watches at the Abilene, Tex. plant of the Times Corp. The investigation has revealed that the correct name of the company is Timex Corp.

The notice of investigation was published in the FEDERAL REGISTER on November 15, 1977 (42 FR 59132). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Timex 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 criteria of section 222 of the Trade Act of 1974 must be met. The investigation has revealed that all of the requirements have been met.

U.S. imports of conventional watches increased from 12.7 million units in 1975 to 14.0 million units in 1976 and increased to 18.4 million units in 1977. The ratio of imports to domestic production increased from 66.7 perent in 1976 to 88.9 percent in 1977.

U.S. imports of nonconventional watches increased from 1.6 million units in 1975 to 5.2 million units in 1976 and increased to 8.7 million units in 1977. The ratio of imports to domestic production increased from 55.9 percent in 1976 to 84.5 percent in 1977.

Evidence developed during the course of the investigation revealed that the closure of the Abilene, Tex. plant occurred in 1977 as imports of both conventional and nonconventional watches in absolute terms reached their highest levels in the past 5 years. Some customers of Timex surveyed had decreased purchases of domestically produced watches and had increased purchases of imported watches.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with watches produced at the Abilene, Tex., plant of the Timex Corp., contributed importantly to the decline in sales or production and to the total or partial separations of workers at that firm. In accordance with the provisions of the act, I make the following certification:

All workers of the Abilene, Tex., plant of the Timex Corp., who became totally or partially separated from employment on or after October 19, 1976 and before December 2, 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 31st day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-22058 Filed 8-7-78; 8:45 am]

[4510-28]

[TA-W-2783]

UNITED STATES STEEL CORP.

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-2783: 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 14, 1977 in response to a worker petition received on December 9, 1977 which was filed by the United Steelworkers of America on behalf of all workers producing all steel products at the Lorain, Ohio plant of the United States Steel Corp. The investigation revealed that seamless and welded carbon pipe and tubing, hot rolled carbon bars, strip and skelp, and billets are produced at the plant.

The notice of investigation was published in the FEDERAL REGISTER on January 10, 1978 (43 FR 1556). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of 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 appropriate subdivision have contributed importantly to the separations, or threats thereof, and to the absolute decline in sales or production.

The Department conducted a survey of some customers buying the Lorain plant's principal products: Tublars and bars. Most customers that responded to the survey increased purchases from the Lorain plant from 1976 to 1977. Those customers who decreased purchases from the Lorain plant either did no importing, reduced imports proportionately, or imported insignificant amounts. Furthermore, production and sales of all products in quantity at the Lorain plant increased absolutely in 1977 compared to 1976. Also, the average number of production workers at the Lorain, Ohio plant increased in 1977 compared to 1976.

The Lorain plant also produces billets, skelp, and strip most of which is used in the manufacture of tubular products at the same facility.

CONCLUSION

After careful review I determine that all workers of the Lorain, Ohio plant of the United States Steel Corp. 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 31st day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-22059 Filed 8-7-78; 8:45 am]

[4510-28]

INVESTIGATIONS REGARDING CERTIFICATIONS OF ELIGIBILITY TO APPLY FOR WORKER ADJUSTMENT ASSISTANCE

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, has instituted investigations pursuant to section 221(a) of the Act and 29 CFR 90.12.

The purpose of each of the investigations is to determine whether absolute or relative increases of imports of articles like or directly competitive with articles produced by the workers' firm or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under title II, chapter 2, of the Act in accordance with the provisions of subpart B of 29 CFR part 90. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

Pursuant to 29 CFR 90.13, the petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210.

Signed at Washington, D.C. this 31st day of July 1978.

HAROLD A. BRATT,
Acting Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner: Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
AMF-Hofran Division AMF, Inc. (Retail, Wholesale & Department Store Union).	Tampa, Fla	July 27, 1978	July 20, 1978	TA-W-4,002	Leather and rubber covered softballs and baseballs.
Carney Bros. Automotive (workers)	Ely, Nev	July 24, 1978	July 19, 1978	TA-W-4,003	General automotive repair.
Cleaner & Hanger Co. (USWA)	Pueblo, Colo	July 27, 1978	July 1, 1978	TA-W-4,004	Steel wire rod, wire rod products, reinforcement wire.
Meyer Daniel Products, Corp. (workers).	Brooklyn, N.Y	July 18, 1978	July 13, 1978	TA-W-4,005	Lampshades.
E. I. du Pont de Nemours & Co., Inc., Potomac River Works (company).	Martinsburg, W. Va	July 25, 1978	July 24, 1978	TA-W-4,006	Finished smokeless powder.
GAF Corp., Building Products Group (Teamsters).	Houston, Tex	July 24, 1978	July 18, 1978	TA-W-4,007	Vinyl asbestos—floor tile.
Genesco, Inc., General Shoe Co., Division (company).	Huntsville, Ala	July 26, 1978	July 24, 1978	TA-W-4,008	Men's footwear.
L. N. Gross Co. (company)	New York, N.Y	do	do	TA-W-4,009	Production office and sales office.
Manhattan Shirt Co., Inc. (ACTWU)	Americus, Ga	July 24, 1978	July 19, 1978	TA-W-4,010	Men's dress and sport shirts and some ladies' blouses.
Mired Foundations, Inc. (ILGWU)	New York, N.Y	July 10, 1978	June 29, 1978	TA-W-4,011	Brassieres and girdles.
F/V Peter & Linda (workers)	Provincetown, Mass	July 26, 1978	July 21, 1978	TA-W-4,012	The catching and selling of whiting and ground fish.
Henry I. Siegel Co., Inc. (ACTWU)	Fulton, Ky	July 20, 1978	July 18, 1978	TA-W-4,013	Men's and ladies' slacks
Do	Dickson, Tenn	do	do	TA-W-4,014	Do.
Sporn Dress Co., Inc. (workers)	Freehold, N.J	July 28, 1978	July 26, 1978	TA-W-4,015	Ladies' gowns, dresses, and pants suits.
Twinkle Undergarment Co., Inc. (workers).	New York, N.Y	July 18, 1978	July 11, 1978	TA-W-4,016	Ladies' undergarments.
Uniroyal, Inc. (company)	Washington, Ind	July 20, 1978	July 18, 1978	TA-W-4,017	Buys vinyl coated fabrics and from this produces rainwear.
United Slipper Co., Inc. (company)	Bridgeport, Conn	July 28, 1978	July 25, 1978	TA-W-4,018	Men's, women's, and children's soft sole bedroom slippers.
United States Steel Corp., Texas Works (USWA).	Baytown, Tex	July 27, 1978	do	TA-W-4,019	Carbon steel pipe.

[FR Doc. 78-22036 Filed 8-7-78; 8:45 am]

NATIONAL ADVISORY COMMITTEE ON OCEANS AND ATMOSPHERE

FEDERAL ORGANIZATION FOR MARINE AND ATOMOSPHEREIC AFFAIRS

Meeting

AUGUST 4, 1978.

Pursuant to Sec. 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. (App. 1976), notice is hereby given that the National Advisory Committee on Oceans and Atmosphere (NACOA) will hold a workshop on the Federal Organization for Marine and Atomspheric Affairs on Thursay and Friday, August 17-18, 1978. These sessions will be held in Room 200A of the Joseph Henry Building of the National Academy of Sciences, 21st Street and Pennsylvania Avenue NW., Washington, D.C., and will begin at 9 a.m. on both days.

The Committee, consisting of 18 non-Federal members, appointed by the President from State and local governments, industry, science, and other appropriate areas, was established by the Congress by Pub. L. 95-63, on July 5, 1977. Its duties are to: (1) Undertake a continuing review, on a selective basis, of national ocean policy, coastal zone management, and the status of the marine and atomospheric science and service programs of the United States; (2) advice the Secretary of Commerce with respect to the carrying out of the programs administered by the National Oceanic and Atomspheric Administration; and (3) submit an annual report to the President and to the Congress setting forth an assessment, on a selective basis, of the status of the Nation's marine and atmospheric activities, and submit such other reports as may from time to time be requested by the President or the Congress.

The agenda will be as follows:

August 17, 1978:

0900—(Room 200A) Opening Remarks, Mr. Marne A. Dubs, NACOA.
Purpose of workshop.
Plan for the workshop and instructions to working groups.
Current Organizational Structure—Dr. James Curlin, Department of Commerce.
Criteria for assessment—Mr. Timothy Hennessey, University of Rhode Island.
Discussion—Mr. Marne A. Dubs, NACOA.
1200—Lunch.
1300—Working group meetings (Rooms to be announced).
- Living Resources (Fisheries)—Mr. Henry J. Cofer, NACOA.
- Offshore Oil, Gas and Minerals, Dr. Donald L. McKernan, Chairman, NACOA.
- Marine Transportation—Mr. Michael R. Naess, NACOA.
- Environmental Protection and Resource Conservation—Ms. Sarah Chasis, NACOA.
- Scientific Research—Dr. John R. Knauss, NACOA.
- Coastal Recreation and Development—Dr. Jack R. Van Lopik, NACOA.

1700—Adjourn.

August 18, 1978:

0900—Working group meetings—continued.
1100—Plenary session (Room 200A).
- Reports of working group chairmen.
- Summary and discussion.

1600—Adjourn.

These sessions are open to the public. However, in view of stringent space limitations, admission must be restricted to those with reservations only. In this connection, persons interested in attending any of these sessions should call the NACOA staff to make reservations, which will be handled on a first-come-first-served basis.

Persons wishing to make formal statements should notify the Chairman in advance of the meeting. The Chairman retains the perogative to place limits on the duration of oral statements and discussions. Written statements may be submitted before or after each session.

Additional information concerning this meeting may be obtained through the Committee's Executive Director, Douglas L. Brooks, whose mailing address is: National Advisory Committee on Oceans and Atmosphere, 3300 Whitehaven Street NW. (Room 434, Page Building No. 1), Washington, D.C. 20235. The telephone numer is 254-8418.

Dated: August 7, 1978.

DOUGLAS L. BROOKS,
Executive Director.

[FR Doc. 78-22295 Filed 8-7-78; 10:58 am]

[7536-01]

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

HUMANITIES PANEL ADVISORY COMMITTEE

Meeting

JULY 26, 1978.

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, as amended) notice is hereby given that a meeting of the Humanities Panel will be held at 806 15th Street NW., Washington, D.C. 20506, in the first floor conference room, from 9 a.m. to 5:30 p.m. on August 25, 1978.

The purpose of the meeting is to review NEH independent fellowship applications in Modern European History submitted to the National Endowment for the Humanities for projects beginning after January 1, 1979.

Because the proposed meeting will consider financial information and disclose information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's delegation of authority to close advisory committee meetings, dated January 15, 1978, I have determined that the meeting would fall within exemptions (4) and (6) of 5 U.S.C. 552b(c) and that it is essential to close the meeting to protect the free exchange of internal views and to avoid interference with operation of the Committee.

It is suggested that those desiring more specific information contact the Advisory Committee Management Officer, Mr. Stephen J. McCleary, 806 15th Street NW., Washington, D.C. 20506, or call area code 202-724-0367.

STEPHEN J. MCCLEARY,
Advisory Committee Management Officer.

[FR Doc. 78-22113 Filed 8-7-78; 8:45 am]

[7536-01]

HUMANITIES PANEL ADVISORY COMMITTEE

Meeting

JULY 26, 1978.

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, as amended) notice is hereby given that a meeting of the Humanities Panel will be held at 806 15th Street NW., Washington, D.C. 20506, in room 807, from 9 a.m. to 5:30 p.m. on August 25, 1978.

The purpose of the meeting is to review NEH independent fellowship applications in Metaphysics, Epistemology, Aesthetics, and Linguistics submitted to the National Endowment for the Humanities for projects beginning after January 1, 1979.

Because the proposed meeting will consider financial information and disclose information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's delegation of authority to close advisory committee meetings, dated January 15, 1978, I have determined that the meeting would fall within exemptions (4) and (6) of 5 U.S.C. 552b(c) and that it is essential to close the meeting to protect the free exchange of internal views and to avoid interference with operation of the Committee.

It is suggested that those desiring more specific information contact the Advisory Committee Management Officer, Mr. Stephen J. McCleary, 806 15th Street NW., Washington, D.C. 20506, or call area code 202-724-0367.

STEPHEN J. MCCLEARY,
Advisory Committee, Management Officer.

[FR Doc. 78-22114 Filed 8-7-78; 8:45 am]

[7536-01]

HUMANITIES PANEL ADVISORY COMMITTEE

Meeting

JULY 26, 1978.

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, as amended,) notice is hereby given that a meeting of the Humanities Panel will be held at 806 15th Street NW., Washington, D.C. 20506, in room 314, from 9 a.m. to 5:30 p.m. on August 26, 1978.

The purpose of the meeting is to review NEH independent fellowship applications in Early European History submitted to the National Endowment for the Humanities for projects beginning after January 1, 1979.

Because the proposed meeting will consider financial information and disclose information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's delegation of authority to close advisory committee meetings, dated January 15, 1978, I have determined that the meeting would fall within exemptions (4) and (6) of 5 U.S.C. 552b(c) and that it is essential to close the meeting to protect the free exchange of internal views and to avoid interference with operation of the Committee.

It is suggested that those desiring more specific information contact the Advisory Committee Management Officer, Mr. Stephen J. McCleary, 806

15th Street NW., Washington, D.C. 20506, or call area code 202-724-0367.

STEPHEN J. MCCLEARY,
Advisory Committee Management Officer.

[FR Doc. 78-22115 Filed 8-7-78; 8:45 am]

[7536-01]

HUMANITIES PANEL ADVISORY COMMITTEE

Meeting

JULY 26, 1978.

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, as amended,) notice is hereby given that a meeting of the Humanities Panel will be held at 806 15th Street NW., Washington, D.C. 20506, in room 314, from 9 a.m. to 5:30 p.m. on August 29, 1978.

The purpose of the meeting is to review NEH independent fellowship applications in Non-European History submitted to the National Endowment for the Humanities for projects beginning after January 1, 1979.

Because the proposed meeting will consider financial information and disclose information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's delegation of authority to close advisory committee meetings, dated January 15, 1978, I have determined that the meeting would fall within exemptions (4) and (6) of 5 U.S.C. 552b(c) and that it is essential to close the meeting to protect the free exchange of internal views and to avoid interference with operation of the Committee.

It is suggested that those desiring more specific information contact the Advisory Committee Management Officer, Mr. Stephen J. McCleary, 806 15th Street NW., Washington, D.C. 20506, or call area code 202-724-0367.

STEPHEN J. MCCLEARY,
Advisory Committee Management Officer.

[FR Doc. 78-22116 Filed 8-7-78; 8:45 am]

[7536-01]

HUMANITIES PANEL ADVISORY COMMITTEE

Meeting

JULY 26, 1978.

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, as amended,) notice is hereby given that a meeting of the Humanities Panel will be held at 806 15th Street NW., Washington, D.C. 20506, in room 314, from 9 a.m. to 5:30 p.m. on August 31, 1978.

The purpose of the meeting is to review NEH Independent Fellowship applications in U.S. History submitted to the National Endowment for the Humanities for projects beginning after January 1, 1979.

Because the proposed meeting will consider financial information and disclose information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's delegation of authority to close advisory committee meetings, dated January 15, 1978, I have determined that the meeting would fall within exemptions (4) and (6) of 5 U.S.C. 552b(c) and that it is essential to close the meeting to protect the free exchange of internal views and to avoid interference with operation of the Committee.

It is suggested that those desiring more specific information contact the Advisory Committee Management Officer, Mr. Stephen J. McCleary, 806 15th Street NW., Washington, D.C. 20506, or call area code 202-724-0367.

STEPHEN J. MCCLEARY,
Advisory Committee Management Officer.

[FR Doc. 78-22117 Filed 8-7-78; 8:45 am]

[7536-01]

HUMANITIES PANEL ADVISORY COMMITTEE

Meeting

JULY 26, 1978.

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, as amended,) notice is hereby given that a meeting of the Humanities Panel will be held at 806 15th Street NW., Washington, D.C. 20506, in room 314, from 9 a.m. to 5:30 p.m. on September 1, 1978.

The purpose of the meeting is to review NEH independent fellowship applications in Religion submitted to the National Endowment for the Humanities for projects beginning after January 1, 1979.

Because the proposed meeting will consider financial information and disclose information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's delegation of authority to close advisory committee meetings, dated January 15, 1978, I have determined that the meeting would fall within exemptions (4) and (6) of 5 U.S.C. 552b(c) and that it is essential to close the meeting to protect the free exchange of internal views and to avoid interference with operation of the Committee.

It is suggested that those desiring more specific information contact the Advisory Committee Management Officer, Mr. Stephen J. McCleary, 806 15th Street NW., Washington, D.C. 20506, or call area code 202-724-0367.

STEPHEN J. MCCLEARY,
Advisory Committee Management Officer.

[FR Doc. 78-22118 Filed 8-7-78; 8:45 am]

[7536-01]

HUMANITIES PANEL ADVISORY COMMITTEE

Meeting

JULY 26, 1978.

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, as amended) notice is hereby given that a meeting of the Humanities Panel will be held at 806 15th Street NW., Washington, D.C. 20506, in room 314, from 9 a.m. to 5:30 p.m. on September 2, 1978.

The purpose of the meeting is to review NEH independent fellowship applications in Political Science and Law submitted to the National Endowment for the Humanities for projects beginning after January 1, 1979.

Because the proposed meeting will consider financial information and disclose information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the chairman's delegation of authority to close advisory committee meetings, dated January 15, 1978, I have determined that the meeting would fall within exemptions (4) and (6) of 5 U.S.C. 552b(c) and that it is essential to close the meeting to protect the free exchange of internal views and to avoid interference with operation of the Committee.

It is suggested that those desiring more specific information contact the Advisory Committee Management Officer, Mr. Stephen J. McCleary, 806 15th Street NW., Washington, D.C. 20506, or call area code 202-724-0367.

STEPHEN J. MCCLEARY,
Advisory Committee Management Officer.

[FR Doc. 78-22119 Filed 8-7-78; 8:45 am]

[7555-01]

NATIONAL SCIENCE FOUNDATION

NATIONAL SCIENCE FOUNDATION APPROPRIATE TECHNOLOGY FORUMS

Program Plan

The Directorate for Applied Science and Research Applications of the National Science Foundation has been directed to design and present to the House Committee on Science and Technology a program plan for appropriate technology. The plan is due by the end of calendar year 1978 for possible implementation in fiscal year

1980. Appropriate technology is technology which is best suited to the specific local cultural, economic, social, and political conditions at the site of application. The design or adaptation of such technology includes an examination of conditions of the site and consideration of several factors normally not identified through the marketplace. Some of these factors include preferences of users for technology which conserves natural resources, is compatible with local labor skills, and which enhances the social and ecological fabric of the site of application. The markets for appropriate technology are varied and widely diffused and include the small farmer, the small businessman, and the small manufacturer.

The Committee has urged the NSF to incorporate full public participation in planning the appropriate technology program. Therefore, the NSF is soliciting the views of representatives from the scientific and nonscientific communities, state and local government, small businesses, professional societies, and from individuals and citizen groups with expertise, experience, or interest in appropriate technology.

The committee further urged the NSF to conduct a number of public workshops during the development of the required comprehensive plan. To comply with this request, the NSF is conducting public forums on appropriate technology throughout the country.

Information about the forums is as follows:

Northwest Forum—Eugene, Oreg.: Participation is encouraged from residents of Alaska, northern California, Hawaii, Idaho, Montana, Oregon, and Washington.
Date and time: September 8, 1978; 9 a.m. to 4 p.m. and September 9, 1978; 9 a.m. to 3:30 p.m.
Place: Bean Complex, University of Oregon, Eugene, Oreg.
Contact person: Gerald Udell, Experimental Center for the Advancement of Invention and Innovation, College of Business Administration, University of Oregon, 131 Gilbert Hall, Eugene, Oreg. 97403, 503-686-3326.

Southeast Forum—Atlanta, Ga: Participation is encouraged from residents of Alabama, Delaware, the District of Columbia, Florida, Georgia, Kentucky, Maryland, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia.
Date and time: September 17, 1978; 12 noon to 5 p.m. and September 18, 1978; 9 a.m. to 5 p.m.
Place: September 17th, Ball Room, Student Center, Georgia Institute of Technology; September 18th, Space Science Technology Building Lecture Hall, Georgia Institute of Technology, Atlanta, Ga.
Contact person: David Clifton, Jr., Georgia Institute of Technology, Engineering Experiment Station, Atlanta, Ga. 30332, 404-894-3841.

West Coast Forum—Tucson, Ariz.: Participation is encouraged from residents of Arizona, Southern California, Nevada, and Utah.
Date and time: September 21, 1978; 8 a.m. to 5 p.m.
Place: Marriott Hotel, 180 W. Broadway, Tucson, Ariz.
Contact person: Kennith E. Foster, Office of Arid Land Studies, University of Arizona, 845 North Park, Tucson, Ariz. 85719, 602-884-1955.

Mid-West Forum—Kansas City, Mo.: Participation is encouraged from residents of Colorado, Iowa, Kansas, Missouri, Nebraska, North Dakota, South Dakota, and Wyoming.
Date and time: October 6, 1978; 9 a.m. to 5 p.m.
Place: Crown Center, Kansas City, Mo.
Contact person: Philip Burgess, Western Governors Policy Office, 3333 Quebec Street, Suite 2959, Denver, Colo. 80207, 303-399-9957.

Southwest Forum—San Antonio, Tex.: Participation is encouraged from residents of Arkansas, Louisiana, New Mexico, Oklahoma, and Texas.
Date and time: October 6, 1978; 8 a.m. to 5 p.m.
Place: Henry B. Gonzalez Convention Center, San Antonio, Tex.
Contact person: Antonio Furino, Center for Studies in Business, Economics, and Human Resources, University of Texas at San Antonio, San Antonio, Tex. 78285, 512-691-4318.

Central States Forum—Indianapolis, Ind.: Participation is encouraged from residents of Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin.
Date and time: October 7, 1978; 9 a.m. to 9 p.m.
Place: Indiana Convention Center, 100 South Capitol Avenue, Indianapolis, Ind.
Contact person: Evan Rogers, Indianapolis Center for Advanced Research, Inc., 1219 West Michigan Street, Indianapolis, Ind. 46202, 317-264-3846.

Northeast Forum—Amherst, Mass.: Participation is encouraged from residents of Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.
Date and time: October 14, 1978; 8:30 a.m. to 4 p.m.
Place: Campus Center, University of Massachusetts, Amherst, Mass.
Contact person: Anthony Krzystofik, School of Business Administration, University of Massachusetts, Amherst, Mass. 01003, 413-549-4930.

For further information about these forms, contact the regional coordinators noted above. The National Science Foundation program manager for these Forums is Mr. Alex Schwarzkopf at 202-634-6204.

Dated: August 3, 1978.

LYNN PRESTON,
Deputy, Office of Problem Analysis.

[FR Doc. 78-22183 Filed 8-7-78; 8:45 am]

[7590-01]

NUCLEAR REGULATORY COMMISSION

ABNORMAL OCCURRENCE EVENT

Degraded Primary Coolant Boundary in a Boiling Water Reactor

Section 208 of the Energy Reorganization Act of 1974, as amended, requires the NRC to disseminate information on abnormal occurrences (i.e., unscheduled incidents or events which the Commission determines are significant from the standpoint of public health and safety). The following incident was determined to be an abnormal occurrence using the criteria published in the FEDERAL REGISTER on February 24, 1977 (42 FR 10950). Appendix A (example II.A.2) of the policy statement notes that a major degradation of the primary coolant pressure boundary of a commercial nuclear powerplant can be considered an abnormal occurrence. The following description of the event also contains the remedial actions taken.

Date and Place.—On June 17, 1978, Iowa Electric Light and Power Co. reported to the NRC an event at the Duane Arnold Power Plant, a boiling water nuclear plant located in Linn County, Iowa.

Nature and Probable Consequences.—The reactor had shut down on June 17, 1978 due to an unrelated problem experienced during a surveillance test. Prior to this unplanned shutdown, a primary coolant system leak of approximately three gallons per minute (gpm) from an unidentified source had been detected by the plant's leakage monitoring equipment. Although this leak rate was within the technical specification limit of five gpm, the licensee took advantage of the unplanned shutdown to perform an inspection to identify the source of the leakage. The leaking water was collected in the reactor building drain system and pumped to the plant's radioactive waste treatment system for processing.

During the inspection of the reactor coolant system piping, a through-wall crack was found in a nickel-steel alloy (Inconel) fitting joining the ten-inch diameter recirculation pipe to the reactor vessel. The recirculation line, a

part of the primary system pressure boundary, directs primary coolant flow to two jet pumps located inside the reactor vessel. The jet pumps are utilized to circulate the primary coolant through the reactor core. There are a total of eight such vessel nozzle penetrations for the reactor's 16 jet pumps. The crack was in the recirculation line to nozzle transition piece, near the attachment weld for the piping leading to the jet pumps. The crack was approximately eight inches long on the outer diameter (i.e., through-wall) and, based on ultrasonic testing results, was determined to extend about three-quarters around the circumference of the inner diameter.

Nondestructive testing of the remaining seven similar transition pieces revealed that five had indications (potential cracks or weld irregularities) that may also require repair; however, these indications do not penetrate through the pipe wall.

Since the leak could not be isolated, such as by closing a valve, for repair by conventional means, special procedures were necessary to make repairs. The leak, however, did not pose a threat to public health or safety. The plant was shutdown, and any leaking water was collected and processed by the radioactive waste treatment system. Water lost from the primary system was replaced by plant systems designed for that purpose. Later, all fuel assemblies were removed from the reactor vessel to facilitate repairs.

The primary coolant pressure boundary is one of several barriers to prevent the release of radioactive materials. Plant operations are not permitted if this boundary is degraded. An emergency core cooling system is available if a pipe should break.

Cause or Causes.—The cause of the cracking has not yet been established. As part of the repair procedure, a failure analysis will be conducted. During vessel fabrication, all eight of these nozzle fittings were mistakenly machined and then weld repaired. Due to the proximity of the crack location to the weld repair area, it is suspected that the weld repair contributed to the propagation of the crack. However, other potential causes are being actively evaluated. The General Electric Co. (GE) has compared the design of the transition pieces utilized in the Duane Arnold facility with those used in other BWR plants and, based on information to date, considers this cracking problem to be specific to the Duane Arnold plant.

ACTION TAKEN TO PREVENT RECURRENCE

Licensee.—The licensee is exploring methods of repair. The plant is expected to be shutdown for several months, depending upon the extent of the problems experienced during repair. The licensee and GE reviewed all planned actions with the NRC in a meeting on July 7, 1978. The licensee is proceeding to remove the cracked nozzle transition piece and will send the specimen to a laboratory for failure analysis. The licensee has performed additional nondestructive examinations of the other seven nozzle transition pieces. Five had indications which could be attributed to either slag, nonfusion or cracks in the area of the repair welds made during fabrication. On this basis, the licensee intends to replace all eight transition pieces.

Reactor Vendor.—The General Electric Co. is continuing efforts to identify the specific cause of the cracking and to pursue any possible generic implications with other BWR plants. GE will keep the NRC informed of their review and meetings will be held as necessary.

NRC.—The NRC has reviewed information submitted by GE which classifies the BWR recirculation line to nozzle transition piece designs utilized in operating BWR facilities into five categories, the most unique of which is that utilized in the Duane Arnold facility. Only two other operating facilities, Brunswick units Nos. 1 and 2, utilize designs similar to that used at Duane Arnold. However, the transition piece cross section utilized in these facilities is thicker (approximately one inch as compared to approximately one-half inch) than that of the Duane Arnold design.

Based on the information currently available, the NRC believes that the combination of the weld repair, the location of the attachment weld for the jet pump piping, and the thin transition piece cross section contributed to the propagation of the crack at Duane Arnold. No other BWR facility is known to have this same combination of factors in its design.

The methods of repair, the cause of the cracking, and any generic implications are being actively pursued with the licensee and reactor vendor. The proposed repair procedures and the failure analysis will be reviewed. Any repairs will be reviewed and inspected before the plant will be allowed to resume operation.

Dated at Washington, D.C., this 2nd day of August 1978.

For the Nuclear Regulatory Commission.

SAMUEL J. CHILK,
Secretary of the Commission.

[FR Doc. 78-21955 Filed 8-7-78; 8:45 am]

[7590-01]

REGULATORY GUIDE

Issuance and Availability

The Nuclear Regulatory Commission has issued a new guide in its Regulatory Guide Series. This 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 evaluating 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 1.143, "Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants," provided design guidance acceptable to the NRC staff relating to seismic and quality group classification and quality assurance provisions for radioactive waste management systems, structures, and components. Further, it describes provisions for controlling releases of liquids containing radioactive materials, e.g., spills or tank overflows, from all plant systems outside reactor containment.

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. Public comments on Regulatory Guide 1.143 will, however, be particularly useful in evaluating the need for an early revision if received by October 6, 1978.

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 divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Divison 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 1st day of August 1978.

For the Nuclear Regulatory Commission.

ROBERT B. MINOGUE,
Director, Office of Standards Development.

[FR Doc. 78-21959 Filed 8-7-78; 8:45 am]

[7590-01]

REGULATORY GUIDE

Issuance and Availability

The Nuclear Regulatory Commission has published proposed revisions to chapters 4 and 18 of Regulatory Guide 5.52, Revision 1, "Standard Format and Content for the Physical Protection Section of a License Application (for Facilities Other Than Nuclear Power Plants)." These chapters have been revised to provide guidance to licensees for preparing the training and qualification plans they will be required to provide under amendments to §§ 73.30(d), 73.30(e), 73.50(a)(4), and 73.50(h) of 10 CFR part 73 and the new appendix B to part 73 entitled "General Criteria for Security Personnel." These amendments are being published at the same time as this proposed guidance but will not become effective for 60 days, at which time this and other guidance will be republished in final form after consideration of public comment. When Regulatory Guide 5.52 is revised in its entirety, these revised chapters will be incorporated.

Comments and suggestions on these chapters should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. In order for comments to be taken into consideration, they should be received no later than September 8, 1978.

In addition to these revised chapters, two training manuals have been issued for comment. These manuals will provide guidance to licensees in developing their training and qualification plans. These are:

NUREG-0464, "Site Security Personnel Training Manual."
NUREG-0465, "Transportation Security Personnel Training Manual."

Single copies of these documents may be obtained by writing to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Bernadine Scharf, Distribution Service Branch.

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

Dated at Rockville, Md., this 1st day of August 1978.

For the Nuclear Regulatory Commission.

ROBERT B. MINOGUE,
Director, Office of Standards Development.

[FR Doc. 78-21958 Filed 8-7-78; 8:45 am]

[7590-01]

REVISION TO THE STANDARD REVIEW PLAN (NUREG-75/087)

Issuance and availability

As a continuation of the updating program for the Standard Review Plan (SRP) previously announded (FEDERAL REGISTER notice dated December 8, 1977), the Nuclear Regulatory Commission's (NRC's) Office of Nuclear Reactor Regulation has published Revision No. 1 to Section Nos. 6.2.1.1.A (PWR Dry Containments Including Sub-Atmospheric Containments), 6.2.1.1.B (Ice Condenser Containments), 6.2.1.2 (Subcompartment Analysis), 6.2.1.5 (Minimum Containment Pressure Analysis for Emergency Core Cooling Performance Capability Studies), 6.2.3 (Secondary Containment Functional Designs) and Revision No. 2 to Section Nos. 6.2.1.1.C (Pressure Suppression Type BWR Containments) and 6.2.2 (Containment Heat Removal Systems of the SRP for the NRC staff's safety review of applications to build and operate light-water-cooled nuclear power reactors. The purpose of the plan, which is composed of 224 sections, is to improve both the quality and uniformity of the NRC staff's review of applications to build new nuclear powerplants, and to make information about regulatory matters widely available, including the improvement of communication and understanding of the staff review process by interested members of the public and the nuclear power industry. The purpose of the updating program is to revise sections of the SRP for which changes in the review plan have been developed since the original issuance in September 1975 to reflect current practice.

Copies of the Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants, which has been identified as NUREG-75/087, are available from the National Technical Information Service, Springfield, Va. 22161. The domestic price for Revision No. 1 of each section is $4. Foreign price information is available from NTIS. A copy of the Standard Review Plan including all revisions published to date is available for public inspection at the NRC's Public Document Room at 1717 H Street NW, Washington, D.C. 20555.

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

Dated at Bethesda, Md., this 31st day of July, 1978.

For the U.S. Nuclear Regulatory Commission.

R. J. MATTSON,
Director, Division of Systems Safety, Office of Nuclear Reactor Regulation.

[FR Doc. 78-21961 Filed 8-7-78; 8:45 am]

[7590-01]

REVISION TO THE STANDARD REVIEW PLAN (NUREG-75/087)

Issuance and Availability

As a continuation of the updating program for the Standard Review Plan (SRP) previously announced (FEDERAL REGISTER notice dated December 8, 1977), the Nuclear Regulatory Commission's (NRC's) Office of Nuclear Reactor Regulation has published Revision No. 1 to Section No. 3.5.1.2, Internally Generated Missiles (Inside Containment); 5.4.7, Residual Heat Removal (RHR) System; 15.0, Introduction; 15.1.5, Steam System Piping Failures Inside and Outside of Containment (PWR); 15.3.3 & 15.3.4, Reactor Coolant Pump Rotor Seizure and Reactor Coolant Pump Shaft Break; and 15.6.5, Loss-of-Coolant Accidents Resulting from Spectrum of Postulated Piping Breaks Within the Reactor Coolant Pressure Boundary, of the SRP for the NRC staff's safety review of applications to build and operate light-water-cooled nuclear power reactors. The purpose of the plan, which is composed of 224 sections, is to improve both the quality and uniformity of the NRC staff's review of applications to build new nuclear powerplants, and to make information about regulatory matters widely available, including the improvement of communication and understanding of the staff review process by interested members of the public and the nuclear power industry. The purpose of the updating program is to revise sections of the SRP for which changes in the review plan have been developed since the original issuance in September 1975 to reflect current practice.

Copies of the Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants, which has been identified as NUREG-75/087, are available from the National Technical Information Service, Springfield, Va. 22161. The domestic price is $70, including first-year supplements. Annual subscriptions for supplements alone are $30. Individual sections are available at current prices. The domestic price for Revision No. 1 to Section No. 15.0 is $4. Foreign price information is available from NTIS. A copy of the Standard Review Plan including all revisions published to date is avail-

able for public inspection at the NRC's Public Document Room at 1717 H Street NW, Washington, D.C. 20555.

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

Dated at Bethesda, Md., this 31st day of July 1978.

For the U.S. Nuclear Regulatory Commission.

ROGER J. MATTSON,
Director, Division of Systems Safety, Office of Nuclear Reactor Regulation.

[FR Doc. 78-21960 Filed 8-7-78; 8:45 am]

[7590-01]

[Construction Permit Nos.: CPRR 139, CPRR 140]

UNION ELECTRIC CO., (CALLAWAY PLANT, UNITS 1 AND 2)

Argument on Issues Relating to Show Cause Order

Notice is hereby given that, pursuant to the Atomic Energy Act of 1954, as amended, and in accordance with Nuclear Regulatory Commission's regulations, an oral argument by counsels for the parties to this show cause proceeding will be heard beginning at 10 a.m. e.d.t., in the U.S. Nuclear Regulatory Commission's hearing room, 5th floor, East-West Towers Building, 4350 East-West Highway, Bethesda, Md., on Wednesday, August 23, 1978.

The Director of the Office of Inspection, April 3, 1978, ordered that:

> The licensee show cause * * * why the license should not be suspended until such time as, the licensee, including its employees agents and contractors engaged in activities under the license, submits to * * * authorized investigations and inspection.

In a notice of hearing, dated May 11, 1978, the Nuclear Regulatory Commission charged the Atomic Safety and Licensing Board to consider and decide two issues set out therein. (43 FR 21389).

A prehearing conference was held on June 16, 1978. At the conference, the licensee and the NRC staff filed a stipulation of facts which was later agreed to by the Intervenor William Smart. Counsel for all parties have agreed that the stipulated factual matters dispose of the first issue raised by the Commission. As to the second issue they have agreed that the remaining matters to be considered include (1) the legal authority of the Commission to conduct an investigation into the cause of dismissal of Mr. Smart, (2) if such authority exists how it may be exercised and (3) the appropriate remedy. Counsel for all of the parties have also agreed that there is no need for an evidentiary hearing to resolve the issues in this case.

Briefs of the respective positions of the parties as to the issues to be decided by the Board will be filed. Oral arguments will provide each counsel an opportunity to further support his or her party's position. Up to 30 minutes will be available for each party's direct argument and 10 minutes for each rebuttal. Requests for additional time will be considered at the beginning of the hearing. Members of the public are invited to attend.

It is so ordered.

Dated at Bethesda, Md., this 1st day of August 1978.

For the Atomic Safety and Licensing Board.

JOHN F. WOLF,
Chairman.

[FR Doc. 78-21956 Filed 8-7-78; 8:45 am]

[8025-01]

SMALL BUSINESS ADMINISTRATION

[Proposal No. 05/05-0131]

BCJ CAPITAL ENTERPRISES, INC.

Application for a License as a Small Business Investment Company

Notice is hereby given of the filing of an application with the Small Business Administration (SBA) pursuant to section 107.102 of the SBA regulations (13 CFR 107.102 (1977)) by BCJ Capital Enterprises, Inc., 10 South LaSalle Street, Suite 707, Chicago, Ill. 60603, for a license to operate as a small business investment company (SBIC) under the provisions of the Small Business Investment Act of 1958 (the act), as amended (15 U.S.C. 661 et seq.).

The proposed officers, directors, and shareholders are:

Name and address, title, and relationship, and percent of ownership

Bernard M. Filler, 1960 Partridge Lane, Highland Park, Ill. 60035, president, treasurer, and director, 50.*

John B. Heyman, Executive House, Paradise Island, New Providence, Bahamas, chairman of the board, secretary, and director, 50.*

The applicant proposes to begin operations with a capitalization of $5,001,250 and will be a source of equity capital and long-term loan funds for qualified small business concerns.

Matters involved in SBA's consideration of the application include the general business reputation and character of the proposed owners and management, and the probability of successful operations of the new company under their management, including adequate profitability and financial soundness, in accordance with the act and regulations.

Notice is further given that any person may, not later than August 23, 1978, submit written comments on the proposed SBIC to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 L Street NW., Washington, D.C. 20416.

A copy of this notice will be published in a newspaper of general circulation in Chicago, Ill.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies.)

Dated: August 2, 1978.

PETER F. MCNEISH,
Deputy Associate Administrator for Investment.

[FR Doc. 78-21932 Filed 8-7-78; 8:45 am]

*These percentages are for the ownership of class A common stock (voting). Class B common stock (nonvoting) is being offered on a private placement basis to no more than 10 investors. It is anticipated that $5,000,000, or approximately 99.9 percent of the private capital, will come from the investment of class B common stock.

[8025-01]

REGION I ADVISORY COUNCIL EXECUTIVE BOARD MEETING

Public Meeting

The Small Business Administration Region I Advisory Council Executive Board Meeting will hold a public meeting at 1 p.m., Wednesday, August 16, 1978, in the conference room, 60 Batterymarch Street, 10th Floor, Boston, Mass., to discuss such matters as may be presented by members, the staff of the Small Business Administration or others attending.

For further information, write or call John J. McNally, U.S. Small Business Administration, 60 Batterymarch Street, 10th Floor, Boston, Mass. 02110, 617-223-4495.

Dated: August 1, 1978.

K DREW,
Deputy Advocate for Advisory Councils.

[FR Doc. 78-21951 Filed 8-7-78; 8:45 am]

[4810-22]

DEPARTMENT OF THE TREASURY

Office of the Secretary

CONDENSER PAPER FROM FINLAND

Antidumping Proceeding

AGENCY: U.S. Treasury Department.

ACTION: Initiation of antidumping investigation.

SUMMARY: This notice is to advise the public that a petition in proper form has been received and an antidumping investigation is being initiated for the purpose of determining

whether condenser paper from Finland is being, or is likely to be, sold at less than fair value within the meaning of the Antidumping Act of 1921, as amended. Sales at less than fair value generally occur when the prices of merchandise sold for exportation to the United States are less than the prices in the home market or to countries other than the United States, or less than the constructed value.

EFFECTIVE DATE: August 8, 1978.

FOR FURTHER INFORMATION CONTACT:

David R. Chapman, Operations Officer, U.S. Customs Service, Office of Operations, Duty Assessment Division, Technical Branch, 1301 Constitution Avenue NW., Washington, D.C. 20229, telephone 202-566-5492.

SUPPLEMENTARY INFORMATION: On June 27, 1978, a petition in proper form was received pursuant to sections 153.26 and 153.27, customs regulations (19 CFR 153.26, 153.27), from counsel on behalf of Crocker Technical Papers, Inc., Kimberly-Clark Corp., and the Stevens Paper Mill, Inc., the sole domestic producers of the subject merchandise, alleging that condenser paper from Finland is being, or is likely to be, sold at less than fair value within the meaning of the Antidumping Act of 1921, as amended (19 U.S.C. 160 et seq.).

For purposes of this notice, the term "condenser paper" means capacitor tissue or condenser paper as provided for in item numbers 252.40 and 256.30 of the Tariff Schedules of the United States, annotated (TSUSA).

Petitioners claim that there is no home market for the subject merchandise. The margins of dumping alleged, ranging from 23 to 31 percent, are based on information presented regarding the price of exports of such or similar merchandise to countries other than the United States (sales to Italy were used by the petitioners). The margins of underselling claimed in the petition are completely accounted for by the alleged dumping margins.

Petitioners allege that sales are being made at prices less than the cost of production, but they have not presented sufficient evidence to support this claim. The allegation of sales at less than the cost of production will not be investigated at this time because there are no reasonable grounds to believe or suspect that sales to countries other than the United States have been made at prices which represent less than the cost of producing the merchandise in question.

Petitioners also have contended that because Finland is a state-controlled economy within the meaning of section 205(c) of the Act, constructed value should be used to establish fair value. However, the sole basis upon which the claim of state control of the economy is made concerns the ownership by agencies of the Finnish Government of the capital of the producer of this merchandise in Finland. The mere ownership of equity by a government has not been regarded as a basis for applying section 205(c). However, petitioners are not foreclosed from the presentation of any facts they have to substantiate their claim during the investigation by the Customs Service.

There appears to be a relationship between the exporter and the importing company in the United States, which may require the use of exporter's sales price to establish the price of the merchandise in the U.S. market.

There is evidence on record concerning injury or likelihood of injury to an industry in the United States. Data concerning sales show a high level of sales in 1974, a large drop due to the recession of 1975, recovery to a point near previous levels in 1976, and a decline in 1977 despite a recovery of demand. Sales in the first quarter of 1978 are below the amount of the first quarter of 1977.

Net operating profits before taxes as a percentage of sales have yet to resume their 1974 level. Figures for the first quarter of 1978 show that the return on sales was well below the rate of return for the first quarter of 1977. This recent reduction of earnings is especially significant in light of efforts made by domestic producers to increase productivity.

Employment levels of the petitioners in the production of condenser paper have declined both in absolute numbers and in man-hours worked. Part of this is due to the recession of 1975 and the steps taken to improve productivity, but petitioners claim that the decline in 1977 in comparison to 1976 was the result of the alleged dumping. Having conducted a summary investigation as required by § 153.29 of the customs regulations (19 CFR 153.29) and having determined as result thereof that there are grounds for so doing, the U.S. Customs Service is instituting an inquiry to verify the information submitted and to obtain the facts necessary to enable the Secretary of the Treasury to reach a determination as to the fact or likelihood of sales at less than fair value.

This notice is published pursuant to section 153.30 of the customs regulations (19 CFR 153.30). A concurrent, similar notice is being published with respect to such or similar merchandise from France.

Dated: August 1, 1978.

ROBERT H. MUNDHEIM,
General Counsel of the Treasury.

[FR Doc. 78-21938 Filed 8-7-78; 8:45 am]

[4810-22]

CONSENSER PAPER FROM FRANCE

Antidumping Proceeding

AGENCY: U.S. Treasury Department.

ACTION: Initiation of antidumping investigation.

SUMMARY: This notice is to advise the public that a petition in proper form has been received and an antidumping investigation is being initiated for the purpose of determining whether condenser paper from France is being, or is likely to be, sold at less than fair value within the meaning of the Antidumping Act of 1921, as amended. Sales at less than fair value generally occur when the prices of merchandise sold for exportation to the United States are less than the prices in the home market or to countries other than the United States, or less than the constructed value.

EFFECTIVE DATE: August 8, 1978.

FOR FURTHER INFORMATION CONTACT:

David R. Chapman, Operations Officer, U.S. Customs Service, Office of Operations, Duty Assessment Division, Technical Branch, 1301 Constitution Avenue NW., Washington, D.C. 20229, telephone 202-566-5492.

SUPPLEMENTARY INFORMATION: On June 27, 1978, a petition in proper form was received pursuant to §§ 153.26 and 153.27, customs regulations (19 CFR 153.26, 153.27), from counsel on behalf of Crocker Technical Papers Inc., Kimberly-Clark Corp., and the Stevens Paper Mill Inc., the sole domestic producers of the subject merchandise, alleging that condenser paper from France is being, or is likely to be, sold at less than fair value within the meaning of the Antidumping Act of 1921, as amended (19 U.S.C. 160 et seq.).

For purposes of this notice, the term "condenser paper" means capacitor tissue or condenser paper as provided for in item numbers 252.40 and 256.30 of the Tariff Schedules of the United States, annotated (TSUSA).

Petitioners claim that there is no home market for the subject merchandise. The margins of dumping alleged, ranging from 60 to 107 percent, are based on information presented regarding the price of exports of such or similar merchandise to countries other than the United States (sales to Italy were used by the petitioners). The margins of underselling claimed in the petition are completely accounted for by the alleged dumping margins.

Petitioners allege that sales are being made at prices less than the cost of production, but they have not presented sufficient evidence to support this claim. The allegation of sales at

less than the cost of production will not be investigated at this time because there are no reasonable grounds to believe or suspect that sales to countries other than the United States have been made at prices which represent less than the cost of producing the merchandise in question.

There appears to be a relationship between the exporter and the importing company in the United States, which may require the use of exporter's sales price to establish the price of the merchandise in the U.S. market.

There is evidence on record concerning injury or likelihood of injury to an industry in the United States. Data concerning sales show a high level of sales in 1974, a large drop due to the recession of 1975, recovery to a point near previous levels in 1976, and a decline in 1977 despite a recovery of demand. Sales in the first quarter of 1978 are below the amount of the first quarter of 1977.

Net operating profits before taxes as a percentage of sales have yet to resume their 1974 level. Figures for the first quarter of 1978 show that the return on sales was well below the rate of return for the first quarter of 1977. This recent reduction of earnings is especially significant in light of efforts made by domestic producers to increase productivity

Employment levels of the petitioners in the production of condenser paper have declined both in absolute numbers and in man-hours worked. Part of this is due to the recession of 1975 and the steps taken to improve productivity, but petitioners claim that the decline in 1977 in comparison to 1976 was the result of the alleged dumping.

Having conducted a summary investigation as required by § 153.29 of the customs regulations (19 CFR 153.29) and having determined as a result thereof that there are grounds for so doing, the U.S. Customs Service is instituting an inquiry to verify the information submitted and to obtain the facts necessary to enable the Secretary of the Treasury to reach a determination as to the fact or likelihood of sales at less than fair value.

This notice is published pursuant to § 153.30 of the customs regulations (19 CFR 153.30). A concurrent, similar notice is being published with respect to such or similar merchandise from Finland.

Dated: August 1, 1978.

ROBERT H. MUNDHEIM,
General Counsel of the Treasury.

[FR Doc. 78-21937 Filed 8-7-78; 8:45 am]

[4810-22]

AUTOMOTIVE AND MOTORCYCLE REPAIR MANUALS FROM THE UNITED KINGDOM

Antidumping Proceeding

AGENCY: U.S. Treasury Department.

ACTION: Initiation of antidumping investigation.

SUMMARY: This notice is to advise the public that a petition in proper form has been received and an antidumping investigation is being initiated for the purpose of determining whether imports of automotive and motorcycle repair manuals from the United Kingdom are being, or are likely to be, sold at less than fair value within the meaning of the Antidumping Act of 1921, as amended. There is substantial doubt that imports of the subject merchandise, allegedly at less than fair value, are the cause of present, or likely future, injury to an industry in the United States. Therefore, the case is being referred to the U.S. International Trade Commission for a determination as to whether there is no reasonable indication of injury.

EFFECTIVE DATE: August 8, 1978.

FOR FURTHER INFORMATION CONTACT:

Mary S. Clapp, Duty Assessment Division, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229, telephone 202-566-5492.

SUPPLEMENTARY INFORMATION: On June 30, 1978, a petition in proper form was received pursuant to §§ 153.26 and 153.27, customs regulations (19 CFR 153.26, 153.27), from counsel on behalf of Clymer Publications, Los Angeles, Calif., alleging that automotive and motorcycle repair manuals from the United Kingdom are being, or are are likely to be, sold at less than fair value within the meaning of the Antidumping Act of 1921, as amended (19 U.S.C. 160 et seq.) (referred to in this notice as the "Act").

Automotive and motorcycle repair manuals are books which describe maintenance and repair procedures to be followed by the reader in connection with repairs to automobiles and motorcycles. They are classified under item No. 270.25 of the Tariff Schedules of the United States, Annotated (TSUSA).

There appears to be a relationship between the exporter and a purchaser in the United States, which would require the use of exporter's sales price to establish the price of the merchandise in the U.S. market.

Margins of dumping alleged, based on a comparison of exporter's sales price with prices in the home market, range from 37 to 40 percent.

There is evidence on record concerning injury or likelihood of injury to the U.S. Industry from the alleged less-than-fair-value imports. Evidence of lost sales has been provided. The data given in the petition shows a decrease in sales of petitioner's motorcycle repair manuals, but also indicates an increase in sales of automotive repair manuals. Statements of earnings indicate no loss of total sales revenue in the last several years.

Clymer performs all the tasks related to the preparation of a book, but subcontracts the actual printing. Nonprinting costs are fixed for books with a given title; therefore, petitioner's costs of production per book decline as the number of books printed increases. The petition asserts that the lower average press run (i.e., number of books printed) for motorcycle repair manuals due to sales of the alleged less-than-fair-value imports has resulted in higher per unit produciton costs. This should lead to lower profit levels which, in fact, have been claimed by the petitioner. However, information contained in statements of earnings does not permit equal comparison for all years, and it is not evident that changes in profit figures are due to imports of the subject merchandise.

The petitioner is unable to provide information regarding market share or volume of imports on a year-by-year basis; figures that are provided for the most recent year appear to be based on conjecture. No data are presented that indicate levels of capital investment, price suppression, or margins of underselling.

Moreover, the petitioner, a small private company, has increased the number of its employees over the past several years.

On the basis of such evidence, it has been concluded that there is substantial doubt of injury or likelihood of injury to an industry in the United States by virtue of such imports from the United Kingdom. Accordingly, the U.S. International Trade Commission is being advised of such doubt pursuant to section 201(c)(2) of the Act (19 U.S.C. 160(c)(2)).

Having conducted a summary investigation as required by section 153.29 of the customs regulations (19 CFR 153.29), and having determined as a result thereof that there are grounds for so doing, the U.S. Customs Service is instituting an inquiry to verify the information submitted and to obtain the facts necessary to enable the Secretary of the Treasury to reach a determination as to the fact or likelihood of sales at less than fair value. Should the International Trade Commission, within 30 days of receipt of the information cited in the preceding

paragraph, advise the Secretary that there is no reasonable indication that an industry in the United States is being or is likely to be injured by reason of the importation of such merchandise into the United States, this investigation will be terminated. Otherwise, the investigation will continue to conclusion.

This notice is published pursuant to § 153.30 of the Customs regulations (19 CFR 153.30).

Dated: August 1, 1978.

ROBERT H. MUNDHEIM,
General Counsel of the Treasury.

[FR Doc. 78-21936 Filed 8-7-78; 8:45 am]

[4810-40]

[Public Debt Series—No. 18-78]

SERIES B-1985

Treasury Notes

AUGUST 3, 1978.

The Secretary of the Treasury announced on August 2, 1978, that the interest rate on the notes designated Series B-1985, described in Department Circular—Public Debt Series—No. 18-78, dated July 27, 1978, will be 8¼ percent. Interest on the notes will be payable at the rate of 8¼ percent per annum.

L. W. PLUMLY,
Acting Fiscal Assistant Secretary.

[FR Doc. 78-21939 Filed 8-7-78; 8:45 am]

[4810-25]

Office of the Secretary

MOTORCYCLES FROM JAPAN

Antidumping: Determination of Sales at Less Than Fair Value and Exclusion From Investigation

AGENCY: U.S. Treasury Department.

ACTION: Determination of sales at less than fair value and exclusion from investigation.

SUMMARY: This notice is to advise the public that an antidumping investigation has resulted in a determination that motorcycles from Japan are being sold at less than fair value. Sales at less than fair value generally occur when the price of merchandise for exportation to the United States is less than the price of such or similar merchandise sold in the home market or to third countries. This case is being referred to the U.S. International Trade Commission for a determination whether such sales have caused or are likely to cause injury to an industry in the United States.

EFFECTIVE DATE: August 8, 1978.

FOR FURTHER INFORMATION CONTACT:

Richard Rimilinger, U.S. Customs Service, Office of Operations, Duty Assessment Division, Technical Branch, 1301 Constitution Avenue NW., Washington, D.C. 20229, telephone 202-566-5492.

SUPPLEMENTARY INFORMATION: On June 8, 1977, information was received in proper form pursuant to sections 153.26 and 153.27, Customs regulations (19 CFR 153.26 and 153.27), indicating that motorcycles from Japan are being, or are likely to be, sold at less than fair value within the meaning of the Antidumping Act, 1921, as amended (19 U.S.C. 160 et seq.) (referred to in this notice as "the act"), this information was submitted by counsel acting on behalf of the Harley-Davidson Motor Co., Inc., s subsidiary of AMF, Inc. On the basis of this information and subsequent preliminary investigation by the Customs Service, an "Antidumping Proceeding Notice" was published in the FEDERAL REGISTER of July 15, 1977 (42 FR 36584).

Pursuant to section 201(b)(2) of the act (19 U.S.C. 160(b)(2)), notice was published in the FEDERAL REGISTER of January 20, 1978 (43 FR 3968), stating that the Secretary had concluded that the determination provided for in section 201(b)(1) of the act (19 U.S.C. 160(b)), could not reasonably be made within 6 months. The determination under section 201(b)(1) of the act (19 U.S.C. 160(b)(1)) was, therefore to be made within no more than 9 months.

A "Withholding of Appraisement Notice" was published in the FEDERAL REGISTER of April 26, 1978 (42 FR 17900-02).

For purposes of this notice, the term "motorcycles" means motorcycles having engines with total piston displacement over 90 cubic centimeters, whether for use on or off the road.

FINAL DETERMINATION OF SALES AT LESS THAN FAIR VALUE

On the basis of information developed in Customs' investigation and for the reasons noted below, I hereby determine that motorcycles from Japan, other than those produced and sold by Suzuki Motor Co,. Ltd., are being sold at less than fair value within the meaning of section 201(a) of the act (19 U.S.C. 160(a)). In the case of motorcycles from Japan produced and sold by Suzuki Motor Co., Ltd., I hereby exclude such merchandise from this determination.

STATEMENT OF REASONS ON WHICH THIS DETERMINATION IS BASED

The reasons and bases for the above final determination are as follows:

a. *Scope of the investigation.* It appears that virtually all imports of the subject merchandise from Japan were manufactured by Honda Motor Co., Ltd., Yamaha Motor Co., Ltd., Kawasaki Heavy Industries, Ltd., and Suzuki Motor Co., Ltd. Therefore, the investigation was limited to these manufacturers.

b. *Basis of comparison.* For the purpose of considering whether the merchandise in question is being, or is likely to be, sold at less than fair value within the meaning of the act, the proper basis of comparison, with the exception of one model sold by Honda Motor Co., Ltd. (the GL 1000 K2), is between exporter's sales price and the home market price of such or similar merchandise on all sales.

In the case of Honda model GL 1000 K2, the proper basis of comparison was between exporter's sales price and sales of such merchandise sold in a third country. Exporter's sales price as defined in section 204 of the act (19 U.S.C. 163) was used since sales by all four manufacturers were made to U.S. firms related to those manufacturers within the meaning of section 207 of the act (19 U.S.C. 166).

Home market price, as defined in section 153.2, Customs regulations (19 CFR 153.2), was used since such or similar merchandise, with one exception, was sold in the home market in sufficient quantities to provide a basis for fair value comparisons. Third-country sales, as defined in section 153.3, Customs regulations (19 CFR 153.3), were used for Honda model GL 1000 K2 since, upon advice of an independent technical consultant, the Treasury Department has determined that there were no sales in the Japanese home market of such or similar merchandise within the meaning of section 212(3) of the act (19 U.S.C. 171(3)).

Sales of the GL 1000 K2 to Canada were selected for fair value comparisons, since the Canadian model was virtually identical to the U.S. model and was, thus, considered to be "such or similar" within the meaning of section 212(3)(A) of the act. Accordingly, no comparisons were made under section 212(3)(B) with merchandise sold in other third countries.

In accordance with section 153.31(b), Customs regulations (19 CFR 153.31(b)), pricing information was obtained concerning imports from Japan sold in the United States during the 8-month period November 1, 1976, through June 30, 1977, and Canadian and home market sales of motorcycles during the period corresponding to the dates of export of those motorcycles sold in the United States during the above 8-month period.

c. *Exporter's sales price.* For the purposes of this determination of sales at

less than fair value, all of the merchandise was sold or agreed to be sold in the United States, before or after the time of importation, by or for the account of the exporter, within the meaning of section 207 of the act. Accordingly, the exporter's sales price was calculated based on prices to unrelated U.S. dealers with deductions for Japanese inland freight and insurance, U.S. duty, U.S. port handling, U.S. inland freight, setup and preparation, tires and tubes excise tax, direct advertising, co-op advertising, discounts, rebates, selling expenses, and sales promotion, as appropriate. An addition was made for the Japanese commodity tax incurred with respect to home market sales but not collected or rebated by reason of exportation to the United States, in accordance with section 204 of the act (19 U.S.C. 163).

After the tentative determination, information was presented indicating that respondents might have paid rebates after the investigatory period in connection with motorcycles sold during the period, in addition to the rebates disclosed to the Customs Service in the course of its investigation. Respondents were requested to supplement their responses to report any such additional rebates. Some supplementary information has been received, and taken into consideration in the calculation of exporter's sales price. A further Customs verification effort directed to the question of unreported rebates is underway. Should it reveal the existence of additional unreported rebates, this final determination of sales at less than fair value will be amended, as appropriate.

d. *Home market price.* For the purposes of this determination of sales at less than fair value, the home market prices have been calculated on the basis of the weighted-average prices to unrelated dealers. Adjustments were made for inland freight, owners' manuals, rebates, discounts, warranty costs, financing expenses, selling expenses, sales promotion, and direct advertising, with an addition for cost of export packing, as appropriate, in accordance with § 153.10, Customs regulations (19 CFR 153.10). Adjustment was made for differences in merchandise sold in the two markets, as appropriate, in accordance with section 153.11, Customs regulations (19 CFR 153.11).

(i) *Model-year adjustment.* It has been claimed by counsel for certain of the respondents that, with respect to 1974, 1975, and 1976 model-year motorcycles sold during the investigatory period, an adjustment should be made to account for the fact that these motorcycles were considered "current" when sold in Japan, where motorcycles are not marketed by model-year designations, but were not considered "current" when sold in the United States, where this merchandise is sold by model-year designation.

Counsel for petitioner has claimed that discounts given in connection with sales of certain prior model-year Japanese motorcycles are not "customary" in the U.S. market, and that such a "custom," if it existed, was established by respondents in order to sell excess inventory and was unrelated to the fact that these motorcycles were of a prior model year.

An adjustment of the type here claimed by respondents must be predicated upon a practice of discounting prior model-year motorcycles. This practice must be shown to be consistent, both as to timing of the discount to coincide with the introduction of new model-year motorcycles and as to the amount of the discount. Further, such a practice must be shown to be carried out in response to consumer perception that prior model-year motorcycles will be discounted. However, the recent introduction of such a practice or custom will not prevent its recognition.

Based on the evidence presented on the above points, it has been concluded that the adustment must be denied. The introduction of new models did not result in an automatic reduction of prices on prior models as part of the alleged custom. Older models were discounted at varying times and in varying amounts and in connection with various promotional programs unrelated to the introduction of new models. Further, when older models constitute a substantial portion of sales (in this case for some exporters from 26 to 58 percent of all sales made in the period of investigation) and, in some cases, continue to be shipped after the introduction of new models, the sales of prior model-year motorcycles may not be disregarded in assessing the exporter's sales policies.

(ii) *Valuation of "differences" in merchandise.* Section 153.11, Customs reguations (19 CFR 153.11), provides that in making comparisons between similar merchandise, due allowance shall be made for differences in the merchandise. Primarily, such allowance will be based upon differences in the cost of manufacture, including differences in the costs of materials, labor, and direct factory overhead. Counsel for petitioner has claimed that such adjustment must be made based on the costs of producing differences in the merchandise which have been previously identified. Counsel for certain of the respondents have urged that the adjustment may be determined by simply comparing the total of all costs of producing the two similar products.

It has been concluded that the methodolgy urged by the respondents may distort the adjustment by introducing cost differences totally extraneous to, and which do not result from, the objective differences in the merchandise. The adjustments for differences in the merchandise have, therefore, been based on those cost differences directly attributable to the objective differences in the merchandise.

During the extended investigatory period, information was requested concerning direct factory overhead expenses applicable to the cost of manufacture of motorcycles sold to the United States and similar merchandise sold in the home market, and if applicable, third countries. This information has been analyzed prior to the final determination and has been utilized in determining differences in cost of manufacture of similar merchandise in the two markets, under § 153.11.

(iii) *Advertising adjustment.* The withholding of appraisement notice in this case stated:

> Petitioner has claimed that advertising expenses directed to the promotion of sales of a particular motorcycle should be deducted from the price of that particular model, rather than allocated over the entire class or kind of merchandise subject to the investigation. While it has been concluded that this claim is well founded, it has not been possible to perform the necessary recalculations in time for this tentative determination. This will be done prior to the final determination.

This statement was intended to reflect the dual concepts of section 153.10(b), Customs regulations (19 CFR 153.10(b)), relating to adjustments for differences in circumstances of sale:

First: Allowable expenses under that provision must bear a direct relationship to the sales which are under consideration, and may not be items of general overhead attributable to all of a company's sales;

Second: Allowable advertising expenses under that provision must attributable to a later sale of the merchandise by a purchaser.

The concepts in section 153.10(b) have been interpreted in previous Treasury practice to mean:

1. The expense must have been incurred with respect to the particular product in question, rather than benefiting the sales of more than one product, the company's entire product line or its institutional image.

2. The expense must have been incurred with respect to the particular geographic market in question, rather than benefiting sales in all markets or markets not under consideration.

3. The expense must relate to materials or advertising media directed to purchasers in later sales; in effect, they must represent an assumption of a cost by the producer that would otherwise be borne by the customer of the producer.

In the instant case, each respondent has stated that it does not maintain records of expenditures in a way which would enable a determination of the advertising expenses incurred with respect to each model of motorcycle sold. Rather respondents' evidence establishes that funds were expended in respect of sales of "motorcycles," and then allocated by value of sales to types of motorcycles. In this case, the allocations of such expenses to models and markets made by each respondent, have been determined to be appropriate.

(iv) *Adjustment for currency value changes.* Counsel for petitioner has requested that Treasury examine whether prices of the subject merchandise have been revised to reflect fully increases in the value of the Japanese yen during the time subsequent to the conclusion of the investigatory period, i.e., June 30, 1977. It is not normally possible, nor generally is it Treasury policy, to examine pricing behavior subsequent to the investigatory period, other than in the context of considering a request for a discontinuance of investigation under § 153.33, Customs regulations (19 CFR 153.33). Under that section, an investigation may be discontinued if no more than "minimal" margins are found, if assurances of no further sales at less than fair value are received, and if the exporter has, in fact, revised prices so as to eliminate sales at less than fair value. None of the three companies, with respect to which sales at less than fair value in more than a de minimis amount have been found, have margins which would be considered "minimal" under existing Treasury practice. Should, however, information be received which would necessitate a revision of the findings of margins set forth in this notice to a level considered minimal, it will be necessary, in view of the significant change in the value of the yen since June 1977, to scrutinize closely the evidence submitted by respondents of the current pricing in the two relevant markets.

e. *Third-country sales.* During our extended investigatory period, additional information was obtained in connection with the comparability of merchandise sold to the United States with that sold in the home market. This information has been reviewed and analyzed by a special consultant selected by the U.S. Customs Service for this purpose. As a result of his analyses, the determination was made that there were no sales of motorcycles in the home market which were considered to be "such or similar" to Honda model GL 1000 K2 within the meaning of section 212(3) of the act. Therefore, third-country sales of this model were examined.

Since the GL 1000 K2 sold to Canada was virtually identical to the U.S. model, Canadian sales information was obtained and verified. For the purposes of this determination of sales at less than fair value, third-country sales price has been calculated on the weighted-average prices to unrelated Canadian dealers. Adjustments were made for: Japanese inland freight, intransit storage costs, Japanese brokerage and handling, ocean freight, marine insurance, Canadian duty, Canadian customs brokerage, Canadian inland freight, Canadian harbor charges, Canadian local delivery and miscellaneous charges, Canadian Federal sales and excise taxes, cash and early payment discounts, and an offset to U.S. selling expenses deducted from exporter's sales price. Also, an adjustment was made for a de minimis difference in the merchandise sold in the two markets, in accordance with § 153.11, Customs regulations (19 CFR 153.11). However, so minor an adjustment on a product of such value does not prevent the consideration of the merchandise under section 212(3)(A) of the act and obviates the need to consider merchandise in other countries under section 212(3)(B).

f. *Result of fair value comparisons.* Using the above criteria, exporter's sales price was found to be lower than the home market and third-country price of such or similar merchandise. Comparisons were made on approximately 90 percent of the total sales of the subject merchandise to the United States by all manufacturers investigated for the period under investigation. Margins were found on approximately 18.8 percent of the sales ranging from 0.9 to 54 percent resulting in a weighted-average margin of 2.59 percent on all sales compared. Weighted-average margins found with respect to the companies under investigation, computed over all sales compared, were as follows: Honda, 2.9 percent; Kawasaki, 7.26 percent; Yamaha, 1.9 percent; and Suzuki, 0.28 percent.

In the case of Suzuki, the weighted-average margin is considered to be de minimis.

The Secretary has provided an opportunity to known interested persons to present written and oral views pursuant to § 153.40, Customs regulations (19 CFR 153.40).

The U.S. International Trade Commission is being advised of this determination.

The order issued April 26, 1978, to withhold appraisement on the subject merchandise from Japan, the notice of which is cited above, is hereby terminated with respect to Suzuki, effective August 8, 1978.

This determination is being published pursuant to section 201(d) of the act (19 U.S.C. 160(d)).

Dated: August 3, 1978.

ROBERT H. MUNDHEIM,
General Counsel of the Treasury.

[FR Doc 78-21995 Filed 8-7-78; 8:45 am]

[7035-01]

INTERSTATE COMMERCE COMMISSION

[Decision Volume No. 14]

DECISION-NOTICE

JULY 21, 1978.

The following applications are governed by special rule 247 of the Commission's rules of practice (49 CFR 1100.247). These rules provide, among other things, that a protest to the granting of an application must be filed with the Commission within 30 days after the date notice of the application is published in the FEDERAL REGISTER. Failure to file a protest, within 30 days, will be considered as a waiver of opposition to the application. A protest under these rules should comply with rule 247(e)(3) of the rules of practice which requires that it set forth specifically the grounds upon which it is made, contain a detailed statement of protestant's interest in the proceeding (as specifically noted below), and shall specify with particularity the facts, matters, and things relied upon, but shall not include issues or allegations phrased generally. A protestant should include a copy of the specific portions of its authority which protestant believes to be in conflict with that sought in the application, and describe in detail the method—whether by joinder, interline, or other means—by which protestant would use such authority to provide all or part of the service proposed. Protests not in reasonable compliance with the requirements of the rules may be rejected. The original and one copy of the protest shall be filed with the Commission, and a copy shall be served concurrently upon applicant's representative, or upon applicant if no representative is named. If the protest includes a request for oral hearing, such request shall meet the requirements of section 247(e)(4) of the special rules and shall include the certification required in that section.

Section 247(f) provides, in part, that an applicant which does not intend timely to prosecute its application shall promptly request that it be dismissed, and that failure to prosecute an application under the procedures of the Commission will result in its dismissal.

Further processing steps will be by Commission notice, decision, or letter which will be served on each party of record. Broadening amendments will

not be accepted after the date of this publication.

Any authority granted may reflect administratively acceptable restrictive amendments to the service proposed below. Some of the applications may have been modified to conform to the Commission's policy of simplifying grants of operating authority.

We find: With the exceptions of those applications involving duly noted problems (e.g., unresolved common control, unresolved fitness questions, and jurisdictional problems) we find, preliminarily, that each common carrier applicant has demonstrated that its (his) proposed service is required by the public convenience and necessity, and that each contract carrier applicant qualifies as a contract carrier and its (his) proposed contract carrier service will be consistent with the public interest and the national transportation policy. We also find prelimarily that each applicant is fit, willing, and able properly to perform the service proposed and to conform to the requirements of the Interstate Commerce Act and the Commission's regulations. This decision is not a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969.

It is ordered: In the absence of legally sufficient protests, filed within 30 days of publication of this decision-notice (or, if the application later becomes unopposed) appropriate authority will be issued to each applicant (except those with duly noted problems) upon compliance with certain requirements which will be set forth in a notification of effectiveness of this decision-notice. To the extent that the authority sought below may duplicate an applicant's existing authority, such duplication shall not be construed as conferring more than a single duplication operating right.

By the Commission, Review Board No. 2, Members: Eaton, Liberman, Board Member Boyle not participating.

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

MC 1263 (Sub-28F), filed June 5, 1978. Applicant: McCARTY TRUCK LINE, INC., 17th and Harris Avenue, Trenton, MO 64683. Representative: Michael J. Wyngaard, 150 East Gilman Street, Madison, WI 57303. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Containers, container closures, container ends and container accessories*, and (2) *materials and supplies used in the manufacture, sale, and distribution of the commodities named in (1) above*, (a) from Mount Vernon and St. Joseph, MO, to points in WI, MN, IA, IL, IN, OH, TN, KY, MS, TX, AL, and AR, (b) from Mansfield, TX, to points in MS, IL, TN, AR, WI, IA, MO, and MN, and (c) from Waupun, Oconomowoc, and Menomonee Falls, WI, to points in IL, TN, KY, MO, OH, IN, IA, TX, MI, and MN. (Hearing site: Madison or Milwaukee, WI.)

MC 1824 (Sub-82F), filed June 5, 1978. Applicant: PRESTON TRUCKING CO., INC., 151 Easton Boulevard, Preston, MD 21655. Representative: Charles S. Perry, (address same as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Animal feed, feed ingredients, additives*, and *materials and supplies used in the manufacture and distribution of animal feeds* (except commodities in bulk), between the facilities of Kal Kan Foods, Inc., at or near Mattoon, IL, on the one hand, and, on the other, points in CT, DE, IN, KY, MA, MD, ME, MI, NC, NH, NJ, NY, OH, PA, RI, TN, VA, VT, WI, and WV, restricted to the transportation of traffic originating at or destined to the facilities of Kal Kan Foods, Inc., at or near Mattoon, IL. (Hearing site: Washington, DC.)

MC 2368 (Sub-78F), filed June 7, 1978. Applicant: BRALLEY-WILLETT TANK LINES, INC., 2212 Deepwater Terminal Road, P.O. Box 495, Richmond, VA 23204. Representative: Steven L. Weiman, Suite 145, 4 Professional Drive, Gaithersburg, MD 20760. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Soy bean meal*, in bulk, from the facilities of Cargill, Inc., at or near Sidney, OH, to points in MD, NC, PA, VA, and WV. (Hearing site: Washington, DC.)

MC 2392 (Sub-114F), filed June 2, 1978. Applicant: WHEELER TRANSPORT SERVICE, INC., 7722 F Street, Omaha, NE 68127. Representative: Leonard A. Jaskiewicz, 1730 M Street NW., Suite 501, Washington, D.C. 20036. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid fertilizer solutions*, in bulk, in tank vehicles, from Blair, NE, to points in IA, MN, ND, SD, WI, and IL. (Hearing site: Omaha, NE.)

MC 5888 (Sub-45F), filed June 19, 1978. Applicant: MID-AMERICAN LINES, INC., 127 West 10th Street, 11th Floor, Kansas City, MO 64105. Representative: Louis A. Hoger (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Fiberglass materials and products*, and *plastic materials and products*, and (2) *materials, equipment, and supplies* used in the installation, manufacture, and packaging of the commodities in (1) above, between points in Franklin and Licking Counties, OH, on the one hand, and, on the other, points in IL, IA, KS, MN, MO, ND, NE, SD, WI, and those in the Upper Peninsula of MI. (Hearing site: Kansas City, MO, or Washington, DC.)

MC 27719 (Sub-7F), filed June 12, 1978. Applicant: HAYES TRUCK LINES, INC., 1701 Bay Street, Tacoma, WA 98401. Representative: Jack R. Davis, 1100 IBM Building, Seattle, WA 98101. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Cellulose fiber mats*, from the facilities of Reichhold Chemicals, at or near Tacoma, WA, to points in WA, OR, and ID. (Hearing site: Tacoma, WA.)

MC 30383 (Sub-16F), filed May 18, 1978. Applicant: JOSEPH F. WHELAN CO., INC., 439 West 54th Street, New York, NY 10019. Representative: Arthur Liberstein, P.O. Box 1409, 167 Fairfield Road, Fairfield, NJ 07006. Authority granted to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Soap, soap products, stearic acid, vegetable stearine, glycerine, oils, cooking fats, cleaning and washing compounds, lard substitutes, toilet preparations, containers, and such commodities as are dealt in by retail food stores* (except commodities in bulk), between New York, NY, on the one hand, and, on the other, points in Monmouth, Mercer, Middlesex, Somerset, Union, Essex, Passaic, Bergen, Morris, and Hudson Counties, NJ, and points in Nassau, Suffolk, Westchester, and Rockland Counties, NY, under continuing contract(s) with Procter & Gamble Manufacturing Co. and Procter & Gamble Distributing Co. (Hearing site: NY.)

MC 30383 (Sub-17F), filed May 24, 1978. Applicant: JOSEPH F. WHELAN CO., INC., 439 West 54th Street, New York, NY 10019. Representative: Arthur Liberstein, P.O. Box 1409, 167 Fairfield Road, Fairfield, NJ 07006. Authority granted to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Soap, soap products, stearic acid, vegetable stearine, glycerine, oils, cooking fats, cleaning and washing compounds, lard substitutes, toilet preparations, containers, and such commodities as are dealt in by retail food stores* (except commodities in bulk), from the facilities of Procter & Gamble Manufacturing Co., at or near Carteret, NJ, to points in Bergen, Essex, Hudson, Mercer, Middlesex, Monmouth, Morris, Passaic, Somerset, and Union Counties, NJ, Nassau, Rockland, Suffolk, and Westchester Counties and New York City, NY, and the facilities of First National Stores, at or

near Windsor Locks, CT, under continuing contract(s) with Procter & Gamble Manufacturing Co. and Procter & Gamble Distributing Co., (Hearing site: New York, NY.)

MC 31389 (Sub-250F), filed June 16, 1978. Applicant: McLEAN TRUCKING CO., a corporation, 617 Waughtown Street, Winston-Salem, NC 27107. Representative: David F. Eshelman, P.O. Box 213, Winston-Salem, NC 27102. Authority granted to operate as a *common carrier*, by motor vehicle, transporting: *General commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Liquid Paper Corp., at or near Greenville, TX, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Dallas, TX or Washington, DC.)

MC 31389 (Sub-251F), filed June 16, 1978. Applicant: McLEAN TRUCKING CO., a corporation, 617 Waughtown Street, Winston-Salem, NC 27107. Representative: David F. Eshelman, P.O. Box 213, Winston-Salem, NC 27102. Authority granted to operate as a *comon carrier*, by motor vehicle, transporting: *General commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of the Brown Printing Co., at or near East Greenville, PA, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: St. Paul, MN or Washington, DC.)

MC 32882 (Sub-94F), filed June 8, 1978. Applicant: MITCHELL BROS. TRUCK LINES, a corporation, 3841 North Columbia Boulevard, Portland, OR 97217. Representative: Lex F. Page, P.O. Box 17039, Portland, OR 97217. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Signs*, and *materials, equipment and supplies* used in the manufacture and erection of signs (except commodities in bulk), (1) from Salt Lake City and Ogden, UT, Las Vegas and Reno, NV, and Phoenix, AZ, to points in AZ, CA, CO, ID, MT, NV, OR, UT, WA, and WY, and (2) from points in AZ, CA, ID, OR, and WA, to Salt Lake City and Ogden, UT, Las Vegas and Reno, NV, and Phoenix, AZ. (Hearing site: Salt Lake City, UT, Portland, OR, or Los Angeles, CA.)

MC 35628 (Sub-401F), filed June 16, 1978. Applicant: INTERSTATE MOTOR FREIGHT SYSTEM, a corporation, 134 Grandville Avenue SW., Grand Rapids, MI 49503. Representative: Michael P. Zell, 134 Granville Avenue SW., Grand Rapids, MI 49503. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meats, meat products, and meat byproducts, and articles distributed by meat-packing houses*, as described in sections A and C of appendix I to the report in Descriptions in Motor Carrier Certificates, 61 MCC 209 and 766, (except hides and commodities in bulk), from Nebraska City, NE, to points in CT, DE, IL, IN, IA, KS, KY, ME, MD, MA, MI, MN, MO, NH, NJ, NY, OH, PA, RI, VT, VA, WV, WI, and DC, restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Kansas City or Wichita, KS.)

MC 61403 (Sub-254F), filed May 24, 1978. Applicant: THE MASON & DIXON TANK LINES, INC., Highway 11-W, P.O. Box 969, Kingsport, TN 37662. Representative: W. C. Mitchell, Suite 1201, 370 Lexington Avenue, New York, NY 10017. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Flammable solvents*, in bulk, in tank vehicles, from the facilities of Inland Chemical Corp., in Henry County, KY, to points in AL, AR, DE, FL, GA, IL, IN, IO, KS, LA, MD, MI, MN, MO, NJ, NY, NC, OH, OK, PA, SC, TN, TX, VA, WV, WI, and DC; and (2) *contaminated flammable solvents*, in bulk, in tank vehicles, from the destinations named in (1) above to the facilities of Inland Chemical Corp., in Henry County, KY. (Hearing site: Louisville, KY.)

MC 63417 (Sub-156F), filed June 8, 1978. Applicant: BLUE RIDGE TRANSFER CO., INC., P.O. Box 13447, Roanoke, VA 24034. Representative: William E. Bain (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Mineral fiber, mineral fiber products, insulating materials, and air filters*, from the facilities of the United States Gypsum Co., at Wabash, IN, to points in AL, AR, CT, DE, FL, GA, KY, LA, MA, ME, MD, MS, NH, NC, NY, NJ, OH, OK, PA, RI, SC, TN, TX, VA, VT, WV, and DC. (Hearing site: Roanoke, VA, or Chicago, IL.)

MC 83539 (Sub-499F), filed June 12, 1978. Applicant: C & H TRANSPORTATION CO., INC., P.O. Box 270535, Dallas, TX 75227. Representative: Thomas E. James (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle over irregular routes, transporting: *Construction equipment, materials, and supplies* (except commodities in bulk), and *self-propelled vehicles*, between Sacramento, CA, and Council Bluffs, IA, on the one hand, and, on the other, points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Wismer and Becker Contracting Engineers, at Sacramento, CA or Council Bluffs, IA. (Hearing site: San Francisco, CA or Dallas, TX.)

MC 107064 (Sub-126F), filed May 25, 1978. Applicant: STEERE TANK LINES, INC., Post Office Box 2998, Dallas, TX 75221. Representative: Hugh T. Matthews, 2340 Fidelity Union Tower, Dallas, TX 75201. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum, petroleum products*, and *chemicals*, in bulk, between the plantsite of Calgon Corp., at or near Pasadena, TX, on the one hand, and, on the other, points in the United States (except TX, AK, and HI). Hearing site: Dallas, TX.)

MC 108973 (Sub-15F), filed June 5, 1978. Applicant: INTERSTATE EXPRESS, INC., 2334 University Avenue, St. Paul, MN 55114. Representative: Joseph J. Dudley, W-1260 First National Bank Building, St. Paul, MN 55101. Authority granted to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Paper and paper products*, from the facilities of Champion International Corp., at or near Ontonagon, MI, to those points in the United States in and east of ND, SD, NE, KS, OK, and TX (except MI); and (2) *materials, equipment, and supplies used in the manufacture and distribution of paper and paper products* (except commodities in bulk), from points in the United States in and east of ND, SD, NE, KS, OK, and TX, to the facilities of Champion International Corp., at or near Ontonagon, MI, under a continuing contract, or contracts, with Champion International Corp., of Hamilton, OH. (Hearing site: Ontonagon, MI, or St. Paul, MN.)

MC 109708 (Sub-85F), filed June 20, 1978. Applicant: INDIAN RIVER TRANSPORT CO., d.b.a. INDIAN RIVER TRANSPORT, INC., P.O. Box AG, Dundee, FL 33838. Representative: Bruce A. Bullock, Suite 610, 7171 Mercy Road, Omaha, NE 68106. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Alcoholic liquors*, in bulk, in tank vehicles, (1) from ports of entry on the international boundary line between the United States and Canada located in MI, to Silverton, OH, in foreign commerce only, restricted to the transportation of traffic originating at Montreal, Quebec, Canada, and (2) from Silverton, OH, to Scobeyville, NJ, and Detroit, MI. Condition: Prior receipt

from applicant of an affidavit setting forth its complementary Canadian authority or explaining why no such Canadian authority is necessary. (Hearing site: Chicago, IL, or St. Louis, MO.)

NOTE.—The restriction and conditions contained in the grant of authority in this proceeding are phrased in accordance with the policy statement entitled Notice to Interested Parties of New Requirements Concerning Applications for Operating Authority to Handle Traffic to and from points in Canada published in the FEDERAL REGISTER on December 5, 1974, and supplemented on November 18, 1975. The Commission is presently considering whether the policy statement should be modified, and is in communication with appropriate officials of the Provinces of Alberta, Saskatchewan, and Manitoba regarding this issue. If the policy statement is changed, appropriate notice will appear in the FEDERAL REGISTER and the Commission will consider all restrictions or conditions which were imposed pursuant to the prior policy statement, regardless of when the condition or restriction was imposed, as being null and void and having no force or effect.

MC 109818 (Sub-25F), filed June 16, 1978. Applicant: WENGER TRUCK LINE, INC., P.O. Box 3427, Davenport, IA 52804. Representative: Larry D Knox, 600 Hubbell Building, Des Moines, IA 50309. Authority Granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Malt beverages*, from points in Jefferson County, CO, to points in IA; and (2) *scrap materials for recycling*, from points in IA, to points in Jefferson County, CO. (Hearing site; Denver, CO, or Kansas City, MO.)

MC 111812 (Sub-573F), filed June 5, 1978. Applicant: MIDWEST COAST TRANSPORT, INC., P.O. Box 1233, Sioux Falls, SD 57101. Representative: Ralph H. Jinks (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Vinyl, ring metals, and chipboard*, from Winchester, VA, New Bedford, MA, Toledo, OH, Chicago, IL, and Burlington, NJ, to Edgerton, MN. (Hearing site: Minneapolis, MN.)

MC 111812 (Sub-575F), filed June 8, 1978. Applicant: MIDWEST TRANSPORT, INC., P.O. Box 1233, Sioux Falls, SD 57101. Representative: David Peterson (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Such commodities* as are dealt in by manufacturers of personal health care and beauty aids products from Teterboro and Englewood, NJ, to Dallas, TX, Chicago, IL, Brisbane, CA, Lawrence, KS, Sparks, NV, and Fort Wayne, IN. (Hearing site: Washington, DC.)

MC 111812 (Sub-576F), filed June 12, 1978. Applicant: MIDWEST COAST TRANSPORT, INC., P.O. Box 1233, Sioux Falls, SD 57101. Representative: Ralph H. Jinks (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Printed matter*, between Waseca, MN, on the one hand, and, on the other, points in AZ, CA, CO, CT, DE, FL, GA, ID, ME, MD, MA, MT, NV, NH, NJ, NM, NY, NC, OH, OR, PA, RI, SC, UT, VT, VA, WA, WV, WY, and DC; and (2) *Materials, equipment, and supplies* used in the manufacture of printed matter (except commodities in bulk and those requiring special equipment), from points in AZ, CA, CO, CT, DE, FL, GA, ID, ME, MD, MA, MT, NV, NH, NJ, NM, NY, NC, OH, OR, PA, RI, SC, UT, VT, VA, WA, WV, WY, and DC, to Waseca, MN. (Hearing site: St. Paul, MN.)

MC 112627 (Sub-29F), filed June 8, 1978. Applicant: OWENS BROS., INC., P.O. Box 247, Dansville, NY 14437. Representative: S. Michael Richards, 44 North Ave., P.O. Box 225, Webster, NY 14580. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Salt and salt products* (except commodities in bulk), from St. Clair, MI, to those points in NY on and west of Interstate Hwy 87. (Hearing site: Detroit, MI, or Buffalo, NY.)

MC 112713 (Sub-215F), filed May 31, 1978. Applicant: YELLOW FREIGHT SYSTEM, INC., P.O. Box 7270, Shawnee Mission, KS 66207. Representative: John M. Records (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *General Commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between Enid and Tulsa, OK, over U.S. Hwy 64, as an alternate route for operating convenience only, serving no intermediate points. (Hearing site: Kansas City, MO, or Washington, DC.)

MC 112822 (Sub-456F), filed June 8, 1978. Applicant: BRAY LINES INC., 1401 North Little Street, P.O. Box 1191, Cushing, OK 74023. Representative: Edward T. Lyons, Jr., 1600 Lincoln Center Building, 1660 Lincoln Street, Denver, CO 80264. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Photographic materials, equipment, and supplies*, from the facilities of Eastman Kodak Co., at or near Windsor, CO, to the facilities of Eastman Kodak Co., at or near Chamblee, GA. (Hearing site: Denver, CO.)

MC 112893 (Sub-52F), filed June 1, 1978. Applicant BULK TRANSPORT CO., a corporation P.O. Box 186, Pleasant Prairie, WI 53518. Representative: John R. Sims, Jr., 915 Pennsylvania Building, 425—13th Street NW., Washington, D.C. 20004. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum and petroleum products*, in bulk, in tank vehicles, between Pewaukee, WI, on the one hand, and on the other, points in IL, IN, IA, KS, KY, MI, MN, MO, NE, ND, OH, PA, and WV. (Hearing site: Chicago, IL.)

MC 113475 (Sub-28F), filed June 15, 1978. Applicant: RAWLINGS TRUCK LINE, INC., Emporia, VA 23847. Representative: Harry J. Jordan, 1000—16th Street NW., Washington, D.C. 20036. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber*, from points in Prince Georges, Charles, Calvert, and St. Marys Counties, MD, to points in VA and NC. (Hearing site: Washington, DC or Richmond, VA.)

MC 114015 (Sub-25F), filed June 8, 1978. Applicant: HUSS, INC., Highway 47 West, P.O. Box 666, Chase City, VA 23924. Representative: Morton E. Kiel, Suite 6193, 5 World Trade Center, New York, NY 10048. Authority granted to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *General commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between those points in the United States in and east of MN, IA, MO, AR, and LA, under continuing contract(s) with Gypsum Co., of Chicago, IL. (Hearing site: Chicago,IL.)

MC 114457 (Sub-395F), filed June 9, 1978. Applicant: DART TRANSIT CO., a corporation, 2102 University Avenue, St. Paul, MN 55114. Representative: James H. Wills (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *water heaters*, between Middleville, MI, Nashville, TN, and Red Granite, WI, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Memphis, TN or St. Paul, MN.)

MC 114457 (Sub-402F), filed June 5, 1978. Applicant: DART TRANSIT CO., a corporation, 2102 University Avenue, St. Paul, MN 55114. Representative: James C. Hardman, Suite 2108, 33 North LaSalle Street, Chicago, IL 60602. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Plastic containers*, from Baltimore, MD, Burlington, WI, Cleveland,

Lima, and Springdale, OH, Elk Grove Village, IL, Houston, TX, Lenexa, KS, and Milltown and New Market, NJ, to those points in the United States in and east of ND, SD, NE, KS, OK, and TX. (Hearing site: Hartford, CT or St. Paul, MN.)

MC 114552 (Sub-166F), filed June 9, 1978. Applicant: SEEN TRUCKING CO., a corporation, P.O. Drawer 220, Newberry, SC 29108. Representative: William P. Jackson, Jr., 3426 N. Washington Boulevard, P.O. Box 1240, Arlington, VA 22210. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Iron and steel articles* (1) from facilities of Jones and Laughlin Steel Corp., at or near Cleveland, OH, to points in AR, KY, and TN, and (2) from the facilities of Jones and Laughlin Steel Corp., at or near Pittsburgh and Aliquippa, PA, to points in VA, NC, SC, GA, FL, AL, MS, AR, LA, OK, TX, and TN. (Hearing site: Washington, DC.)

MC 114632 (Sub-167F), filed June 8, 1978. Applicant: APPLE LINES, INC., P.O. Box 287, Madison, SD 57042. Representative: Michael L. Carter (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meats, meat products, and meat byproducts, dairy products, and articles distributed by meatpacking houses*, as described in sections A, B, and C of appendix I to the report in Descriptions in Motor Carrier Certificates, 61 MCC 209 and 766 (except hides and commodities in bulk) (1) from the facilities of John Morrell & Co., at or near (a) Estherville, Sioux City, and Humboldt. IA; (b) St. Paul, Mn, and (c) Sioux Falls, SD, to points in CT, DE, ME, MA, MD, NH, NJ, NY, PA, RI, VT, VA, WV, and DC and (2) from the facilities of John Morrell & Co., at or near (a) Sioux Falls, SD, and (b) Estherville, IA, to points in WI, restricted to the transportation of traffic originating at the named origin facilities and destined to the indicated destinations. (Hearing site: Chicago, IL or Minneapolis, MN.)

NOTE.—Dual operations are involved.

MC 114632 (Sub-168F), filed June 7, 1978. Applicant: APPLE LINES, INC., P.O. Box 287, Madison, SD 57042. Representative: Michael L. Carter (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meats, meat products, and meat byproducts, and articles distributed by meatpacking houses*, as described in sections A, and C of appendix I to the report in Descriptions in Motor Carrier Certificates, 61 MCC 209 and 766 (except hides and commodities in bulk), from the facilities of John Morrell & Co., at or near Fort Smith, AR, to points in IL, IN, MI, OH, and WI, restricted to the transportation of traffic originating at the named origin facilities and destined to the indicated destinations. (Hearing site: Chicago, IL.)

NOTE.—Dual operations are involved.

MC 115357 (Sub-9F), filed June 9, 1978. Applicant: TAT, a corporation, 800 Wyoming Street, Kansas City, MO. Representative: Marvin Handler, 100 Pine Street, Suite 2550, San Francisco, CA 94111. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Automobiles*, in secondary movements, in truckaway service, between Houston, TX, on the one hand, and, on the other, points in CO, IA, KS, NE, and OK. (Hearing site: San Francisco, CA or Kansas City, MO.)

NOTE.—The person or persons which appear to be engaged in common control must either file an application under Section 5(2) of The Interstate Commerce Act or submit and affidavit indicating why such approval is unnecessary.

MC 115603 (Sub-14F), filed June 5, 1978. Applicant: TURNER BROS. TRUCKING CO., INC., P.O. Box 94626, Oklahoma City, OK 73109. Representative: J. Michael Alexander, 136 Wynnewood Professional Building, Dallas, TX 75224. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Bentonite clay and lignite coal* (except commodities in bulk), from points in Crook County, WY, and Phillips County, MT, to points in the United States (except AK and HI), restricted to the transportation of traffic originating at the facilities of American Colloid Co., in Crook County, WY, and Phillips County, MT. (Hearing site: San Francisco, CA or Denver, CO.)

MC 115826 (Sub-320F), filed June 13, 1978. Applicant: W. J. DIGBY, INC., 1960-31st Street, Denver, CO 80217. Representative: Howard Gore (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meats, meat products, and meat byproducts*, and *articles distributed by meat-packing houses*, as described in sections A and C of appendix I to the report in Descriptions in Motor Carrier Certificates, 61 MCC 209 and 766, from points in KS, MO, IA, and NE, to points in AZ, CA, CO, ID, MT, MN, UT, OR, WA, and WY. (Hearing site: Denver, CO.)

MC 116763 (Sub-418F), filed June 5, 1978. Applicant: CARL SUBLER TRUCKING, INC., North West Street, Versailles, OH 45380. Representative: H. M. Richters (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Such commodities as are dealt in or used by manufacturers and converters of paper and paper products* (except commodities which because of size or weight require the use of special equipment), from the facilities of Georgia-Pacific Corp., at or near Gary, IN, to points in OH, PA, DE, MD, NJ, NY, TN, VA, WV, CT, MA, NH, VT, RI, ME, KY, MI, WI, and DC. (Hearing site: Boston, MA.)

MC 117119 (Sub-696F), filed June 19, 1978. Applicant: WILLIS SHAW FROZEN EXPRESS, INC., P.O. Box 188, Elm Springs, AR 72728. Representative: L. M. McLean (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Frozen foods*, (except in bulk), from the facilities of Chef Pierre, Inc., at or near Forest, MS, to points in AZ, CA, CO, ID, KS, MI, MT, NE, NV, ND, OK, OR, SD, TX, UT, WA, and WY. (Hearing site: Chicago, IL.)

MC 117613 (Sub-26F), filed June 2, 1978. Applicant: D. M. BOWMAN, INC., Route 2, Box 43A1, Williamsport, MD 21795. Representative: Edward N. Button, 1329 Pennsylvania Avenue, P.O. Box 1417, Hagerstown, MD 21740. Authority granted to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Waste oils*, (a) from points in MD, DE, WV, VA, NJ, and DC, to Coraopolis, PA, and (b) from points in MD, DE, WV, VA, and DC, to Clayton, NJ; and (2) *reclaimed oils*, from Coraopolis, PA, to points in MD, DE, WV, VA, NJ, and DC, under continuing contract(s) with Wiseman Oil Corp., of Pittsburgh, PA. (Hearing site: DC.)

NOTE.—Dual operations are involved.

MC 118159 (Sub-268F), filed June 14, 1978. Applicant: NATIONAL REFRIGERATED TRANSPORT, INC., P.O. Box 51366, Dawson Station, Tulsa, OK 74151. Representative: Warren Troupe, 2480 E. Commercial Boulevard, Fort Lauderdale, FL 33308. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Plastic articles and plastic materials* (except commodities in bulk), and (2) *equipment and supplies* used in the manufacture and distribution of the commodities named in (1) above (except commodities in bulk), between the facilities of Mobil Chemical Co., Plastics Division, in Newton, Fulton, DeKalb and Rockdale Counties, GA, on the one hand, and, on the other, points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the named facilities. (Hearing site: Chicago, IL.)

MC 119422 (Sub-62F), filed June 7, 1978. Applicant: EE JAY MOTOR

TRANSPORTS, INC., 15th and Lincoln Streets, East St. Louis, IL 62204. Representative: Ernest A. Brooks II, 1301 Ambassador Building, 411 North 7th Street, St. Louis, MO 63101. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Plastic pellets*, in bulk, in tank vehicles, from the facilities of East St. Louis Terminal & Storage Co., at East St. Louis, IL, to points in MO, IN, IA, KS, KY, OH, AR, TN, NE, MI, WI, and MN, restricted to the transportation of traffic having an immediately prior movement by rail. (Hearing site: St. Louis, MO or Springfield, IL.)

MC 119493 (Sub-205F), filed May 24, 1978. Applicant: MONKEM CO., INC., P.O. Box 1196, Joplin, MO 64801. Representative: Lawrence F. Kloeppel (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehcle, over irregular routes, transporting: (1) *Flour, corn meal, and grits*, from Buhler and Inman, KS, to points in CT, DE, IA, KS, ME, MD, MA, MI, MN, NE, NH, NJ, NY, ND, OH, OK, PA, RI, SD, VT, WI, and DC, and (2) *flour*, from McPherson, KS, to points in CT, DE, IA, KS, ME, MD, MA, MI, MN, NE, NH, NJ, NY, ND, OH, OK, PA, RI, SD, VT, WI, and DC. (Hearing site: Springfield or Kansas City, MO.)

MC 119493 (Sub-210F), filed June 2, 1978. Applicant: MONKEM CO., INC., P.O. Box 1196, Joplin, MO 64801. Representative: Lawrence F. Kloeppel (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Feed and feed ingredients, animal and poultry medicinal health products, and pesticides*, from Kansas City, MO, to points in AL, CT, DE, FL, GA, MD, MA, ME, MN, NJ, NY, NH, NC, ND, RI, SC, SD, VA, VT, WV, and DC; (2) *animal and poultry medicinal health products, and pesticides*, from Kansas City, MO, to points in AR, IL, IA, KS, LA, MS, MO, NE, OK, TN, and TX; (3) *materials and supplies* used in the manufacture and distribution of the commodities named in (1) and (2) above, from the named destinations in (1) and (2) above, to Kansas City, MO; and (4) *feed and feed ingredients, and materials and supplies used in the manufacture of feed and feed ingredients*, between Kansas City, MO, and points in AL, AR, IN, KY, LA, MI, MN, OK, TN, and WI. (Hearing site: Kansas City or Joplin, MO.)

MC 119654 (Sub-43F), filed June 9, 1978. Applicant: HI-WAY DISPATCH, INC., 1401 West 26th Street, Marion, IN 46952. Representative: Norman R. Garvin, 1301 Merchants Plaza, Indianapolis, IN 46204. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Mufflers, tail and exhaust pipes, and shock absorbers*, and (2) *clamps, bolts, and brackets* for the commodities named in (1) above, from Chicago, IL, to points in OH. (Hearing site: Indianapolis, IN or Chicago, IL.)

MC 119702 (Sub-61F), filed June 12, 1978. Applicant: STAHLY CARTAGE CO., a corporation, 119 South Main Street, P.O. Box 486, Edwardsville, IL 62025. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street NW., Washington, DC 20001. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles, from forsyth, IL, to points in IN and KY. (Hearing site: St. Louis, MO or DC.)

MC 119702 (Sub-62F), filed June 12, 1978. Applicant: STAHLY CARTAGE CO., a corporation, 119 South Main Street, P.O. Box 486, Edwardsville, IL 62025. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street NW., Washington, DC 20001. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Inedible tallow*, in bulk, in tank vehicles, from Mason City, IL, to points in IN and MO. (Hearing site: St. Louis, MO or DC.)

MC 119988 (Sub-147F), filed June 19, 1978. Applicant: GREAT WESTERN TRUCKING CO., INC., Highway 103 East, P.O. Box 1384, Lufkin, TX 75901. Representative: Paul D. Angenend, P.O. Box 2207, 1806 Rio Grande, Austin, TX 78768. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Leonardite* (except in bulk), from points in Brewster County, TX, to points in LA and OK. (Hearing site: Dallas, TX or Washington, DC.)

MC 123263 (Sub-9F), filed June 6, 1978. Applicant: FLOYD R. WANGERIN AND LORAINE C. WANGERIN, a partnership, d.b.a. WANGERIN TRUCKING CO., Rural Route No. 2, Stephenson, MI 49887. Representative: Michael S. Varda, 121 South Pinckney Street, Madison, WI 53703. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Animal mineral feed*, from the facilities of Bullard Feed Co., at Chicago, IL, to Fond du Lac, WI, Milford, IN, Lansing, MI, and points in the Upper Penninsula of MI; (2) *dry animal and poultry feeds*, in bags, from Clinton, IA, to points in WI and the Upper Penninsula of MI; and (3) *laboratory feed products*, from Richmond, IN, to Arlington Heights, IL. (Hearing site: Milwaukee, WI or Chicago, IL.)

MC 123407 (Sub-461F), filed June 8, 1978. Applicant: SAWYER TRANSPORT, INC., South Haven Square, U.S. Highway 6, Valparaiso, IN 46383 Representative: H. E. Miller, Jr., (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Flat glass*, from the facilities of C-E Glass Combustion Engineering, Inc., at or near St. Louis, MO, to points in the United States (except AK and HI). (Hearing site: Washington, DC.)

MC 123407 (Sub-463F), filed June 6, 1978. Applicant: SAWYER TRANSPORT, INC., South Haven Square, U.S. Highway 6, Valparaiso, IN 46383. Representative: H. E. Miller, Jr. (Same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporating: *Plastic articles and materials* (except commodities in bulk), from Bremen, IN, to points in the United States (except AK, HI, and IN). (Hearing site: Chicago, IL.)

MC 123407 (Sub-464F), filed June 8, 1978. Applicant: SAWYER TRANSPORT, INC., South Haven Square, U.S. Highway 6, Valparaiso, IN 46383. Representative: H. E. Miller, Jr. (Same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporating: (*1*) *Petroleum and petroleum products, in containers*, from the facilities of Sun Oil Co., at Tulsa, OK, to points in IL, IA, MI, MN, and WI: and (2) *containers*, from points in IL, IA, MI, MN, and WI, to the facilities of Sun Oil Co., at Tulsa, OK. (Hearing site: Washington, DC.)

MC 124078 (Sub-822F), filed June 15, 1978. Applicant: SCHWERMAN TRUCKING CO., a corporation, 611 South 28th Street, Milwaukee, WI 53215. Representative: Richard H. Prevette, P.O. Box 1601, Milwaukee, WI 53201. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum lubricating oil*, in bulk, in tank vehicles, from Carrollton, GA, to points in NC, SC, TN, and VA. (Hearing site: Atlanta, GA.)

MC 124078 (Sub-823F), filed June 19, 1978. Applicant: SCHWERMAN TRUCKING CO., a corporation, 611 South 28th Street, Milwaukee, WI 53215. Representative: Richard H. Prevette, P.O. Box 1601, Milwaukee, WI 53201. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, tranporting: *Fly ash*, in bulk, from points in AL and TN, to the Yellow Creek Nuclear Plant, at on near Iuka, MS. (Hearing site: Nashville, TN.)

MC 124887 (Sub-58F), filed June 6, 1978. Applicant: SHELTON TRUCK-

ING SERVICE, INC., Route 1, Box 230, Altha, FL 32421. Representative: Sol H. Proctor, 1101 Blackstone Building, Jacksonville, FL 32202. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber*, from points in MS, to points in AL, FL, GA, NC, and SC. (Hearing site: Birmingham, AL.)

MC 125335 (Sub-22F), filed June 14, 1978. Applicant: GOOD-WAY, INC., P.O. Box 2283, York, PA 17405. Representative: Gailyn L. Larsen, 521 South 14th Street, P.O. Box 81849, Lincoln, NE 68501. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Confectionery and cough drops* (except commodities in bulk), from Reading, PA, to points in AR, IL, IN, IA, KS, LA, MI, MN, MS, MO, NE, OH, TX, and WI, restricted to the transportation of traffic originating at the facilities of Luden's Inc., at Reading, PA, and destined to the indicated destinations. (Hearing site: Reading, PA, or Harrisburg, PA.)

MC 125358 (Sub-25F), filed June 19, 1978. Applicant: MID WEST TRUCK LINES, LTD., 1216 Fife Street, Winnipeg, Manitoba., Canada. Representative: James E. Ballenthin, 630 Osborn Building, St. Paul, MN 55102. Authority granted to opertate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Such commodities* as are used in the manufacture, assembly, and repair of automotive buses, from points in IN, MI, and OH, to the port of entry on the international boundary line between the United States and Canada at Pembina, ND, restricted to (1) the transportation in foreign commerce only, (2) the transportation of traffic destined to Winnipeg, Manitoba, Canada, and to operations performed, under continuing contract(s) with Motor Coach Industries, of Winnipeg, Manitoba, Canada. Condition: Applicant must present evidence of complementary Canadian authority or demonstrate why no such authortiy is needed. (Hearing site: St. Paul, MN.)

NOTE.—Dual operations are involved. The restrictions and conditions contained in the grant of authority in this proceeding are phrased in accordance with the policy statement entitled "Notice to Interested Parties of New Requirements Concerning Applications for Operating Authority to Handle Traffic to and From Points in Canada" published in the FEDERAL REGISTER on December 5, 1974, and supplemented on November 18, 1975. The Commission is presently considering whether the policy statement should be modified, and is in communication with appropriate officials of the provinces of Alberta, Saskatchewan, and Manitoba regarding this issue. If the policy statement is changed, appropriate notice will appear in the FEDERAL REGISTER and the Commission will consider all restrictions or conditions which were imposed pursuant to the prior policy statement, regardless of when the the condition or restriction was imposed, as being null and void and having no force or effect.

MC 125433 (Sub-156F), filed June 5, 1978. Applicant: F-B TRUCK LINE CO., a corporation, 1945 South Redwood Road, Salt Lake City, UT 84104. Representative: David J. Lister (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Carpet and rug cushioning, carpet lining, plastics, and plastic products, and rubber* (except commodities in bulk), from the facilities of the General Tire & Rubber Co., in Orange and Alameda Counties, CA, to points in OR, WA, ID, MT, MY, NV, and UT. (Hearing site: Los Angeles, CA, or Salt Lake City, UT.)

MC 125433 (Sub-157F), filed June 5, 1978. Applicant: F-B TRUCK LINE CO., a corporation, 1945 South Redwood Road, Salt Lake City, UT 84104. Representative: David J. Lister (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Copper rod and copper cathode*, (except commodities in bulk), from the San Manuel, AZ, to points in the United States (except AK, HI, and AZ). (Hearing site: Phoenix, AZ, or Salt Lake City, UT.)

MC 125433 (Sub-158F), filed June 6, 1978. Applicant: F-B TRUCK LINE CO., a corporation, 1945 South Redwood Road, Salt Lake City, UT 84104. Representative: David J. Lister (same address as applicant). Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Plastic pipe*, from Watsonville, CA, to points in the United States (except AK, HI, and CA). (Hearing site: San Francisco, CA, or Salt Lake City, UT.)

MC 127303 (Sub-39F), filed June 7, 1978. Applicant: ZELLMER TRUCK LINES, INC., P.O. Box 343, Granville, IL 61326. Representative: E. Stephen Heisley, 666 11th Street NW., No. 805, Washington, DC 20001. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Malt beverages*, from Pabst, GA, to points in OH, IL, IN, and MI; and (2) *Used containers and pallets*, from points in OH, IL, IN, and MI to Pabst, GA. (Hearing site: Chicago, IL or DC.)

MC 127303 (Sub-40F), filed June 7, 1978. Applicant: ZELLMER TRUCK LINES, INC., P.O. Box 343, Granville, IL 61326. Representative: E. Stephen Heisley, 666 11th Street NW., No. 805, Washington, DC 20001. Authority granted to operate as a *common carries*, by motor vehicle, over irregular routes, transporting: *Animal feed, feed ingredients, additives, and materials and supplies used in the manufacture and distribution of animal feeds*, (except commodities in bulk), between the facilities of Kal Kan Foods, Inc., at or near Mattoon, IL, on the one hand, and, on the other, those points in the United States in and east of ND, SD, NE, KS, OK, and TX, restricted to the transportation of traffic originating at or destined to the facilities of Kal Kan Foods, Inc., at or near Mattoon, IL. (Hearing site: Chicago, IL, or DC.)

MC 127539 (Sub-68F), filed June 14, 1978. Applicant: PARKER REFRIGERATED SERVICE, INC., 1108 54th Avenue East, Tacoma, WA 98424. Representative: Michael B. Crutcher, 2000 IBM Building, Seattle, WA 98101. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Such merchandise* as is dealt in by grocery and food business houses, (except commodities in bulk, in tank vehicles), in vehicles equipped with mechanical refrigeration, (1) from the facilities of Kraft, Inc., at or near Pocatello, ID, to points in AZ, CA, MT, NM, NV, OR, TX, UT, and WA, and (2) from points in AZ, CA, MT, UT, and WA, to the facilities of Kraft, Inc., at or near Pocatello, ID, restricted to the transportation of traffic originating at the indicated origins and destined to the indicated destinations. (Hearing site: Boise, ID, or Salt Lake City, UT.)

MC 128409 (Sub-5F), filed June 16, 1978. Applicant: HAROLD A. MILLER, Box 623, Moorhead, MN 56560. Representative: Richard P. Anderson, 502 First National Bank Building, Fargo, ND 58102. Authority granted to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Sugar*, in bulk, in tank vehicles, from Hillsboro and Drayton, ND, and East Grand Forks, Chaska, Renville, Moorhead, and Crookston, MN, to points in MN, IA, WI, and IL; and (2) *materials and supplies* used by sugar beet processing plants, between those points in ND on and east of ND Hwy 18, on the one hand, and, on the other, points in MN, under continuing contract(s) with American Crystal Sugar Co., of Moorhead, MN. (Hearing site: Fargo, ND or Minneapolis-St. Paul, MN.)

MC 133689 (Sub-205F), filed June 16, 1978. Applicant: Overland Express, Inc., 719 First Street SW., New Brighton, MN 55112. Representative: Robert P. Sack, P.O. Box 6010, West St. Paul, MN 55118. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Heat exchangers*, and *equipment, materials, and supplies* used in the manufacture of heat exchangers, be-

tween Cloquet, McGregor, and St. Paul, MN, on the one hand, and, on the other, points in AL, AR, CT, DE, FL, GA, IL, IN, IA, KS, KY, ME, MD, MA, MI, MS, MO, NE, NH, NJ, NY, NC, OH, PA, RI, SC, TN, VT, VA, WV, WI, and DC. (Hearing site: St. Paul, MN.)

MC 133689 (Sub-206F), filed June 16, 1978. Applicant: OVERLAND EXPRESS, INC., 719 First Street SW., New Brighton, MN 55112. Representative: Robert P. Sack, P.O. Box 6010, West St. Paul, MN 55118. Authority granted to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Automobile ramps, automobile jack stands, and automobile accessories,* from Chelsea, MA, to points in GA, IL, IN, IA, MI, MN, NE, ND, SD, and WI. (Hearing site: St. Paul, MN.)

MC 134477 (Sub-241F), filed May 30, 1978. Applicant: SCHANNO TRANSPORTATION, INC., 5 West Mendota Road, West St. Paul, MN 55118. Representative: Robert P. Sack, 33 East Wentworth, West St. Paul, MN 55118. Authority granted to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Such commodities* as are dealt in by retail department stores (except foodstuffs and commodities in bulk), from points in GA, NC, and SC, to points in MN, restricted to the transportation of traffic originating at the indicated origins and destined to the indicated destination State. (Hearing site: Minneapolis, MN.)

MC 136247 (Sub-16F), filed June 7, 1978. Applicant: WRIGHT TRUCKING, INC., P.O. Box 346, Jamestown, ND 58401. Representative: Richard P. Anderson, 502 First National Bank Building, Fargo, ND 58102. Authority granted to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Building maintenance* and *janitorial equipment and supplies* (except commodities in bulk, in tank vehicles), between the facilities of Team Laboratory Chemical Corp., at or near Bismarck, ND, on the one hand, and, on the other, points in the United States (except AK, HI, and ND), restricted to the transportation of traffic originating at or destined to the named facilities. (Hearing site: Bismarck or Fargo, ND.)

MC 138438 (Sub-26F), filed June 16, 1978. Applicant: D. M. BOWMAN, INC., Route 2, Box 43A1, Williamsport, MD 21795. Representative: Edward N. Button, 1329 Pennsylvania Avenue, P.O. Box 1417, Hagerstown, MD 21740. Authority granted to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Plastic pipe, fittings, valves, and hydrants* from the facilities of Clow Corp., at or near Buckhannon, WV, to points in VA, MD, DE, NJ, PA, CT, VT, RI, MA, NY, NH, ME, and DC. (Hearing site: Chicago, IL.)

NOTE.—Dual operations are involved.

MC 138875 (Sub-90F), filed June 9, 1978. Applicant: SHOEMAKER TRUCKING CO., a corporation, 11900 Franklin Road, Boise, ID 83705. Representative: F. L. Sigloh, 11900 Franklin Road, Boise, ID 83705. Authority granted to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Door hardware and accessories,* from the facilities of J. G. Schmidt, Inc., in Green Brook Township, NJ, to points in AZ, CA, CO, ID, MT, NV, OR, UT, WA, and WY. (Hearing site: Washington, DC.)

MC 139269 (Sub-14F), filed June 6, 1978. Applicant: C. P. CRASKA, INC., 10422 Cosby Manor Road, Utica, NY 13502. Representative: Murray J. S. Kirshtein, 118 Bleecker Street, Utica, NY 13501. Authority granted to operate as a *common carrier,* by motor vehicle, over irregualr routes, transporting: *Frozen foods,* (except in bulk), from the facilities of General Foods Corp., at Avon, NY, to points in CT, MA, ME, NH, and RI, restricted to the transportation of traffic originating at the named origin facilites and destined to the indicated destinations. (Hearing site: New York or Rochester, NY.)

MC 140033 (Sub-54F), filed June 6, 1978. Applicant: COX REFRIGERATED EXPRESS, INC., 10606 Goodnight Lane, Dallas, TX 75220. Representative: E. Larry Wells, Suite 1125, Exchange Park, P.O. Box 45538, Dallas, TX 75245. Authority granted to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Building and roofing materials,* from Mobile, AL, to points in Harris County, TX. (Hearing site: Houston, TX.)

Note.—Dual operations are involved.

MC 141358 (Sub-2F), filed June 19, 1978. Applicant: S&M CORP., 14 Middletown Avenue, North Haven, CT 06473. Representative: Arthur Liberstein, P.O. Box 1409, 167 Fairfield Road, Fairfield, NJ 07006. Authority granted to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: *Such commodities* as are dealt in by retail department stores, between points in CT, ME, MD, MA, NH, NJ, NY, OH, PA, RI, and VT, under continuing contract(s) with Giltex, Inc., of North Haven, CT. (Hearing site: North Haven, CT.)

MC 141532 (Sub-23F), filed June 14, 1978. Applicant: PACIFIC STATES TRANSPORT, INC., 35433 16th Avenue South, Federal Way, WA 98003. Representative: Miles L. Kavaller, 315 South Beverly Drive, Suite 315, Beverly Hills, CA 90212. Authority granted to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Plastic pipe and plastic pipe fittings,* from points in CA, to points in AZ, CO, ID, KS, MT, NE, NV, NM, ND, OK, OR, SD, TX, UT, WA, and WY. (Hearing site: Los Angeles, CA.)

MC 142062 (Sub-13F), filed June 5, 1978. Applicant: VICTORY FREIGHTWAY SYSTEM , INC., P.O. Box 62, Sellerburg, IN 47172. Representative: William P. Jackson, Jr., 3426 North Washington Boulevard, P.O. Box 1240, Arlington, VA 22210. Authority granted to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: *Such commodities* as are manufactured or distributed by a manufacturer of aluminum and aluminum products, from the facilities of Reynolds Metals Co., at or near Louisville, KY, to those points in the United States in and west of MN, IA, MO, AR, and MS (except CA, OR, TX, WA, AK, and HI) under continuing contract(s) with Reynolds Metals Co., of Louisville, KY. (Hearing site: Louisville, KY.)

MC 142263 (Sub-1F), filed June 5, 1978. Applicant: METEGHAN TRUCKING, LTD., a corporation, P.O. Box 152, Meteghan, Digby County, NS, Canada BOW 2JO. Representative: James E. Mahoney, 84 State Street, Boston, MA 02109. Authority granted to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Rags,* (1) from points in CT and MA, to Portland, ME, restricted to the transportation of traffic having an immediately prior movement by water, and (2) from points in CT and MA, to the ports of entry on the international boundary line between the United States and Canada, at or near Calais and Houlton, ME. Condition: (1) Prior receipt from applicant of an affidavit setting forth its appropriate complementary Canadian authority or explaining why no such Canadian authority is necessary, (2) the person or persons which appear to be engaged in common control must either file an application under section 5(2) of the Interstate Commerce Act or submit an affidavit indicating why such approval is unnecessary. (Hearing site: Boston, MA, or Portland, ME.)

NOTE.—Some of the restriction and conditions contained in the grant of authority in this proceeding are phrased in accordance with the policy statement entitled notice to interested parties of new requirements concerning applications for operating authority to handle traffic to and from points in Canada published in the FEDERAL REGISTER on December 5, 1974, and supplemented on November 18, 1975. The Commission is presently considering whether the policy statement should be modified and is in communi-

cation with appropriate officials of the Provinces of AB, SK, and MB regarding this issue. If the policy statement is changed, appropriate notice will appear in the FEDERAL REGISTER and the Commission will consider all restrictions or conditions which were imposed pursuant to the prior policy statement, regardless of when the condition or restriction was imposed, as being null and void and having no force or effect.

MC 142753 (Sub-1F), filed May 15, 1978. Applicant: D. A. D. TRANSPORT CORP., 3832 New Cummings Road, Chattanooga, TN 37409. Representative: Daniel O. Hands, Suite 200, 205 West Toughy Avenue, Park Ridge, IL 60068. Authority granted to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: *Such commodities as are dealt in by grocery and food business houses, discount department stores, and chain drugstores* (except frozen foods and commodities in bulk), between the facilities of Kitchen Fresh, Inc., at Chattanooga, TN, on the one hand, and, on the other, points in the United States (except AK, HI, and TN), under continuing contract(s) with Kitchen Fresh, Inc., of Chattanooga, TN. (Hearing site: Chattanooga, TN, or Atlanta, GA.)

MC 143059 (Sub-16F), filed June 14, 1978. Applicant: MERCER TRANSPORTATION CO. a corporation, P.O. Box 11129, Louisville, KY 40211. Representative: Clayte Binion, 1108 Continental Life Building, Fort Worth, TX 76102. Authority granted to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: (1) *bentonite clay* (except in bulk), and *Lignite coal,* from points in Crook County, WY, and Phillips County, MT, to points in the United States (except AK and HI); (2) *bentonite clay* (except in bulk), from points in Big Horn County, WY, to Points in AR, CA, LA, NM, OK, and TX; and (3) *lignite coal,* from points in Bowman County, ND, to points in AR, CA, LA, NM, OK, and TX, restricted in (1), (2), and (3) above to the transporation of traffic originating at the facilities of American Colloid Co. in the above-named counties. (Hearing site: Chicago, IL, or Washington, DC.)

MC 143568 (Sub-3F), filed June 16, 1978. Applicant: SIMMONS TRUCKING, INC., P.O. Box 71, Glenwood, MO 63541. Representative: Frank W. Taylor, Jr., Suite 600, 1221 Baltimore Avenue, Kansas City, MO 64105. Authority granted to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Sand, gravel, and limestone,* from the facilities of Kaser Construction Co., in Clark and Scotland Counties, MO, to points in IA and IL. (Hearing site: Des Moines, IA, or Kansas City, MO.)

MC 143775 (Sub-5F), filed June 1, 1978. Applicant: PAUL YATES, INC., 6601 West Orangewood, Glendale, AZ 85301. Representative: Charles E. Creager, 1329 Pennsylvania Avenue, P.O. Box 1417, Hagerstown, MD 21740. Authority granted to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: (1) *Drugs, toilet articles, and health aids,* and (2) *materials, equipment, and supplies* used in the distribution of the commodities named in (1) above, between Allegan, MI, on the one hand, and, on the other, points in the United States (except AK, HI, and MI). (Hearing site: Washington, DC.)

NOTE.—Dual operations are involved.

MC 143917 (Sub-3F), filed June 7, 1978. Applicant: SAM YOUNG, INC., P.O. Box 76, R.R. 1, Wolcott, IN 47995. Representative: Donald W. Smith, P.O. Box 40659, Indianapolis, IN 46240. Authority granted to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: (1) *Foodstuffs,* from the facilities of Griffith Laboratories U.S.A., Inc., at (a) Union City and Los Angeles, CA, (b) Remington, IN, (c) Alsip and Chicago, IL, (d) Lithonia, GA, (e) Union, NJ, and (f) Maryland, TN, to points in the United States (except AK and HI); and (2) *materials and supplies* used in the manufacture of foodstuffs, from points in the United States (except AK and HI), to the origin facilities named in (1) above, under continuing contract(s) with Griffith Laboratories U.S.A., Inc., of Alsip, IL. (Hearing site: Chicago, IL.)

MC 144122 (Sub-12F), filed June 5, 1978. Applicant: CARRETTA TRUCKING, INC., South 160 Route 17 North, Paramus, NJ 07652. Representative: Joseph Carretta (same address as applicant). Authority granted to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Staples and staple guns,* from the facilities of Arrow Fastener Co., Inc., at Saddle Brook, NJ, to Little Rock, AR, and points in OK, LA, and TX, restricted to the transportation of traffic originating at the named origin facilities and destined to the indicated destinations. (Hearing site: New York, NY, or Washington, DC.

NOTE.—Dual operations are involved.

MC 144122 (Sub-13F), filed June 5, 1978. Applicant: CARRETTA TRUCKING, INC., South 160 Route 17 North, Paramus, NJ 07652. Representative: Joseph Carretta (same address as applicant). Authority granted to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Staples and staple guns,* from the facilities of Arrow Fastener Co., Inc., at Saddle Brook, NJ to Reno, NV, Salt Lake City, UT, Denver, CO, Phoenix and Tucson, AZ, and points in CA, OR, and WA, restricted to the transportation of traffic originating at the named origins and destined to the indicated destinations. (Hearing site: New York, NY, or Washington, DC.)

NOTE.—Dual operations are involved.

MC 144122 (Sub-15F), filed June 5, 1978. Applicant: CARRETTA TRUCKING, INC., South 160 Route 17 North, Paramus, NJ 07652. Representative: Joseph Carretta (same address as applicant). Authority granted to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Staples and staple guns,* from the facilities of Arrow Fastener Co., Inc., at Saddle Brook, NJ, to Wilkesboro, Charlotte, Greenville, and Greensboro, NC, Atlanta and Conyers, GA, Pelham, Montgomery, and Birmingham, AL, Nashville, Memphis, Knoxville, and Chattanooga, TN, Jacksonville, Orlando, Tampa, St. Petersburg, and Miami, FL, and Columbia, SC, restricted to the transportation of originating at the named origins and destined to the indicated destinations, (Hearing site: New York, NY, or Washington, DC.)

NOTE.—Dual operations are involved.

MC 144821F, filed May 30, 1978. Applicant: FREEDOM FREIGHTWAYS, INC., 9060 Latty Avenue, St. Louis, MO 63134. Representative: Ernest A. Brooks II, 1301 Ambassador Building, St Louis, MO 63101. Authority granted as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Such commodities as are dealt in or used by retail filling stations and automobile service centers* (except commodities in bulk), from Compton, Ca, Grand Prairie, TX, Ferndale, MI, Hazelwood, MO, Bedford Heights, OH, Mount Laurel, NJ, Tampa, FL, Denver CO, Minneapolis, MN, Jackson, MS, Des Moines, IA, Madison, WI, New Orleans, LA, Atlanta, GA, Dothan and Birmingham, AL, and Florence and Rock Hill, SC, to points in the United States (except AK and HI). (Hearing site: Washington, DC.)

MC 144823 (Sub-1F), filed June 1, 1978. Applicant: B & K TRUCKING, INC., 6623 West Kimberly Road, Davenport, IA 52804. Representative: James M. Hodge, 1980 Financial Center, Des Moines, IA 50309. Authority granted to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: *Such commodities as are dealt in by grocery and food business houses,* from the facilities of Ralston Purina Co., at or near Clinton, IA, to Hazelwood, Bridgeton, and St. Louis, MO, under continuing contract(s) with Ralston Purina Co., of St. Louis, MO. (Hearing site: Chicago, IL, or St. Louis, MO.)

MC 144867 (Sub-1F), filed June 8, 1978. Applicant: R & J TRANSPORT, INC., 1612 Iris Drive, Manitowoc, WI 54220. Representative: Michael J. Wyngaard, 150 East Gilman Street, Madison, WI 53703. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Papermaking machinery, and equipment, parts, and accessories* for papermaking machinery, between Neenah, WI, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Milwaukee or Madison, WI.)

MC 144888 (Sub-2F), filed June 14, 1978. Applicant: BIL-RIC TRANSPORT SYSTEMS, INC., 92 East Main Street, Sommerville, NJ 08876. Representative: Joel J. Nagel, 19 Back Drive, Edison, NJ 08817. Authority granted to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Sodium bicarbonate, sodium carbonate,* and *cleaning, scouring, and washing compounds* (except commodites in bulk), from the facilities of Church and Dwight Co., Inc., at or near Syracuse, NY, to points in AL, FL, GA, KY, LA, MS, NC, SC, TN, VA, and WV, under continuing contract(s) with Church & Dwight Co., Inc., of Piscataway, NJ. (Hearing site: Newark, NJ, or New York, NY.)

MC 144908F, filed June 16, 1978. Applicant: ZENITH TRANSPORT, LTD., 2131 Willingdon Avenue, Burnaby, British Columbia, Canada V5C 5J4. Representative: George R. LaBissoniere, 1100 Norton Building, Seattle, WA 98104. Authority granted to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Wire* and *nails*, between the ports of entry on the international boundary line between the United States and Canada at or near Blaine, Lynden, and Sumas, WA, on the one hand, and, on the other, points in CA, OR, and WA, restricted to the transportation of traffic originating at or destined to points in British Columbia, Canada, under continuing contract(s) with Three Island Steel Co., Ltd., of New Westminister, British Columbia, Canada. Condition: Prior receipt from applicant of an affidavit setting forth its complementary Canadian authority or explaining why no such Canadian authority is necessary. (Hearing site: Seattle, WA.)

NOTE.—(1) The restriction and conditions contained in the grant of authority in this proceeding are phrased in accordance with the policy statement entitled "Notice to Interested parties of New Requirements Concerning Applications for Operating Authority to Handle Traffic to and From Points in Canada" published in the FEDERAL REGISTER on December 5, 1974, and supplemented on November 18, 1975. The Commission is presently considering whether the policy statement should be modified, and is in communication with appropriate officials of the Provinces of Alberta, Saskatchewan, and Manitoba regarding this issue. If the policy statement is changed, appropriate notice will appear in the FEDERAL REGISTER and the Commission will consider all restrictions or conditions which were imposed pursuant to the prior policy statement, regardless of when the condition or restriction was imposed, as being null and void and having no force or effect. (2) Dual operations may be involved.

MC 144908 (Sub-1F), filed June 16, 1978. Applicant: ZENITH TRANSPORT, LTD., 2131 Willingdon Avenue, Burnaby, British Columbia Canada V5C 5J4. Representative: George R. LaBissoniere, 1100 Norton Building, Seattle, WA 98104. Authority granted to operate as a *contractor carrier*, by motor vehicle, over irregular routes, transporting: *Sugar syrup*, in containers, between the ports of entry on the international boundary line between the United States and Canada at or near Blaine, Lynden, and Sumas, WA, on the one hand, and, on the other, points in CA, OR, and WA, restricted to the transportation of traffic originating at or destined to points in British Columbia, Canada, under continuing contract(s) with British Columbia Sugar Refining Co., Ltd., of Vancouver, British Columbia, Canada. Condition: Prior receipt from applicant of an affidavit setting forth its complementary Canadian authority or explaining why no such Canadian authority is necessary. (Hearing site: Seattle, WA.)

NOTE.—(1) The restriction and conditions contained in the grant of authority in this proceeding are phrased in accordance with the policy statement entitled "Notice to Interested Parties of New Requirements Concerning Applications for Operating Authority to Handle Traffic to and From Points in Canada" published in the FEDERAL REGISTER on December 5, 1974, and supplemented on November 18, 1975. The Commission is presently considering whether the policy statement should be modified, and is in communication with appropriate officials of the Provinces of Alberta, Saskatchewan, and Manitoba regarding this issue. If the policy statement is changed, appropriate notice will appear in the FEDERAL REGISTER and the Commission will consider all restrictions or conditions which were imposed pursuant to the prior policy statement, regardless of when the condition or restriction was imposed, as being null and void and having no force or effect. (2) Dual operations may be involved.

PASSENGER AUTHORITY

MC 98713 (Sub-7F), filed May 30, 1978. Applicant: ORANGE BELT STAGES, a corporation, 525 East Acequia, Visalia, CA 93277. Representative: Frank S. Bayley, Three Embarcadero Center, Suite 2300, San Francisco, CA 94111. Authority granted to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Passengers and their baggage*, in the same vehicles with passengers, in round-trip charter and special operations, beginning and ending at Burrell, Coalinga, Huron, Kingsbury, Lanare, Orange Cove, Parlier, Reedley, Riverdale, San Joaquin, and Selma, CA, and points in Tulare, Kings, Kern, and San Luis Obispo Counties, CA, and extending to points in the United States (including AK, but excluding CA and HI). (Hearing site: Visalia or Fresno, CA.)

[FR Doc. 78-21577 Filed 8-7-78; 8:45 am]

[7035-01]

[Ex Parte No. 241, Rule 19; 12th Rev. Exemption No. 128]

ATCHISON, TOPEKA & SANTA FE RAILROAD CO., ET AL

Exemption Under Mandatory Car Service Rules

TO: The Atchison, Topeka & Santa Fe Railroad Co.; Chicago, Milwaukee, St. Paul & Pacific Railroad Co.; Chicago, Rock Island & Pacific Railroad Co.; Consolidated Rail Corp.; Illinois Central Gulf Railroad Co.; Louisville & Nashvile Railroad Co.; Missouri-Illinois Railroad Co.; Missouri Pacific Railroad Co.; Seaboard Coast Line Railroad Co.

It appearing, That the railroads have mutually agreed to the use of each other's empty plain cars having mechanical designations "XM", *"XMI", *"XMIH", "FM"-less than 200,000 lbs., "GA", "GB", "GD", "GH", and "GS" and bearing reporting marks assigned to such carriers.

It further appearing, That these railroads have mutually agreed to participate in an Expanded Clearinghouse Project in which each road will treat the cars of the other roads as system cars, with the Car Service Division of the AAR acting as agent.

It is ordered, That pursuant to the authority vested in me by Car Service Rule 19, empty plain cars described in the Official Railway Register, I.C.C.-R.E.R. No. 407, issued by W. J. Trezise, or successive issues thereof, as having mechanical designations "XM", *"XMI", *"XMIH", "FM"-less than 200,000 lbs., "GA", "GB", "GD", "GH", and "GS" and bearing the following reporting marks are exempt from the provisions of Car Service Rules 1 and 2, while on the lines of any of the railroads named below:

The Atchison, Topeka & Santa Fe Railroad Co. Reporting Marks: ATSF Effective August 22, 1976.

Chicago, Milwaukee, St. Paul & Pacific Railroad Co. Reporting Marks: MILW Effective July 15, 1976.

Chicago, Rock Island & Pacific Railroad Co. Reporting Marks: RI-ROCK Effective September 12, 1976.

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*Mechanical designations "XMI" and "XMIH" added.

Consolidated Rail Corp. Reporting Marks: BCK-CNJ-CR-DL&W-EL-ERIE-LV-NH-NYC-PAE-PC-PRR-RDG-TOC. Effective November 6, 1977.

Illinois Central Gulf Railroad Co. Reporting Marks: ICG-GM&O-IC. Effective August 22, 1976.

Louisville & Nashville Railroad Co. Reporting Marks: L&N-CIL-MON-NC. Effective August 15, 1976.

Missouri-Illinois Railroad Co. Reporting Marks: MI. Effective July 15, 1976.

Missouri Pacific Railroad Co. Reporting Marks: MP-C&EI-KO&G-T&P. Effective July 15, 1976.

Seaboard Coast Line Railroad Co. Reporting Marks: SCL-ACL-C&WC-SAL. Effective August 15, 1976.

It is further ordered, That this order will become effective for specific ownerships on dates to be set by the Car Service Division as each road is phased into the Project participants, and to advise the undersigned.

Effective 12:01 a.m., July 29, 1978, and continuing in effect until further order of this Commission.

Issued at Washington, D. C., July 17, 1978.

INTERSTATE COMMERCE COMMISSION,
JOEL E. BURNS,
Agent.

[FR Doc. 78-22046 Filed 8-7-78; 8:45 am]

[7035-01]

[Ex Parte No. 241, Rule 19; 32nd Rev. Exemption No. 12]

ATLANTIC AND WESTERN RAILWAY, ET AL.

Exemption Under Mandatory Car Service Rules

To all railroads: It appearing, That the railroads named herein own numerous plain boxcars; that under present conditions there is virtually no demand for these cars on the lines of the car owners; that return of these cars to the car owners would result in their being stored idle on these lines; 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 plain boxcars owned by the railroads listed herein, resulting in unnecessary loss of utilization of such cars.

It is ordered, That pursuant to the authority vested in me by Car Service Rule 19, plain boxcars described in the Official Railway Equipment Register, ICC-R.E.R. 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 the provisions of Car Service Rules 1(a), 2(a), and 2(b). (See note.)

Atlantic and Western Ry.
Reporting Marks: ATW.

Chicago & Illinois Midland Railway Co.
Reporting Marks: CIM.

Fonda, Johnstown and Gloversville Railroad Co.
Reporting Marks: FJG.

Hartford and Slocomb Railroad Co.
Reporting Marks: HS.

Hillsdale County Railway Company Inc.
Reporting Marks: HCRC.

Maryland and Pennsylvania Railroad Co.
Reporting Marks: MPA.

Pickens Railroad Co.
Reporting Marks: PICK.

Roscoe, Snyder and Pacific Railway Co.
Reporting Marks: RSP.

Wellsville, Addison & Galeton Railroad Corp.
Reporting Marks: WAG.

Effective August 1, 1978, and continuing in effect until further order of this Commission.

Issued at Washington, D.C., July 26, 1978.

INTERSTATE COMMERCE COMMISSION,
JOEL E. BURNS,
Agent.

XXX Louisiana Midland Railway Company deleted.

NOTE.—Does not include boxcars with mechanical designation "XMI".

[FR Doc. 78-22044 Filed 8-7-78; 8:45 am]

[7035-01]

[Rev. Service Order No. 1252; ICC Order No. 62, Amdt. No. 1]

CHESAPEAKE AND OHIO RAILWAY CO.

Rerouting Traffic

To all railroads: Upon further consideration of ICC Order No. 62 (The Chesapeake and Ohio Railway Co.) and good cause appearing therefor:

It is ordered, ICC Order No. 62 is amended by substituting the following paragraph (g) for paragraph (g) thereof:

(g) Expiration date. This order shall expire at 11:59 p.m., August 14, 1978, unless otherwise modified, changed, or suspended.

Effective date. This order shall become effective at 11:59 p.m., July 31, 1978.

This amendment shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association. a copy of this amendment shall be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., July 26, 1978.

INTERSTATE COMMERCE COMMISSION,
JOEL E. BURNS, *Agent.*

[FR Doc. 78-22042 Filed 8-7-78; 8:45 am]

[7035-01]

[Corrected Service Order No. 1304; Exception No. 8]

CONSOLIDATED RAIL CORP.

Decision

Decided: August 1, 1978.

The Consolidated Rail Corp. (CR) owns 5,213 jumbo covered hopper cars subject to Corrected Service Order No. 1304. On July 1, 1978, 1,036, or 19.9 percent of these cars were being used in unit-grain-train services, 3,104 for general grain traffic and 1,073 for transporting commodities other than grain.

On July 26, 1978, CR reported that it had a surplus of jumbo covered hopper cars available for general grain traffic but that because of the provisions of Corrected Service Order No. 1304 limiting to twenty percent (20 percent) of ownership the number of jumbo covered hopper cars it may use in unit-grain-train services, it is unable to furnish an additional one-hundred-car unit-grain-train requested by one of its shippers and that it is unable to substitute thirty-three (33) of its own cars for a like number of private cars in an existing unit-grain-train in order to release these private cars for needed maintenance. Use by CR of an additional one hundred thirty-three (133) of its cars in unit-grain-train service will not impair its ability to furnish jumbo covered hopper cars to general grain shippers at the present level of orders for these cars.

It is ordered, Pursuant to the authority vested in the Railroad Service Board by Section (a)(6) of Corrected Service Order No. 1304, the Consolidated Rail Corp. (CR) is authorized to place an additional one hundred thirty-three (133) jumbo covered hopper cars in unit-grain-train service regardless of the provisions of section (a)(5) of this order.

By the Railroad Service Board, members Joel E. Burns, Robert S. Turkington, and John R. Michael. Member John R. Michael not participating.

Effective: August 1, 1978.

Expires: September 30, 1978.

JOEL E. BURNS,
Chairman, Railroad Service Board.

[FR Doc. 78-22045 Filed 8-7-78; 8:45 am]

[7035-01]

[Revised Service Order No. 1252; ICC Order No. 65]

CP RAIL

Rerouting Traffic

To all Railroads: In the opinion of Joel E. Burns, Agent, CP Rail is unable to transport promptly traffic requiring movement between Detroit, Mich., and Windsor, Ontario, via the car ferry operated by the Norfolk and Westen Railway Co. (NW) and used by CP Rail, because of a strike of employees of NW.

It is ordered, (a) CP Rail being unable to transport traffic requiring movement between Detroit, Mich., and Windsor, Ontario, via the car ferry operated by the NW and used by CP Rail, because of a strike of employees of NW, CP Rail is authorized to divert or reroute such traffic via any availabe route to expedite the movement. Traffic necessarily diverted by authority of this order shall be rerouted so as to preserve as nearly as possible the participation and revenues of other carriers provided in the original routing.

(b) *Concurrence of receiving roads to be obtained* The railroad rerouting cars in accordance with this order shall receive the concurrence of other railroads to which such traffic is to be diverted or rerouted, before the rerouting or diversion is ordered.

(c) *Notification to shippers.* Each carrier rerouting cars in accordance with this order, shall notify each shipper at the time each shipment is rerouted or diverted and shall furnish to such shipper the new routing provided under this order.

(d) Inasmuch as the diversion or rerouting of traffic is deemed to be due to carrier disability, the rates applicable to traffic diverted or rerouted by said agent shall be the rates which were applicable at the time of shipment on the shipments as originally routed.

(e) In executing the directions of the Commission and of such agent provided for in this order, the common carriers involved shall proceed even though no contracts, agreements, or arrangemts now exist between them with reference to the divisions of the rates of transportation applicable to said traffic. Divisions shall be duing the time this order remains in force, those voulntarily agreed upon by and between said carriers; or upon failure of the carriers to so agree, said divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

(f) Effective date. This order shall become effective at 10:45 p.m., July 25, 1978.

(g) Expiration date. This order shall expire at 11:59 p.m., August 4, 1978, unless otherwise modified, changed, or suspended.

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service an car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association. A copy of this order shall be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., July 25, 1978.

INTERSTATE COMMERCE COMMISSION,
JOEL E. BURNS,
Agent.

[FR Doc. 78-22043 Filed 8-7-78; 8:45 am]

[7035-01]

FOURTH SECTION APPLICATIONS FOR RELIEF

AUGUST 3, 1978.

This application for long-and-short-haul relief has been filed with the ICC.

Protests are due at the ICC within 15 days from the date of publication of this notice.

FSA No. 43592, Southwestern Freight Bureau, Agent's No. B-765, rates on beet or cane sugar, from origins in Minnesota and North Dakota, to Fort Smith, Ark., in Supplement 264 to its Tariff 45-F, ICC 5010, to become effective August 30, 1978. Grounds for relief—market competition.

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-22041 Filed 8-7-78; 8:45 am]

[7035-01]

[Notice No. 137]

MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

AUGUST 8, 1978.

The following are notices of filing of applications for temporary authority under section 210a(a) of the Interstate Commerce Act provided for under the provisions of 49 CFR 1131.3. These rules provide that an original and six (6) copies of protests to an application may be filed with the field official named in the FEDERAL REGISTER publication no later than the 15th calendar day after the date the notice of the filing of the application is published in the FEDERAL REGISTER. One copy of the protest must be served on the applicant, or its authorized representative, if any, and the protestant must certify that such service has been made. The protest must identify the operating authority upon which it is predicated, specifying the "MC" docket and "Sub" number and quoting the particular portion of authority upon which it relies. Also, the protestant shall specify the service it can and will provide and the amount and type of equipment it will make available for use in connection with the service contemplated by the TA application. The weight accorded a protest shall be governed by the completeness and pertinence of the protestant's information.

Except as otherwise specifically noted, each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application.

A copy of the application is on file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., and also in the ICC Field Office to which protests are to be transmitted.

MOTOR CARRIERS OF PROPERTY

MC 5227 (Sub-39 TA), filed June 14, 1978. Applicant: ECKLEY TRUCKING, INC., P.O. Box 201, Mead, NE 68041. Representative: Gailyn L. Larsen, Peterson, Bowman, Larsen & Swanson, 521 South 14th Street, P.O. Box 81849, Lincoln, NE 68501. Authority sought to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Iron and steel articles,* (1) from Chicago, IL, and points in its commercial zone, to points in the States of AR, MO, NE, KS, KY, MN, and CO; (2) from Jersey City, NJ, and points in its commercial zone, to points in the States of AR, LA, TN, and TX; (3) from Canonsburg, PA, and points in its commercial zone, to points in the States of TX, OK, LA, MO, MN, VA, WV, IA, IL, KS, and NE; (4) from Wilmington, DE, and points in its commercial zone to points in the States of TX, OK, LA, MO, MN, VA, WV, IA, IL, KS, and NE; (5) from New Orleans, LA, and points in its commercial zone, to points in the States of TN, MI, OH, MN, and KY; and (6) from Houston, TX, and points in its commercial zone to points in the States of AR, LA, MO, and OK, for 180 days. Supporting shipper: North Pacific Lumber Co., Charles H. Wyatt, Manager, Trucking Division, P.O. Box 3915, Portland, OR. Send protests to: District Supervisor Max H. Johnston, Interstate Commerce Commission, 285 Federal Building and U.S. Courthouse, 100 Centennial Mall North, Lincoln, NE 68508.

MC 8948 (Sub-110TA), filed June 14, 1978. Applicant: WESTERN GILLETTE, INC., 1077 Gorge Boulevard, P.O. Box 471, Akron, OH 44309. Representative: William O. Turney, Suite 1010, 7101 Wisconsin Avenue, Washington, DC 20014. Authority sought to

operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum and petroleum products*, in bulk, in tank vehicles, from Richmond and Sacramento, CA, and points in their commercial zones to points in Washoe, Lyon, Douglas, Churchill, and Storey Counties, NV, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Chevron U.S.A., Inc., P.O. Box 2569, 7700 Edgewater Drive, Oakland, CA 94614. Send protests to: James Johnson, District Supervisor, Interstate Commerce Commission, 731 Federal Building, 1240 East Ninth Street, Cleveland, OH 44199.

MC 41406 (Sub-84TA), filed June 14, 1978. Applicant: ARTIM TRANSPORTATION SYSTEM, INC., 7105 Kennedy Avenue, P.O. Box 2176, Hammond, IN 46323. Representative: E. Stephen Heisley, Suite 805, 666 11th Street NW., Washington, DC 20001. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Iron and steel articles*, from the facilities of Illinois-Birmingham Bolt Co., Inc., at or near Kankakee, IL, to the facilities of Virginia-Birmingham Bolt Co., Inc., at or near Duffield, VA, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Illinois-Birmingham Bolt Co., Inc., Henry L. Leonard, General Manager, P.O. Box 1208, Birmingham, AL 35201. Send protests to: Lois N. Stahl, Transportation Assistant, Interstate Commerce Commission, 219 South Dearborn Street, Room 1386, Chicago, IL 60604.

MC 57778 (Sub-22TA), filed June 14, 1978. Applicant: MICHIGAN REFRIGERATED TRUCKING SERVICE, INC., 6134 West Jefferson Avenue, Detroit, MI 48209. Representative: William B. Elmer, 21635 East Nine Mile Road, St. Clair Shores, MI 48080. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foodstuffs*, in mechanically refrigerated equipment from Chicago, IL, to Detroit, MI, and points in its commercial zone, for 180 days. Supporting shipper(s): There are approximately eight statements of support attached to the application which may be examined at the Interstate Commerce Commission in Washington, DC, or copies thereof which may be examined at the field office named below. Send protests to: Timothy S. Quinn, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 604 Federal Building and U.S. Courthouse, 231 West Lafayette Boulevard, Detroit, MI 48226.

MC 64932 (Sub-584 TA), filed June 14, 1978. Applicant: ROGERS CARTAGE CO., 10735 South Cicero Avenue, Oak Lawn, IL 60453. Representative: William F. Farrell (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid cleaning compound, corrosive material*, in bulk, in rubber-lined top unloading tank vehicles from the plantsite of Oxy Metal Industries, Parker Division, at Morenci, MI, to the plantsite of Continental Can Co., Milwaukee, WI, and the plantsite of Schlitz Container Division, Jos. Schlitz Brewing Co., at Oak Creek, WI, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Oxy Metal Industries Corp., Albert J. Latcha, Supervisor, Corporate Traffic Department, 21441 Hoover Road, Warren, MI 48089. Send protests to: Lois M. Stahl, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Everett McKinley Dirksen Building, 219 South Dearborn Street, Room 1386, Chicago, IL 606604.

MC 106603 (Sub-177TA), filed June 14, 1978. Applicant: DIRECT TRANSIT LINES, INC., 200 Colrain Street SW., P.O. Box 8008, Grand Rapids, MI 49508. Representative: Martin J. Leavitt, P.O. Box 400, Northville, MI 48167. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Refractories* from White Cloud, MI, to points in OH, PA, NY, WV, and MD, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): North American Refractories Co., East 14th and Euclid Avenue, 900 Hanna Building, Cleveland, OH 44155. Send protests to: C. R. Flemming, District Supervisor, Interstate Commerce Commission, Room 225, Federal Building, Lansing, MI 48933.

MC 108207 (Sub-480 TA), filed June 14, 1978. Applicant: FROZEN FOOD EXPRESS, 318 Cadiz Street, P.O. Box 225838, Dallas, TX 75265. Representative: M. W. Smith (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Canned and bottled foodstuffs*, in vehicles equipped with mechanical refrigeration, from Cade and Lozes, LA, to points in IA, KS, MO, MN, NE, and OK, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Bruce Foods, Inc., P.O. Box 1030, New Iberia, IA 70560. Send protests to: Opal M. Jones, Interstate Commerce Commission, 1100 Commerce Street, Room 13C12, Dallas, TX 75242.

MC 111812 (Sub-577TA), filed June 14, 1978. Applicant: MIDWEST COAST TRANSPORT, INC., P.O. Box 1233, Sioux Falls, SD 57101. Representative: Ralph H. Jinks (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Such commodities* as are dealt in by retail department stores, except foodstuffs and items of unusual value, from Columbus, OH, to Missoula and Helena, MT, for 180 days. Supporting shipper(s): Gamble-Skogmo, Inc., P.O. Box 458, Minneapolis, MN 55440. Send protests to: J. L. Hammond, District Supervisor, Interstate Commerce Commission, Bureau of Operations, Room 455, Federal Building, Pierre, SD 57501.

MC 113666 (Sub-135TA), filed June 14, 1978. Applicant: FREEPORT TRANSPORT, INC., 1200 Butler Road, Freeport, PA 16229. Representative: D. R. Smetanick, Vice President, (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry animal and poultry feed ingredients*, in bulk, in tank vehicles, from Willow Island, WV, to Chattanooga, TN, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): American Cyanamid Co., P.O. Box 400, Princeton, NJ 08540. Send protests to: John J. England, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 2111 Federal Building, 1000 Liberty Avenue, Pittsburgh, PA 15222.

MC 119560 (Sub-19TA), filed June 14, 1978. Applicant: SOUTHERN BULK HAULERS, INC., P.O. Box 278, Harleyville, SC 29448. Representative: Frank A. Graham, Jr. 707 Security Federal Building, Columbia, SC 29201. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber* from plant site of Westvaco Lumber, Division of Westvaco Development Corp. at Summerville, SC, to points in FL, GA, KY, MD, NC, NJ, NY, OH, PA, TN, VA, and WV, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Westvaco Lumber, Division of Westvaco Development Corp., P.O. Box 1210, Summerville, SC 29483. Send protests to: Strotheid, District Supervisor, Interstate Commerce Commission, Room 302, 1400 Building, Columbia, SC 29201.

MC 119789 (Sub-480TA), filed June 14, 1978. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Repre-

sentative: Lewis Coffey (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Drugs and medicines*, (1) from New Brunswick, Somerset, and South Plainfield, NJ, and Michigan City, IN, to Eastgate, WA; (2) from Michigan City, IN, to La Mirada, CA; Atlanta, GA; Mission, KS, and Houston, TX; (3) from Los Angeles, CA, to Houston, TX, and Atlanta, GA; and (4) from New Brunswick, South Plainfield, and Somerset, NJ, to Sharonville, OH, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): E. R. Squibb & Sons, Inc., Georges Road, New Brunswick, NJ 08903. Send protests to: Opal M. Jones, Interstate Commerce Commission, 1100 Commerce Street, Room 13C12, Dallas, TX 75242.

MC 120257 (Sub-45TA), filed June 14, 1978. Applicant: K. L. BREEDEN & SONS, INC., P.O. Box 207, Ore City, TX 75683. Representatives: Bernard H. English, 6270 Firth Road, Ft. Worth, TX 76116, and Nolan Killingsworth, P.O. Box 207, Ore City, TX 75683. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Iron and steel coils and iron and steel sheets*, from Birmingham, AL, to Points in AR, LA, OK, TN, and TX, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Brothers Steel, Inc., P.O. Box 34421, Dallas, TX 75234. Send protests to: Opal M. Jones, Interstate Commerce Commission, 1100 Commerce Street, Room 13C12, Dallas, TX 75242.

MC 128353 (Sub-4TA), filed June 14, 1978. Applicant: LEE J. PRENTICE, P.O. Box 325, West Bend, IA 50597. Representative: Thomas E. Leahy, Jr., 1980 Financial Center, Des Moines, IA 50309. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Crushed rock*, in bulk, from Webster City and Gilmore City, IA, to the facilities of Southern Minnesota Beet Sugar Coop at or near Renville, MN, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Weaver Construction Co., P.O. Box 338, Mason City, IA 50402. Send protests to: Herbert W. Allen, District Supervisor, Bureau of Operations, Interstate Commerce commission, 518 Federal Building, Des Moines, IA 50309.

MC 136501 (Sub-3TA), filed June 14, 1978. Applicant: CARDOSI CONTRACT REFRIGERATED EXPRESS, INC., 5885 Jet Way Drive, Arlington, TN 30328. Representative: Mr. Bill R. Davis, Suite 101, Emerson Center, 2814 New Spring Road, Atlanta, Ga 30339. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Foodstuffs*, in containers, from Humboldt, TN to points in the United States (including AK, but excluding HI), under a continuing contract or contracts with Pure Packed Foods, Inc., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Pure Packed Foods, Inc., 5885 Jet Way Drive, Arlington, TN 38002. Send protests to: Mr. Floyd A. Johnson, District Supervisor, Interstate Commerce Commission, 100 North Main Building, Suite 2006, 100 North Main Street, Memphis, TN 38103.

MC 138438 (Sub-25A), filed June 14, 1978. Applicant: D. M. BOWMAN, INC., Route 2, Box 43A1, Williamsport, MD 21795. Representative: Edward N. Button, 1329 Pennsylvania Avenue, P.O. Box 1417, Hagerstown, MD 21740. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Plastic pipe, fittings, valves, hydrants, and materials and supplies* used in the installation thereof from Buckhannon, WV and its commercial zone to points in VA, MD, DE, NJ, PA, CT, VT, RI, MA, NY, NH, ME, and DC, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Clow Corp., 1211 W. 22nd Street, Oak Brook, IL 65021. Send protests to: Interstate Commerce Commission, 12th and Constitution Avenue NW., Room 1413, W. C. Hersman, District Supervisor, Washington, DC 20423.

MC 138732 (Sub-13TA), filed June 14, 1978. Applicant: OSTERKAMP TRUCKING, INC., 764 North Cypress Street, P.O. Box 5545, Orange, CA 92667. Representative: Michael R. Eggleton, 67 Larkstone Center, Danville, CA 94526. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber, lumber products, plywood, particleboard, and wood products*, from points in OR, to points in NV Counties of Carson City, Churchill, Douglas, Lyon, Mineral, Storey and Washoe, for 180 days. Supporting shipper(s): (1) American Forest Products Corp., 2740 Hyde Street, San Francisco CA 94109. (2) California Cascade Industries, P.O. Box 130026, Sacramento, CA 95813. (3) Bohemia, Inc., 2280 Oakmond Way, Eugene, OR 97401, and (4) B&C Builders Supply, P.O. Box 1208, Sparks, NV. Send protests to: Irene Carlos, Transportation Assistant, Interstate Commerce Commission, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012.

MC 138762 (Sub-24TA), filed June 14, 1978. Applicant: MUNICIPAL TANK LINES LTD, P.O. Box 3500, Calgary, AB, Canada T2P 2P9. Representative: D. S. Vincent (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Soybean oil and soybean meal*, in bulk, from the facilities of Cargill, Inc., at or near Sidney, OH to ports of entry on the United States-Canada international boundary line located in MI and NY, restricted to traffic destined to points in the Province of ON, for 180 days. Supporting shipper(s): Harold E. Bernero, Traffic Manager, Cargill, Inc., 2400 Industrial Drive Sidney, OH 45365. Send protests to: District Supervisor Paul J. Labane, Interstate Commerce Commission, 2602 First Avenue North, Billings, MT 59101.

MC 141097 (Sub-18TA), filed June 14, 1978. Applicant: CAL-TEX, INC., P.O. Box 1678, 2300 Harbor Boulevard, No. 8, Costa Mesa, CA 92626. Representative: Kellner & Steffire, Greg P. Steffire, 700 South Flower Street, Suite 1724, Los Angeles, CA 90017. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Snythetic yarn, synthetic fiber, and materials, supplies and equipment* used in the manufacture and sale thereof, between points in NC, SC and GA, on the one hand, and, on the other, points in the United States, for 180 days. Restricted to traffic originating at or destined to the facilities of Pharr Yarns, Inc., under a continuing contract or contracts with Pharr Yarns, Inc., Supporting shipper(s): Pharr Yarns, Inc., McAdenville, NC. Send protests to: Irene Carlos, Transportation Assistant, Interstate Commerce Commission, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012.

MC 142508 (Sub-21TA), filed June 14, 1978. Applicant: NATIONAL TRANSPORTATION, INC., P.O. Box 37465, 10810 South 144th Street, Omaha, NE 68137. Representative: Lanny N. Fauss (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Malt beverages*, in containers from the facilities of Joseph Schlitz Brewing Co. at Milwaukee, WI to Omaha, NE and Council Bluffs, IA, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): (1) R. C. Griffith, Inc., Robert C. Griffith, President, 11th Street and First Avenue, Council Bluffs, IA, and (2) Nebraska Distributing Co., Tony Howard, President, 211 Walnut Street,

Omaha, NE 68108. Send protests to: District Supervisor Carroll Russell, Interstate Commerce Commission, Suite 620, 110 North 14th Street, Omaha, NE 68102.

MC 143154 (Sub-3TA), filed June 13, 1978. Applicant: ARTHUR E. PAMIN, JR. & STEVEN V. BIDLAKE, d.b.a. MOLITOR TRUCKING, 6450 Highway 10 West, P.O. Box 4027, Missoula, MT 59801. Representative: Charles A. Murray, Jr., 207A Behner Building, 2822 Third Avenue North, Billings, MT 59101. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Pencil slats and products* used in the production of pencil slats, and boxes, paper and packaging materials, between points in MT, ID, and CA, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): (1) C. R. Caldwell, Plant Manager, Blackfoot Indian Writing Co., Box 729, Browning, MT 59417. (2) Jackie L. Maier, Slat Sales Supervisor, California Cedar Products, P.O. Box 528, Stockton, CA 95201. Send protests to: Paul J. Labane, District Supervisor, Interstate Commerce Commission, 2602 First Avenue North, Billings, MT 59101.

MC 144145 (Sub-4TA), filed June 13, 1978. Applicant: GILBERT TRUCK LINES, INC., South Alger Road, Route 2, Ithaca, MI 48847. Representative: James R. Davis, 1018 Michigan National Tower, Lansing, MI 48933. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Soybean meal and soybean hulls*, in bulk, from the facilities of Cargill, Inc., located at or near Sidney, OH, to points in IL, IN and MI, for 180 days. Supporting shipper(s): Cargill, Inc., 2400 Industrial Drive, Sidney, OH 45365. Send protests to: C. R. Flemming, District Supervisor, Interstate Commerce Commission, 225 Federal Building, Lansing, MI 48933.

MC 144809 (Sub-2TA), filed June 2, 1978. Applicant: POSEY TRUCK LINES, INC., Route 2, Box 219, Taft, TN 38488. Representative: Roland M. Lowell, 618 United American Bank Building, Nashville, TN 37219. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Products of Amana Refrigeration, Inc., including heating and air conditioning units, trash compactors, stoves, ranges, furnaces and microwave ovens*, between the facilities of Amana Refrigeration, Inc., at or near Fayetteville, TN, on the one hand, and, on the other, AR, IL, IN, IA, KY, MI, and OH, under a continuing contract, or contracts, with Amana Refrigeration, Inc., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Amana Refrigeration, Inc., Wilson Parkway, Fayetteville, TN 37334. Send protests to: Glenda F. Kuss, Transportation Assistant, Suite A-422—U.S. Court House, 801 Broadway, Nashville, TN 37203.

MC 144893TA, filed June 13, 1978. Applicant: NORMAN HOWARD, d.b.a., HOWARD TRUCKING OF UTAH, 1755 East 800 North, P.O. Box 502, St. George, UT 84770. Representative: J. Ralph Atkin, 60 North 300 East, P.O. Box 339, St. George, UT 84770. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Print paper for newspapers*, from Pomona, CA, to Denver, Longmont, Colorado Springs, Fort Collins, and Pueblo, CO, and return, under a continuing contract, or contracts, with Garden State Paper Co., for 180 days. Supporting shipper(s): Garden State Paper Co., P.O. Box 2364, Pomona, CA 91766. (Donald Adams Transportation Manager) Send protests to: Lyle D. Helfer, District Supervisor, Interstate Commerce Commission, 5301 Federal Building, Salt Lake City, UT 84138.

MC 144911TA, filed June 14, 1978. Applicant: STEVE ELLIS, d.b.a. STEVE'S BODY SHOP & TOWING, East Highway 50, Box 203, Yankton, SD 57078. Representative: William T. Kafka, 2110 Broadway, Yankton, SD 57078. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Towing and setting up of mechanically broken down and wrecked vehicles and tractor units*, from and to Yankton, SD—from and to the states of SD, ND, NE, KS, OK, TX, MT, WY, CO, MN, IA, MO, IL, IN, and OH, for 180 days. Supporting shipper(s): Truck-Trailer Sales & Service, Inc., P.O. Box 95, Yankton, SD 57078. Drotzmann, Inc., East Highway 50, P.O. Box 667, Yankton, SD 57078. Send protests to: J. L. Hammond, District Supervisor, Interstate Commerce Commission, Bureau of Operations, Room 455, Federal Building, Pierre, SD 57501.

PASSENGER CARRIER

MC 144885TA, filed June 13, 1978. Applicant: CARLOS M. LOPEZ & JAIRO A. LOPEZ, d.b.a. TRICENTENNIAL TOURS AND TRANSPORTS, 162 Temple Street, New Haven, CT 06510. Representative: Jairo A. Lopez, 2 Knox Street, West Haven, CT 06516. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Passengers and their baggage* in round-trip special and charter operations, from New Haven to all points in Connecticut, MA, NY and NJ, for 180 days. Supporting shipper(s): There are approximately (10) statements of support attached to the application which may be examined at the Interstate Commerce Commission in Washington, DC, or copies thereof which may be examined at the field office named below. Send protests to: J. D. Perry, Jr., Interstate Commerce Commission, 135 High Street, Room 324, Hartford, CT 06101.

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-22048 Filed 8-7-78; 8:45 am]

[7035—01]

[Notice No. 21]

SPECIAL PROPERTY BROKERS

AUGUST 3, 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 (1) copy of a verified statement in opposition limited in scope to matters regarding applicant's fitness within 30 days after this notice. Statements must be mailed to:

Broker Entry Staff, Room 2379, Interstate Commerce Commission, Washington, D.C. 20423.

Opposing parites shall serve (1) copy of the statement in opposition concurrently upon aplicant'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.

B-78-55, filed April 24, 1978. Applicant: NATIONAL TRUCK BROCKERAGE, INC., 219 West Main Street, Humboldt, TN 57035. Representative: Harold R. Gunn, 1211 Main Street, Humboldt, TN 57035.

B-78-57, filed April 24, 1978. TRANS-SAVE, INC., 6114 Bent Tree Court, Charlotte, NC 28212. Representative: Robert D. McDonnell, 723 Law Building, Charlotte, NC 28202.

B-78-63 filed May 9, 1978. Applicant: IMPERIAL VAN LINES, INC., 2805 Columbia Street, Torrance, CA 90503. Representative: Alan F. Wohlstetter, 1700 K Street NW., Washington, D.C. 20006

B-78-68 filed May 3, 1978. Applicant: ADVO-SYSTEM, INC. 239 Service Road West, Hartford, CT 06120. Representative: Ronald I Shapss, 450 Seventh Avenue, New York, NY 10001.

B-78-73 filed May 26, 1978. Applicant: FORT PITT CONSOLIDATORS, INC. 1601 Penn Avenue, Ambassador West, Pittsburgh, PA 15221. Representative:

Maury S. Sheer (same address as applicant).

B-78-75, filed May 24, 1978. Applicant: L. E. COPPERSMITH, 350 South Figueroa Street, Suite 956, Los Angeles, CA 90071. Representative: L. E. Coopersmith (same address as applicant).

B-78-80, filed June 19, 1978. Applicant: AMODIO MOVING, INC., 600 East Street, New Britain, CT 06051. Representative: Robert J. Gallagher, 1000 Connecticut Avenue NW., Suite 1200, Washington, D.C. 20036.

B-78-83 filed July 11, 1978. Applicant: KENNETH J. GREEN, 10 Allen Place, Fairlawn, NJ 07410.

B-78-91 filed July 13, 1978. Applicant: BARY BLACK, 400 Sip Avenue, Jersey City, NJ 07306. Representative: Ronald I. Shapss, 450 Seventh Avenue, New York, NY 10001.

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-22040 Filed 8-7-78; 8:45am]

[7035-01]

[Notice No. 14]

TEMPORARY AUTHORITY TERMINATION

The temporary authorities granted in the dockets listed below have expired either as a result of final action granting or denying the issuance of a certificate or permit in a corresponding application for permanent authority, on the date indicated below:

Temporary authority application	Final action or certificate or permit	Date of action
Greyhound Lines, Inc., Greyhound Tower, Suite 1602, Phoenix, Ariz. 85077, MC-1515-227TA.	MC-1515-240	Jan. 12, 1978.
Greyhound Lines, Inc., Greyhound Tower, Phoenix, Ariz. 85077, MC-1515-232TA.	MC-1515-235	Jan. 4, 1978.
Kroblin Refrigerated Xpress, Inc., 2125 Commercial St., Waterloo, Iowa 50702, MC-30844-593TA.	MC-30844-591	Jan. 13, 1978.
Mercer Trucking Co., North 1414 Fancher Rd., P.O. Box 11585, Spokane, Wash. 99211, MC-43685-21TA.	MC-43685-23	Jan. 12, 1978.
Gilbert Carrier Corp., 1 Gilbert Dr., Secaucus, N.J. 07094, MC-52579-161TA.	MC-52579-164	Jan. 5, 1978.
Smith & Solomon Truck Co., How Lake, New Brunswick, N.J. 08902, MC-59264-62TA.	MC-59264-64	Jan. 16, 1978.
Roy Stone Transfer Corp., P.O. Box 385, Collinsville, Va. 24078., MC-61825-67TA.	MC-61825-69	Jan. 13, 1978.
Frontier Delivery, Inc., 620 Elk St., Buffalo, N.Y. 14210, MC-104675-39TA.	MC-104675-40	Jan. 12, 1978.
Schilli Motor Lines, Inc., P.O. Box 123, Remington, Ind. 47977, MC-106674-242TA.	MC-106674-244	May 17, 1978.
Midwest Coast Transport, Inc., 900 West Delaware, P.O. Box 1233, Sioux Falls, S. Dak. 57104, MC-111812-530TA.	MC-111812-532	Jan. 13, 1978.
J & M transportation Co., Inc., P.O. Box 488, Milledgeville, Ga. 31061, MC-115311-231TA.	MC-115311-229	Apr. 13, 1978.
Colonial Refrigerated Transportation, Inc., P.O. Box 168, Concord, Tenn. 37922, MC-115841-541TA.	MC-115841-543	Jan. 4, 1978.
Asphalt Transport, Inc., P.O. Box 10416, Jefferson, La. 70121, MC-117088-5TA.	MC-117088-6	Jan. 11, 1978.
Hirschbach Motor Lines, Inc., 5000 South Lewis Blvd., P.O. Box 417, Sioux City, Iowa 51102, MC-117686-176TA.	MC-117686-173	Jan. 13, 1978.
Nationwide Carriers, Inc., P.O. Box 104, Maple Plain, Minn., 55359, MC-117940-227TA.	MC-117940-222	May 15, 1978.
McFarland and Hullinger, 915 North Main St., P.O. Box 238, Tooele, Utah 84074, MC-120279-8TA.	MC-120279-7	Jan. 13, 1978.
Fredonia Truck Line, Inc., Highway 96 and Jackson St., Fredoniz, Kans. 66736, MC-123056-5TA.	MC-123056-6	Jan. 11, 1978.
Floyd Duneow, Inc., 1728 Industrial Park Blvd., Fergus Falls, Minn. 56537, MC-127187-25TA.	MC-127187-26	Jan. 4, 1978.
Wayne Daniel Truck, Inc., P.O. Box 303, Mount Vernon, Mo. 65712, MC-133591-37TA.	MC-133591-35	Jan. 4, 1978.
Customized Parts Distribution, Inc., 2701 South Bayshore Dr., Miami, Fla. 33133, MC-136291-7TA.	MC-136291-6	Jan. 12, 1978.
Olen Burrage Trucking, Inc., Route 9, Box 22-A, Philadelphia, Miss. 39350, MC-136315-16TA.	MC-136315-18	May 8, 1978.
Space Carriers, Inc., 444 Lafayette Rd., St. Paul, Minn. 55101, MC-136512-13TA.	MC-136512-14	Jan. 13, 1978.
American Central Transport, Inc., 230 St. Clair Ave., East St. Louis, Mo. 62201, MC-138741-34TA.	MC-138741-33	Jan. 12, 1978.
Ray Wagner & Son Trucking Co., Inc., Box 117, Owen, Wis. 54460, MC-139196-14TA.	MC-139196-16	Jan. 13, 1978.
Brooks Transportation, Inc., 30650 Carter Rd., Solon, Ohio 44139, MC-139254-10TA.	MC-139254-6	Dec. 22, 1977.
Rexford C. Greer, d.b.a. American Truck Stop, U.S. Route 15, Mansfield, Pa. 16933, MC-142881-TA.	MC-142881-1	Jan. 12, 1978.
Network Transportation Systems, Inc., 35 Brown St., Washington, N.J. 07822, MC-142957-TA.	MC-142957-1	Jan. 16, 1978.
C. T. S. Lines, Inc., 602 Airport Rd., Greenville, S.C. 29615, MC-143083TA.	MC-143083-3	Jan. 10, 1978.
Weaver Transportation Co., 5452 Oakdale Rd., Smyrna, Ga. 30080, MC-143276-1TA.	MC-143276-3	Do.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-22047 Filed 8-7-78; 8:45 am]

sunshine act meetings

This section of the FEDERAL REGISTER contains notices of meetings published uner the "Government in the Sunshine Act" (Pub. L. 94-409), 5. U.S.C. 552b(e)(3).

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[6712-01]

1

FEDERAL COMMUNICATIONS COMMISSION.

TIME AND DATE: 9 a.m., Thursday, July 27, 1978.

PLACE: Room 856, 1919 M Street NW., Washington, D.C.

STATUS: Open Commission meeting.

CHANGES IN THE MEETING: The following items have been added or rescheduled and the time of the meeting changed to 9 a.m.:

Agenda, Item No. and Subject

The following item has been added to the open meeting:

Complaints and Compliance, 1, request for declaratory ruling by WTCG (TV) regarding use of its facilities by a candidate for public office who intends to use a hypnotist.

The following item which was previously announced on July 20, 1978 to be held in a closed meeting has been rescheduled as part of the open meeting:

General, 7, review of staff ruling which partially denied the Freedom of Information Act request filed by Faulkner Radio, Inc.

CONTACT PERSON FOR MORE INFORMATION:

Samuel M. Sharkey, FCC, Public Information Office, telephone 202-632-7260.

Issued: August 1, 1978.

[S-1601-78 Filed 8-4-78; 10:55 am]

[6712-01]

2

FEDERAL COMMUNICATIONS COMMISSION.

TIME AND DATE: 9:30 a.m., Tuesday, August 8, 1978.

PLACE: Room 856, 1919 M Street NW., Washington, D.C.

STATUS: Open Commission meeting.

MATTERS TO BE CONSIDERED:

Agenda, Item No. and Subject

General.—1. Land Transfer to State of Alaska for expansion of Anchorage international airport and lease agreement for additional property for the Commission's Anchorage monitoring station. 2. Telegraphy examinations for handicapped applicants for operator licenses in the amateur radio service. 3. Fee refund program—status. 4. Fiscal year 1980 Budget estimates to OMB—priorities. 5. Fiscal year 1979 Policy research.

Safety and Special Radio Services.—1. Deregulation of part 97 of the Commission's rules regarding emissions authorized in the amateur radio service.

Common Carrier.—1. Request for review of Common Carrier Bureau grant of KTS 203 to Illinois Bell Telephone Co. filed by Radio Relay Corp.—Illinois and Rogers Radio Communication Services. 2. American Satellite Corp.'s applications for transmit/receive earth stations at Blue Bell, Pa. and Roseville, Minn. (File Nos. 67/68-DSE-P/L-78). 3. Application for special permission No. 986 filed by ITT World Communications Inc. 4. Petitions for partial suspension and partial rejection of Comsat tariff revisions. 5. Press parties' motion to terminate the docket No. 20667 inquiry into the need for preferential rates for press use of domestic private line service. 6. Adoption of rules for the regulation of cable television pole attachments. 7. Applications of A.T. & T., et al. for authority to supplement facilities between Bell Telephone Cos. and Independent Telephone Cos. 8. Applications of A.T. & T., et al. for authority under section 214(a) of the Communications Act of 1934 to supplement existing circuits between various locations throughout the Continental United States.

Cable Television.—1. Petitions for reconsideration of memorandum opinion and order in docket 19995 (network nonduplication protection removed from significantly viewed signals).

Renewal.—1. Petition for clarification of Commission policy regarding the limitation on a transferee or assignee's ability to incorporate into a renewal application, certain ascertainment efforts conducted pursuant to the 1971 Primer. 2. Petitions to deny 1977 renewal applications of eight television licensees in Los Angeles, Calif. filed by Sue Gottfried, et al. 3. Petition to deny renewal application of station KJAZ(FM), Alameda, Calif. filed by the Committee for open media.

Aural.—1. Application for a construction permit for a new FM station (BPE-10,049) New, Portland, Tex. Media Properties, Inc.

Television.—1. Mutually exclusive applications for a new TV station on channel 30, Jacksonville, Fla. 2. Application for review of action of Chief, Broadcast Bureau, denying request to retain application as unacceptable for filing and accepting for new STV station on Channel 54, Baltimore, Md. 3. Application of Puerto Rico Broadcasting Inc. for a CP for a new TV on channel 18, San Juan, P.R.

Broadcast.—1. Amendment of the Commission's rules to add a new program type, "community service" program, to the program definitions for commercial television stations and related matters. 2. Petition for reconsideration of the memorandum opinion and order denying a petition to institute a notice of inquiry and proposed rulemaking on the airing of public service announcements by broadcast licensees. 3. Notice of proposed rulemaking concerning origination of solicitations for contributions by VHF translators (RM-2739) and of emergency messages by TV and FM translators (RM-2740). 4. Notice of inquiry concerning the future role of low-power television and television translators; memorandum opinion and order denying two petitions for rulemaking designed to establish a proposed "communicasting" low-power television service (RM-2846) and memorandum opinion and order addressing and denying petitions for rulemaking filed by Cablecom General, Inc. (RM-2751) and Communications Services, Inc. (RM-2826). 5. Motion for declaratory ruling filed by KCMC, Inc. licensee of station, KTL-TV, Texarkana, Tex. (docket No. 18110).

Complaints and Compliances.—1. Fairness doctrine complaint filed by Council on Religion and the Homosexual against KVOF-TV, San Francisco.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

CONTACT PERSON FOR MORE INFORMATION:

Samuel M. Sharkey, FCC Public Information Officer, telephone 202-632-7260.

Issued: August 2, 1978.

[S-1602-78 Filed 8-4-78; 10:55 am]

[6712-01]

3

FEDERAL COMMUNICATIONS COMMISSION.

TIME AND DATE: 9 a.m., Tuesday, August 8, 1978.

PLACE: Room 856, 1919 M Street NW., Washington, D.C.

STATUS: Open Commission meeting.

CHANGES IN THE MEETING: The following item has been added:

Agenda, Item No. and Subject

General.—6 Congressional request to conduct several studies relative to a reallocation of channel 7, New York City to Trenton, N.J.

CONTACT PERSON FOR MORE INFORMATION:

Samuel M. Sharkey, FCC, Public Information Office, telephone 202-632-7260.

Issued: August 4, 1978.

[S-1607-78 Filed 8-4-78; 2:12 pm]

[6714-01]

4

FEDERAL DEPOSIT INSURANCE CORPORATION.

TIME AND DATE: 10 a.m., August 11, 1978.

PLACED: Room 6135, FDIC Building, 550 17th Street NW., Washington, D.C.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

APPLICATIONS FOR FEDERAL DEPOSIT INSURANCE

Washington County State Bank a proposed new bank to be located at 100 River Road, McIntosh, Ala., for Federal deposit insurance.

Frontier Bank, a proposed new bank to be located at 6623 Evergreen Way, Everett, Wash., for Federal deposit insurance.

Mid State Bank, a proposed new bank to be located at 106 West Locust Street, Waterville, Wash., for Federal deposit insurance.

APPLICATIONS FOR CONSENT TO ESTABLISH BRANCHES

Chaton State Bank, Chaton, Ala., for consent to establish a branch on the east side of old U.S. Highway 43, approximately 75 yards south of its intersection with River Road, McIntosh, Ala.

United Mutual Savings Bank, New York, N.Y., for consent to establish a branch at 556 Main Street, Islip (incorporated area), town of Islip, N.Y.

REQUEST PURSUANT TO SECTION 19 OF THE FEDERAL DEPOSIT INSURANCE ACT FOR CONSENT TO SERVICE OF A PERSON CONVICTED OF AN OFFENSE INVOLVING DISHONESTY OR A BREACH OF TRUST AS A DIRECTOR, OFFICER OR EMPLOYEE OF AN INSURED BANK

Name of person and of bank authorized to be exempt from disclosure pursuant to the provisions of subsection (c)(6) of the Government in the Sunshine Act (5 U.S.C. 552b(c)(6)).

APPLICATIONS FOR CONSENT TO MERGE AND TO ESTABLISH BRANCHES

Suburban Trust Co., Hyattsville, Md. an insured State nonmember bank, for consent to merge under its charter and title with Free State Bank & Trust Co., Potomac, Md., also an insured State nonmember bank, and for consent to establish the two offices of Free State Bank & Trust Co. as branches of the resultant bank.

APPLICATION FOR CONSENT TO CONSOLIDATE AND TO ESTABLISH BRANCHES

Citizens National Bank, Ogden, Utah, for consent to consolidate under a new State charter, and with the title of "The Citizens Bank," with Kamas State Bank, Kamas, Utah, an insured State nonmember bank and for consent to establish the sole office of Kamas State Bank as a branch of the new bank, which is to be operated as an insured State nonmember bank.

RECOMMENDATIONS REGARDING LIQUIDATION OF A BANK'S ASSETS ACQUIRED BY THE CORPORATION IN ITS CAPACITY AS RECEIVER, LIQUIDATOR, OR LIQUIDATING AGENT OF THOSE ASSETSS

Case No. 43,597-I—American City Bank & Trust Co., National Association, Milwaukee, Wis.

Case No. 43,598-I—American City Bank & Trust Co., National Association, Milwaukee, Wis.

Case No. 43,601-NR—United States National Bank, San Diego, Calif.

Case No. 43,607-I—Franklin National Bank, New York, N.Y.

Case No. 43,611-NR—United States National Bank, San Diego, Calif.

Memorandum re: Skyline National Bank, Denver, Colo.

Memorandum re: First Augusta Bank & Trust Co., Augusta, Ga.

Memorandum re: The Hamilton National Bank of Chattanooga, Chattanooga, Tenn.

RECOMMENDATIONS WITH RESPECT TO THE INITIATION OR TERMINATION OF CEASE-AND-DESIST PROCEEDINGS, TERMINATION-OF-INSURANCE PROCEEDINGS, OR SUSPENSION OR REMOVAL PROCEEDINGS AGAINST CERTAIN INSURED BANKS, OR OFFICERS, OR DIRECTORS THEREOF

Names of persons and names and locations of banks authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(6), (c)(8), and (c)(9)(A)(ii) of the Government in the Sunshine Act (5 U.S.C. 552b(c)(6), (c)(8), and (c)(9)(A)(ii)).

PERSONNEL ACTIONS REGARDING APPOINTMENTS, PROMOTIONS, ADMINISTRATIVE PAY INCREASES, REASSIGNMENTS, RETIREMENTS, SEPARATIONS, REMOVALS, ETC.

Names of employees authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(2) and (c)(6) of the Government in the Sunshine Act (5 U.S.C. 552b(c)(2) and (c)(6)).

CONTACT PERSON FOR MORE INFORMATION:

Alan R. Miller, Executive Secretary, 202-389-4446.

[S-1604-78 Filed 8-4-78; 11:50 am]

[6714-01]

5

FEDERAL DEPOSIT INSURANCE CORPORATION

TIME AND DATE: 10:30 a.m., August 11, 1978

PLACE: Board Room, 6th Floor, FDIC Building, 550—17th Street, N.W., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Disposition of minutes of previous meetings.

APPLICATIONS FOR FEDERAL DEPOSIT INSURANCE

Latimer State Bank, a proposed new bank to be located at 301 West Main Street, Wilburton, Okla., for Federal deposit insurance.

First Bank & Trust, a proposed new bank to be located at the southwest corner of Highway 51 and Townsquare, Springtown, Tex., for Federal deposit insurance.

APPLICATION FOR CONSENT TO MERGE AND ESTABLISH BRANCHES

Atlantic Bank of Springfield, Jacksonville, Fla., an insured State nonmember bank, for consent to merge under its charter, and with the title of "Atlantic Bank of Jacksonville," with Atlantic Bank of West Jacksonville, Atlantic Bank of Lake Forest, Atlantic Bank of South Jacksonville, Atlantic Bank of Normandy, and Atlantic University Bank, all of Jacksonville, Fla., and for consent to establish the six existing and one approved but unopened offices of the other five banks as branches of the resultant bank.

APPLICATION FOR CONSENT TO MERGE, TO ESTABLISH BRANCHES, AND TO REDESIGNATE THE MAIN OFFICE LOCATION

West Side Bank, Scranton, Pa., an insured State nonmember bank, for consent to merge under its charter, and with the title of "First State Bank," with the First National Bank of Hawley, Hawley, Pa.; for consent to establish the three offices of the First National Bank of Hawley as branches of the resultant bank; and for consent to redesignate the present main office of the First National Bank of Hawley as the main office of the resultant bank.

APPLICATION FOR CONSENT TO MERGE, TO ESTABLISH BRANCHES, AND TO ISSUE AND RETIRE CAPITAL

Franklin Bank & Trust Co., Franklin, Ind., an insured State nonmember bank, for consent to merge under its charter and title with the Edinburg State Bank, Edinburg, Ind., also an insured State nonmember bank; for consent to establish the three office of the Edinburg State Bank as branches of the resultant bank; and for consent to issue and retire capital.

REQUEST BY THE COMPTROLLER OF THE CURRENCY FOR A REPORT ON THE COMPETITIVE FACTORS INVOLVED IN THE PROPOSED CONSOLIDATION OF GARDEN STATE NATIONAL BANK, PARAMUS, N.J., WITH THE NATIONAL STATE BANK, ELIZABETH, N.J., ELIZABETH, N.J.

RECOMMENDATIONS REGARDING THE LIQUIDATION OF A BANK'S ASSETS ACQUIRED BY THE CORPORATION IN ITS CAPACITY AS RECEIVER, LIQUIDATOR, OR LIQUIDATING AGENT OF THOSE ASSETS

Case No. 43,470-L (Amended)—The Drovers' National Bank of Chicago, Chicago, Ill.

Case No. 43,602-L—The Drovers' National Bank of Chicago, Chicago, Ill.
Case No. 43,603-L—State Bank of Clearing, Chicago, Ill.
Case No. 43,614-L—Banco Credito y Aborro Ponceno Ponce, P.R.
Case No. 43,615-L—State Bank of Clearing, Chicago, Ill.
Case No. 43,615-L—International City Bank & Trust Co., New Orleans, La.
Memorandum re: The Hamilton Bank & Trust Co., Atlanta, Ga.

RECOMMENDATIONS WITH RESPECT TO PAYMENT FOR LEGAL SERVICES RENDERED AND EXPENSES INCURRED IN CONNECTION WITH RECEIVERSHIP AND LIQUIDATION ACTIVITIES

Bronson, Bronson & McKinnon, San Francisco, Calif., in connection with the liquidation of First State Bank of Northern Calif., San Lesadro, Calif.
Potter, Anderson & Corroon, Wilmington, Del., in connection with the liquidation of assets acquired by the corporation from Farmers Bank of the State of Delaware, Dover, Del.
Chapman & Cutler, Chicago, Ill., in connection with the liquidation of the Drovers' National Bank of Chicago, Chicago, Ill.
Reggs & Lane, Pensacola, Fla., in connection with the liquidation of International City Bank & Trust Co., New Orleans, La.
Reynolds, Ridings & Hargis, Oklahoma City, Okla., in connection with the liquidation of International City Bank & Trust Co., New Orleans, La.
Schumann, Heasios, Kennelly & Dorsent, Jersey City, N.J., in connection with the liquidation of First State Bank of Hudson County, Jersey City, N.J.
Hays, Scholer, Pierman, Hays & Handler, New York, N.Y., in connection with the receivership of American Bank & Trust Co., New York, N.Y.
Hays, Scholar, Pierman, Hays & Handler, New York, N.Y., in connection with the liquidation of Franklin National Bank, New York, N.Y.
Taback & Ryans, Jericho, N.Y., in connection with the liquidation of Franklin National Bank, New York, N.Y.
J. Randolph Pelzer, P.A., North Charleston, S.C., in connection with the liquidation of American Bank & Trust, Orangeburg, S.C.
Meredith, Donnell & Edmonds, Corpus Christi, Tex., in connection with the liquidation of Northeast Bank of Houston, Houston, Tex.
Memorandum proposing the payment of a second dividend of 16 percent in connection with the receivership of Citizens State Bank, Carrizo Springs, Tex.
Memorandum proposing the leasing of additional Division of Bank Supervision Training Center Lodging Facilities.
Resolution spending the Budget Year 1978 Manning Table for the Division of Bank Supervision, Minneapolis Region, to establish a Clerk (Office Services) GG-301-5 position.
Resolution amending the Budget Year 1978 Manning Table for the Division of Bank Supervision, Omaha Region, to establish two Clerk-Typist GG-322-3/4 positions.
Memorandum and resolution proposing the delegation to the General Counsel and the Director of the Division of Liquidation or their designees of authority to initiate litigation in connection with the Corporation's liquidation activities.

REPORTS OF COMMITTEES AND OFFICERS

Minutes of the actions approved by the Committee on liquidations, loans and purchases of assets pursuant to authority delegated by the Board of Directors.
Reports of the Director of the Division of Bank Supervision with respect to applications or requests approved by him and the various regional directors pursuant to authority delegated by the Board of Directors.
Reports of security transactions authorized by the Chairman.

CONTACT PERSON FOR MORE INFORMATION:

Alan R. Miller, Executive Secretary, 202-389-4446.

[S-1603-78 Filed 8-4-78; 11:43 am]

[7020-02]

[USITC SE-78-38]

INTERNATIONAL TRADE COMMISSION.

TIME AND DATE: 2 p.m., Thursday, August 17, 1978.

PLACE: Room 117, 701 E Street NW., Washington, D.C. 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda.
2. Minutes.
3. Ratifications.
4. Petitions and complaints (if necessary).
5. Perchlorethylene from Belgium, France, and Italy (Invs. AA1921-Inq. -14, -15, and -16)—briefing and vote.
6. Any items left over from previous agenda.

CONTACT PERSON FOR MORE INFORMATION:

Kenneth R. Mason, Secretary, 202-523-0161.

[S-1606-78 Filed 8-4-78; 2:12 pm]

[7600-01]

7

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION.

TIME AND DATE: 10 a.m., August 11, 1978.

PLACE: Room 1101, 1825 K Street NW., Washington, D.C.

STATUS: This meeting is subject to being closed by a vote of the Commissioners taken at the beginning of the meeting.

MATTERS TO BE CONSIDERED: Discussion of specific cases in the Commission adjudication process.

CONTACT PERSON FOR MORE INFORMATION:

Ms. Lottie Richardson, 202-634-7970.

Dated: August 4, 1978.

[S-1605-78 Filed 8-4-78; 2:12 pm]

[7910-01]

8

RENEGOTIATION BOARD.

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 43 FR 31504, July 21, 1978.

PREVIOUSLY ANNOUNCED DATE AND TIME OF MEETING: Tuesday, August 8, 1978; 10 a.m.

CHANGE IN MEETING: Cancellation.

CONTACT PERSON FOR MORE INFORMATION: Kelvin H. Dickinson, Assistant General Counsel-Secretary, 2000 M Street NW., Washington, D.C. 20446, 202-254-8277.

Dated: August 3, 1978.

HARRY R. VAN CLEVE,
Acting Chairman.

[S-1600-78 Filed 8-4-78; 10:55 am]

federal register

TUESDAY, AUGUST 8, 1978
PART II



DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Housing—Federal Housing Commissioner

■

HOUSING ASSISTANCE PAYMENTS PROGRAMS

Section 8 Existing Housing and Section 23 Existing Housing; Amendment of Schedule B

[4210-01]

Title 24—Housing and Urban Development

CHAPTER VIII—OFFICE OF ASSISTANT SECRETARY FOR HOUSING—FEDERAL HOUSING COMMISSIONER, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket R-78-516]

PART 803—SECTION 23 HOUSING ASSISTANCE PAYMENTS PROGRAM

PART 888—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM—FAIR MARKET RENTS AND CONTRACT RENT AUTOMATIC ANNUAL ADJUSTMENT FACTORS

Amendment of Schedule B—Section 8 Existing Housing and Section 23 Existing Housing.

AGENCY: Department of Housing and Urban Development (HUD).

ACTION: Final rule.

SUMMARY: HUD is amending for certain market areas the schedule that sets forth the fair market rents for the Section 23 and Section 8 Housing Assistance Payments Programs for Existing Housing. Fair market rents for these market areas have been recalculated in response to comments received from HUD field offices and the general public on the schedule published for comment on February 14, 1978.

EFFECTIVE DATE: August 8, 1978.

FOR FURTHER INFORMATION CONTACT:

Bernard Horn, Acting Director, Office of Economic and Market Analysis, P.D. & R., HUD, Washington, D.C. 20410, 202-755-5870. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: HUD gave notice on February 14, 1978, at 24 FR 6402, that it was proposing to amend title 24 of the Code of Federal Regulations by revising part 803, schedule B, and part 888, schedule B. The comment period closed March 1, 1978.

By the deadline, the Department had received approximately 100 comments from the general public and HUD field offices in response to the February 14 publication. Most of the comments requested increases in the schedules.

To avoid delay in providing needed rent increases while the comments were being considered, HUD published for effect on March 29, 1978, at 24 FR 13182-13337 the proposed schedule with some modifications based on requests for changes from HUD field offices. However, in the preamble to the March 29 publication, HUD announced that, if warranted, additional amendments to the schedule would be made once all comments received were analyzed. All comments have been carefully considered and the data submitted has been verified with our field offices. As a result of those comments which could not be analyzed by the March 29 publication date, additional amendments are now being published for effect.

A finding of inapplicability regarding the National Environmental Policy Act of 1969 has been made in accordance with HUD procedures. A copy of this finding of inapplicability will be available for public inspection during regular business hours at the Office of the Rules Docket Clerk, Office of General Counsel, Room 5218, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, D.C. 20410.

Accordingly, title 24, part 888, schedule B, and part 803, schedule B are revised as set forth below.

(Sec. 7(d), Department of HUD Act 42 U.S.C. 3535(d).)

Issued at Washington, D.C., July 28, 1978.

LAWRENCE B. SIMONS,
Assistant Secretary for Housing—Federal Housing Commissioner.

U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
SECTION 8 & 23 HOUSING ASSISTANCE PAYMENTS PROGRAMS

SCHEDULE B- FAIR MARKET RENTS FOR EXISTING HOUSING(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAM)

REGION 1		0 BEDROOMS	1 BEDROOM	2 BEDROOMS	3 BEDROOMS	4 BEDROOMS
BANGOR,MAINE INSURING OFFICE						
SMSA: PORTLAND, ME						
SMSA PART:CUMBERLAND	NON-ELEVATOR:	171	201	237	278	326
STATE:ME	ELEVATOR:	188	221	261	306	358
SMSA PART:YORK	NON-ELEVATOR:	171	201	237	278	326
STATE:ME	ELEVATOR:	188	221	261	306	358
NON SMSA						
COUNTY:AROOSTOOK	NON-ELEVATOR:	155	183	216	238	260
STATE:ME	ELEVATOR:	171	201	238	262	286
REGION 2						
CAMDEN,NEW JERSEY AREA OFFICE						
SMSA: WILMINGTON, DE-NJ-MD						
COUNTY:SALEM	NON-ELEVATOR:	179	196	241	306	365
STATE:NJ	ELEVATOR:	197	216	265	337	400
NON SMSA						
COUNTY:CAPE MAY	NON-ELEVATOR:	184	210	250	276	304
STATE:NJ	ELEVATOR:	203	232	275	304	334
COUNTY:OCEAN	NON-ELEVATOR:	211	225	*267	297	326
STATE:NJ	ELEVATOR:	232	248	294	327	359
NEW YORK,NEW YORK AREA OFFICE						
SMSA: NEW YORK CITY, NY-NJ						
COUNTY:BRONX	NON-ELEVATOR:	206	234	275	318	360
STATE:NY	ELEVATOR:	228	258	304	349	397
COUNTY:KINGS	NON-ELEVATOR:	206	234	275	318	360
STATE:NY	ELEVATOR:	228	258	304	349	397
COUNTY:NEW YORK	NON-ELEVATOR:	206	234	275	318	360
STATE:NY	ELEVATOR:	228	258	304	349	397
COUNTY:PUTNAM	NON-ELEVATOR:	206	234	275	318	360
STATE:NY	ELEVATOR:	228	258	304	349	397
COUNTY:QUEENS	NON-ELEVATOR:	206	234	275	318	360
STATE:NY	ELEVATOR:	228	258	304	349	397
COUNTY:RICHMOND	NON-ELEVATOR:	206	234	275	318	360
STATE:NY	ELEVATOR:	228	258	304	349	397
COUNTY:ROCKLAND	NON-ELEVATOR:	221	251	296	342	387
STATE:NY	ELEVATOR:	243	276	325	375	426
COUNTY:WESTCHESTER	NON-ELEVATOR:	206	234	275	318	360
STATE:NY	ELEVATOR:	228	258	304	349	397
NEWARK,NEW JERSEY AREA OFFICE						
SMSA: NEW YORK CITY, NY-NJ						
COUNTY:BERGEN	NON-ELEVATOR:	206	234	275	318	360
STATE:NJ	ELEVATOR:	228	258	304	349	397
REGION 3						
BALTIMORE,MARYLAND AREA OFFICE						
SMSA: WILMINGTON, DE-NJ-MD						
COUNTY:CECIL	NON-ELEVATOR:	179	196	241	306	365
STATE:MD	ELEVATOR:	197	216	265	337	400
NON SMSA						
COUNTY:ALLEGANY	NON-ELEVATOR:	90	115	139	193	213
STATE:MD	ELEVATOR:	101	126	153	212	234
CHARLESTON,WEST VIRGINIA INSURING OFFICE						
NON SMSA						
COUNTY:BARBOUR	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:BERKELEY	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:DODDRIDGE	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:GRANT	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:HAMPSHIRE	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230

NOTE: FAIR MARKET RENTS (FMR) MAY BE CALCULATED FOR FIVE AND SIX BEDROOM UNITS AS FOLLOWS:
5-BR = 150 PERCENT OF 2-BR FMR; 6-BR = 175 PERCENT OF 2-BR FMR

PREPARED BY HUD - EMAD (CO), MARCH 05, 1978

U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
SECTION 8 & 23 HOUSING ASSISTANCE PAYMENTS PROGRAMS

SCHEDULE B- FAIR MARKET RENTS FOR EXISTING HOUSING(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAM)

REGION 3		0 BEDROOMS	1 BEDROOM	2 BEDROOMS	3 BEDROOMS	4 BEDROOMS
CHARLESTON,WEST VIRGINIA INSURING OFFICE						
NON SMSA						
COUNTY:HARDY	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:HARRISON	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:JEFFERSON	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:LEWIS	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:MARION	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:MASON	NON-ELEVATOR:	100	120	146	167	184
STATE:WV	ELEVATOR:	110	132	161	184	202
COUNTY:MONONGALIA	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
CHARLESTON,WEST VIRGINIA INSURING OFFICE						
NON SMSA						
COUNTY:MORGAN	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:PENDLETON	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:PRESTON	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:RANDOLPH	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:TAYLOR	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:TUCKER	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
COUNTY:UPSHUR	NON-ELEVATOR:	124	141	169	189	209
STATE:WV	ELEVATOR:	136	155	186	208	230
PITTSBURGH,PENNSYLVANIA AREA OFFICE						
SMSA: JOHNSTOWN, PA						
COUNTY:CAMBRIA	NON-ELEVATOR:	140	165	200	225	250
STATE:PA	ELEVATOR:	154	182	220	248	275
COUNTY:SOMERSET	NON-ELEVATOR:	140	165	200	225	250
STATE:PA	ELEVATOR:	154	182	220	248	275
RICHMOND,VIRGINIA AREA OFFICE						
SMSA: LYNCHBURG, VA						
COUNTY:AMHERST	NON-ELEVATOR:	135	167	205	272	290
STATE:VA	ELEVATOR:	149	184	226	299	319
COUNTY:APPOMATTOX	NON-ELEVATOR:	135	167	205	272	290
STATE:VA	ELEVATOR:	149	184	226	299	319
COUNTY:CAMPBELL	NON-ELEVATOR:	135	167	205	272	290
STATE:VA	ELEVATOR:	149	184	226	299	319
INDEP. CITY:LYNCHBURG	NON-ELEVATOR:	135	167	205	272	290
STATE:VA	ELEVATOR:	149	184	226	299	319
SMSA: PETERSBURG-COLONIAL HEIGHTS-HOPEWELL, VA						
COUNTY:DINWIDDIE	NON-ELEVATOR:	145	184	224	256	280
STATE:VA	ELEVATOR:	160	202	246	272	308
COUNTY:PRINCEGEORGE	NON-ELEVATOR:	145	184	224	256	280
STATE:VA	ELEVATOR:	160	202	246	272	308
INDEP. CITY:COLONIAL HEI	NON-ELEVATOR:	145	184	224	256	280
STATE:VA	ELEVATOR:	160	202	246	272	308
INDEP. CITY:HOPEWELL	NON-ELEVATOR:	145	184	224	256	280
STATE:VA	ELEVATOR:	160	202	246	272	308
INDEP. CITY:PETERSBURG	NON-ELEVATOR:	145	184	224	256	280
STATE:VA	ELEVATOR:	160	202	246	272	308
SMSA: RICHMOND, VA						
COUNTY:NEW KENT	NON-ELEVATOR:	168	196	244	282	310
STATE:VA	ELEVATOR:	174	215	268	309	341

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PREPARED BY HUD - EMAD (CO), MARCH 05, 1978

U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
SECTION 8 & 23 HOUSING ASSISTANCE PAYMENTS PROGRAMS

SCHEDULE B- FAIR MARKET RENTS FOR EXISTING HOUSING(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAM)

REGION 3		0 BEDROOMS	1 BEDROOM	2 BEDROOMS	3 BEDROOMS	4 BEDROOMS
RICHMOND,VIRGINIA AREA OFFICE						
SMSA: LYNCHBURG, VA						
NON SMSA						
COUNTY:MONTGOMERY	NON-ELEVATOR:	124	167	190	227	306
STATE:VA	ELEVATOR:	136	183	209	250	337
RICHMOND,VIRGINIA AREA OFFICE						
NON SMSA						
COUNTY:PULASKI	NON-ELEVATOR:	124	154	194	234	254
STATE:VA	ELEVATOR:	136	169	213	257	279
WILMINGTON,DELAWARE INSURING OFFICE						
SMSA: WILMINGTON, DE-NJ-MD						
COUNTY:NEW CASTLE	NON-ELEVATOR:	179	196	241	306	365
STATE:DE	ELEVATOR:	197	216	265	337	400
REGION 4						
ATLANTA,GEORGIA AREA OFFICE						
SMSA: CHATTANOOGA, TN-GA						
COUNTY:CATOOSA	NON-ELEVATOR:	146	160	196	274	298
STATE:GA	ELEVATOR:	159	175	215	302	328
COUNTY:DADE	NON-ELEVATOR:	146	160	196	274	298
STATE:GA	ELEVATOR:	159	175	215	302	328
COUNTY:WALKER	NON-ELEVATOR:	146	160	196	274	298
STATE:GA	ELEVATOR:	159	175	215	302	328
NON SMSA						
COUNTY:HABERSHAM	NON-ELEVATOR:	107	124	150	168	199
STATE:GA	ELEVATOR:	0	0	0	0	0
COUNTY:HARRIS	NON-ELEVATOR:	129	147	176	196	216
STATE:GA	ELEVATOR:	0	0	0	0	0
CORAL GABLES,FLORIDA INSURING OFFICE						
SMSA: FORT MYERS, FL						
COUNTY:LEE	NON-ELEVATOR:	173	204	242	274	286
STATE:FL	ELEVATOR:	190	224	266	301	315
COLUMBIA,SOUTH CAROLINA AREA OFFICE						
NON SMSA						
COUNTY:CHEROKEE	NON-ELEVATOR:	130	150	180	220	250
STATE:SC	ELEVATOR:	143	165	198	242	275
COUNTY:LEE	NON-ELEVATOR:	110	130	155	180	200
STATE:SC	ELEVATOR:	121	143	171	198	220
COUNTY:MARLBORO	NON-ELEVATOR:	110	130	150	185	220
STATE:SC	ELEVATOR:	121	143	165	204	242
COUNTY:OCONEE	NON-ELEVATOR:	130	150	180	220	250
STATE:SC	ELEVATOR:	143	165	198	242	275
GREENSBORO,NORTH CAROLINA AREA OFFICE						
NON SMSA						
COUNTY:CABARRUS	NON-ELEVATOR:	103	119	142	160	176
STATE:NC	ELEVATOR:	112	131	156	175	194
COUNTY:IREDELL	NON-ELEVATOR:	103	119	142	160	176
STATE:NC	ELEVATOR:	112	131	156	175	194
COUNTY:PERSON	NON-ELEVATOR:	126	144	175	204	223
STATE:NC	ELEVATOR:	137	159	191	223	244
COUNTY:ROWAN	NON-ELEVATOR:	103	119	142	160	176
STATE:NC	ELEVATOR:	112	131	156	175	194
COUNTY:SCOTLAND	NON-ELEVATOR:	126	144	175	204	223
STATE:NC	ELEVATOR:	137	159	191	223	244
COUNTY:STANLY	NON-ELEVATOR:	103	119	142	160	176
STATE:NC	ELEVATOR:	112	131	156	175	194
COUNTY:WILSON	NON-ELEVATOR:	114	130	157	176	195
STATE:NC	ELEVATOR:	126	143	172	193	215
JACKSONVILLE,FLORIDA AREA OFFICE						
NON SMSA						
COUNTY:COLUMBIA	NON-ELEVATOR:	135	156	186	209	233
STATE:FL	ELEVATOR:	147	172	205	231	254
COUNTY:MARION	NON-ELEVATOR:	137	160	191	215	236
STATE:FL	ELEVATOR:	152	174	211	235	259

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PREPARED BY HUD - EMAD (CO), MARCH 05, 1978

U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
SECTION 8 & 23 HOUSING ASSISTANCE PAYMENTS PROGRAMS

SCHEDULE B- FAIR MARKET RENTS FOR EXISTING HOUSING(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAM)

REGION 4		0 BEDROOMS	1 BEDROOM	2 BEDROOMS	3 BEDROOMS	4 BEDROOMS
KNOXVILLE,TENNESSEE AREA OFFICE						
SMSA: CHATTANOOGA, TN-GA						
COUNTY:HAMILTON	NON-ELEVATOR:	146	160	196	274	298
STATE:TN	ELEVATOR:	159	175	215	302	328
COUNTY:MARION	NON-ELEVATOR:	146	160	196	274	298
STATE:TN	ELEVATOR:	159	175	215	302	328
COUNTY:SEQUATCHIE	NON-ELEVATOR:	146	160	196	274	298
STATE:TN	ELEVATOR:	159	175	215	302	328
TAMPA,FLORIDA INSURING OFFICE						
SMSA: ORLANDO, FL						
COUNTY:ORANGE	NON-ELEVATOR:	163	189	227	273	290
STATE:FL	ELEVATOR:	180	208	249	300	317
COUNTY:OSCEOLA	NON-ELEVATOR:	163	189	227	273	290
STATE:FL	ELEVATOR:	180	208	249	300	317
COUNTY:SEMINOLE	NON-ELEVATOR:	163	189	227	273	290
STATE:FL	ELEVATOR:	180	208	249	300	317
REGION 5						
DETROIT,MICHIGAN AREA OFFICE						
SMSA: BAY CITY, MI						
COUNTY:BAY	NON-ELEVATOR:	146	169	225	263	289
STATE:MI	ELEVATOR:	161	185	248	289	318
GRAND RAPIDS,MICHIGAN INSURING OFFICE						
NON SMSA						
COUNTY:GRD TRAVERSE	NON-ELEVATOR:	176	203	229	265	328
STATE:MI	ELEVATOR:	194	223	252	292	361
REGION 6						
LITTLE ROCK,ARKANSAS AREA OFFICE						
NON SMSA						
COUNTY:UNION	NON-ELEVATOR:	104	123	147	165	184
STATE:AR	ELEVATOR:	116	136	162	181	203
NEW ORLEANS,LOUISIANA AREA OFFICE						
SMSA: NEW ORLEANS, LA						
PARISH:JEFFERSON	NON-ELEVATOR:	138	159	190	221	253
STATE:LA	ELEVATOR:	151	173	208	241	277
PARISH:ORLEANS	NON-ELEVATOR:	138	158	190	221	253
STATE:LA	ELEVATOR:	151	173	208	241	277
PARISH:ST BERNARD	NON-ELEVATOR:	138	158	190	221	253
STATE:LA	ELEVATOR:	151	173	208	241	277
PARISH:ST TAMMANY	NON-ELEVATOR:	138	158	190	221	253
STATE:LA	ELEVATOR:	151	173	208	241	277
NON SMSA						
PARISH:ACADIA	NON-ELEVATOR:	114	132	158	177	197
STATE:LA	ELEVATOR:	123	144	172	192	214
PARISH:IBERVILLE	NON-ELEVATOR:	114	132	158	177	197
STATE:LA	ELEVATOR:	123	144	172	192	214
PARISH:ST CHARLES	NON-ELEVATOR:	122	140	170	197	217
STATE:LA	ELEVATOR:	134	154	185	216	239
PARISH:ST JAMES	NON-ELEVATOR:	114	132	158	177	197
STATE:LA	ELEVATOR:	123	144	172	192	214
PARISH:ST MARTIN	NON-ELEVATOR:	114	132	158	177	197
STATE:LA	ELEVATOR:	123	144	172	192	214
PARISH:ST MARY	NON-ELEVATOR:	114	132	158	177	197
STATE:LA	ELEVATOR:	123	144	172	192	214
PARISH:TANGIPAHOA	NON-ELEVATOR:	114	132	158	177	197
STATE:LA	ELEVATOR:	123	144	172	192	214
PARISH:VERMILION	NON-ELEVATOR:	114	132	158	177	197
STATE:LA	ELEVATOR:	123	144	172	192	214
PARISH:WASHINGTON	NON-ELEVATOR:	114	132	158	177	197
STATE:LA	ELEVATOR:	123	144	172	192	214
SAN ANTONIO,TEXAS AREA OFFICE						
SMSA: AUSTIN, TX						
COUNTY:WILLIAMSON	NON-ELEVATOR:	165	189	227	263	288
STATE:TX	ELEVATOR:	181	207	247	287	317

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PREPARED BY HUD - EMAD (CO), MARCH 05, 1978

U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
SECTION 8 & 23 HOUSING ASSISTANCE PAYMENTS PROGRAMS

SCHEDULE B- FAIR MARKET RENTS FOR EXISTING HOUSING(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAM)

		0 BEDROOMS	1 BEDROOM	2 BEDROOMS	3 BEDROOMS	4 BEDROOMS
REGION 6						
SHREVEPORT,LOUISIANA INSURING OFFICE						
SMSA: ALEXANDRIA, LA						
PARISH:GRANT	NON-ELEVATOR:	128	147	178	206	227
STATE:LA	ELEVATOR:	140	160	194	225	248
PARISH:RAPIDES	NON-ELEVATOR:	128	147	178	206	227
STATE:LA	ELEVATOR:	140	160	194	225	248
SMSA: MONROE, LA						
PARISH:OUACHITA	NON-ELEVATOR:	128	147	178	206	227
STATE:LA	ELEVATOR:	140	160	194	225	248
SMSA: SHREVEPORT, LA						
PARISH:BOSSIER	NON-ELEVATOR:	128	147	178	206	227
STATE:LA	ELEVATOR:	140	160	194	225	248
PARISH:CADDO	NON-ELEVATOR:	128	147	178	206	227
STATE:LA	ELEVATOR:	140	160	194	225	248
PARISH:WEBSTER	NON-ELEVATOR:	128	147	178	206	227
STATE:LA	ELEVATOR:	140	160	194	225	248
NON SMSA						
PARISH:LINCOLN	NON-ELEVATOR:	113	130	156	180	199
STATE:LA	ELEVATOR:	124	143	171	198	220
REGION 7						
DES MOINES,IOWA INSURING OFFICE						
NON SMSA						
COUNTY:DICKINSON	NON-ELEVATOR:	149	164	185	200	230
STATE:IA	ELEVATOR:	164	180	204	220	253
KANSAS CITY,KANSAS AREA OFFICE						
NON SMSA						
COUNTY:CALDWELL	NON-ELEVATOR:	124	143	172	193	211
STATE:MO	ELEVATOR:	137	156	189	211	232
COUNTY:DAVIESS	NON-ELEVATOR:	124	143	172	193	211
STATE:MO	ELEVATOR:	137	156	189	211	232
COUNTY:GRUNDY	NON-ELEVATOR:	124	143	172	193	211
STATE:MO	ELEVATOR:	137	156	189	211	232
COUNTY:HARRISON	NON-ELEVATOR:	124	143	172	193	211
STATE:MO	ELEVATOR:	137	156	189	211	232
COUNTY:LIVINGSTON	NON-ELEVATOR:	124	143	172	193	211
STATE:MO	ELEVATOR:	137	156	189	211	232
COUNTY:MERCER	NON-ELEVATOR:	124	143	172	193	211
STATE:MO	ELEVATOR:	137	156	189	211	232
OMAHA,NEBRASKA AREA OFFICE						
NON SMSA						
COUNTY:RED WILLOW	NON-ELEVATOR:	118	150	171	214	236
STATE:NE	ELEVATOR:	129	165	188	235	260
TOPEKA,KANSAS INSURING OFFICE						
NON SMSA						
COUNTY:HARVEY	NON-ELEVATOR:	111	135	157	185	197
STATE:KS	ELEVATOR:	122	149	173	204	217
REGION 8						
HELENA,MONTANA INSURING OFFICE						
NON SMSA						
COUNTY:RICHLAND	NON-ELEVATOR:	136	153	184	201	222
STATE:MT	ELEVATOR:	150	168	204	222	244
REGION 9						
FRESNO, CALIFORNIA INSURING OFFICE						
NON SMSA						
COUNTY:TULARE	NON-ELEVATOR:	162	184	217	285	316
STATE:CA	ELEVATOR:	178	202	239	314	347
HONOLULU,HAWAII AREA OFFICE						
NON SMSA						
COUNTY:KAUAI	NON-ELEVATOR:	219	250	291	375	406
STATE:HI	ELEVATOR:	0	0	0	0	0
LOS ANGELES,CALIFORNIA AREA OFFICE						
SMSA: LOS ANGELES-LONG BEACH, CA						
COUNTY:LOS ANGELES	NON-ELEVATOR:	180	204	241	308	350
STATE:CA	ELEVATOR:	198	225	266	339	385

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U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
SECTION 8 & 23 HOUSING ASSISTANCE PAYMENTS PROGRAMS

SCHEDULE B- FAIR MARKET RENTS FOR EXISTING HOUSING(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAM)

REGION 10		0 BEDROOMS	1 BEDROOM	2 BEDROOMS	3 BEDROOMS	4 BEDROOMS
BOISE,IDAHO INSURING OFFICE						
SMSA: BOISE CITY, ID						
COUNTY:ADA	NON-ELEVATOR:	174	197	247	270	298
STATE:ID	ELEVATOR:	190	216	270	297	328
NON SMSA						
COUNTY:BLAINE	NON-ELEVATOR:	170	190	225	250	275
STATE:ID	ELEVATOR:	187	209	248	275	302
COUNTY:BONNEVILLE	NON-ELEVATOR:	180	200	240	265	290
STATE:ID	ELEVATOR:	198	220	264	292	319
COUNTY:FREMONT	NON-ELEVATOR:	170	190	225	250	275
STATE:ID	ELEVATOR:	187	209	248	275	302
COUNTY:MADISON	NON-ELEVATOR:	155	171	205	226	250
STATE:ID	ELEVATOR:	170	188	225	248	275
COUNTY:TWIN FALLS	NON-ELEVATOR:	170	190	225	250	275
STATE:ID	ELEVATOR:	187	209	248	275	302
PORTLAND,OREGON AREA OFFICE						
NON SMSA						
COUNTY:BAKER	NON-ELEVATOR:	135	155	180	215	237
STATE:OR	ELEVATOR:	149	171	198	237	261
COUNTY:CLATSOP	NON-ELEVATOR:	156	177	211	243	264
STATE:OR	ELEVATOR:	171	198	231	267	291
COUNTY:DOUGLAS	NON-ELEVATOR:	143	162	194	222	244
STATE:OR	ELEVATOR:	157	178	213	244	269
COUNTY:GRANT	NON-ELEVATOR:	135	155	180	215	237
STATE:OR	ELEVATOR:	149	171	198	237	261
COUNTY:JACKSON	NON-ELEVATOR:	165	190	220	265	305
STATE:OR	ELEVATOR:	182	209	242	292	336
COUNTY:JOSEPHINE	NON-ELEVATOR:	145	175	225	260	285
STATE:OR	ELEVATOR:	160	193	248	286	314
COUNTY:TILLAMOOK	NON-ELEVATOR:	156	177	211	243	264
STATE:OR	ELEVATOR:	171	198	231	267	291
COUNTY:UNION	NON-ELEVATOR:	135	155	180	215	237
STATE:OR	ELEVATOR:	149	171	198	237	261
COUNTY:WALLOWA	NON-ELEVATOR:	135	155	180	215	237
STATE:OR	ELEVATOR:	149	171	198	237	261
COUNTY:YAMHILL	NON-ELEVATOR:	160	180	215	270	295
STATE:OR	ELEVATOR:	176	198	237	297	325
SEATTLE,WASHINGTON AREA OFFICE						
SMSA: SEATTLE-EVERETT, WA						
COUNTY:KING	NON-ELEVATOR:	177	202	243	304	331
STATE:WA	ELEVATOR:	194	223	267	334	364
COUNTY:SNOHOMISH	NON-ELEVATOR:	177	202	243	304	331
STATE:WA	ELEVATOR:	194	223	267	334	364
NON SMSA						
COUNTY:KITSAP	NON-ELEVATOR:	162	194	243	304	330
STATE:WA	ELEVATOR:	178	213	267	334	363
COUNTY:WHATCOM	NON-ELEVATOR:	159	181	217	260	312
STATE:WA	ELEVATOR:	175	199	239	286	343
SPOKANE,WASHINGTON INSURING OFFICE						
SMSA: RICHLAND-KENNEWICK, WA						
COUNTY:BENTON	NON-ELEVATOR:	165	201	245	314	354
STATE:WA	ELEVATOR:	182	221	270	345	389
COUNTY:FRANKLIN	NON-ELEVATOR:	165	201	245	314	354
STATE:WA	ELEVATOR:	182	221	270	345	389
NON SMSA						
COUNTY:LATAH	NON-ELEVATOR:	155	171	205	226	250
STATE:ID	ELEVATOR:	170	188	225	248	275
COUNTY:NEZ PERCE	NON-ELEVATOR:	155	171	205	226	250
STATE:ID	ELEVATOR:	170	188	225	248	275
COUNTY:WALLA WALLA	NON-ELEVATOR:	125	172	245	308	339
STATE:WA	ELEVATOR:	138	189	270	339	373

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PREPARED BY HUD - EMAD (CO), MARCH 05, 1978

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[FR Doc. 78-21713 Filed 8-7-78; 8:45 am]

federal register

TUESDAY, AUGUST 8, 1978
PART III



DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

■

PROTECTION AND ENHANCEMENT OF ENVIRONMENTAL QUALITY

Departmental Procedures

[4210-01]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

[Docket No. N-78-887]

PROCEDURES FOR PROTECTION AND ENHANCEMENT OF ENVIRONMENTAL QUALITY

Amendments to Departmental Procedures

AGENCY: Department of Housing and Urban Development.

ACTION: Notice.

SUMMARY: HUD is soliciting comments on proposed amendments to the Departmental procedures to change certain practices affecting the protection and enhancement of enviromental quality. In order to avoid duplicative analysis and documentation in connection with conducting environmental reviews greater flexibility is proposed in the size and type of project requiring an environmental impact statement. Additional changes are proposed for updating an EIS, to clarify HUD's review requirements with respect to historic preservation, and to modify the description of exempt rehabilitation and modernization projects to reflect more accurately environmental impacts. This amendment would also expand the public disclosure principle of Executive Order 11514 as amended, and provide the authority for the Department to carry out its responsibilities under Executive Order 11988, Floodplain Management, and Executive Order 11990, Protection of Wetlands.

The effect of this amendment would clarify departmental practices with respect to protection and enhancement of environmental quality. The proposed flexible thresholds would more accurately reflect differences among areas wherein housing actions occur and simplify departmental procedures in carrying out its NEPA responsibilities.

COMMENTS DUE DATE: September 7, 1978.

ADDRESS: Comments should be addressed to: Office of the Rules Docket Clerk, Office of the General Counsel, Room 5218, 451 Seventh Street SW., Washington, D.C. 20410.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard H. Broun, Office of Environmental Quality, room 7258, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, D.C. 20410; telephone 202-755-6308.

SUPPLEMENTARY INFORMATION: The changes proposed in this notice have been developed to address needs which have become apparent from HUD program operations during the last several years. During this interval, interagency discussions have also been occurring with a view towards unifying the approach which HUD, the Veterans Administration, and the Farmers Home Administration use in applying the National Environmental Policy Act and related requirements to their respective housing programs. Since January 1978 the Council on Environmental Quality has been chairing an interagency effort directed towards these goals. Because the three agencies are in general agreement with these goals, and because the three agencies will have to revise their NEPA procedures in accordance with CEQ's new regulations (published for comment June 9, 1978 at 43 FR 25230), work towards unification of the agency procedures will continue intensively during the next several months. The agencies will also consider other related needs, such as the development of standard forms, written guidance, training, and the "early start" procedure (43 FR 797). Therefore, in addition to the comments hereby solicited on the changes proposed to the HUD regulations, comments on the broader needs of HUD, VA, and FmHA programs and on the general question of regulatory unification are also being requested by this notice. Copies of all comments submitted to the HUD docket will be provided to CEQ, VA, and FmHA.

With regard to the HUD programs, the intent of the proposed changes and the major issues involved are as follows:

Flexible Housing Thresholds Requiring EIS's

HUD considers various qualitative factors in determining whether a particular HUD action requires the preparation of an environmental impact statment (EIS). In addition, for certain actions HUD has a fixed threshold of 500 units as an automatic decision point for determining whether a proposed housing action requires an EIS. In effect, HUD is using a numerical standard to identify "a major Federal action significantly affecting the quality of the human environment." On the basis of 3 years of experience HUD has concluded that this fixed numerical threshold of 500 units does not adequately reflect differences among areas wherein housing actions occur, such as differences in population size and growth, the extent of development, or the service capacity of communities involved. Metropolitan areas, as an example, do not have the characteristics of nonmetropolitan or sparsely developed areas, and housing developments of a given scale will have less impact in urban or urbanizing locations than in less developed areas.

Therefore, paragraph 5.d of chapter would be amended by adding a new subparagraph (5), and while retaining the qualitative factors which are considered in HUD's review process and which may independently require an EIS, HUD proposes to shift from a single automatic threshold for housing actions to a flexible system of thresholds which would more nearly reflect the impact on areas where the proposed housing action is to occur. Housing actions covered by the flexible threshold cover approvals under all HUD programs affecting new multifamily construction, subdivisions, property disposition, nonexempt rehabilitation, and such other housing programs as may be subject to NEPA. The proposed amendment includes a table of flexible thresholds which vary with the population of counties within Standard Metropolitan Statistical Areas (SMSA). Safeguards against leapfrog development would also be provided. HUD will continue to require an EIS for developments of significant scale while allowing smaller scale proposals to proceed subject to an environmental review at a lower level than an EIS. HUD would also retain the present qualitative factors that would require an EIS regardless of the number of units proposed.

The table included in this amendment would provide a range of thresholds from 500 units to 2,500 units, and would be based on the population size of the community, and applied as follows:

a. For housing actions that would occur within the urbanizing belt of an SMSA county, which includes the urbanized area defined by the Bureau of the Census and a band 2-miles wide beyond, the threshold would be that number in the table opposite the population class in which the county's population falls.

b. For actions that would occur beyond the urbanizing belt, and in non-SMSA counties, the 500-unit threshold would be applicable.

c. If it can be documented that significant development has occurred beyond—but contiguous to—the defined urbanized area, HUD may expand the perimeter of the urbanizing belt to include such areas plus a 2-mile zone beyond.

d. In defining the urbanizing belt HUD may include the whole of any census tract or untracted incorporated place for which any part falls within the 2-mile limit. The urbanizing belt would in no case extend beyond the SMSA county's boundary.

The thresholds are applied to population figures based on the Bureau of the Census latest population estimates published in the P-25 series of current

population reports. Although the initial application of these thresholds would be to the population data for 1975, the Department would apply revised figures as they become available for subsequent years. When the Bureau of the Census population estimate for a given SMSA county, or county equivalent, indicates that there has been a loss in population since the last decennial census, HUD would use the most recent decennial census figures.

Actions Not Subject to EIS Threshold Criteria

Paragraph 5. of chapter 2 would be amended by adding a new subparagraph e. thereto entitled "Project Level Actions Not Subject to EIS Threshold Criteria." This new subparagraph would establish procedures whereby an EIS which was prepared by HUD, a grantee of HUD pursuant to 24 CFR Part 58, or another Federal agency, and which anticipated a subsequent action requiring an EIS, could be used by HUD as the environmental review and clearance of the subsequent action, provided a special environmental clearance meeting certain conditions is completed. In addition, subparagraph e. would provide for the same procedure for conducting an environmental review if an adequate areawide or similar broad scale EIS has already been completed.

Aggregation

When two or more projects are located in close proximity, or are otherwise interrelated, so as to affect the environment, they should be aggregated in a single environmental clearance. Therefore, paragraph 5.a(5) of chapter 2 is amended to establish criteria for a higher level environmental clearance or EIS when separate subdivision or multifamily projects do not exceed threshold requirements but may be located in such a manner as to have a common impact on resources, infrastructure, and public services.

Property Disposition

A number of changes are proposed to reflect and adapt to various types of property disposition actions including vacant land. Paragraph 5.d. of chapter 2 would be amended by adding two new subparagraphs, (6) and (7). Subparagraph 5.d.(6) would provide that EIS thresholds would not apply to multifamily dispositions actions when certain conditions are met. With respect to disposition actions involving one-to-four family structures, subparagraph 5.d.(7) and appendix A-1 would utilize the management methodology of the planned program approach (PPA) and its planned program areas for decision points and the application of special and EIS thresholds identified in appendix A-1. Additional changes would be made in appendix A-1 to reflect and clarify decision points and thresholds with respect to property disposition including provisions for the use of only special clearances below an EIS for multifamily actions. In such cases, normal clearances would not be utilized.

Decision Points and Historic Preservation

Paragraph 2.h. of chapter 1 would be amended to provide that the decision points for environmental clearances set forth in appendix A-1 and appendix A-2 shall also be the decision points for historic preservation review procedures. Decision points would also be clarified for those cases where a project or program has already commenced prior to the first proposal for a HUD action or undertaking.

Paragraph 5.a.(6) of chapter 2 would be amended to provide that HUD's historic preservation procedures, conducted in accordance with HUD regulations, the National Historic Preservation Act of 1966 and Advisory Council on Historic Preservation requirements, shall be carried out in conjunction with prescribed environmental procedures. Terminology relating to the National Register of Historic Places would also be revised to make it technically accurate.

Notice of Intent To Prepare and File an Environmental Impact Statement

Paragraph 5.d. of Chapter 2 would be amended to provide for the publication and dissemination by HUD of a notice of intent to File an environmental impact statement (EIS). The principle of informing the public that an EIS is about to be prepared already exists for housing projects under the "early start" procedures. This amendment would expand this public disclosure principle to all EIS's prepared by HUD and conform more specifically to Executive Order 11514 and the CEQ guidelines.

Rehabilitation

The exemption from all environmental reviews for rehabilitation and modernization projects is revised to provide that such projects must meet certain density, use, and cost criteria. For additional clarification the definition of "substantial rehabilitation" has been dropped from the terminology section of chapter 1 as being no longer needed.

EIS Supplement

When additional information is discovered or changes are made in the basic assumptions of the final EIS, the final EIS would be updated by the use of an EIS supplement. This procedure is limited to contemplated changes which are subsequent to the HUD action which was predicated on the previous final EIS. Therefore:

a. Paragraph 2 of chapter 1 would be amended by adding a new subparagraph 1. defining a supplement to a final environmental impact statement.

b. Paragraph 5.a.(9) of chapter 2 would be amended to allow for the use of a supplement when updating a final environmental impact statement.

c. Paragraph 5.a.(9) of chapter 2 would be amended by adding a new subparagraph (d) which identifies the conditions and the procedures for the issuance of a supplement to a final EIS.

Appendices A-1 and A-2

Appendix A-1 and appendix A-2 would be completely revised and reorganized to (a) consolidate in a single printing all prior amendments made to these appendices, and (b) revise the arrangement of material between appendix A-1 and appendix A-2 for improved clarity.

The HUD procedures for protection and enhancement of environmental quality are now available only as published in the Federal Register. The procedures were initially published in the Register under the subtitle "Handbook 1390.1." However, HUD never issued the environmental procedures in handbook form under the HUD unified issuance system. Consequently, repeated use of the term "handbook" has been confusing to the public. To remove this confusion and to respond to the proposed regulations of the Council on Environmental Quality (43 FR 25230), HUD intends to revise the complete set of procedures and republish them as a regulation. In the interim, HUD will delete the reference to Handbook 1390.1, and simply refer to "Procedures for Protection and Enhancement of Environmental Quality."

With respect to the above proposed amendments, interested persons are invited to participate in the making of the final rule by submitting written comments or views on the proposed amendments. To facilitate HUD's review of written comments, reviewers are requested to clearly identify the amendment to which the comments are addressed. Comments should be filed with the Rules Docket Clerk, Room 5218, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, D.C. 20410. All relevant comments received on or before the date specified above will be considered before adoption of the final rule. Copies of comments will be available for examination during business hours at the above address.

A finding of inapplicability with respect to environmental impact has

been prepared in accordance with the Department's environmental procedures. A copy of this finding is available for inspection and copying in the office of the rules docket clerk at the above address.

Accordingly, the Department's environmental procedures, previously published on July 18, 1973 (38 FR 19182) and subsequently amended on November 4, 1974 (39 FR 38922), June 11, 1976 (41 FR 23878), March 9, 1977 (42 FR 13208), and January 4, 1978 (43 FR 797), are hereby proposed to be further amended as follows:

1. Paragraph 1 of chapter 1 is to be amended by adding a new subparagraph i as follows:

i. Executive Order 11988 (42 FR 26951, May 25, 1977) and Executive Order 11990 (42 FR 26961, May 25, 1977) which call for heads of agencies to issue or amend procedures to avoid adverse impacts on and to avoid support of development in wetlands and floodplains.

2. Paragraph 5.d. of chapter 2 is amended by adding a new subparagraph (5), thereto, as follows:

(5) *Threshold determination.* An EIS shall be prepared for any action exceeding the thresholds identified in appendix A-1. Set forth below are the criteria for determining the threshold within the range of 500–2,500 units.

(a) The applicability of this subparagraph is limited to areas identified as urbanizing belts falling within an SMSA. Urbanizing belts are identified as the delineated Urbanized Areas, as defined by the Bureau of the Census, plus a 2-mile zone around the outer boundaries of such areas. In cases where this 2-mile zone borders or includes a portion of an incorporated place lacking census tracts, *or*, when the 2-mile zone borders or includes a portion of a census tract, then the next outer boundary of such incorporated place or census tract may be used to delineate the outer limit of the urbanizing belt. In no case shall the urbanizing belt extend beyond the SMSA boundary.

(b) In cases where the environmental clearance officer believes that, due to urban development occuring since the last Bureau of Census update, this delineation does not adequately identify urbanizing belts (for example, in rapidly growing areas), the ECO may request an expansion of the belt. The request will include information related to the same criteria that the Bureau of Census used in its designation of the urbanized area, but the request must include more recent information than the last Bureau of Census update. The request must also include a suggested redlineation of the urbanizing belt, either on a map, or in adequate specificity so that the redelineation can be drawn on a map. The request should be submitted through the area office manager and the regional environmental clearance officer, to the Assistant Secretary for Community Planning and Development for final determination. The assistant secretary for CPD may, following an evaluation of the request, authorize an expansion of the defined urbanizing belt.

TABLE 1.—*Flexible EIS thresholds.*

SMSA county population range	Threshold (units)
1,500,000+	2,500
1,000,000 to 1,499,999	2,100
750,000 to 999,999	1,800
600,000 to 749,999	1,500
500,000 to 599,999	1,200
400,000 to 499,999	1,000
300,000 to 399,999	900
200,000 to 299,999	800
100,000 to 199,999	700
50,000 to 99,999	600
Under 50,000	500

(c) The flexible EIS threshold table (table No. 1), shows threshold numbers (units) which are to be applied to the SMSA county or county equivalent (independent city) population data. These data are to be drawn from the Bureau of Census population estimates for 1975 published in the P-25 series of current population reports. Although the initial application of these thresholds will be to these population figures for 1975, the Department will apply revised figures as they become available for subsequent years.

However, when the population estimate for a given SMSA county indicates that there has been a loss in population since the last decennial census, HUD will use the most recent decennial census figures.

(d) Since some environmental reviews will be in process when this change in thresholds becomes effective, the following transition rules shall apply to those situations where an EIS would have been required under the previous thresholds but will not be required under the new flexible thresholds:

(i) Where a draft EIS has been published for public comment, the EIS process, including the issuance of a final EIS, shall be completed or the termination process described in (iv) below shall be completed before the required decision point is reached.

(ii) Where a notice of intent to file an EIS has been published but a draft EIS has not been published for public comment, the EIS process shall be completed or the termination prcoess described in (iv) below shall be completed before the required decision point is reached.

(iii) The option of deciding not to continue the full EIS process is not available in cases where HUD has based the need for an EIS on qualitative reasons irrespective of project size and the HUD threshold.

(iv) Where an EIS already in process is to be terminated, as provided by subparagraph (i) and (ii) above, the area office shall complete a special environmental clearance and a finding of inapplicability; shall give full consideration to all comments which may have been received in response to a notice of intent to prepare an EIS or in response to a draft EIS; and shall publish a notice of intent to terminate an EIS. Such notice shall be published and disseminated in the same manner as a notice of intent to file an EIS as described in paragraph 5.d.(1). The notice may be brief but shall identify the name, character, site and location of the project or program for which further processing of an EIS is to be terminated, set forth the circumstances and reasons for discontinuing further EIS processing, indicate that the special clearance required by this subparagraph has been completed and indicate where and when it is available for public review, describe how any comments received in response to a notice of intent to prepare an EIS or in response to a draft EIS were considered, and state that HUD proposes to approve the project or program under consideration in no less than fifteen (15) calendar days from the date the notice is published.

3. Paragraph 5, of chapter 2 is amended by adding a new subparagraph e. thereto, as follows:

e. *Project level actions not subject to EIS threshold criteria.* It is the policy of the Department to avoid duplicative analysis and documentation and undue delays in connection with environmental reviews. Accordingly, where any final environmental impact statement has been listed in the FEDERAL REGISTER for a project level action or where an areawide or similar broad scale final EIS has been so listed and the EIS anticipated a subsequent project level action requiring an environmental clearance, then the EIS threshold criteria contained in appendix A-1 and appendix A-2 shall not apply to that subsequent action if the following conditions are met:

(1) A special environmental clearance has been completed and concurred in by the applicable environmental clearance officer, resulting in a finding that the proposed project is not a new major Federal action significantly affecting the quality of the human environment.

(2) In addition to the content prescribed elsewhere in this subparagraph, the special environmental clearance shall include:

(i) References to the prior EIS and its evaluation of the environmental factors affecting the proposed subsequent action subject to NEPA;

(ii) An evaluation of any environmental factors which may not have been previously assessed, or which may have significantly changed;

(iii) An analysis showing that the proposed project is consistent with the location, use, and density assumptions for the site and with the timing and capacity of the circulation, utility, and other supporting infrastructure assumptions in the prior environmental impact statement;

(iv) Documentation showing that where the previous EIS required mitigating measures or other corrective action, these are completed to the extent reasonable given the current state of development.

(3) The prior final environmental impact statement has been kept current in the following ways:

(i) The EIS has been filed or updated within five (5) years;

(ii) The EIS has been updated in accordance with significant revisions made to the underlying assumptions (covering at least those items in 5.e.(2)(iii) above) as may be stated in the comprehensive plan or major elements thereof or other public policy revisions;

(iii) The EIS has been updated to reflect new environmental issues and data or legislation and implementing regulations which the Department of Housing and Urban Development has determined to have significant environmental impact on the areas covered by the prior EIS.

(4) There is no litigation pending in connection with the prior EIS, and no final judicial finding of inadequacy of the prior EIS has been made.

4. The second sentence of paragraph 5.a.(5) of chapter 2 is deleted and replaced by the following:

For example, individual projects which do not exceed threshold requirements shall be aggregated for determining the level of environmental clearance or applicable threshold under the following conditions:

(a) When the applicant's locally approved development plan or the applicant's control of the site (through ownership, option, or otherwise) indicates a total development that would exceed threshold requirements; or

(b) When separate applications, for which feasibility letters have not been issued, have been received or expected to be received (within 60 days) on neighboring sites (whose boundaries are within 2,000 feet) indicates a total development that would exceed threshold requirements.

This aggregation requirement shall not apply when the area office ECO determines that natural or manmade features are located in such a manner as to clearly separate developments.

5. Paragraph 2 of chapter 1 is amended by deleting subparagraph 1. in its entirety. A new subparagraph 1. is added as follows:

1. *EIS supplement.* For the purpose of these procedures, the term "EIS supplement" shall be used to identify a product and a two-stage process, for updating a final environmental impact statement when additional information is discovered or when actions are being contemplated which would change the basic assumptions of the most recent final EIS. The EIS supplement is limited to contemplated actions which are subsequent to HUD's approval of, or commitment to, the project's original proposals.

6. The second sentence of paragraph 5.a.(1) of chapter 2, is deleted in its entirety and replaced by the following:

These shall include an individual action on a one-to-four family dwelling and training grants. Rehabilitation or modernization projects are also included provided that: (i) Unit densities are not increased more than 20 percent; (ii) the project does not involve a change in use from residential to nonresidential use or from one class of nonresidential use to another class of use; or (iii) the cost of rehabilitation is less than 75 percent of the total cost of replacement after rehabilitation.

7. Paragraph 2.h. of chapter 1 is deleted in its entirety and is replaced by the following:

h. *Decision points.* Those points of Federal commitment in the decisionmaking process before which both prescribed environmental clearances and historic preservation review procedures (see paragraph 5.a.(6)) must be completed. HUD decision points are set forth in appendices A-1 and A-2 of these procedures. When a project or program has proceeded in its implementation past those designated decision points prior to the first proposal for a HUD action, and where there has been no prior HUD involvement, then the first positive HUD action, signifying HUD approval or commitment to such project or program without which such project or program could not proceed, shall be deemed the decision point.

8. The title, first paragraph, and the last sentence of section 5.a.(6) are deleted and replaced by the following:

(6) *Properties included in or eligible for inclusion in the National Register of Historic Places.* All HUD actions and undertakings involving decision points defined herein are subject to a historic preservation review through procedues prescribed by the Department or otherwise in accord with procedures of the Advisory Council on Historic Preservation, 36 CFR 800 (37 FR 24146, November 14, 1972) and the requirements of section 106 of the National Historic Preservation Act of 1966. This review serves to determine whether a proposed action or undertaking will affect a property included in, or eligible for inclusion in, the National Register of Historic Places; and, if such a property is involved, to avoid or mitigate adverse effects to the fullest extent practicable. The historic preservation review must be accomplished before the proposed action or undertaking proceeds past the relevant decision points set forth in either appendix A-1 or appendix A-2. To the extent possible, this review shall be carried out in conjunction with the environmental review procedures, including the special clearance or environmental impact statement required by appendix A-1 and appendix A-2. Where environmental impact statements are required, they should reflect and describe the historic preservation review. Where environmental reviews are not required, historic preservation reviews are nonetheless required prior to the decision points defined in appendix A-1 and appendix A-2.

9. Paragraph 5.d. of chapter 2 is amended by adding a new subparagraph (1) and renumbering all of the existing numerical subparagraphs from (2) thru (5). The new subparagraph (1) shall read as follows:

(1) *Notice of intent to file an environmental impact statement.* Immediately after determining that an EIS is required a notice of intent to file an EIS shall be prepared. Such notice may be brief but shall (i) identify the name, character, size and location of the project or program to which the EIS relates, (ii) solicit the comments of all interested parties respecting the environmental impacts of the project or program, (iii) indicate the time (not less than ten (10) calendar days), manner, form and address for the submission of comments, and (iv) specify an estimated date for completion and distribution of the draft EIS. Copies of the notice of intent to file an EIS shall be sent to the local news media, individuals and groups known to be interested in the project or program, local, State, and Federal agencies, the appropriate regional office of the Environmental Protection Agency, the appropriate A-95 clearinghouses, and others believed appropriate. Such notice shall be published at least once in a newspaper of general circulation in the affected community. If such newspaper is of a type specializing in the publication of legal, real estate, commercial or other notices, listings and advertisements and is not of a type subscribed to and read by the general public as a source of news of general public interest, then such notice shall also be published at least once in a newspaper which is a source of news of general public interest or shall be published in such other manner deemed most likely to inform residents of the affected community.

10. Paragraph 5.a.(9) of chapter 2 is amended as follows:

A. The first paragraph of subparagraph (9) is deleted and the following inserted:

(9) *Updating environmental clearances.* Environmental clearances shall be updated by revision, EIS supplement, amendment or addendum to the original clearance under the following circumstances;

B. Paragraph 5.a.(9) of chapter 2 is amended by adding a new subparagraph (d), thereto, as follows:

(d) *Special procedures for the issuance of a supplement to the final environmental impact statement.* The issuance of a supplement to the final EIS may be used in accord with appendix A-1 or appendix A-2 when, subsequent to HUD approval of, or commitment to, the proposed project, changes are contemplated that would result in a modification of the impact of the proposals or component activities addressed in the current final EIS. Immediately after determining that a supplement to the current final environmental impact statement is required, a notice of intent to issue a supplement to the final environmental impact statement shall be prepared in accordance with the procedure for the issuance of a notice of intent to file an environmental impact statement. The supplement to the final environmental impact statement shall be prepared covering the changes contemplated and circulated in accordance with the procedure for preparing a draft and final environmental impact statement.

11. Paragraph 5.a.(7) of chapter 2 is amended as follows:

a. The first sentence of subparagraph a. is deleted and replaced by the following:

Project level actions involving other than HUD insured projects, subdivisions, property disposition programs and low-rent housing projects.

B. Paragraph 5.a.(7) of chapter 2 is amended by adding a new subparagraph c., thereto, as follows:

c. *Property disposition programs.* The environmental clearance form in appendix C-5 may be used in conducting the required environmental clearance(s) involving HUD property disposition actions. Program instructions as approved by the Assistant Secretary for CPD may modify this form to adapt it to property disposition actions.

12. The first two sentences of paragraph 5.a.(9)(c) are deleted and replaced by the following:

HUD environmental clearance is required for component activities whose environmental activities were not addressed in sufficient detail in an original and current environmental clearance for a larger action. Where a prior clearance is current and anticipated a subsequent action, no new clearance on the proposed subsequent action is required except as required by paragraph 5.e. Required environmental clearances shall focus on the environmental impact of the specific project and site and need not treat the environmental impact on the more comprehensive level addressed in the original environmental impact statement.

13. Paragraph 5.d. of chapter 2 is amended by adding a new subparagraph (6), thereto; as follows:

(6) *Special procedure for multifamily property disposition actions.* The EIS thresholds set forth in appendix A-1 do not apply to multifamily property disposition actions when all the following conditions are met: (i) No change of use in the property can reasonably be expected within one year of the HUD action. For the purposes of this subparagraph no change in use means: unit density is not changed more than 20 percent; there is no change in use from residential to nonresidential use or from one class of nonresidential use to another class of use; or if rehabilitation is involved prior to disposition, the cost of rehabilitation is less than 75 percent of the total cost of replacement after rehabilitation. (ii) A special clearance and finding of no significant effect has been completed and a notice of this effect has been published and disseminated in the same manner as a notice of intent to file an environmental impact statement as described in paragraph 5.d.(1). The notice may be brief, but shall be published at least 20 days prior to the HUD action; describe why no change of use as set forth in this handbook is involved; indicate that a special clearance has been prepared and approved in accordance with this subparagraph; state where and when it is available for public inspection; identify the name, character, size and location of the project or disposition action to which the special clearance relates; indicate the anticipated date of HUD approval; invite comments concerning the need for an EIS; and indicate that such comments (if received at least 5 days before the anticipated HUD approval date) will be considered before a final decision is made. (iii) All communications received in accordance with subparagraph (ii) above are carefully considered in accordance with paragraph 5.a.(3).

14. Paragraph 5.d. of Chapter 2 is amended by adding a new subparagraph (7), thereto, as follows:

(7) *Special procedure for one-to-four family property disposition actions.* The special and EIS thresholds set forth in appendix A-1 apply to the number of units in inventory in a planned program area of a PPA (planned program approach). The number in inventory shall be determined no more than 30 days prior to approval of the PPA. In addition, individual planned program areas, or portions thereof, should be aggregated in accordance with paragraph 5.a.(5) before applying the appropriate threshold. A new clearance of a planned program area of a PPA (which has previously received an environmental clearance) is required when previously approved modes of disposition are changed; when new acquisitions since the last environmental clearance reach or exceed the special or EIS threshold; or when the units in the inventory reach or exceed the applicable threshold.

15. Appendix A-1 and Appendix A-2 are deleted in their entireties and replaced by the following new Appendices:

APPENDIX A-1

DECISION POINTS AND THRESHOLDS FOR ENVIRONMENTAL CLEARANCES

All environmental clearances shall be completed before the applicable decision points set forth below for Departmental Programs except as they may be inapplicable or inappropriate (see paragraph 2.h). The thresholds shall apply to the activities which have been aggregated in accordance with paragraphs 5.a(5) and (9) and 5.d.(7). Consult the Assistant Secretary for Community Planning and Development for decision points and thresholds for programs or other actions not listed.

PROGRAM	DECISION POINTS	SPECIAL CLEARANCE THRESHOLDS	EIS THRESHOLDS 1/
Concentrated Code Enforcement Program	Approval of application or major amendatory	All new Concentrated Code Enforcement Areas	When required purusant to paragraph 5d or Appendix A-2
Demonstration Projects 2/	Approval of contract or of demonstration site	Cost totaling $500,000 in new construction	When required pursuant to paragraph 5d or Appendix A-2
HOUSING ASSISTANCE OR INSURANCE:			
New Construction 3/ 4/ 5/			
--subdivisions of one-to-four family structures	Issuance of feasibility letter or major change in letter or project (ASP-6)	100 lot subdivision where typical lot size is 6,000 sq. ft. or greater: 200 lot subdivision where typical lot size is under 6,000 sq. ft.	500 to 2,500 units (see paragraph 5.d.(5))
--multifamily Structures	Issuance of SAMA letter or major change in letter or project. Reservation of contract authority to State and local agencies for interest reduction assistance and rent supplement payments for uninsured projects 6/	200-unit multifamily housing project or requested mortgage amount exceeds $5,000,000	500 to 2,500 units (see paragraph 5.d.(5))

PROGRAM	DECISION POINTS	SPECIAL CLEARANCE THRESHOLDS	EIS THRESHOLDS
--Public Housing	Letter of notification of tentative site approval or approval of major change	200-unit public housing project	500 to 2,500 units (see paragraph 5.d.(5))
--College Housing	Approval of fund reservation for college housing or major amendatory	200-unit student project	500 to 2,500 units (see paragraph 5.d.(5))
--Mobile Homes	Issuance of SAMA letter or major change in letter or project	200-unit mobile home park	500 to 2,500 units (see paragraph 5.d.(5))
--Nursing Homes	Issuance of SAMA letter or major change in letter or project.	200-bed nursing home	500 to 2,500 beds (see paragraph 5.d.(5))
--Hospitals 7/	Issuance of SAMA letter or major change in letter or project.	200-bed hospital	500 to 2,500 beds (see paragraph 5.d.(5))
--Group practice facilities	Issuance of SAMA letter or major change in letter or project.	Facilities with site acreage of 50,000 sq. ft., or gross floor area of 30,000 sq. ft.	When required pursuant to paragraph 5.d. or Appendix A-2.
--Section 8 Housing Assistance Payments Program 8/	Notification of selection of preliminary proposals	200-unit project	500 to 2,500 units (see paragraph 5.d.(5))
Section 223(f) 3/, 4/, 9/			
--Purchase	Issuance of conditional commitment	None	None
--Refinancing	Issuance of firm commitment	None	None
Rehabilitation (except rehab exempt per paragraph 5.a.(1) 3/, 4/, 5/	Feasibility determination	Same as for new construction	Same as for new construction

PROGRAM	DECISION POINTS	SPECIAL CLEARANCE THRESHOLDS	EIS THRESHOLDS
Modernization (Public Housing)	Approval of FHA's Final Application	200-units/demolition	500 to 2,500 units/demolition (see paragraph 5.d.(5))
PROPERTY DISPOSITION PROGRAM 4/			
--Vacant Land	Approval of Planned Program Approach (PPA). If none, approval of the disposition program.	200-units based on prospective use 10/	500 to 2,500 units based on prospective use 10/
--one-to-four family structures	Approval of Planned Program Approach (PPA). If none, approval of the disposition program	200-unit project 11/	500 to 2,500 units (see paragraph 5.d.(5)) 11/
--Multifamily structures	Approval of the disposition program	Any multifamily project	500 to 2,500 units (see paragraph 5.d.(5))
--College housing	Approval of the disposition program	Any student project	500 to 2,500 units (see paragraph 5.d.(5))
--Mobile homes	Approval of the disposition program	Any unit mobile home park	500 to 2,500 units (see paragraph 5.d.(5))
--Nursing homes	Approval of the disposition program	Any bed nursing home	500 to 2,500 beds (see paragraph 5.d.(5))
--Hospitals 7/	Approval of the disposithe program	Any bed hospital	500 to 2,500 beds (see paragraph 5.d.(5))
--Group practice facilities	Approval of the disposition program	Same as new construction	When required pursuant to paragraph 5.d. or Appendix A-2.
Model Cities	Approval of application for individual project within Model Cities Program 12/ 13/	See appropriate categorical program	See appropriate categorical program.
Neighborhood Facilities 14/	Approval of allocation order or approval subject to validation of funds	Site acreage of 50,000 sq. ft., or gross floor area of 30,000 sq. ft.	When required pursuant to paragraph 5.d. or Appendix A-2.

PROGRAM	DECISION POINTS	SPECIAL CLEARANCE THRESHOLDS	EIS THRESHOLDS
	(whichever is sooner), or approval of major amendatory.		
Open Space Land 14/	Approval of allocation order or approval subject to validation of funds (whichever is sooner) or approval of major amendatory. Approval for Conversion.	1) All sanitary landfill projects 2) Impoundment of 2 surface acres or 25 acre feet of water 3) 50 acres 4) All conversions of open space land acquired with HUD assistance to non-open space uses not originally approved by HUD	When required pursuant to paragraph 5.d. or Appendix A-2.
Public Facility Loans 14/	Approval of allocation order or approval subject to validation of funds (whichever is sooner)or approval of major amendatory.	See Water and Sewer	When required pursuant to paragraph 5.d. or Appendix A-2
Urban Renewal, 15/ Conventional	Approval of Part I or approval of major amendatory.	All urban renewal projects	When required pursuant to paragraph 5.d. or Appendix A-2
Neighborhood Development Program 14/	Approval of allocation order or approval subject to validation of funds, whichever is sooner.	1) All first year NDP's and conversions from conventional urban renewal to NDP 2) Subsequent action years: To the extent that the urban renewal plan has not been previously evaluated and/or changes in area or plans	When required pursuant to paragraph 5.d. or Appendix A-2

PROGRAM	DECISION POINTS	SPECIAL CLEARANCE THRESHOLDS	EIS THRESHOLDS
Water and Sewer	Approval of application or major amendatory.	1) All above ground reservoirs and stand pipes 2) All source development projects, including major river impoundments, raw water reservoirs, well fields, and treatment plants 3) Treated water transmission or sewage collection lines which pass through, are adjacent to, or serve undeveloped areas of 50 acres or more	When required pursuant to paragraph 5.d. or Appendix A-2
Flood & Disaster Insurance Program	Issuance of special flood plain or mudslide area delineations.	1) Variance from normal practice defined by FIA	When required pursuant to paragraph 5.d. or Appendix A-2
	Community eligibility ity eligibility	2) Variance of land use and control measures from established FIA criteria	
Community Development Block Grant Program under Title I of the Housing and Community Development Act of 1974, where an applicant has been deemed by HUD to lack legal capacity to assume environmental responsibilities. 16/	Approval of application or amendment required to be submitted to HUD for approval; or in those cases where a preapplication is required, the invitation to submit a full application	All new Community Development Block Grant Program applications and all second and succeeding year applications containing any new or changed program activity not covered in a previous environmental review.	When required pursuant to 24 CFR Part 58.25

Footnotes To Appendix A-1

1. In addition to the quantitative factors listed under this column, paragraph 5.d., Appendix A-2 or Appendix B-1 may apply requiring an Environmental Impact Statement.

   If a project level action was anticipated and adequately evaluated by a prior EIS, Areawide, or similar broad scale environmental clearance, a new Environmental Impact Statement may not be necessary. (See paragraph 5.e.)

2. All demonstration projects resulting in new construction of $500,000 are included; other demonstration projects are generally exempt.

3. Project selection criteria are not a substitute for environmental clearance.

4. It is recognized that in high density areas, size alone need not necessarily imply a significant impact on the quality of the human environment. Therefore, special exemption to the EIS threshold may be granted by the Assistant Secretary CPD for quantitative purposes where typical densities in the immediate environs of a project processed as multi-family exceeds 50 units per acre. Area-wide waivers may be granted for large dense urban areas or sectors thereof having such densities and meeting criteria established by the Assistant Secretary. Delegations of authority to approve such waivers may be granted to the Regional Offices at the discretion of the Assistant Secretary.

   The automatic EIS thresholds for projects processed as multi-family do not apply (and a waiver is not required) for projects already constructed where the HUD action is solely approval of subsidies when the following conditions are satisfied:

   (a) The Housing project is located in a previously cleared HUD assisted urban renewal project area and HUD has approved residential reuse on the parcels;

   (b) A Special Environmental Clearance for the housing project has been completed and indicates no unresolved environmental problems;

   (c) Regarding the urban renewal project, the remaining options subject to the Federal review have no significant environmental impact;

   (d) There is no known opposition on environmental grounds; and

   (e) The project exceeds the 50 unit per acre density requirement for a waiver described above.

5. Phase three Breakthrough housing projects are subject to environmental clearance procedures in the same way as other housing projects.

6. This Handbook shall also apply to HUD approval of interest subsidy on existing properties. However, the environmental assessment does not have to address the impact of the construction of the project on the environment since it has already taken place. All other environmental factors must be assessed.

7. HEW has the lead role in environmental evaluation and clearance of proposed hospitals. HUD has responsibility for clearance and conformance with Departmental policies and standards to the extent that such clearance is not conducted by HEW.

8. Notification of the Selection of a Final Proposal shall be deemed to be notification of Selection of a Preliminary Proposal for the purpose of decision points.

9. The environmental assessment for a Section 223(f) application will be made by performing a Normal Environmental Clearance. Special Clearances or Environmental Impact Statements will not be prepared, since properties with undesirable environmental features will not be accepted. (Paragraph 5-5, HUD Handbook 4565.1).

10. The Special and EIS thresholds for vacant land shall be determined by the number of units of whatever type of housing is expected to be located on the land when rebuilt and fully utilized. Unless otherwise known, the expected number of units should be the maximum allowed on the land in question under existing zoning or equivalent local law.

11. See paragraph 5.d.(7) before applying thresholds for disposition actions of one-to-four family structures.

12. See paragraph 5.a. (5) and (9). For individual projects within the Model Cities program which receive Model Cities supplemental grants but which derive the majority of their Federal assistance from another agency, such as HEW, the other agency is considered lead agency and responsible for the environmental clearance. For a project which receives all or most of its funding from Model Cities grants, HUD is responsible for the appropriate environmental clearance.

13. For projects using supplementary funds which result in the construction or acquisition of capital facilities not included in HUD categorical programs, the appropriate environmental clearance shall be prepared prior to the award of the supplemental grant.

14. Project selection systems are not a substitute for environmental clearance.

15. For projects in the National Capital area refer to an agreement between HUD and the National Capital Planning Commission relative to NCPC preparing Draft EIS's.

16. Under the CDBG Program, the applicant assumes the environmental review responsibilities otherwise applicable to HUD and carries them out in accordance with 24 CFR Part 58 unless the applicant has been deemed by HUD to lack legal capacity to do so.

APPENDIX A-2 Other HUD Actions With Special Requirements

ACTION	DECISION POINT	REQUIREMENT
New construction or non-exempt rehabilitation of residential or other noise sensitive land uses such as nursing homes, hospitals, group practice facilities, in unacceptable noise zone (Circular 1390.2) 1/	Decision point stated in Appendix A-1	Environmental Impact Statement
New construction or non-exempt rehabilitation of residential or other noise sensitive land uses such as nursing homes, hospitals, group practice facilities, in Discretionary (Normally Unacceptable) noise zone (Circular 1390.2) which is new development in a largely undeveloped area 1/	Decision point stated in Appendix A-1	Environmental Impact Statement
New construction or non-exempt rehabilitation of residential or other noise	Decision point stated in Appendix A-1	Special Environmental Clearance

ACTION	DECISION POINT	REQUIREMENT
sensitive land uses in Discretionary (Normally Unacceptable) noise zone (Circular 1390.2), which is infill in existing development 1/		
New Communities;--New Projects:		
--Debt Guarantee, or certification of eligibility or interest loan	Authorization by NCDC Board of offer of commitment, or certification of eligibility, or approval of interest loan	Environmental Impact Statement
New Communities;--Previously Approved Projects:		
--Amendment to the Development Plan resulting in a change in project land use 2/, or total population, by 30% or more, or closeout of project.	Approval by Secretary	Environmental Impact Statement Supplement
--Amendment to the Development Plan which requires the prior approval of the Secretary and which concerns a change in project land use 2/, or total population, by less than 30%	Approval by Secretary	Special Environmental Clearance 3/
--Any amendment to Development Plan (other than those described above) which requires the prior approval of the Secretary	Approval by Secretary	Normal Environmental Clearance 3/
--Additional guarantee, or other financial arrangement including investment (other than a change in management and/or ownership alone):		
--predicated on a future change in project land use 2/, or total population, which would require the approval of the Secretary	Approval by NCDC	Special Environmental Clearance 3/

ACTION	DECISION POINT	REQUIREMENT
--Not predicated on a future change in project land use 2/, or total population, which would require the approval of the secretary	Approval by NCDC	Normal Environmental Clearance 3/
Any project which has an effect on a property included in, or eligible for inclusion in, the National Register of Historic Places.	Decision point stated in Appendix A-1	Special Environmental Clearance
Any project which has an adverse effect on a property included in, or eligible for inclusion in, the National Register of Historic Places, except where the effect has been mitigated and resulted in a signed Memorandum of Agreement pursuant to 26 CFR Part 800 and the project or program would not otherwise require an EIS.	Decision point stated in Appendix A-1	Environmental Impact Statement 4/
Legislation	Departmental decision to sponsor legislation	Finding of Inapplicability or Draft and Final Environmental Impact Statement
Regulations which have a potential for significantly affecting the quality of the human environment	Publication in Federal Register of notice of proposed rulemaking	Finding of Inapplicability or Draft Environmental Impact Statement
	Promulgation	Final Environmental Impact Statement, where applicable
Policy and guidance documents which have potential for significantly affecting the quality of the human environment	A-85 clearance	Finding of Inapplicability or Draft Environmental Impact Statement
	Promulgation	Final Environmental Impact Statement, where applicable

FOOTNOTES TO APPENDIX A-2

1. Project actions affected by Circular 1390.2 require that projects located in the Unacceptable or Discretionary-Normally Unacceptable noise exposure zone require special approvals and must incorporate noise attenuation measures.

2. A change in project land use means a change in amount, absorption, intensity, or location of a category of land use.

3. A Finding of Inapplicability which may follow these levels of environmental review shall not be effective without the concurrence of the Assistant Secretary for Community Planning and Development. A Normal or Special Environmental Clearance will be replaced by the requirement for an EIS or EIS Supplement if, in the opinion of the Assistant Secretary for CPD, such is warranted.

4. Request review by Advisory Council on Historic Preservation.

Section 7(d), Department of HUD Act (42 U.S.C. 3535(d)).

Issued at Washington, D.C., on July 28, 1978.

JAY JANIS,
Acting Secretary of Housing and Urban Development.

[FR Doc. 78-21717 Filed 8-7-78; 8:45 am]

federal register

TUESDAY, AUGUST 8, 1978
PART IV



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

STANDARDS FOR INSTITUTIONAL REVIEW BOARDS FOR CLINICAL INVESTIGATIONS

Proposed Establishment of Regulations

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 16, 56, 71, 171, 180, 310, 312, 314, 320, 330, 361, 430, 431, 601, 630, 1003, and 1010]

[Docket No. 77N-0350]

STANDARDS FOR INSTITUTIONAL REVIEW BOARDS FOR CLINICAL INVESTIGATIONS

Proposed Establishment of Regulations

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This is a proposal to clarify existing regulations governing the activities of institutional review boards (IRB) that review clinical investigations involving human subjects and new human drug products. The proposed rule would extend these regulations to include IRB's that review clinical investigations involving human subjects and articles other than new human drug products regulated by the Food and Drug Administration (FDA). The proposed regulations are intended to provide greater protection of the rights and safety of subjects involved in clinical investigations and to help assure the quality and integrity of the resulting data that are submitted to FDA in support of applications for permission to conduct further research or to market regulated products.

DATES: Comments by December 6, 1978.

ADDRESS: Written comments, preferably four copies and identified by docket No. 77N-0350, may be submitted to the office of the Hearing Clerk (FHA-305), Food and Drug Administration, room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

John Petricciani, Division of Pathology (HFB-400), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, Md. 20014, 301-496-5491.

SUPPLEMENTARY INFORMATION: Although informed consent is an important part of the protection of human subjects participating in clinical investigations, this proposal is being published without a comprehensive definition of "informed consent" to provide an early opportunity for interested persons to review and comment on the proposed standards and procedures for institutional review. The agency will be publishing shortly a companion proposal that will define "informed consent."

The agency also intends to hold three open hearings to give the public an opportunity to make oral comments on both proposals. A notice of the date and location of these hearings will be published later with the proposed definitions of "informed consent."

The comment period for this proposal will close on December 6, 1978. However, the Commissioner of Food and Drugs recognizes that it may not be possible to publish the "informed consent" proposal, and schedule and hold the public hearings on both proposals within that time period. The Commissioner advises interested persons that he is prepared to extend the comment period on this proposal as appropriate.

The Commissioner believes that a complete revision of FDA requirements relating to IRB's is needed because: (1) Current regulations have not been comprehensively reviewed in 7 years, (2) actions by the Department of Health, Education, and Welfare (HEW), the Congress, and the World Medical Assembly suggest a need to extend IRB requirements to types of clinical investigations involving human subjects other than those on new human drugs, (3) wherever possible, IRB requirements adopted by FDA should be identical to or compatible with HEW regulations as well as IRB regulations issued by other Federal agencies, (4) the General Accounting Office (GAO) has recommended changes in current FDA regulations, (5) Congress, in enacting the Medical Device Amendments of 1976 (Pub. L. 94-295), provided for IRB's in clinical investigations of devices intended for human use, and (6) the new FDA bioresearch monitoring program, designed to assure compliance with FDA requirements to protect human research subjects and reinforce the validity and reliability of clinical data submitted to FDA, can be more efficiently and effectively conducted with the utilization of IRB's and with uniform, agencywide regulatory standards regarding IRB's. Each of these matters is discussed in further detail below.

Since 1971, FDA has required institutional review of clinical investigations subject to regulation by the agency and involving institutionalized human subjects or noninstitutionalized subjects where an institution agrees to assume responsibility for the investigation. The benefits of institutional review include appraisal of local conditions and standards, acquaintance with investigators, subject groups, and the setting in which the investigation is proposed to be conducted, independence from competing interests, and sensitivity to ethical and scientific concerns in the community and the society at large. In addition, IRB's can review ongoing investigations and oversee the continuing safety of the subjects as well as the adherence of the investigation to the approved protocol and other understandings and regulations. Current FDA requirements for IRB review are set forth in the texts of the forms FD-1571, FD-1572, and FD-1573 used for exemptions for investigational new drug studies (21 CFR 312.1(a)(2), form FD-1571, item 10.c.; 21 CFR 312.1(a)(12), form FD-1572, item 3.; and 21 CFR 312.1(a)(13) form FD-1573, item 2a.). When originally adopted, the agency indicated that it was considering extending these requirements to all other drug investigations under FDA jurisdiction (36 FR 5037; March 11, 1971). The Commissioner has for some time also desired to review and codify existing requirements. Since 1971, several events have indicated increased acceptance of and reliance upon the concept of local, independent review of human research to evaluate the scientific justification for and ethical acceptability of exposing human beings to risk. These developments, which increase the advisability of a substantial revision and extension of current FDA regulations, include:

(1) HEW guidelines on institutional review for research involving human subjects that is supported by HEW grant or contract were codified in 1974 into regulation form, after public notice and extensive comments from interested persons (45 CFR part 46, subpart A; see 39 FR 18914; May 30, 1974). These regulations were subject to technical amendments in 1975 (40 FR 11854; March 13, 1975). These regulations reflected experience that HEW had gathered under earlier guidelines, guidelines which were also the source of FDA's 1971 regulations. The new HEW rules modified and improved upon the older ones, but created certain inconsistencies between FDA's standards regarding regulated research and the Department's standards regarding funded research. Since 1974, the HEW regulations have served as a model for other Federal agencies that support human experimentation. See, e.g. 10 CFR part 745 adopted by the Energy Research and Development Administration in the FEDERAL REGISTER of November 30, 1976 (41 FR 52434) and regulations proposed by the Consumer Product Safety Commission in the FEDERAL REGISTER of September 2, 1976 (41 FR 37120). The Commissioner believes that, wherever possible, FDA's regulations should be compatible with, if not identical to, HEW's and those of other Federal agencies. A multiplicity of dissimilar and inconsistent Federal requirements is burdensome to institu-

tions, IRB's, and the process of clinical investigation.

(2) Congress endorsed the concept of institutional review in section 212(a) of the National Research Act of 1975 (42 U.S.C. 747(a)), which directs the Secretary of HEW to require IRB review of all biomedical and behavioral research involving human subjects conducted at or sponsored by an institution receiving a grant or contract under the Public Health Service Act. Although this includes biomedical research involving human subjects when such research is regulated or reviewed by FDA under the Federal Food, Drug, and Cosmetic Act (the "act") if it is conducted by a Public Health Service grantee or contractor, it does not extend to institutions not receiving such financial support. The Commissioner believes that it would be consistent with the congressional intent for FDA to use its existing statutory authority to apply an IRB review requirement wherever it is both reasonable and feasible.

(3) The Declaration of Helsinki, a set of principles adopted by the World Medical Assembly (an international body of experts concerned with health and scientific matters) was revised in 1975 to recommend that every biomedical research protocol be given "to a specially appointed independent committee for reconsideration, comment, and guidance" (sec. I(2)). (A copy of the amended declaration is on display in the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.) The agency has previously acknowledged the declaration as reflecting the most widely accepted standards for biomedical research involving human subjects. (See 38 FR 24220 (Sept. 6, 1973); 40 FR 16053, (Apr. 9, 1975); and 21 CFR 312.20.) Although it might be argued that the process by which FDA reviews the investigational use of new drugs and will, in the future, review certain medical devices fulfills this recommendation, the Commissioner believes the declaration contemplates a committee more closely acquainted with the investigator and the setting in which the clinical investigation will be conducted.

(4) When the Medical Device Amendments of 1976 were enacted, reference to institutional review was incorporated for the first time in the act, in section 520(g) (21 U.S.C 360j(g)). Congress clearly approved such review as a means of protecting subjects while encouraging research in medical devices for human use. In the FEDERAL REGISTER of August 20, 1976 (41 FR 35282), the Commissioner proposed regulations governing investigational device exemptions (IDE) under section 520(g) of the act, including implementing institutional review requirements. (See 21 CFR part 812, subpart D of that proposal.) Comments filed on that proposal have been reviewed and utilized in preparing this notice. In the FEDERAL REGISTER of May 12, 1978 (43 FR 20726) the Commissioner issued portions of the IDE proposal as a tentative final regulation. Those provisions in the IDE proposal that duplicate or overlap substantially with the requirements proposed in this document have been deleted from the tentative final regulation. The Commissioner will review comments on this proposed rule promptly and will issue in final form at least those proposed provisions that are essential to the promulgation of comprehensive final regulations governing the investigational use of medical devices.

(5) The General Accounting Office (GAO) published a report entitled "Federal Control of New Drug Testing Is Not Adequately Protecting Human Test Subjects and the Public" (July 15, 1976); chapter 4 of this report evaluated institutional review requirements and made recommendations for improvement. A copy of this report is also on display in the Office of the Hearing Clerk, Food and Drug Administration. This proposal is a step in implementing some of the GAO recommendations.

(6) Finally, FDA has recently reassessed its responsibilties, needs, and priorities in the entire area of biomedical research, including safety testing of substances in animals, monitoring of clinical investigations by sponsors, the role of institutional review boards, and the obligations of clinical investigators. The agency, the Congress, and others have recently become concerned about the validity and reliability of scientific data on the safety and effectiveness of products regulated by FDA. Much of the history of this review, with special emphasis on the quality and integrity of safety data derived from nonclinical laboratory studies, is discussed in the preamble to the proposal on good laboratory practices published in the FEDERAL REGISTER of November 19, 1976 (41 FR 51206). Congressional and Presidential action in the summer of 1976 appropriated to FDA $16.3 million and authorized over 600 new positions to carry out expanded activities in the area of bioresearch monitoring.

In conjunction with this legislative action, the Commissioner has established a "Bioresearch Monitoring Program" to develop and implement an agencywide program for all aspects of preclinical testing and clinical research relating to FDA-regulated products. The program is managed by an intra-agency steering committee that oversees several task forces assigned to consider specific matters. The Institutional Review Board Task Force has the responsibility for: (1) Developing an agency strategy to define the responsibilities of IRB's in clinical investigations involving human subjects which are regulated by FDA or which involve products regulated by FDA and (2) assuring that these duties are adequately and reliably performed. To meet these goals, the task force proposed the following:

1. Promulgation of agencywide regulations that would set forth the responsibilities of IRB's and enforcement procedures; these proposed regulations are based upon existing FDA regulations for investigational new drug studies, proposed regulations for investigational use of medical devices and comments received on them, and FDA experience.

2. Issuance of an agencywide compliance program that would include enforcement policies, regular inspections of IRB's, and special inspections initiated by FDA to audit particular investigations.

3. Development of appropriate organizational structures or mechanisms and data systems to be used for planning and scheduling inspections under the compliance program and for reviewing and evaluating the results of individual inspections as well as the overall program.

PURPOSES OF INSTITUTIONAL REVIEW

Institutional review began when a few institutions treating patients or conducting medical research established internal committees to review research grant applications and other proposed clinical investigations, and to advise responsible officials within the institution on whether the proposed projects should be permitted. Reviews and advice originally emphasized scientific aspects of studies, and IRB's were composed principally of physicians and other health scientists; but these professionals, from the beginning, considered the ethical implications of research. Increasingly, officers of institutions found that sensitivity to community standards of ethics, as well as involvement of nonscientists, was important in considering planned studies; as a result, lawyers, the clergy, ethicists, and other nonscientists from outside the institution were added to IRB's. The original concept remained, however, that the board was to advise the officers of the institution on the acceptability of the proposed study within the institution; this advice naturally involved, but was not limited to, the obligations of the institution to its patients and subjects.

In the 1960's, the National Institutes of Health of HEW began requiring IRB review as part of the process of providing grants and contracts for re-

search involving human subjects. The purposes were several: First, such requirement would provide HEW with an assurance that community standards would be considered in determining the acceptability of a proposed investigation, a goal difficult to attain with centralized review at the level of the Federal Government. Second, it would provide patients and subjects additional protection. Specifically, an IRB is generally capable of making a better informed judgment about the potential risks and benefits of the proposed study than an individual subject; thus, IRB review supplements the use of informed consent as a safeguard of the rights and safety of the subject. Third, IRB review would relieve HEW of the burden of reviewing an application that would subsequently be unacceptable within the institution in which the investigation is proposed to be conducted. In addition, the process of IRB review and approval of a study, providing a review anticipating, in part, HEW's review, could substantially improve the quality of a research protocol. To assure a certain degree of independence of the IRB's in reviewing proposed investigations, HEW required outside membership on each IRB (i.e., at least one or more members cannot be associated with the institution other than by virtue of participation on the board) and stated that no application for a research grant or contract would be approved unless it had IRB approval (i.e., the officers of the institution could not overrule a negative decision by a board). In taking these steps, HEW effectively created a new relationship between the IRB's and the government, altered to some degree the relationship between the IRB's and the parent institutions, and implied a special duty on the part of an IRB to protect subjects, in addition to its duties to the institution and to HEW.

These various roles of IRB's have, as noted earlier, become widely accepted among research scientists throughout the world. Such review is now performed for clinical investigations that do not involve institutionalized patients or subjects. Thus, it may no longer be strictly appropriate to call the process "institutional review." Indeed, in many situations other names are used, such as "human experimentation committee" and "clinical investigations review board"; FDA itself conducts review of all human studies funded by the agency through its "Research Involving Human Subjects" or "RIHS" Committee. Committee and boards to review clinical investigations may be created and appointed under the auspices of a local or State government health agency, a community hospital, a private or public medical school, a county or State medical society, the State medical licensing board, or an independent nonprofit group such as a foundation or society interested in a particular health concern, e.g., kidney disease or family planning, or an organization involved in intergroup communications, e.g., the American Arbitration Association. Because of the lack of any consistent terminology in this area, and in view of the widespread current use of the phase "institutional review," the Commissioner has elected to adopt that phrase in this proposal. However, the Commissioner advises readers not to interpret this usage as limiting the intent of this proposal to research involving institutionalized subjects or conducted by an institution; likewise, the term "institution," as used in this notice, is not limited to hospitals and other health-care establishments. The Commissioner welcomes comments suggesting more understandable and comprehensive terminology for use in subsequent notices and orders.

In addition to the generally accepted purposes for IRB review of clinical investigations involving humans, the Commissioner seeks two new goals in this proposal. First, local IRB review can provide ongoing review of an investigation to assess, for example, conformity with the approved protocol, including any approved amendments. Ongoing review enhances protection of subjects by assuring that any changes in protocol are reviewed and approved in advance. Essential to the decision to authorize exposure of humans to risk is a conclusion on the potential benefits to the subjects and/or to scientific knowledge. Any action or failure to act during the investigation that adversely affects the ability of the investigation to yield these benefits may, as a consequence, destroy the justification for the risk. Further exposure of humans may no longer be warranted, even though no change in the actual risks has occurred. Thus, ongoing review includes more than evaluating reports of new safety concerns; it may cover other aspects of the conduct of the clinical investigation.

Second, apart from subject protection, continuing review of an ongoing clinical investigation by an IRB can provide FDA with greater confidence in the quality and integrity of the data submitted at the conclusion of the investigation. As noted earlier, and discussed in detail in the preamble to the good laboratory practices proposal, FDA, the Congress, and others have recently become quite concerned about the validity and reliability of scientific data on the safety and effectiveness of products regulated by FDA. Although much of the concern has focused on long-term toxicology testing in animals, the substantial increases in FDA's budget and operating resources included a mandate that the agency assure the quality and integrity of data generated by studies in humans as well. It immediately appeared, from past experience with IRB's and from the lack of other available local independent processes to examine ongoing research, that IRB's could assist FDA in carrying out this mandate. The Commissioner does not intend, however, that IRB's undertake major new responsibilities to assure data validity. Rather, the agency contemplates that the present activities or IRB's in ascertaining adherence to approved protocols, reviewing proposed modifications in protocols, and considering the capability of individual investigators and of supporting facilities to carry out protocols, will serve as an important adjunct to other programs that FDA is undertaking to increase its assurance of the reliability of clinical scientific data. These programs include development of regulations governing the conduct of clinical investigators and the obligations of sponsors and monitors of clinical investigations proposed in the FEDERAL REGISTER of September 27, 1977 (42 FR 49612), more extensive FDA oversight of ongoing clinical investigations, and more frequent in-depth audits of data presented to the agency.

UNIFORM FDA STANDARDS FOR INSTITUTIONAL REVIEW BOARDS

For the reasons described earlier, the Commissioner has elected to propose a single set of standards applicable to all IRB's involved in the initial review, approval, and continuing review of clinical investigations involving human subjects that require prior FDA review or that are subsequently submitted to FDA in support of an application for a research or marketing permit. This regulation, if adopted, may not eliminate the need in the future to propose additional requirements relevant to the particular article under study, but it will reduce the potential for duplicative and inconsistent regulations or interpretations of policy. The Commissioner recognizes that a single IRB may, at any one time, be reviewing investigations on a variety of products that are regulated by several of the separate bureaus of FDA, e.g., Bureau of Drugs, Bureau of Biologics, and Bureau of Medical Devices. In addition, the IRB may also be reviewing the same or other investigations subject to institutional review requirements of HEW or other Federal departments or agencies. A uniform standard will thus ease the burdens on these boards in complying with the applicable regulations.

To achieve this objective, the Commissioner proposes to add a new Part 56 to Title 21 of the Code of Federal

Regulations to be entitled "Institutional Review Boards." This proposed new part will be codified in "Subchapter A—General Provisions" of FDA's regulations, thereby applying to all regulated products that are involved in human experimentation. This proposal revises and extends current FDA standards on IRB review to most investigations involving human subjects when such investigations are regulated by or submitted to FDA, lists definitions applicable to the part, presents the requirements for the organization and operation of an IRB, and establishes standards and procedures for taking appropriate regulatory actions in the event of noncompliance with these regulations. Additionally, this proposal contains specific amendments needed for conformance to existing FDA regulations.

To assure uniform standards, any clinical investigation required to have IRB review would be within the scope of the part, whether the investigation required the prior review of any of the bureaus of FDA, e.g., Drugs, Biologics, or Medical Devices, or whether the investigation did not receive prior FDA review but was subsequently submitted, or held for FDA inspection, in support of an application to one of those bureaus, or to the Bureau of Foods or the Bureau of Radiological Health. This statement of scope is set forth in proposed § 56.1.

The particular requirements in proposed part 56 are based upon: (1) The current regulations regarding institutional review for investigational studies on new drugs (set forth in 21 CFR 312.1(a)(2), form FD-1571, item 10.c.; 21 CFR 312.1(a)(12), form FD-1572, item 3.; and 21 CFR 312.1(a)(13), form FD-1573, item 2a.) (the "IND regulations"), (2) the experience of the Bureau of Drugs and the Bureau of Biologics in administering these regulations, (3) the proposed regulations regarding institutional review for investigational studies on certain medical devices for human use published in the IDE proposal, (4) comments received on the IDE proposal, and (5) regulations regarding institutional review for clinical studies funded or supported by HEW (45 CFR Part 46, Subpart A).

Circumstances in Which an IRB Is or Is Not Required

Under the IND regulations, IRB review is required whenever the human subjects involved in the clinical investigation are institutionalized or whenever the investigation is conducted by an individual affiliated with an institution that assumes responsibility for the investigation. The IDE proposal followed these two principles and added a third: IRB review is required whenever the investigation is conducted in an institution that has an IRB meeting FDA standards (proposed § 812.60(a)(3)).

The Commissioner believes the purposes and processes of IRB review are now so widely accepted, and its value so generally recognized, that all clinical investigations should undergo such review unless circumstances clearly make it unnecessary, or infeasible, or contrary to the patient's interest. Therefore, the Commissioner is proposing in § 56.2(a) to make IRB review and approval a general precondition to an application for a permit to conduct a clinical investigation that is subject to requirements under section 505(i), 507(d), or 520(g) of the act for prior submission to FDA for review, and in some cases approval, before the investigation may be commenced. The Commissioner further proposes in § 56.2(b) that FDA generally will not consider any data or information that has been derived from a clinical investigation in support of an application for a research or marketing permit unless the investigation was conducted under an IRB. This rule would not mean that the results of the investigation need not be submitted to FDA. The usual rule that all data and information relevant to a particular article, e.g., a proposed or marketed product, must be submitted remains in effect. Finding that the investigation is not acceptable in support of an application for a research or marketing permit means that the agency will not authorize further testing or futher marketing if the claim for safety or effectiveness of the product is based upon that investigation. This approach reflects current agency policy: even in situations where the scientific validity of an investigational drug study is not in question, FDA may receive data but not use them in support of a decision to approve testing or commercial distribution of a drug because of ethical improprieties in the conduct of the study. (21 CFR 312.20.)

The Commissioner recognizes that there may be situations in which the IRB requirement may be unnecessary, redundant, or contrary to the interests of a subject. For example, a late "phase 3" drug study will frequently involve several investigators treating noninstitutionalized individuals in separate areas under the same protocol; multiple review is extremely burdensome and, by this time, the drug will usually have been studied in several settings employing IRB's. Or, for another example, in an emergency FDA may be asked to add an investigator to a particular investigation to provide the test article to a single patient only; prior IRB review would delay administration of the article and might jeopardize the subject's health. The Commissioner therefore proposes in § 56.2(c) to waive the IRB requirement in certain specified situations and to accept an application for waiver in other situations upon a showing that the requirement is not necessary either for protecting the subjects involved or for assuring the validity or reliability of the scientific data. The section provides, however, that the requirement will not be waived in three situations; (1) When the clinical investigation involves institutionalized human subjects; (2) When the clinical investigation is conducted on the premises of, or utilizes personnel or resources of, an institution having an IRB meeting FDA's standards; and (3) When the Commissioner finds that the risks to the subjects in the investigation justify utilizing an IRB review.

The Commissioner is also proposing to waive the requirements for IRB review for all studies that were commenced prior to, and that are to be completed within 1 year following, the effective date of these proposed regulations and were not otherwise required under FDA regulations to have such review. This "grandfather clause" will avoid rejection of studies that would result from a retroactive application of the IRB requirements.

In addition to expanding the types of clinical investigations covered, the Commissioner emphasizes that the major change in this proposal from existing investigational new drug (IND) regulations is to require institutional review prior to submission of a proposed study that is subject to IND or investigational device exemption (IDE) requirements. The current IND requirements merely require an assurance that IRB review will be obtained prior to actual commencement of the investigation. The change is proposed to enable FDA to rely on IRB's to screen out studies that would not be performed even if FDA reviewed them favorably, and to provide FDA with better information on the IRB's being utilized by sponsors and investigators under IND's and IDE's.

Definitions

Section 56.3 contains proposed definitions for all of the special terms used in part 56. Many technical terms can be variably or imprecisely interpreted by persons affected by the proposed regulations; these terms are defined to provide a common basis of understanding for the agency, clinical investigators, the regulated manufacturers and other sponsors of clinical studies, and the general public. In addition, other definitions have been proposed for more precisely describing the extent and applicability of the proposed regulations.

In proposed § 56.3(a), the term "act" is limited to the Federal Food, Drug, and Cosmetic Act, as amended. This is

consistent with definitions appearing elsewhere in FDA's regulations. Other statutes, when discussed, will be mentioned by name, e.g., the Public Health Service Act.

A new definition required by the decision to make these proposed regulations agencywide in scope is the term "application for research or marketing permit" in § 56.3(b). This definition includes all of the various requirements for submission of scientific data and information to the agency under its regulatory jurisdiction, even though in certain cases no permission is technically required from FDA for the conduct of a proposed activity with a particular product, i.e., carrying out research or continuing to market a product. The term is intended solely as a shorthand way of referring to at least 22 separate categories of data and information that are now, or in the near future will become, subject to requirements for submission to the agency.

To facilitate further the applicability of a single set of regulations to all studies involving products or articles coming within the agency's purview, the Commissioner is proposing in § 56.3(c) to describe each such study as a "clinical investigation," which is defined as any experiment involving a test article (defined below) which experiment involves human subjects and either: (1) Is subject to requirements under sections 505(i), 507(d), or 520(g) of the act for prior submission to FDA for review, and in some cases approval, before it can be commenced, or (2) is not subject to requirements for prior submission but the results of which are intended to be later submitted to, or held for inspection by, FDA as part of an application for a research or marketing permit. Within the category of clinical research, the definition excludes studies that do not utilize any test articles, or do not utilize them in a manner that requires prior FDA approval or subsequent FDA review because the studies are not regulated by or intended to be submitted to FDA. The definition also excludes studies that do not involve human subjects.

The terms "institution," "institutional review board," and "institutionalized subject" are defined for the first time in proposed § 56.3 (d), (e), and (f). Although since 1971 FDA has had a requirement that clinical drug investigations involving institutionalized subjects be reviewed and monitored by an institutional review committee or board, no guidelines defining the outer limits of these concepts have been issued.

The Commissioner proposes that the definition of "institution" include any corporation, scientific or academic establishment, or government agency that engages in the conduct of research on human subjects or in the delivery of medical services to individuals; this definition would therefore include: a university that performs research with students, a retirement home that primarily provides housing and personal care to the elderly but also cares for health needs of residents, and a manufacturer that uses its employees as subjects in the course of product development.

The term "institutional review board" is defined as any board, committee, or other formally organized group created to review research involving human subjects, approve the initiation of such research, monitor its conduct, and when necessary suspend or terminate the research. The Commissioner notes that the use of the word "board" reflects terminology of the National Research Act of 1975 (Pub. L. 93-348), HEW regulations (45 CFR Part 46), and discussions of the National Commission on the Protection of Human Subjects in Biomedical and Behavioral Research. However, the Commissioner also recognizes that existing FDA regulations, e.g., 21 CFR 312.1, use the term "committee" as does section 520(g) of the act. The Commissioner believes there is no practical difference between the two words and has elected to follow Departmental terminology.

An "institutionalized subject," as defined, includes two categories: First, any individual who is voluntarily confined on the premises of, and in the care of, an institution for more than 1 day; outpatients are excluded from the definition in keeping with existing FDA policy. Second, any individual involuntarily confined for any period of time in an institution such as a penal facility or a hospital by civil commitment. Because of the involuntary nature of the confinement and the general absence of any therapeutic need for an experimental article, the Commissioner believes the IRB protection should apply in every such situation. Thus, these proposed regulations will continue to require institutional review of all clinical investigations involving an institutionalized subject.

Proposed § 56.3(k) defines "subject" as any individual who is or becomes a participant in a clinical investigation, either as the recipient of the test article or as a control. The term also includes both healthy or normal individuals and patients to whom the test article might offer a therapeutic benefit. This definition is in accord with past FDA policy. The term is limited to human beings.

Other proposed definitions include terms to describe those who initiate and carry out clinical investigations: "sponsor," "investigator," and "sponsor-investigator." The word "sponsor" is currently defined in 21 CFR 310.3(j) and 510.3(k), but the Commissioner believes this definition is unsatisfactory in that it fails to distinguish the other commonly used word "investigator," which is not defined. While these terms are widely understood, their precise meanings are difficult to express. The key distinctions seem to lie between one who initiates the project (the sponsor) and one who actually conducts the study (the investigator). These distinctions have been incorporated in the proposed definitions, in proposed § 56.3 (g), (h), and (i), together with a further distinction: investigators must be individuals, while sponsors are defined as "persons," which term includes an individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit thereof, and any other legal entity. The Commissioner believes that these distinctions will clarify the participants' respective roles and duties.

Many studies, approximately 45 percent of IND's in the Bureau of Drugs, for example, are initiated and actually conducted by the same individual; this investigator may personally carry out the study or may do so with other investigators responsible to him or her. The Commissioner believes it important to identify the hybrid role of the "sponsor-investigator" and, where appropriate in FDA's regulations regarding clinical investigations, to allow special provisions for that role. Thus, proposed § 56.3(j) defines this term. Unlike the term "sponsor," the term "sponsor-investigator" is limited to individuals. For purposes of this proposal, the sponsor-investigator has the obligations of both a sponsor and an investigator.

In § 56.3(l) the Commissioner proposes to define the term "test article" to describe those items being studied that are subject to FDA's jurisdiction and to these regulations. The term includes those new drugs, biologics for human use, and medical devices for human use, studies of which require prior review by FDA under an IND or IDE. In addition, the term includes food additives, color additives, cosmetics, drug products and biological products for human use, electronic products, and medical devices for human use. The broad definition of "test article" is intended to include substances for which clinical investigations are submitted to FDA in support of an application for permission to market a product, but which investigations need not be conducted under an IND or IDE, e.g., studies on food additives or cosmetics, certain drug bioavailability studies described in 21 CFR 320.31, and studies on medical devices for human use not required to be submitted to FDA for prior review under proposed 21 CFR part 812. As noted earli-

er, however, a test article is covered by these regulations only if it is used in a clinical investigation involving human subjects.

REVIEW BY INSTITUTION

The agency has consistently held that review and approval of a proposed clinical investigation by an IRB does not preclude a subsequent decision by the institution itself to reject the investigation. The Commissioner recognizes that factors in addition to scientific validity and ethical acceptability must be taken into account by officials of the institution in deciding whether to authorize a particular investigation. At the same time, agency policy has been that a clinical investigation rejected by an IRB cannot be authorized later by the institution unless the IRB itself rescinds the rejection. In the absence of such a prohibition, the board would become purely advisory and its responsibilities eliminated. These principles are restated in proposed § 56.8. Comments received on the IDE proposal suggested that an institution be allowed to create a "super-IRB" or an "appellate IRB" which could reverse or overrule decisions of more particularized IRB's, i.e., those decisions dealing with a particular type of test article. The Commissioner advises that the agency has no objection to an arrangement for a full committee and specialized subcommittees if both the parent IRB and the particularized "sub-IRB's" meet the requirements of part 56. Appeals of adverse IRB determinations to other institutional bodies that do not meet the requirements of part 56, however, would not be allowed under the proposed regulation. (See also the discussion of proposed § 56.34 below.) The National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, created by mandate of the National Research Act of 1975, has received many comments relating to an IRB appeal mechanism. The Commissioner advises that FDA will carefully review the recommendations of the National Commission in this area once they are published and propose any appropriate changes in FDA regulations.

ORGANIZATION AND PERSONNEL

Proposed subpart B establishes general requirements for the organization and composition of an IRB. Most of these proposed requirements follow existing FDA and HEW requirements. The board must be composed of at least five persons with varying backgrounds. To assure sufficient diversity to evaulate the proposed clinical investigation in terms of science, law, professional ethics, and community attitudes, no IRB shall be composed entirely of members of a single professional group, or of only one sex. In addition, diversity in the racial and cultural composition of the IRB is required. Ideally, the membership would reflect both general competence in scientific matters and sensitivity to ethical concerns. Proposed § 56.21(a) describes the types of individuals who would contribute to this goal: Physicians, lawyers, clergy ethicists, consumers, social scientists, other scientists and nonscientists. This listing should not, however, be interpreted as requiring one individual from each category. The IDE proposal referred to scientific expertise to evaluate each particular proposed investigation. Comments objected that this would necessitate a large number of medical or other scientific specialists as members to assure such expertise. The Commissioner has revised this language to follow more closely current HEW regulations, so that the section requires "professional competence necessary to comprehend the scientific nature of the investigation." This revision should alleviate many of the concerns expressed by the comments.

Proposed § 56.21(b) requires that the records of an IRB identify each member by name, earned degrees, occupation and title, and other information sufficient to describe each member's chief anticipated contribution to the board's deliberations.

Proposed §§ 56.25 and 56.26 adopt from existing HEW regulations two types of requirements to protect the independence and objectivity of an IRB. Section 56.25 that a board may not consist entirely of officials or employees of the institution in which the clinical investigation is to be performed. Section 56.26 excludes any member of the board who is involved in the investigation itself from participating in the IRB's deliberations, except to respond to requests for information. In addition, no investigator or sponsor shall participate in the selection of members for an IRB to review the sponsor's or sponsor-investigator's proposed investigations, unless expressly permitted by FDA upon a showing that such participation is essential. Other conflicting interests are also forbidden, and responsibility is left to the IRB to determine whether a member has a conflicting interest. Both sections provide that the records of an IRB identify any relationships between members and institutions, sponsors, and investigators and the extent to which a member participated in reviewing an investigation in which he or she had a conflicting interest.

Comments on the IDE proposal questioned whether compensation by a sponsor for the administrative expenses of an IRB and/or the services of the members of an IRB would be considered to violate the section analogous to proposed § 56.26(a). The Commissioner believes that reimbursement for IRB expenses probably should be permitted. Extension of an IRB concept to areas where it has not been primarily used will necessitate more IRB activity and consequently more administrative expenses for documenting activities, recordkeeping, liability insurance, and similar overhead expenditures. It is not reasonable to expect that these new costs will always be borne by the institutions or bodies that create and operate the IRB's. The Commissioner is more concerned about payment by a sponsor, directly or indirectly, for the services of IRB members. The difficulties of locating individuals willing to serve on IRB's, especially persons not affiliated with the institution, may be increased by requiring more clinical investigations to be reviewed by IRB's. At the same time, the potential problems of allowing reasonable compensation appear serious. The Commissioner does not propose, in this notice, any specific resolution of either the question of administrative expenses or the matter of member compensation; comments are especially invited to address these points, describing whether a need exists for financial assistance for sponsors and, if a need exists, ways to permit it while minimizing any conflicts of interests.

The Commissioner recognizes that an IRB may not be large enough or adequately composed to consider the scientific and safety issues of every complex and specialized clinical investigation. In such cases, the committee may wish to use a subcommittee or consultants to assist its review, provided the members of the subcommittee or the consultants also do not have any conflict of interest. The Commissioner intends to allow for such flexibility, and proposed § 56.34 explicitly authorizes use of nonvoting consultants.

PROCEDURES FOR REVIEW OF CLINICAL INVESTIGATIONS BY AN IRB

Subpart E sets forth the general and specific procedures to be followed by an IRB in its review of proposed and ongoing clinical investigations. Maximum flexibility in the operations of the board is intended. Thus, the board may have its own procedures for conducting reviews and for reporting actions to the investigator, to the parent institution, and, where appropriate, to the sponsor. Most of the proposed requirements reflect existing FDA or HEW regulations, or only modest extensions of these guidelines.

The first requirement, contained in proposed § 56.80, states the obligation of the board to put its procedures in writing, and to follow those proce-

dures. Comments on the IDE proposal suggested that discretion be left to the institution to decide whether it, or its IRB, should promulgate the board's procedures. The Commissioner has adopted this suggestion.

Proposed § 56.82 describes requirements for a quorum by which an IRB is to do business. First, all significant business, such as approval or suspension of an investigation, must be done by a quorum, as described in the regulations. Second, a quorum must consist of a majority of the members, unless the board has 20 or more members, in which case 10 members shall constitute a quorum. Third, at least one licensed physician, one scientist, and one nonscientist, e.g., lawyer, clergy, or consumer, must be present for a quorum. Finally, a quorum shall be determined by the members present at a meeting; proxy votes, telephone conferences, and votes by mail are not acceptable methods of carrying out important IRB activities. Responses to similar sections in the IDE proposal expressed concern that requiring certain types of individuals to be present for a quorum could produce a veto power on behalf of one person. Often cited was the lay representative, who, by staying away, could prevent IRB action. No specific examples of such incidents were provided. The Commissioner doubts that board members would be that irresponsible and believes that any pattern of such conduct might justify removal of the offending member from the board. The Commissioner therefore concludes that the presumed problem can be dealt with and that the general goal of balanced participation in IRB decisions justifies the quorum requirement. Other comments on the IDE proposal expressed concern that the quorum requirement could prevent IRB action in emergency situations, because of the possible unavailability of members who are not employed by the institution, e.g., lay members. The Commissioner does not believe that this problem is great. If unexpected toxicity appears with use of the test substance, emergency action to suspend the study to protect subjects can be taken by officials of an institution, upon advice of the available IRB members, without formal IRB action. Emergency action to deviate from a portocol in order to reduce or eliminate a risk to subjects will not require prior IRB review and formal board action under FDA regulations governing IND's; these regulations (21 CFR 312.1(a)(2) FD-1571 item 10.c) appear to provide sufficient flexibility to deal with emergencies. The Commissioner believes other actions should be taken by a balance quorum. Further comments are invited on these issues, however.

As described in proposed § 56.85, the IRB shall base its evaluation of a clinical investigation upon a review of the investigational plan or protocol agreed upon by the investigator and the sponsor, reports of pertinent past investigations involving the test article, the materials to be used in obtaining consent of subjects, and any other information that the board considers necessary to a thorough evaluation of the investigation. Upon receipt of a submission, the IRB shall notify the investigator or sponsor, as appropriate, of the date of receipt and shall inform him or her that the investigation may not begin until the board has approved it and until the investigation otherwise meets FDA requirements, e.g., an IND or IDE has been filed and no objections has been received from FDA. The board may ask for additional information and may recommend modifications or conditions to the investigator before deciding to approve or reject the investigation.

The IRB should review the protocol and supporting information and decide, as soon as possible after receipt of the information, whether to approve or disapprove a proposed clinical investigation. The IRB shall notify, in writing, the investigator, the institution, and, if appropriate, the sponsor of the board's decisions. If the board disapproves the investigation, its written notification shall include a statement of the reasons therefor, as provided in proposed § 56.85(e).

A current requirement, reiterated in § 56.87(a) of this proposal, mandates the IRB to review each ongoing clinical investigation at intervals appropriate to the degree of risk, but in no case less often than once a year. The board may, as part of its continuing review of approved investigations, decide that its approval of a particular investigation should be withdrawn and the investigation be suspended or terminated; this is provided for in proposed § 56.87(b). This decision may be made at any time during the investigation and should occur as soon as possible after discovery of the grounds for such action. If an IRB decides to suspend or terminate an investigation, it shall notify in writing the investigator responsible for the conduct of the investigation and the institution of its decision, including a statement of the reasons for withdrawing its approval. It may also, if appropriate, notify the sponsor of the investigation.

Criteria for Review

An institutional review board must evaluate a clinical investigation not only in terms of its scientific validity and medical soundness, but also in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes. Because of the many factors a board must consider in determining to approve or disapprove a study, FDA has not in the past attempted to provide criteria for IRB approval or disapproval of investigations. The enactment of the Medical Device Amendments of 1976, however, established a new role for IRB's in the regulatory scheme and specifically provided that FDA require prior submission of IDE studies to a board unless "the process of review by [an IRB] is inadequate * * *" (section 520(g)(3)(A)(ii)(II) of the act (21 U.S.C. 360j(g)(3)(A)(ii)(II))). It has therefore become necessary for FDA to provide some guidance in defining what an IRB review must consist of to be adequate under this section of the act. This was originally contained in § 812.66 (e) and (f) of the IDE proposal and was the subject of many comments. The Commissioner believes that it is appropriate to extend IRB review standards, as modified, based on the comments, to all IRB's participating in clinical investigations subject to proposed part 56. Proposed § 56.90 does not attempt to include all the grounds on which a board might base such decisions; proposed § 56.90(a) authorizes an IRB to disapprove a study on any of the grounds within the scope of review conferred on the board by the institution that created it. The Commissioner recognizes that situations may arise where matters that would be of great concern to an IRB might be insufficient for action by FDA, e.g., where the study is at odds with local ethical and moral standards or where the board's responsibility extends into areas such as allocating financial or other resources among research programs in the institution.

In contrast, proposed § 56.90(b) outlines those factors that mandate disapproval in every situation, because they directly affect the validity of the clinical investigation or the rights and safety of the subjects. The Commissioner proposes to set forth the following criteria as specific grounds necessitating disapproval of a proposed clinical investigation by the board:

A board shall disapprove, and may suspend or terminate, a clinical investigation if it finds that:

(1) The information on the basis of which the board is evaluating the study is found to contain any untrue statement or omission of a fact material to the board's evaluation. Clearly, a reliable determination of the safety of the test article for purposes of initiating human studies cannot be made if the data on which such determination is to be made are either false or incomplete.

(2) The reports of prior investigations with the test article are found in-

adequate to support a conclusion that clinical trials are reasonably safe.

(3) The investigator responsible for the conduct of the investigation does not possess the scientific training and experience needed to conduct an investigation of the safety, and, where appropriate, effectiveness of the test article.

(4) The available clinical laboratory facilities are inadequate to assure that the investigation will be conducted properly and in conformity with the protocol.

(5) The clinical investigation exposes the human subjects to undue risks. In assessing whether the risks to the subjects are undue, the board shall consider, among other factors, whether the sum of the benefits to the subjects and the importance of the knowledge to be gained justify allowing the subjects to participate, whether the subjects will be adequately protected, whether informed consent will be obtained, and whether the investigation will be subjected to continuing review by the IRB. This provision parallels HEW regulations in 45 CFR 46.102(b).

(6) The investigation does not conform to, or is not being conducted in accordance with, the understandings of the board and the requirements of FDA (e.g., IND and IDE regulations and informed consent standards).

The Commissioner recognizes that, in certain cases, the facts which would require the IRB to disapprove an investigation might not come to the board's attention until after it had already approved the investigation. In these cases, proposed § 56.90(b) provides that the board may suspend or terminate approval of that investigation, but does not mandate such action because of the complexities relating to the ongoing care of subjects, particularly patients, in the study. The decision to suspend or terminate an investigation involves additional factors such as risks to subjects from the action, the need for availability of continuing medical care for subjects in the event of suspension or termination, and the right of subjects to participate in the decision. The board is directed in proposed § 56.92 to consider these matters in determining whether to suspend or terminate a clinical investigation and what should be done regarding continuing observation of subjects.

Records and Reports

An IRB is required to prepare and maintain records on its activities with regard to individual clinical investigations. This obligation, which is current FDA policy, is proposed to be set forth in § 56.185. Among the records that must be kept are the materials submitted to the board by the investigator or sponsor, the information regarding board members required by subpart B of proposed part 56, minutes and other records of meetings, including a written summary of every discussion and decision on a substantive issue, recommendations and actions of the board, and dated reports of successive reviews.

Current FDA regulations require that IRB records be retained 3 years after the completion or discontinuance of an IND study. This is not consistent with the record retention requirements applicable to the IND investigators. The Commissioner proposes in § 56.195 to eliminate this discrepancy, and to clarify other minor ambiguities in the existing regulations. As proposed, all data and information required by these IRB regulations shall be retained for one of the following three alternative periods, whichever is shortest:

(1) A period of at least 2 years following the date on which an application for a research or marketing permit, in support of which the results of the clinical investigation were submitted, is approved by FDA;

(2) A period of at least 5 years following the date on which the results of the clinical investigation are submitted to FDA in support of an application for a research or marketing permit; or

(3) In other situations (e.g., where the clinical investigation does not result in the submission of data in support of an application for a research or marketing permit), a period of at least 2 years following the date on which the study is completed, terminated, or discontinued.

Compliance and Enforcement

Defining the role that IRB's play in reviewing proposals for and the performance of studies involving human subjects, to protect the rights and safety of subjects and to help assure that the data produced are valid and useful for the scientific and regulatory decisions made by FDA, constitutes a major clarification of FDA policy. It does, however, raise the question of how to assure that IRB's fulfill the standards found to be necessary or desirable by FDA, and what to do if a board fails to meet these standards. Several options are available, and each has an appropriate place in FDA's compliance program. The regulatory sanctions available for use in cases of noncompliance include:

(1) Notifying the IRB of deficiencies observed during an inspection. It will be the practice of an FDA investigator to do this before leaving the premises upon concluding an inspection.

(2) issuing more formal warnings that important discrepancies between the conditions observed and regulatory standards must be corrected for the IRB to avoid more serious regulatory action. This step generally will be accomplished through formal regulatory correspondence.

(3) Determining that data from one or more specific clinical investigations will not be considered by FDA in support of an application for a research or marketing permit. This determination would not mean that the data from completed studies need not be submitted to FDA. The usual rule that all data and information relevant to a particular article, e.g., a proposed or marketed product, must be submitted remains in effect. A finding that a clinical investigation is not acceptable in support of an application for a research or marketing permit means that the agency will not authorize further research or future marketing if the claim of safety or effectiveness of the product, or other condition necessary for such research or marketing, is based upon that investigation. Rejection of a particular investigation from consideration in support of an application is provided for by statute in the procedures and criteria for determining whether the application is approvable under the act or the Public Health Service Act. For example, a determination that a faulty study precludes a finding that a new drug is safe would be made in accordance with the procedures set forth in section 505(d) of the act and 21 CFR Part 314. Accordingly, no special procedures need be prescribed. The standards for IRB organization and operation thus represent amplification of the legal requirements regarding evidence of safety and, where applicable, effectiveness, necessary to approve an application for a research or marketing permit.

(4) Disqualifying an IRB as an acceptable reviewer of clinical investigations. Disqualification which the Commissioner believes should be uncommon, would mean that no new clinical investigation subject to prior submission to FDA, i.e., via an IND or IDE, would be authorized if it were to be conducted under review of the board. Further, it would mean that similar ongoing investigations under its review could be terminated or suspended until transferred to another board for review. It would also mean that data and information from any clinical investigation reviewed by the board might not be considered in support of an application for a research or marketing permit. In this case, the determination that data generated under the review of the board are not acceptable in support of an application is not limited to a particular study but may extend to all investigations reviewed by the board that may have been affected by the substandard acts or omissions. This sanction would be uti-

lized when the deficiencies found with an IRB are of such a widespread or fundamental nature that the rights and safety of subjects in, or the quality and integrity of, a number of investigations reviewed by the board have probably been compromised, or when the IRB has failed to comply with FDA's standards after previous warnings from FDA.

A similar concept on the sanctions available to deal with noncomplying IRB's in the IDE proposal evoked probably more comment, and more intense objection, than any other aspect of that proposal. The Commissioner believes that this was due, at least in part, to an inadequate explanation of the agency's need for such a sanction and to a misapprehension of the frequency with which disqualification might be used. The Commissioner believes disqualification is an important alternative to rejection of specific investigations and legal prosecution (discussed below) because it can reduce by consolidation the number of FDA investigations and administrative proceedings that might be required if FDA acted only on a study-by-study basis. This mechanism also can permit the agency to accept the results of an investigation that it might otherwise have to reject for lack of any alternative sanctions; this would result in repetition of the study with an unnecessary risk to human subjects. Disqualification obviates using judicial proceedings except for the most deliberate or flagrant offenses. Unlike rejection of a specific investigation and legal prosecution, disqualification is not explicitly provided for by statute, although it is implicit in section 520(g) of the act with respect to IRB review of device investigations. This necessitates promulgation of regulations describing the procedures for and consequences of imposing this sanction; much of the remainder of this preamble is devoted to this matter. This extensive discussion should not, however, be read as implying that disqualification is the exclusive or even the primary administrative action for noncompliance with these regulations. Disqualification will be used only when the Commissioner concludes that lesser sanctions have not been or probably will not be effective in achieving compliance.

(5) Obtaining a court injunction against further violations of the act and implementing regulations. This form of judicial action has not previously been utilized by FDA to enforce the regulations regarding clinical investigations such as standards regarding IRB's, but may be considered in the future if appropriate.

(6) Recommending prosecution of a board, its institution, the investigator and/or the sponsor of a clinical investigation for violations of Federal criminal laws, including violations of the act and/or the United States Criminal Code (e.g., 18 U.S.C. 1001). Because in most instances the board is not under a direct statutory obligation to FDA, the circumstances in which this sanction might be utilized are few in number and extraordinary in nature.

The Commissioner is aware of the wide range of severity in these sanctions. He has directed the preparation of a compliance program identifying the administrative and legal sanctions which FDA may invoke upon findings of various types of noncompliance. These sanctions and the internal procedures by which they will be applied will be contained in an FDA compliance program guide to be made publicly available upon its completion, now projected for late this year. An understanding of this document should assuage fears that boards not in compliance with the IRB standards will be subject to unreasonable penalties.

Disqualification of an IRB

Food and Drug Administration experience in enforcing regulations pertaining to the conduct of persons carrying out clinical investigations subject to the agency's jurisdiction has indicated a need for administrative sanctions in addition to court enforcement proceedings and rejection of data on a study-by-study basis. Criminal prosecutions are serious, demand significant resources, and may be unappropriate when the noncompliance does not reflect criminal intent, bad faith, or gross negligence. Study-by-study audits and proceedings to reject data also cost much in time and resources; they may be redundant if the violations are pervasive, or inappropriate if the data are scientifically valid. For these reasons, FDA has in the past used another sanction, termed the "disqualification process," to obtain compliance with the requirements regarding clinical investigators (see 21 CFR 312.1(c) and 511.1(c)).

Disqualification, in the case of clinical investigators, has simply meant that an investigator is no longer eligible to receive investigational drugs under the investigator's own or someone else's IND. It imposes no fine; it attaches no financial liability, except to the extent that an investigator may be unable to fulfill a research contract; it does not revoke a medical license or institutional privileges. The disqualification of an investigator is intended to achieve two objectives: First, it precludes a disqualified investigator from access to any test article until the investigator can demonstrate his or her ability and willingness to conform to the standards for conducting clinical investigations essential to assure scientifically sound and ethical research; second, disqualification provides a mechanism for refusing to accept data prepared by the investigator in support of an application for a research or marketing permit. Disqualification has not been used with great frequency by FDA.

After reassessing FDA's experience with disqualification, evaluating the available alternatives for enforcement of these regulations, reviewing and the comments received on the IDE proposal, and considering the factors just discussed, the Commissioner has tentatively decided that the disqualification mechanism should continue to be used by FDA in all areas of clinical investigation and for all involved parties, including IRB's. In addition to these factors cited in favor of this sanction, many participants in the development and marketing of products regulated by FDA, including sponsors, investigators, and agency officials, are familiar with this process because of its use in the IND process; as IRB's gain experience with FDA, the Commissioner expects that they will better understand the disqualification mechanism and be less anxious that it may be used capriciously.

The proposed regulations governing disqualification of IRB's are ser forth in subpart K of part 56. Proposed § 56.200 codifies the purposes of disqualification to state clearly the meaning of this administration action.

Comments received on the IDE proposed disqualification regulations, and statements made at a public hearing before the Commissioner on the proposed disqualification regulations regarding nonclinical testing facilities as part of the good laboratory practice rulemaking initiated in the Federal Register of November 19, 1976 (41 FR 51206), objected to the way in which the grounds for disqualification were set forth in these documents. Comments and statements are on display in the office of the Hearing Clerk, Food and Drug Administration, as part of the records of those proceedings (docket No. 76N-0324 and 76N-0400, respectively). The Commissioner concurs that, as drafted, those proposals implied that disqualification could occur as the result of insignificant deficiencies in meeting regulatory standards, and suggested that FDA might in the future invoke this sanction far more frequently than indicated in the preambles to those proposals.

To clarify FDA's intent in proposing the disqualification mechanism and to minimize the possible abuse of this sanction in the future, the Commissioner proposes, in § 56.202, a more restrictive statement of the grounds for disqualification of an IRB. An IRB may be disqualified only if the Commissioner finds all three of the follow-

ing: (1) That the board failed to comply with one or more of the standards set forth in part 56 or in any other FDA regulations regarding standards for IRB's, e.g., any supplemental requirements in the IND or IDE regulations; (2) that the noncompliance adversely affected the validity of the data produced in the investigation, and/or the rights and/or safety of the human subjects; and (3) that other lesser regulatory actions, such as warnings or rejection of data from individual clinical investigations, have not been or probably will not be adequate to achieve compliance by the board. These requirements assure that the sanction will not be used in trivial situations but only when the violation compromised the integrity of the investigation or the interests of the subjects. The proposed regulation further requires the Commissioner to consider the availability, and past or probable effectiveness, of lesser sanctions as alternatives to disqualification. It would not, however, preclude disqualification without a prior warning or other regulatory action where the IRB's activities evidence a deliberate violation of FDA standards or a flagrant disregard of the IRB's obligations.

The Commissioner proposes, in § 56.204, to establish a uniform procedure to be followed by the several FDA bureaus regulating or reviewing clinical investigations on articles subject to FDA jurisdiction. Each bureau will be initially responsible for administering the IRB regulations for the products and substances under its purview, as part of processing applications for research and marketing permits submitted to that bureau. In those cases where the bureau believes that rejection of specific investigations and other remedies is inadequate to achieve compliance, the Commissioner may elect to begin the disqualification proceedings by providing a notice of the proposed action to the board; there would be an opportunity for a regulatory hearing before the Commissioner or a person designated by him; and final action on the proposed disqualification would be taken only by the Commissioner or a person to whom this authority had been officially delegated.

The written notice provided to the IRB upon commencement of a disqualification proceeding shall contain the following items of information, in accordance with 21 CFR 16.22(a). (1) The notice shall specify the facts that are believed to justify disqualification. (2) The notice shall state that the board has an opportunity for a regulatory hearing on the proposed disqualification before the Commissioner, or a person designated by him, and that such hearing will be conducted in accordance with the provisions of 21 CFR part 16, the procedural regulations for regulatory hearings before FDA. (3) The notice shall state the time within which a hearing may be requested, which shall not be less than 3 working days from the receipt of the notice; except in cases where safety of subjects requires immediate action, ample time would be allowed the board to prepare for and appear at the hearing. (4) The notice shall contain the name, address, and telephone number of the FDA official who has been designated by the Commissioner as presiding officer for the regulatory hearing and to whom any request may be filed by registered mail, telegram, telex, personal delivery, or any other mode of written communication.

In the past under the disqualification regulations pertaining to clinical investigators, the Bureau of Drugs has provided an "informal" conference with the officer who issued the notice before the "formal" disqualification hearing (see 21 CFR 312.1(c)(1)). These conferences frequently had many formal trappings, such as stenographic transcripts, and were often followed by the contemplated hearing. This process doubled the time and expense of all parties involved without discernable benefit. The Commissioner has therefore decided not to provide for such an informal conference in these regulations. The procedures proposed should provide adequate flexibility and fairness to all parties.

Comments on the disqualification procedures contained in the IDE proposal objected that the regulatory hearing process denied an adversary hearing, a right to counsel, transcripts, cross-examination, and an appeal mechanism. The Commissioner advises that regulatory hearings under part 16 provide all of those safeguards as well as others essential to due process. Interested persons are referred to those regulations for a complete description of the procedures proposed to be applicable to disqualification proceedings and may comment on the adequacy and appropriateness of these procedures for purposes of disqualification of IRB's.

If, after the regulatory hearing or after the time for requesting a hearing expires without a request being made, the Commissioner upon an evaluation of the administrative record, makes the findings required for disqualification, he shall prepare and issue a final order disqualifying the IRB. Proposed § 56.206 provides that the final order shall include a statement of the basis for the disqualification. If, on the other hand, the Commissioner determines not to make these findings, he shall issue a final order terminating the disqualification proceeding and shall include a statement of the basis for his decision to terminate the proceeding.

Once a final order has been issued, the Commissioner shall so notify the IRB and the institution that established it. If the board is disqualified, the Commissioner will also notify, to the extent possible, the sponsor of every clinical investigation subject to an IND or IDE that the IRB reviewed. Because FDA does not usually receive information about other clinical investigations before they are completed and submitted to the agency, it will not generally be possible to notify sponsors of uncompleted studies. Comments on this provision in the IDE proposal requested that the sponsors and/or the investigators of clinical investigations under review by a board be notified at the commencement, rather than the completion, of disqualification proceedings. The justification offered was that these individuals might wish to protect their interest in continuing an investigation or in knowing that the results of the investigation would be accepted by FDA later. The Commissioner is concerned that such notification might lead to excessively complicated multiparty proceedings that are unnecessary. As discussed below, after the decision to disqualify is made, questions regarding the status of ongoing investigations and the acceptability of data will be considered and any interests affected will be heard. The Commissioner is not convinced that every potentially affected sponsor and investigator should be notified every time disqualification of an IRB is proposed, but he invites further comment on this matter. The Commissioner does believe, however, that other HEW agencies dealing with IRB's should be notified of problems promptly. Therefore, proposed § 56.213(c) requires the Commissioner to provide other components of HEW with such information simultaneously with a proposal to disqualify the board.

Once an institutional review board has been disqualified, no new clinical investigation requiring prior review by FDA, as well as institutional review, will be authorized by FDA if it is to be conducted under the review of the disqualified board; this rule is proposed in § 56.210(a). Because the agency has no statutory authority to suspend or terminate clinical investigations not done under an IND or IDE, it will not be possible to deny permission to conduct these investigations when they involve a disqualified IRB.

In issuing an order disqualifying an IRB, the Commissioner must consider what, if anything, should be done regarding ongoing investigations that involve the board. Several options are available: allowing the investgations to proceed for a period of time to permit

completion or to permit corrective actions; limiting the continuation of the investigations to subjects who are already participating; requiring tranfer of responsibility for the further review of the investigation to an IRB that is in compliance with FDA standards; or terminating the investigation completely. A special concern is the subject who cannot be safely withdrawn from the investigation because, for example, the subject has an implanted investigational device that must be surgically removed, or because abrupt withdrawal of the investigational drug may create a life-threatening problem. Clearly, some provision must be made for such cases if ongoing investigations are to be suspended upon disqualification of an IRB. The Commissioner does not believe it possible, much less advisable, to require that any particular option be used for ongoing investigations. This choice must be made, on a study-by-study basis, considering the nature of the investigation, the number of subjects involved, the risks to them from suspension of the study, and the need for further review by an acceptable IRB. Section § 56.210(b) of the proposed regulations authorizes, but does not require, the actions that might be taken. The Commissioner specially invites comments on these proposals and suggestions for other ways to address this sensitive problem.

Proposed § 54.210(c) provides that each application for a research or marketing permit, approved or not, that contains or relies upon a clinical investigation conducted under the review of a disqualified IRB may be examined to determine whether the study was, or would be, essential to FDA's decision to approve the application. This authority is also discretionary, and would depend on the types of problems that led to disqualification and the nature of the investigation involved. If it is determined that, without the results of the investigation in question, further clinical trials would not have been allowed or a product license would not have been approved, FDA will then determine whether data from the investigation are acceptable, notwithstanding disqualification.

To avoid FDA's having to audit every such investigation, any study reviewed by an IRB prior to or after disqualification but before reinstatement may be presumed to be unacceptable, and the person relying on the data resulting from the investigation may be required to establish that the data were not affected by the circumstances which led to disqualification. The sponsor or applicant may be required to submit validating information. If FDA determines that the clinical investigation was or would be essential, and is not acceptable, it will be eliminated from the consideration of the application for a research or marketing permit. Elimination of such data may serve as "new information" justifying termination of an IND or IDE, initiation of the withdrawal of approval of a product license, or the revocation of a product monograph or standard.

Under proposed § 56.210(d), the FDA will not consider, in support of any application for a research or marketing permit, any clinical investigation begun under the review of an IRB after it has been disqualified. This rule does not, however, relieve the applicant from any requirement under any other applicable statute or regulation that all data and information regarding clinical experience with the article in question be submitted to the agency.

The Commissioner advises that it is not necessary that an IRB be disqualified for the agency to reject consideration of a particular clinical investigation in support of an application for a research or marketing permit. The criteria set forth in the statute and regulations applicable to each type of application, together with the regulations regarding the conduct of clinical investigations, will still be used to evaluate the scientific validity and meaning of the results of each investigation. The agency may apply these regulations to a particular investigation and determine that it is so inadequate in terms of science or ethics that it will not or should not support a claim of safety or effectiveness for a product. If the sponsor of the product wishes to contest this finding, the opportunity to do so will be provided in the procedures for denying or withdrawing the approval of the application.

The Commissioner believes that it is contrary to the public interest to provide a two-step process whereby a particular investigation would be disqualified under procedures similar to those proposed in subpart K of part 56, and then the application itself would be denied under procedures set forth in other regulations. Efficiency and fairness suggest that these issues be resolved at the same time in one proceeding, if that is required. It may be that, although a particular investigation is not acceptable, other data and information in the application will support a product's safety or effectiveness, and therefore no proceeding is necessary to rule on the acceptability of the particular investigation. Likewise, the agency may choose to reject individual investigations without disqualifying an IRB when, for example, the investigation was performed during a period when the IRB was not in compliance with FDA standards, but the IRB has since come into compliance.

The Commissioner further advises that it is likely that the usual formal regulatory action taken for noncompliance will be rejection of individual investigations and that disqualification of an IRB will be reserved for the rare cases where the rejection of a particular investigation is an inadequate regulatory response.

The agency believes that it should affirmatively provide information regarding the disqualification of an IRB to entities having professional dealings with that board, such as other Federal, State or local government agencies supporting research studies. Many objections were received to this aspect of disqualification in the IDE proposal. The Commissioner believes, however, that because a number of Federal agencies have adopted very similar standards regarding IRB's in conjunction with human experimentation supported, by grant or contract, with the taxpayers' dollars, a Federal agency that finds an IRB out of compliance with those standards has a duty to notify its sister agencies. Moreover, the Commissioner believes that providing such information is within the purpose of section 705 of the act (21 U.S.C. 375).

Because the Commissioner recognizes that the consequences of such notice could have a serious adverse effect on the board and its members, he believes that the board and its members must be aware that such notice is one of the results of disqualification. *Cf. Wisconsin* v. *Constantineau*, 400 U.S. 433 (1971). Proposed § 56.213(a) expressly authorizes FDA to notify other entities when the Commissioner believes that such disclosure would further the public interest or would promote compliance with the applicable FDA standards. This determination is within the discretion of the Commissioner upon consideration of the circumstances justifying the disqualification, any mitigating conditions, and the degree to which other agencies or persons are involved with the ongoing activities of the board. If he gives any notice, the Commissioner shall provide a copy of the final disqualification order, indicate its legal meaning, and state that FDA is not advising or recommending that the person notified take any action upon the matter. A copy of each notification shall be given to the board.

Both the determination that an IRB has been disqualified and the administrative record regarding such determination are disclosable to the public under the Freedom of Information Act (5 U.S.C. 552) and under the FDA public information regulations (21 CFR part 20) as records relating to an administrative enforcement action that has been completed. This is stated in proposed § 56.213(b).

Because disqualification of an IRB may be neither a sufficient nor an appropriate sanction in every case, the Commissioner believes that disqualification must be independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by law. Proposed § 56.215 makes clear, therefore, that FDA may at any time recommend institution of any appropriate judicial proceedings, civil or criminal, and any other appropriate regulatory action, in addition to or in lieu of, and prior to, simultaneously with, or subsequent to, disqualification. This would, of course, include refusing to consider a particular investigation in support of a particular application, the regulatory action that probably will be most commonly used in cases of significant noncompliance with the IRB standards. The agency may also refer the matter to another Federal, State, or local governmental agency for such action as that agency determines to be appropriate.

Disqualification is principally a remedial action to prevent future violations, to assure that the rights and safety of subjects are appropriately protected and that data in support of applications are produced under circumstances that increase the likelihood of their scientific validity. Thus, the Commissioner concludes that disqualification should continue indefinitely until the agency finds that the IRB can and will fulfill the requirements imposed under these proposed standards.

Proposed § 56.219 authorizes the Commissioner to reinstate an IRB, i.e., to determine that it may again review investigations under an IND or IDE, and that data from investigations under its review may once again be considered in support of applications for research or marketing permits, if he finds that the board can provide adequate assurances that it will operate in compliance with FDA standards. An IRB that wishes to be reinstated shall explain to the Commissioner why it believes reinstatement is warranted, and shall provide a detailed description of the corrective actions the board has taken or intends to take to assure that the acts or omissions that led to its disqualification will not recur. The Commissioner may condition reinstatement upon the board's passing a subsequent FDA inspection.

In fairness to the IRB, all persons or organizations notified under proposed § 56.213(a) of the board's previous disqualification must be notified when it is later reinstated; proposed § 56.219 so provides. Once reinstated, an IRB may thereafter review additional new clinical investigations. A determination that an IRB has been reinstated is also disclosable to the public under the Freedom of Information Act and under 21 CFR Part 20 as records relating to completed administrative enforcement actions.

Legal Authority

The results of literally hundreds of clinical investigations are submitted to FDA each year by persons seeking regulatory action by the agency. To obtain a marketing license, clinical research data are offered to support the safety and effectiveness or functionality of a product, e.g., a food or color additive, or a drug, biologic or medical device for human use. Even where a license is not required or already has issued, such data may be relied upon to demonstrate the bioavailability of a marketed drug, the general recognition of safety of a product, or the absence of any need for premarket approval or a product standard for a device. In evaluating the enormous volume of clinical investigations filed with FDA, many types of scientific and regulatory review must be devoted to these studies apart from determining their ethical and scientific acceptability and their basic validity, e.g., to interpret the results and to evaluate the status of the affected products in light of the results. Given the limited resources within the agency, the Commissioner believes that FDA must have standards to screen out those clinical investigations that are likely to be unacceptable and thus should not be authorized by FDA or that warrant little further evaluation in support of a product application. Promulgating these standards provides one process for making this judgment. While compliance with the requirements for IRB review does not guarantee the ethical or scientific acceptability of, or the validity of data from, a clinical investigation, failure to comply increases substantially the probability that the results will not be useful to FDA. Moreover, as noted elsewhere in this preamble, the regulations reflect principles recognized by the scientific community as essential to sound research involving human subjects. Thus, these standards will assist FDA in identifying those investigations that cannot be permitted to be carried out or considered in support of an application for a research or marketing permit.

Under section 701(a) of the Act, the Commissioner is empowered to promulgate regulations for the efficient enforcement of the Act. Previously, the Commissioner has issued regulations (21 CFR 314.111(a)(5)) for determining whether a clinical investigation of a drug intended for human use, among other things, was scientifically reliable and valid, in the words of the Act: "adequate and well-controlled," to support approval of a new drug. These regulations were issued under section 701(a) of the Act and have been upheld by the Supreme Court (see *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973); see also *Upjohn Co.* v. *Finch*, 422 F.2d 944 (6th Cir. 1970) and *Pharmaceutical Manufacturers Association* v. *Richardson*, 318 F. Supp. 301 (D. Del. 1970)).

Furthermore, sections 505(i), 507(d), and 520(g) of the Act regarding clinical investigations that require prior FDA authorization, direct the Commissioner to promulgate regulations to protect the public health in the course of those investigations. For the reasons discussed at the outset of this notice, the Commissioner finds that IRB's are an essential element to safeguard the right and safety of human subjects in virtually all studies conducted under those sections of the Act. Section 520(g) of the Act further necessitates the establishment of regulations regarding the functioning of local institutional review committees to review proposed clinical testing of certain medical devices. These proposed regulations are intended to fulfill these mandates.

The Commissioner has therefore concluded that legal authority to promulgate these regulations regarding clinical investigators exists under sections 505(i), 507(d), 520(g), and 701(a) of the Act, as essential to protection of the public health and safety and to enforcement of the agency's responsibilities under sections 406, 408, 409, 502, 505, 506, 507, 510, 513, 514, 515, 516, 518, 519, 520, 601, 706, and 801 of the Act, as well as the responsibilities of FDA under sections 351 and 354 to 360F of the Public Health Service Act.

Inspections of Institutional Review Boards

It follows from the authority to promulgate these regulations that FDA also has authority to prescribe the terms on which it will accept data generated in a clinical investigation reviewed by an IRB.

Therefore, the agency will not consider data from a clinical investigation in support of an application for a research or marketing permit unless the board that reviewed the investigation consents to inspection by FDA. This rule is set forth in proposed § 56.15(b). The Commissioner believes that this requirement does not infringe on any right or obligations of an IRB or its institution that may, at any time, refuse to consent to inspection or withdraw its consent. In this event, however, FDA will not consider the results of the study in support of an application and may consider disqualifying the board. This action may adversely affect the status of an application submitted by a third person, e.g., the sponsor of a study under a grant or contract; but this is strictly a matter

between those parties. The Commissioner advises all persons who sponsor, under grant or contract, clinical investigations that may be submitted to FDA to consider including provisions regarding FDA inspections in the grant or contract. Such a provision is especially important if the board is not otherwise aware that the results of the investigation may be submitted to FDA.

Inspections of many IRB's will not necessarily be conditioned upon consent. Under section 704(a) of the act, FDA may inspect establishments, including consulting laboratories, in which certain drugs and devices are processed or held, and may examine research data that would be subject to reporting and inspection pursuant to section 505 (i) or (j), 507 (d) or (g), 519, or 520(g) of the act. (See in this regard 21 CFR 200.10.) Thus, most sponsors and many investigators under IND's and IDE's, and those institutions in which such studies are conducted, would be subject to FDA inspection whether or not they consented.

The Commissioner wishes to point out that since 1971 FDA has exercised authority to inspect IRB's. Between 1971 and 1976, for example, approximately 75 IRB inspections were completed by the Bureau of Drugs. Language in the current regulations regarding FDA's authority has, however, been interpreted by some, e.g., the GAO in its recent report, to mandate periodic inspections. The agency intends to inspect IRB's on both a random basis and in response to particular problems. The number of IRB's inspected and the depth to which they will be audited remain a function of available FDA resources. Therefore, the Commissioner proposes in § 56.15 to restate FDA's authority and at the same time to eliminate any possible interpretation that FDA will inspect IRB's at any preestablished frequency.

The current FDA policies regarding inspection of records of clinical investigations require clarification. During FDA inspections of clinical investigators and institutions in which studies were conducted, agency officials were occasionally refused access to records containing the names of human subjects, on grounds of the confidentiality of the physician-patient relationship and the subject's right to privacy. Numerous questions and objections were also submitted regarding statements about FDA inspections of records regarding clinical investigations made in the IDE proposal. Therefore, the Commissioner finds it necessary to state clearly and publicly when FDA will request access to such records, and if such access is requested, how the agency will safeguard the privacy of subjects.

First, the agency does not need to inspect medical history records routinely. The scientific evluation of case report forms, and of summary tables proposed from the data in these forms, is the basic mechanism by which FDA assesses the study data. However, the agency's inspections have uncovered a significant number of errors of omission and commission in information submitted to the agency. For this reason FDA has initiated an inspectional program that includes the onsite audit of certain data submitted to the agency. During this audit, access to the subject's identification is incidental to the review of such records. When such records are reviewed, as described in current regulations, "the names of the subjects need not be divulged unless the records of the particular subjects require a more detailed study of the cases, or unless there is a reason to believe that the records do not represent actual studies or do not represent actual results obtained" (see § 312.1(a) (21 CFR 312.1(a))). To assure the privacy of individually identifiable medical records, FDA has implemented clear and extraordinarily exacting guidelines for FDA personnel who conduct inspections of medical records containing the names of individual research subjects. Before an inspection, FDA personnel will generally notify the IRB of FDA's intent to inspect the IRB's records, with a view to arranging a mutually convenient inspection time. Agency personnel must invite a representative of the IRB to be present with them throughout GDA's records review, and they must inform the representative that he or she may see the records which they may wish to copy and may review any records that are copied. Agency personnel may not copy medical records containing the names of research subjects, and the representative is to be given the right to delete any information that could identify an individual subject, except when: (1) The agency has reason to believe that the consent of human subjects was not obtained; or (2) there is reason to believe that the records do not represent actual studies, or do not represent actual results obtained. The exceptions to the prohibition against the copying of individually identifiable medical records by FDA personnel rest primarily on the need to determine whether a given research subject in fact exists and whether the research subject in fact participated in the investigation. Where an individually identifiable medical record is copied and reviewed by the agency, the record is properly safeguarded within FDA and is used or disseminated under conditions that protect the privacy of the individual to the fullest possible extent consistent with laws relating to public disclosure of information (Freedom of Information and Privacy Act regulations) and the law enforcement responsibilities of the agency.

The Commissioner proposes in § 56.15(a) that an IRB permit authorized FDA personnel, at reasonable times and in a reasonable manner, and only for purposes of verification of the data and information submitted to FDA: (a) To inspect all records required by these regulations, (b) to copy such records that do not identify the names of human subjects or from which the identifying information has been deleted, and (c) to copy such records that identify the names of human subjects, without deletion of the identifying information, upon notice that FDA has reason to believe that the consent of human subjects was not obtained, that the reports submitted by the investigator to the sponsor, or to the IRB, do not represent actual cases or actual results obtained, or that such reports or other required records appear to be otherwise false or misleading.

The Commissioner recognizes the highly sensitive nature of this provision, as reflected in the many comments already received by FDA on the IDE proposal. The Commissioner welcomes reasoned discussions of the issues involved and specific proposals under which patient confidentiality could be further protected without compromising the ability of FDA to verify clinical data submitted in support of applications for research or marketing permits.

Conforming Amendments

The Commissioner is proposing to amend the procedural regulations (21 CFR 16.1) regarding regulatory hearings before the FDA to add a cross-reference to the procedures proposed in this notice regarding disqualification of an IRB.

The current definitions of the term "sponsor" found in 21 CFR 310.3(j) and 510.3(k) are to be superseded by the proposed definition in § 56.3(i) discussed above. Therefore, the Commissioner is proposing to eliminate the current definitions.

Because of the clarifications of the standards regarding IRB's, the Commissioner proposes to revise the IND regulations in 21 CFR 312.1(a), forms FD-1571, FD-1572, and FD-1573, to correspond with the proposed part 56. Rather than repeat these provisions in the forms in this proposal, which might confuse readers and lead to duplicative comments, the Commissioner gives notice that the forms will be revised in the final order to reiterate the standards proposed here, as modified in light of the comments received.

The Commissioner also proposes to add or revise provisions in regulations regarding food and color additives, new drug applications, bioavailability, and bioequivalence testing requirements, OTC drug products, radioactive drugs, antibiotic drugs, biological product licenses, cosmetics, and electronic products, to incorporate appropriate implementing provisions for, and cross-references to, part 56.

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. 406, 408, 409, 502, 503, 505, 506, 507, 510, 513-516, 518-520, 601, 701(a), 706, and 801, 52 Stat. 1049-1054 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-518 as amended, 72 Stat. 1785-1788 as amended, 74 Stat. 399-407 as amended, 76 Stat. 794-795 as amended, 90 Stat. 540-546, 560, 562-574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360c-360f, 360h-360j, 361, 371(a), 376, and 381)) and the Public Health Service Act (secs. 215, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 262, 263b-263n)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes that chapter I of title 21 of the Code of Federal Regulations be amended as follows:

SUBCHAPTER A—GENERAL

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. In § 16.1, by adding new paragraph (b)(27) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(27) Section 56.204(b), relating to disqualifying an institutional review board.

2. By adding new part 56 to read as follows:

PART 56—INSTITUTIONAL REVIEW BOARDS

Subpart A—General Provisions

Sec.
56.1 Scope.
56.2 Circumstances in which an institutional review board is required; exemptions.
56.3 Definitions.
56.8 Review by institution.
56.15 Inspection of an institutional review board.

Subpart B—Organization and Personnel

56.21 Diversity of membership of an institutional review board.
56.25 Relationship between members and institution.
56.26 Relationship between members and sponsor, investigator, or investigation.
56.34 Consultants.

Subparts C and D—[Reserved]

Subpart E—Board Operations

56.80 Written procedures for review of clinical investigations by an institutional review board.
56.82 Quorum requirements.
56.85 Procedures for initial review of a clinical investigation.
56.87 Procedures for continuing review and suspension or termination of a clinical investigation.
56.90 Criteria for disapproval, suspension, or termination of a clinical investigation.
56.92 Order to suspend or terminate a clinical investigation.

Subparts F through I—[Reserved]

Subpart J—Records and Reports

56.185 Records of an institutional review board.
56.195 Retention of records.

Subpart K—Disqualification of an Institutional Review Board

56.200 Purpose.
56.202 Grounds for disqualification.
56.204 Notice of and opportunity for a hearing on proposed disqualification.
56.206 Final order on disqualification.
56.210 Actions on disqualification.
56.213 Public disclosure of information regarding disqualification.
56.215 Alternative or additional actions to disqualification.
56.219 Reinstatement of a disqualified institutional review board.

AUTHORITY Secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 513-516, 518-520, 601, 701(a), 706, and 801, Pub. L. 717, 52 Stat. 1049-1054 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-518 as amended, 72 Stat. 1785-1788 as amended, 74 Stat. 399-407 as amended, 76 Stat. 794-795 as amended, 90 Stat. 540-546, 560, 562-574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360c-360f, 360h-360j, 361, 371(a), 376, and 381), secs. 215 351, 354-360F, Pub. L. 410, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 262, 263b-263n).

Subpart A—General Provisions

§ 56.1 Scope.

This part contains the general standards for the composition, operation, and responsibility of an institutional review board that reviews clinical investigations regulated by the Food and Drug Administration under sections 505(i), 507(d), and 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, cosmetics, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Additional specific standards for the composition, operation, and responsibility of an institutional review board that reviews clinical investigations involving particular test articles and products may be found in other parts, e.g., parts 312 and 812, of this chapter. Compliance with these parts is intended to protect the rights and safety of human subjects involved in such investigations and to help assure the quality and integrity of the data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 507, 510, 513-516, 518-520, 601, 706, and 801 of the act and sections 351 and 354-360F of the Public Health Service Act.

§ 56.2 Circumstances in which an institutional review board is required; exemptions.

(a) Except as provided in paragraph (c) of this section, the Food and Drug Administration will not accept any application for a research permit for a clinical investigation (as required in parts 312 and 812 of this chapter) unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an institutional review board meeting the requirements of this part.

(b) Except as provided in paragraph (c) of this section, the Food and Drug Administration will not consider in support of an application for a research or marketing permit any data or information that has been derived from a clinical investigation unless that investigation had been approved by, and was subject to initial and continuing review by, an institutional review board meeting the requirements of this part. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulation to submit the results of the investigation to the Food and Drug Administration.

(c) (1) The Food and Drug Administration will waive the requirement for institutional review board review whenever the investigation commenced prior to and was completed within 1 year following (insert effective date of this section) and was not otherwise subject to requirements for institutional review under Food and Drug Administration regulations prior to that date.

(2) Except as provided in this paragraph (c)(2), the Food and Drug Administration will waive the requirement on request of an applicant, if the Commissioner determines that the requirement is not necessary either for protecting the subjects involved or for assuring the validity or reliability of the scientific data (e.g., in a phase 3

investigational drug study (see § 312.1(a)(2), form FD-1571, item 10, of this chapter) on outpatient subjects). Any applicant for a research or marketing permit may include a request for waiver, with supporting information, in the application. In the case of applications for a research permit granted on an emergency basis, such request for waiver may be made over the telephone and be granted orally by the Food and Drug Administration at the same time the emergency application is approved on an oral basis, and may be conditioned upon subsequent review by an institutional review board. Written confirmation of any oral request for and grant of a waiver shall be included in the official application submitted subsequent to the emergency authorization of such application. The requirement will not be waived in any of the following situations:

(i) When the clinical investigation involves institutionalized human subjects.

(ii) When the clinical investigation is conducted on the premises of an institution that has an institutional review board meeting the requirements of this part.

(iii) When the Food and Drug Administration determines that the risks to the subjects justify such review.

§ 56.3 Definitions.

As used in this part:

(a) "Act" means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-392)).

(b) "Application for research or marketing permit" includes:

(1) A color additive petition, described in part 71 of this chapter.

(2) Data and information regarding a substance submitted as part of the procedures for establishing that a substance is generally recognized as safe for a use which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §§ 170.35 and 570.35 of this chapter.

(3) A food additive petition, described in part 171 of this chapter.

(4) Data and information regarding a food additive submitted as part of the procedures regarding food additives permitted to be used on an interim basis pending additional study, described in § 180.1 of this chapter.

(5) Data and information regarding a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in section 406 of the act.

(6) A "Notice of Claimed Investigational Exemption for a New Drug," described in part 312 of this chapter.

(7) A new drug application, described in part 314 of this chapter.

(8) Data and information regarding the bioavailability or bioequivalence of drugs for human use submitted as part of the procedures for issuing, amending, or repealing a bioequivalence requirement, described in part 320 of this chapter.

(9) Data and information regarding an over-the-counter drug for human use submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, described in part 330 of this chapter.

(10) Data and information regarding a prescription drug for human use submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, to be described in this chapter.

(11) Data and information regarding an antibiotic drug submitted as part of the procedures for issuing, amending, or repealing regulations for such drugs, described in part 430 of this chapter.

(12) An application for a biological product license, described in part 601 of this chapter.

(13) Data and information regarding a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, described in part 601 of this chapter.

(14) An "Application for an Investigational Device Exemption," described in part 812 of this chapter.

(15) Data and information regarding a medical device for human use submitted as part of the procedures for classifying such devices, described in section 513 of the act.

(16) Data and information regarding a medical device for human use submitted as part of the procedures for establishing, amending, or repealing a standard for such device, described in section 514 of the act.

(17) An application for premarket approval of a medical device for human use, described in section 515 of the act.

(18) A product development protocol for a medical device for human use, described in section 515 of the act.

(19) Data and information regarding an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for such products, described in section 358 of the Public Health Service Act.

(20) Data and information regarding an electronic product submitted as part of the procedures for obtaining a variance from any electronic product performance standard, as described in § 1010.4 of this chapter.

(21) Data and information regarding an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from a radiation safety performance standard, as described in § 1010.5 of this chapter.

(22) Data and information regarding an electronic product submitted as part of the procedures for obtaining an exemption from notification of a radiation safety defect or failure of compliance with a radiation safety performance standard, described in subpart D of part 1003 of this chapter.

(c) "Clinical investigation" means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i), 507(d), or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies.

(d) "Institution" means a person (other than an individual) who engages in the conduct of research on subjects or in the delivery of medical services to individuals, as a primary activity or as an adjunct to providing residential or custodial care to humans. The term includes, for example, a hospital, retirement home, prison, academic establishment, and pharmaceutical or device manufacturer. The word "facility" as used in section 520(g) of the act is deemed to be synonomous with the term "institution" for purposes of this part.

(e) "Institutional review board" means any board, committee, or other group formally designated by an institution for the purposes of reviewing clinical investigations or other types of biomedical research involving humans as subjects, approving the initiation of such investigations or research, overseeing the conduct of such investigations or research, and/or terminating or suspending such investigations or research when necessary for the protection of the subjects. The term has the same meaning as the phrase "institutinal review committee" as used in section 520(g) of the act.

(f) "Institutionalized subject" means:

(1) A subject who is voluntarily confined for a period of more than 24 continuous hours on the premises of, and in the care of, and institution (e.g., a hospital inpatient or a retirement home resident), whether or not that

institution is a sponsor of the clinical investigation; and

(2) A subject who is involuntarily confined for any period of time in a penal institution (e.g., jail, workhouse, house of detention, or prison), or another institution (e.g., a hospital) by virtue of a sentence, order, decree, or judgment under a criminal or civil statute, or awaiting arraignment, commitment, trial, or sentencing under such a statute, or by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal facility.

(g) "Investigator" means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving a subject).

(h) "Person" includes any individual, partnership, corporation, association, scientific or academic establishment, Government agency or organizational unit of a Government agency, and any other legal entity.

(i) "Sponsor" means a person who initiates a clinical investigation, but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(j) "Sponsor-investigator" means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., it does not include a corporation or agency. The obligations of a sponsor-investigator under this part include both those of a sponsor and those of an investigator.

(k) "Subject" means a human who is or becomes a participant in a clinical investigation, either as a recipient of the test article or as a control. A subject may be either a person in normal health or a patient to whom the test article might offer a therapeutic benefit or provide diagnostic information or a better understanding of a disease or metabolic process.

(l) "Test article" means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, cosmetic, electronic product, or any other article subject to regulation under the Act or under sections 351 or 354-360F of the Public Health Service Act.

56.8 Review by institution.

Approval by an institutional review board of a clinical investigation may be subject to further appropriate review and approval, disapproval, suspension, or termination by officials of the institution. Disapproval, suspension, or termination of such an investigation by an institutional review board, however, may not be overruled by such officials.

56.15 Inspection of an institutional review board.

(a) An institutional review board shall permit an authorized employee of the Food and Drug Administration, at reasonable times and in a reasonable manner, for purposes of verification of case reports and other information prepared as part of the data and information to be submitted by the sponsor to the Food and Drug Administration and of assessment of compliance with the requirements set forth in this and other parts, e.g., parts 312 and 812 of this chapter:

(1) To inspect records required to be made or kept by the institutional reivew board as part of, or relevant to, its activities relating to clinical investigations;

(2) To copy such records which do not identify the names of human subjects or from which the identifying information has been deleted; and

(3) To copy such records that identify the human subjects, without deletion of the identifying information, but only upon notice that the Food and Drug Administration has reason to believe that the consent of human subjects was not obtained, that the reports submitted by the investigator to the sponsor (or to the institutional review board) do not represent actual cases or actual results obtained, or that such reports or other required records apprear to be otherwise false or misleading.

(b) The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institutional review board that reviewed the investigation refuses to allow an inspection under this section. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable statute or regulation to submit the results of the investigation to the Food and Drug Administration.

Subpart B—Organization and Personnel

56.21 Diversity of membership of an institutional review board.

(a) An institutional review board shall be composed of not fewer than five individuals with varying cultural backgrounds to assure complete and adequate review of the clinical investigation. The board shall be sufficiently qualified through the maturity, experience, and expertise of its members and diversity of its membership to insure respect for its advice and counsel for safeguarding the rights and safety of subjects. In addition to possessing the professional competence necessary to comprehend the scientific nature of the investigation, the board must be able to ascertain the acceptability of a study in terms of institutional commitments and regulations (where appropriate), applicable law, standards of professional conduct and practice, and community attitudes. Such board shall include at least one licensed physician, as well as individuals whose primary concerns are in nonscientific areas (e.g., lawyers, clergy, ethicists, consumers, and social scientists). No board shall consist entirely of members of only one sex, race, or professional group.

(b) The records of a board shall identify each member by name, earned degrees if any, occupation and title, and other pertinent indications of experience (such as board certification or licenses) sufficient to describe each member's chief anticipated contributions to such board's deliberations.

56.25 Relationship between members and institution.

(a) The institutional review board shall not consist entirely of individuals who are officers, employees, or agents of, or are otherwise associated with, the institution, apart from their membership on the institutional review board.

(b) The records of a board shall identify the employment or other relationship between each member and the institution, including the membership on the board (e.g., full-time employee, part-time employee, a member of governing panel or board, paid consultant, or unpaid consultant).

§ 56.26 Relationship between members and sponsor, investigator, or investigation.

(a) No member of an institutional review board shall participate in the board's initial or continuing review of any clinical investigation in which the member has a conflicting interest, or of any investigation involving an investigator or sponsor who participated in his or her selection for the board, except to provide information requested by the board. The board is responsi-

ble for determining whether a member has a conflicting interest. No investigator or sponsor shall participate in the selection of members for a board that will review his or her investigation. The Food and Drug Administration may waive the requirements of this section upon a request contained in the relevant application for a research or marketing permit; the request shall contain information describing the reasons why it is necessary for the investigator or sponsor to participate in the selection of board members.

(b) The records of a board shall identify the employment or other relationship between each member and the investigator or sponsor of any clinical investigation reviewed by the board (e.g., full-time employee, part-time employee, member of the governing board or panel, paid consultant, or unpaid consultant). If any such relationship exists, the records shall describe the extent to which the member participated in the initial or continuing review of the investigation.

§ 56.34 Consultants.

An institutional review board may, at its discretion, invite persons with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the board. Such persons may not vote with the board.

Subparts C and D [Reserved]

Subpart E—Board Operations

§ 56.80 Written procedures for review of clinical investigations by an institutional review board.

An institutional review board shall follow written procedures for conducting its initial and continuing review and monitoring of clinical investigations and for reporting its findings and actions to the investigator, the institution, and, where appropriate, the sponsor. Such procedures may be promulgated by the institution or by the board.

§ 56.82 Quorum requirements.

(a) An institutional review board shall conduct all significant business (e.g., approval, disapproval, suspension, or termination of a clinical investigation, or approval of a consent form) by a quorum of its members present at a meeting. The quorum shall be defined in the written procedures of the board, consistent with the requirements of this section.

(b) The number of members to constitute a quorum may not be less than a majority of the members of the board, unless the board has 20 or more members, in which case 10 members shall constitute a quorum.

(c) A quorum shall consist of a least one licensed physician, one scientist, and one nonscientist (e.g., lawyer or clergy).

(d) A quorum shall be determined only by members present at a meeting. Proxy votes, telephone conferences, and votes by mail shall not constitute a meeting or presence at a meeting.

§ 56.85 Procedures for initial review of a clinical investigation.

(a) An institutional review board shall not approve a proposed clinical investigation until it has received in writing and reviewed the investigational plan or protocol, reports of pertinent prior animal and human studies conducted with the test article, and the materials to be used in obtaining consent of subjects.

(b) Upon receipt of a proposed investigation, the board shall inform in writing the investigator or sponsor, as appropriate, of the date of such receipt and that the investigation may not begin until the board notifies the investigator or sponsor, as appropriate, that it has approved the investigation and until the sponsor has complied with any other preinvestigation requirements of the Food and Drug Administration.

(c) If the board has any question regarding the proposed investigation, or desires any further information, it may request the investigator or sponsor to provide the necessary information or materials as written amendments to the submission. The board may advise the investigator or sponsor, as appropriate, on modifications, conditions, or other amendments to the investigational plan or protocol and/or the material to be used to obtain consent of subjects, which might improve the acceptability of the proposed investigation to the board. Any modifications, conditions, or other amendments to the investigational plan or protocol shall be made in writing as amendments to the submission.

(d) The board should review and approve or disapprove a proposed investigation as soon as possible after receipt of the submission and any amendments in response to requests or advice from the board.

(e) The board shall notify in writing the investigator or the sponsor, as appropriate, and the institution, of its decision to approve or disapprove the proposed investigation. If the board decides to disapprove an investigation, it shall include in its written notification a statement of the reasons for its decision.

§ 56.87 Procedures for continuing review and suspension or termination of a clinical investigation.

(a) An institutional review board shall continue to review a clinical investigation that it has approved until the investigation is concluded or is discontinued. Such continuing review shall be undertaken at intervals appropriate to the degree of risk, but not exceeding 1 year, to assure that the investigation is being conducted in compliance with the requirements, understandings, and recommendations of the board and with the requirements of the act and implementing regulations (e.g., parts 312 and 812 of this chapter).

(b) A board may, at any time, suspend or terminate a previously approved clinical investigation. The board shall notify in writing the investigator or the sponsor, as appropriate, and the institution of its decision to take such action, including a statement of the reasons for its decision.

§ 56.90 Criteria for disapproval, suspension, or termination of a clinical investigation.

(a) An institutional review board may disapprove, suspend, or terminate a clinical investigation for any of the reasons within the scope of review conferred upon the board by the institution that created it. It shall state its reasons in writing. A board may reconsider its action, with or without submission of additional information, and the decision of a board of any one institution regarding a proposed clinical investigation shall not preclude a different decision by the board of another institution that might consider the same investigation.

(b) A board shall disapprove, and may suspend or terminate, a clinical investigation if it finds that:

(1) The information submitted to the board contains an untrue statement of fact material to the board or omits material information required by the board to review and evaluate the clinical investigation.

(2) The report of prior investigations with the test article is inadequate to support a conclusion that it is reasonably safe to initiate or continue the clinical investigation.

(3) The investigator does not possess the scientific training and experience appropriate to qualify the investigator as a suitable expert to investigate the safety and, where appropriate, effectiveness of the test article.

(4) The available clinical laboratory facilities and medical support are inadequate to assure that the clinical investigation will be conducted properly and in conformity with the protocol.

(5) The clinical investigation exposes or will expose subjects to undue risks.

In assessing risks, the board shall consider, among other factors:

(i) Whether the risks to the subject are so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks;

(ii) Whether the rights and safety of subjects will be adequately protected;

(iii) Whether legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the requirements of § 310.102 or subpart F of part 812 of this chapter; and

(iv) Whether the conduct of the clinical investigation will be or is being reviewed by the sponsor and by the board at intervals appropriate to the degree of perceived risk.

(6) The clinical investigation does not conform to, or is not being conducted in accordance with, the submission to the board and the requirements of the Act and implementing regulations (e.g., parts 312 and 812 of this chapter).

§ 56.92 Order to suspend or terminate a clinical investigation.

If an institutional review board decides to order the suspension or termination of a clinical investigation, it shall include in its order provisions regarding any subject who has previously been allowed to participate in the investigation and who either would (if the investigation were not suspended or terminated) continue to receive the test article or have it used involving him or her, or who would not continue to receive it or have it used involving him or her but who remains under the supervision of the investigator. Such provisions shall take into account, among other factors, the risks to the subject from the withdrawal of the test article or from its continued administration by another physician, the need for further medical supervision, the availability of qualified medical personnel, and the rights of the subject, including the right to participate in the decision as to future care.

Subparts F Through I [Reserved]

Subpart J—Records and Reports

§ 56.185 Records of an institutional review board.

An institutional review board shall prepare and maintain adequate documentation of its activities regarding each clinical investigation, including the following:

(a) Records of information submitted to the board by an investigator and/or the sponsor;

(b) Information on board members required under subpart B of this part;

(c) Attendance at and minutes of board meetings, including a written summary of the discussion of any substantive issues and their resolution;

(d) Board recommendations and actions, with a record of the number of members voting in favor of and against the decision; and

(e) Dated reports of successive reviews as they are performed.

§ 56.195 Retention of records.

An institutional review board shall retain the records required by this part regarding a particular clinical investigation for whichever of the following periods is shortest:

(a) A period of 2 years following the date on which the test article is approved by the Food and Drug Administration for marketing for the purposes which were the subject of the investigation;

(b) A period of 5 years following the date on which the results of the investigation are submitted to the Food and Drug Administration in support of or as part of an application for a research or marketing permit for the test article for the purposes that were the subject of the investigation; or

(c) In other situations (e.g., where the investigation does not result in the submission of the data from the investigation in support of an application for a research or marketing permit), a period of 2 years following the date on which the entire clinical investigation (not merely the investigator's portion of an investigation involving more than one investigator) is completed, terminated, or discontinued, or the exemption under which the investigation is being conducted is terminated or withdrawn by the Food and Drug Administration.

Subpart K—Disqualification of an Institutional Review Board

§ 56.200 Purpose.

The purposes of disqualification of an institutional review board that fails to comply with the standards set forth in this part (or other regulations regarding such boards in this chapter) may be one or both of the following:

(a) To preclude it from reviewing clinical investigations subject to requirements for prior submissin to the Food and Drug Administration under section 505(i), 507(d), or 520(g) of the Act until such time as it becomes likely that it will abide by such regulations of that such violations will not recur. This will assure that all such clinical investigations are under the review of a board that complies with appropriate Federal standards. The determination to disqualify an institutional review board does not necessarily constitute a finding or recommendation that the board or any of its members should be subject to other sanctions by the institution that created it or by sponsors of clinical investigations under its review.

(b) To preclude the consideration of any clinical investigations in support of applications for a research or marketing permit from the Food and Drug Administration, which investigations have been conducted under the review of the board until such time as the investigations are subject to review by an institutional review board that complies with the applicable standards, or that it can be adequately demonstrated that such violations did not occur during, or affect the validity or acceptability of, a particular investigation or investigations. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable statute or regulation to submit the results of the investigation to the Food and Drug Administration.

§ 56.202 Grounds for disqualification.

The Commissioner may disqualify an institutional review board upon finding all of the following:

(a) The institutional review board failed to comply with any of the regulations set forth in this part or other regulations regarding such boards in this chapter;

(b) The noncompliance adversely affected the validity of the clinical investigation or the rights or the safety of the subjects; and

(c) Other lesser regulatory actions (e.g., warnings or rejection of data from individual investigations) have not been or will probably not be adequate to assure that the board will comply with such regulations in the future.

§ 56.204 Notice of an opportunity for a hearing on proposed disqualification.

(a) Whenever the Commissioner has information indicating that grounds exist under § 56.202 which in the Commissioners's opinion may justify disqualification of an institutional review board, the Commissioner may issue to the board a written notice proposing that the board be disqualified.

(b) A hearing on the disqualification of an institutional review board shall be conducted in accordance with the requirements for a regulatory hearing set forth in part 16 of this chapter.

§ 56.206 Final order on disqualification.

(a) If the Commissioner, after the regulatory hearing or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, makes the finding required in § 56.202, the Commissioner shall issue a final order disqualifying the institutional review board. Such order shall include a statement of the basis for

that determination and shall prescribe any actions (set forth in § 56.210(b)) to be taken with regard to ongoing clinical investigations being conducted under the review of the board. Upon issuing a final order, the Commissioner shall notify (with a copy of the order) the board of the action, as well as the institution that established the board, the sponsor of each clinical investigation subject to requirements for prior submission to the Food and Drug Administration which was under the review of the board, and the investigators of such investigations who were under the review of the board.

(b) If the Commissioner, after a regulatory hearing or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, determines not to make the findings required in § 56.202, the Commissioner shall issue a final order terminating the disqualification proceeding. Such order shall include a statement of the basis for that determination. Upon issuing a final order, the Commissioner shall notify the board and provide a copy of the order.

§ 56.210 Actions on disqualification.

(a) No clinical investigation subject to requirements for prior submission to the Food and Drug Administration and to requirements for institutional review board review under § 56.2 will be authorized by the Commissioner if such investigation is to be conducted under the review of a disqualified board.

(b) The Commissioner, after considering the nature of each ongoing clinical investigation subject to requirements for prior submission to the Food and Drug Administration which is being conducted under the review of the board, the number of subjects involved, the risks to them from suspension of the investigation, and the need for involvement of an acceptable institutional review board, may direct, in the final order disqualifying a board under § 56.206(a), that one or more of the following actions be taken with regard to each such investigation:

(1) The investigation may be terminated or suspended in its entirety until the board is reinstated under § 56.219 or another board accepts responsibility for review of the investigation.

(2) No new subject shall be allowed to participate, or be requested to participate, in the investigation until the board is reinstated under § 56.219 or another board accepts responsibility for review of the investigation.

(3) Any subject who has previously been allowed to participate in the investigation and who remains under the supervision of an investigator, but who is no longer receiving the test article or having it used involving him or her (i.e., one having followup monitoring by the investigation or one acting as a control) should continue to be monitored by the investigator but shall not again receive the test article, or have it used involving him or her, until the board is reinstated under § 56.219 or another board accepts responsibility for review of the investigation.

(4) Any subject who has been allowed to participate in the investigation and who, but for suspension of the investigation, would continue to receive the test article or have it used involving him or her, shall not receive it or have it used until either:

(i) Another board accepts resonsibility for review of the investigation, or

(ii) The clinical investigator determines in writing that it is contrary to the health of the subject to defer further use of the test article until another board can assume responsibility for review of the investigation. In such a case, the Commissioner may impose any further conditions that the Commissioner deems appropriate to protect the rights and safety of the subject.

(c) Once an institutional review board has been disqualified, each application for a research or marketing permit, whether approved or not, containing or relying upon any clinical investigation conducted under the review of the board may be examined to determine whether the investigation was or would be essential to a regulatory decision regarding the application. If it is determined that the investigation was or would be essential, the Commissioner shall also determine whether the investigation is acceptable, notwithstanding the disqualification of the board. Any investigation reviewed by a board before or after its disqualification may be presumed to be unacceptable, and the person relying on the investigation may be required to establish that the investigation was not affected by the circumstances which led to disqualification of the board, e.g., by submitting validating information. If the investigation is determined to be unacceptable, such investigation shall be eliminated from consideration in support of the application, and such elimination may serve as new information justifying the termination or withdrawal of approval of the application.

(d) No clinical investigation begun under the review of an institutional review board after the date of its disqualification shall be considered in support of any application for a research or marketing permit, unless the board has been reinstated under § 56.219. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable statute or regulation to submit the results of the investigation to the Food and Drug Administration.

§ 56.213 Public disclosure of information regarding disqualification.

(a) Upon issuance of a final order disqualifying an institutional review board, the Commissioner may notify all or any interested persons. Such notice may be given in the discretion of the Commissioner whenever the Commissioner believes that such disclosure would further the public interest or would promote compliance with the regulations set forth in this part. Such notice, if given, shall include a copy of the final order issued under § 56.206(a) and shall state that the disqualification constitutes a determination by the Commissioner that the board is not eligible to review clinical investigations subject to requirements for prior submission to the Food and Drug Administration and that the results of any clinical investigations conducted under the review of the board may not be considered by the Food and Drug Administration in support of any application for a research or marketing permit. The notice shall further state that it is given because of the professional relations between the board and the person notified and that the Food and Drug Administration is not advising or recommending that any action be taken by the person notified.

(b) A determination that an institutional review board has been disqualified and the administrative record regarding such determination are disclosable to the public under part 20 of this chapter.

(c) Whenever the Commissioner has reason to believe that an institutional review board may be subject to disqualification, the Commissioner shall so notify other agencies in the Department of Health, Education, and Welfare that support research involving human subjects at the time of or after proposing disqualification of the board under § 56.204(a).

§ 56.215 Alternative or additional actions to disqualification.

Disqualification of an institutional review board under this subpart is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Commissioner may, at any time, through the Department of Justice institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at

the time of, or after, disqualification. The Commissioner may also refer pertinent matters to another Federal, State, or local government agency for such action as that agency determines to be appropriate.

§ 56.219 Reinstatement of a disqualified institutional review board.

(a) An institutional review board that has been disqualified may be reinstated as eligible to review clinical investigations subject to requirements for prior submission to the Food and Drug Administration, or as acceptable to be the reviewer of clinical investigations to be submitted to the food and Drug Administration, if the Commissioner determines, upon an evaluation of a written submission from the board, that the board can adequately assure that it will operate in compliance with the standards set forth in this part and other applicable regulations in this chapter, e.g., parts 312 or 812.

(b) A disqualified board that wishes to be so reinstated shall present in writing to the Commissioner reasons why it believes it should be reinstated and a detailed description of the corrective actions it has taken or intends to take to assure that the acts or omissions that led to disqualification will not recur. The Commissioner may condition reinstatement upon the board's being found in compliance with the applicable regulations upon an inspection.

(c) If a board is reinstated, the Commissioner shall so notify the board and all persons who were notified under § 56.213 of the disqualification of the board. A determination that a board has been reinstated is disclosable to the public under part 20 of this chapter.

PART 71—COLOR ADDITIVE PETITIONS

3. By amending part 71:

a. In § 71.1 by adding new paragraph (i) to read as follows:

§ 71.1 Petitions.

* * * * *

(i) If clinical investigations involving human subjects are involved, petitions filed with the Commissioner under section 706(b) of the act shall include statements regarding each such clinical investigation contained in the petition that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.22(c) of this chapter.

b. In § 71.6 by adding a new sentence at the end of paragraph (b) to read as follows:

§ 71.6 Extension of time for studying petitions; substantive amendments; withdrawal of petitions without prejudice.

* * * * *

(b) * * * If clinical investigations involving human subjects are involved, additional information or data submitted in support of filed petitions shall include statements regarding each such clinical investigation from which the information or data are derived, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.2(c) of this chapter.

* * * * *

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

PART 171—FOOD ADDITIVE PETITIONS

4. By amending part 171:

a. In § 171.1 by adding new paragraph (m) to read as follows:

§ 171.1 Petitions.

* * * * *

(m) If clinical investigations involving human subjects are involved, petitions filed with the Commissioner under section 409(b) of the act shall include statements regarding each such clinical investigation relied upon in the petition that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.2(c) of this chapter.

b. In § 171.6 by adding a new sentence at the end of the paragraph to read as follows:

§ 171.6 Amendment of petition.

* * * If clinical investigations involving human subjects are involved, additional information and data submitted in support of filed petitions shall include statements regarding each such clinical investigation from which the information or data are derived that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.2(c) of this chapter.

PART 180—FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS OR IN CONTACT WITH FOOD PENDING ADDITIONAL

Part 180 is amended in § 180.1 by adding a new paragraph (c)(6) to read as follows:

§ 180.1 General.

* * * * *

(c) * * *

(6) If clinical investigations involving human subjects are involved, such investigations filed with the Commissioner shall include, with respect to each investigation, either a statement that the investigation has been or will be conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter; or a statement that the investigation is not subject to such requirements in accordance with § 56.2(c) of this chapter.

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 310—NEW DRUGS

§ 310.3 [Amended]

5. Part 310 is amended in § 310.3 *Definitions and interpretations,* by deleting and reserving paragraph (j).

PART 312—NEW DRUGS FOR INVESTIGATIONAL USE

6. Part 312 is amended in § 312.1 by redesignating paragraph (d)(11) as (d)(12) and adding a new paragraph (d)(11).

§ 312.1 Conditions for exemption of new drugs for investigational use.

* * * * *

(d) * * *

(11) The clinical investigations are not being conducted in compliance with the requirements regarding institutional review set forth in this part or part 56 of this chapter; or

* * * * *

PART 314—NEW DRUG APPLICATIONS

7. Part 314 is amended:

a. In § 314.1 by adding a new item 16 to form FD-356H in paragraph (c)(2) and by redesignating paragraph (f)(7) as (f)(8) and adding a new paragraph (f)(7) to read as follows:

§ 314.1 Applications.

* * * * *

(c) * * *

(2) * * *

Form FD-356H—Rev. 1974:

* * * * *

16. *Conduct of clinical investigations.* Statements regarding each clinical investigation involving human subjects contained in the application that it either was conducted in compliance with the requirements for institutional review set forth in Part 56

of this chapter or was not subject to such requirements in accordance with § 56.2(c) of this chapter.

* * * * *

(f) * * *

(7) Statements regarding each clinical investigation involving human subjects contained in the application that it either was conducted in compliance with the requirements the institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.2(c) of this chapter.

* * * * *

b. In § 314.8 by adding a new paragraph (n) to read as follows:

§ 314.8 Supplemental applications.

* * * * *

(n) A supplemental application that contains clinical investigations involving human subjects shall include statements by the applicant regarding each such investigation that it either was conducted in compliance with the requirements for institutional review set forth in Part 56 of this chapter or was not subject to such requirements in accordance with § 56.2(c) of this chapter.

c. In § 314.9 by adding new paragraph (e) to read as follows:

§ 314.9 Insufficient information in application.

* * * * *

(e) The information contained in an application shall be considered insufficient to determine whether a drug is safe and effective for use unless the application includes statements regarding each clinical investigation involvings human subjects contained in the application that it either was conducted in compliance with the requirements for institutional review set forth in Part 56 of this chapter or was not subject to such requirements in accordance with § 56.2(c) of this chapter.

d. In § 314.12 by adding new paragraph (e) to read as follows:

§ 314.12 Untrue statements in application.

* * * * *

(e) Any clinical investigation involving human subjects contained in the application subject to the requirements for institutional review set forth in part 56 of this chapter was not conducted in compliance with such requirements.

e. In § 314.110 by adding new paragraph (a)(11) to read as follows:

§ 314.110 Reasons for refusing to file applications.

(a) * * *

(11) The applicant fails to include in the application statements regarding each clinical investigation involving human subjects contained in the application that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.2(c) of this chapter.

* * * * *

f. In § 314.111 by adding paragraph (a)(11) to read as follows:

§ 314.111 Refusal to approve the application.

(a) * * *

(11) Any clinical investigation involving human subjects contained in the application subject to the requirements for institutional review set forth in Part 56 of this chapter was not conducted in compliance with such requirements.

* * * * *

g. In § 314.115 by adding new paragraph (c)(7) to read as follows:

§ 314.115 Withdrawal of approval of an application.

* * * * *

(c) * * *

(7) That any clinical investigation involving human subjects contained in the application subject to the requirements for institutional review set forth in Part 56 of this chapter was not conducted in compliance with such requirements.

* * * * *

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

8. Part 320 is amended:

a. In § 320.31 by adding a new paragraph (f) to read as follows:

§ 320.31 Applicability of requirements regarding a "Notice of Claimed Investigational Exemption for a New Drug."

* * * * *

(f) An in vivo bioavailability study in humans shall be conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, regardless of whether the study is conducted under a "Notice of Claimed Investigational Exemption for a New Drug."

b. in § 320.57 by adding a new paragraph (e) to read as follows:

§ 320.57 Requirements of the conduct of in vivo bioequivalence testing in humans.

* * * * *

(e) If a bioequivalence requirement provides for in vivo testing in humans, any person conducting such testing shall comply with the requirements of § 320.31.

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

9. Part 330 is amended in § 330.10 by adding new paragraph (e) to read as follows:

§ 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

* * * * *

(e) *Institutional review.* Information and data submitted under this section after (insert effective date of this paragraph) shall include statements regarding each clinical investigation involving human subjects, from which the information and data are derived, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.2(c) of this chapter.

PART 361—PRESCRIPTION DRUGS FOR HUMAN USE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED: DRUGS USED IN RESEARCH

10. Part 361 is amended in § 361.1 by revising paragraph (d)(9) to read as follows:

§ 361.1 Radioactive drugs for certain research uses.

* * * * *

(d) * * *

(9) *Approval by an institutional review board.* The investigator shall obtain the review and approval of an institutional review board that conforms to the requirements of part 56 of this chapter.

* * * * *

PART 430—ANTIBIOTIC DRUGS; GENERAL

11. Part 430 is amended in § 430.20 by adding new paragraph (g) to read as follows:

§ 430.20 Procedure for the issuance, amendment, or repeal of regulations.

* * * * *

(g) No regulation providing for the certification of an antibiotic drug for human use shall be issued or amended unless each clinical investigation involving human subjects on which the issuance or amendment or the regulation is based was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.2(c) of this chapter.

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

12. Part 431 is amended in § 431.17 by adding a new paragraph (l) to read as follows:

§ 431.17 New antibiotic and antibiotic-containing products.

* * * * *

(l) Statements regarding each clinical investigation involving human subjects contained in the request that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.2(c) of this chapter.

SUBCHAPTER F—BIOLOGICS

PART 601—LICENSING

13. Part 601 is amended:

a. In § 601.2 by revising paragraph (a) to read as follows:

§ 601.2 Applications for establishment and product licenses; procedures for filing.

(a) *General.* To obtain a license for any establishment or product, the manufacturer shall make application to the Director, Bureau of Biologics, on forms prescribed for such purpose, and in the case of an application for a product license, shall submit data derived from laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity, and potency; statements regarding each clinical investigation involving human subjects contained in the application that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.2(c) of this chapter, a full description of manufacturing methods; data establishing stability of the product through the dating period; sample(s) representative of the product to be sold, bartered, or exchanged or offered, sent, carried or brought for sale, barter or exchange; summaries of results of tests performed on the lot(s) represented by the submitted sample(s); and specimens of the label, enclosures and containers proposed to be used for the product. An application for license shall not be considered as filed until all pertinent information and data are received from the manufacturer by the Bureau of Biologics. The applicant shall also include an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the biological product pursuant to § 25.1 of this chapter. In lieu of the procedures described in this paragraph, applications for radioactive biological products shall be handled as set forth in paragraph (b) of this section.

* * * * *

b. In § 601.25 by revising paragraph (h)(1) and adding a new paragraph (l) to read as follows:

§ 601.25 Review procedures to determine that licensed biological products are safe, effective, and not misbranded under prescribed, recommended, or suggested conditions of use.

* * * * *

(h) *Additional studies.* (1) Within 30 days following publication of the final order, each licensee for a biological product designated as requiring further study to justify continued marketing on an interim basis, pursuant to paragraph (f)(3) of this section, shall satisfy the Commissioner of Food and Drugs in writing that studies adequate and appropriate to resolve the questions raised about the product have been undertaken, or the Federal Government may undertake these studies. Any study involving a clinical investigation that involves human subjects shall be conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, unless it is not subject to such requirements in accordance with § 56.2(c) of this chapter. The Commissioner may extend this 30-day period if necessary, either to review and act on proposed protocols or upon indication from the licensee that the studies will commence at a specified reasonable time. If no such commitment is made, or adequate and appropriate studies are not undertaken, the product licenses shall be revoked.

* * * * *

(l) *Institutional review.* Information and data submitted under this section after (insert effective date of this paragraph) shall include statements regarding each clinical investigation involving human subjects that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.2(c) of this chapter.

* * * * *

c. By revising § 601.30 to read as follows:

§ 601.30 Licenses required; products for controlled investigation only.

Any biological or trivalent organic arsenical manufactured in any foreign country and intended for sale, barter, or exchange shall be refused entry by collectors of customs unless manufactured in an establishment holding an unsupended and unrevoked establishment and product license. Unlicensed products which are not imported for sale, barter, or exchange and which are intended solely for purposes of controlled investigation involving human subjects are admissible only if the investigation is conducted in accordance with section 505 of the Federal Food, Drug, and Cosmetic Act, as amended, and, if subject to them, in compliance with the requirements for institutional review set forth in part 56 of this chapter.

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

14. Part 630 is amended:

By revising the first sentence of § 630.11 to read as follows:

§ 630.11 Clinical trials to qualify for license.

To qualify for license, the antigenicity of the vaccine shall have been determined by clinical trials of adequate statistical design conducted in compliance with part 56 of this chapter, unless exempted under § 56.2. * * *

b. By revising the first sentence of § 630.31 to read as follows:

§ 630.31 Clinical trials to qualify for license.

To qualify for license, the antigenicity of the vaccine shall have been determined by clinical trials of adequate statistical design conducted in compliance with part 56 of this chapter, unless exempted under § 56.2 of this chapter, by subcutaneous administration of the product. * * *

c. By revising § 630.51 to read as follows:

§ 630.51 Clinical trials to qualify for license.

To qualify for license, the antigenicity of Mumps Virus Vaccine, Live,

shall be determined by clinical trials conducted in compliance with part 56 of this chapter, unless § 56.2 of this chapter, that follow the procedures prescribed in exempted under § 630.31 except that the immunogenic effect shall be demonstrated by establishing that a protective antibody response has occurred in at least 90 percent of each of the five groups of mumps-susceptible individuals, each having received the parenteral administration of a virus vaccine dose which is not greater than that which was demonstrated to be safe in field studies (§ 630.50(b)) when used under comparable conditions.

d. By revising § 630.61 to read as follows:

§ 630.61 Clinical trials to qualify for license.

To qualify for license, the antigenicity of Rubella Virus Vaccine, Live, shall be determined by clinical trials conducted in compliance with part 56 of this chapter, unless exempted under § 56.2 of this chapter, that follow the procedures prescribed in § 630.31 except that the immunogenic effect shall be demonstrated by establishing that a protective antibody response has occurred in at least 90 percent of each of the five groups of rubella susceptible individuals, each having received the parenteral administration of a virus vaccine dose which is not greater than that which was demonstrated to be safe in field studies when used under comparable conditions.

e. By revising the first sentence of § 630.81 to read as follows:

§ 630.81 Clinical trials to qualify for license.

In addition to demonstrating that the measles component meets the requirements of § 630.31, the measles and smallpox antigenicity of the final product shall be determined by clinical trials of adequate statistical design conducted in compliance with part 56 of this chapter, unless exempted under § 56.2 of this chapter, and with three consecutive lots of final vaccine manufactured by the same methods and administered as recommended by the manufacturer. * * *

PART 1003—NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

15. In § 1003.31 by revising paragraph (b) to read as follows:

§ 1003.31 Granting the exemption.

(b) Such views and evidence shall be confined to matters relevant to whether the defect in the product or its failure to comply with an applicable Federal standard is such as to create a significant risk of injury, including genetic injury, to any person and shall be presented in writing unless the Secretary determines that an oral presentation is desirable. Where such evidence includes clinical investigations involving human subjects, the data submitted shall include, with respect to each clinical investigation, either a statement that each investigation was conducted in compliance with the requirements set forth in part 56 of this chapter; or a statement that the investigation is not subject to such requirements in accordance with § 56.2(c) of this chapter.

SUBCHAPTER I—RADIOLOGICAL HEALTH

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

16. Part 1010 is amended:

a. By amending § 1010.4 by adding paragraph (b)(1)(xi) to read as follows:

1010.4 Variances.

* * * * *

(b) * * *

(1) * * *

(xi) If the electronic product is used in a clinical investigation involving human subjects and subject to the requirements for institutional review set forth in part 56 of this chapter, the investigation shall be conducted in compliance with such requirements.

* * * * *

b. In § 1010.5 by revising paragraph (c)(12) to read as follows:

§ 1010.5 Exemptions for products intended for United States Government use.

* * * * *

(c) * * *

(12) Such other information required by regulation or by the Director, Bureau of Radiological Health, to evaluate and act on the application. Where such information includes clinical investigations involving human subjects, the information shall include, with respect to each clinical investigation, either a statement that each investigation was conducted in compliance with the requirements set forth in part 56 of this chapter; or a statement that the investigation is not subject to such requirements in accordance with § 56.2(c) of this chapter.

* * * * *

Interested persons may, on or before December 6, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in the heading of this document. Recevied comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

NOTE.—The Food and Drug Administration has determined that this document does not contain a major proposal requiring preparation of an economic impact statement under Executive Order 11821 (as amended by Executive Order 11949) and OMB Circular A-107. A copy of the economic impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Dated: August 1, 1978.

DONALD KENNEDY,
Commissioner of Food and Drugs.

[FR Doc. 78-21789 Filed 8-7-78; 8:45 am]

federal register

TUESDAY, AUGUST 8, 1978
PART V



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

OBLIGATIONS OF CLINICAL INVESTIGATORS OF REGULATED ARTICLES

Proposed Establishment of Regulations

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 16, 54, 71, 170, 171, 180, 310, 312, 314, 320, 330, 361, 430, 431, 510, 511, 514, 570, 571, 601, 630, 1003, and 1010]

[Docket No. 77N-0278]

OBLIGATIONS OF CLINICAL INVESTIGATORS OF REGULATED ARTICLES

Proposed Establishment of Regulations

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This proposal would clarify existing regulations concerning persons who conduct clinical investigations on new drug products and would extend these regulations to include persons who conduct clinical investigations on other products regulated by the Food and Drug Administration (FDA). This proposal is based upon findings in inspections of clinical investigators that existing requirements are not being fully followed and may be subject to varying interpretations, upon recommendations of the General Accounting Office (GAO) regarding FDA regulation of new drug testing, and upon an evaluation of the need for such regulations to implement both the Medical Device Amendments of 1976 (Pub. L. 94-295) and the agency's bioresearch monitoring program for assuring the validity of scientific data from human and animal studies.

DATE: Written comments by November 6, 1978.

ADDRESS: 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:

Marilyn L. Watson, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301 443-6490.

SUPPLEMENTARY INFORMATION: The proposed regulations are intended to assure adequate protection of the rights and safety of subjects involved in clinical investigations and the quality and integrity of the resulting data submitted to FDA in support of applications for permission to conduct further research or to market regulated products, while providing sufficient flexibility and latitude for innovative clinical research in the interest of the public health.

Circumstances Creating a Need for This Proposal

The Commissioner of Food and Drugs believes that a complete revision of the regulations governing the conduct of clinical investigators is needed because (1) current regulations have not been comprehensively reviewed in 15 years, (2) FDA inspections have disclosed numerous deviations from current standards by investigators, (3) these discrepancies may be related, at least in part, to misunderstandings over the precise meaning of FDA requirements as currently written, (4) the General Accounting Office has recommended changes in current FDA regulations, (5) the Medical Device Amendments of 1976 mandate the FDA to develop standards for clinical investigators of devices for human use, and (6) the new FDA bioresearch monitoring program, designed to assure the validity and reliability of clinical and nonclinical data submitted to the agency, can be more efficiently and effectively conducted with uniform, agencywide regulatory standards. Each of these matters is discussed in further detail in this preamble.

For several years FDA has been planning to revise substantially the regulations governing drug research which implement sections 505(i), 507(d), and 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i), 357(d), and 360b(j)). Many of the current regulations were first issued in 1963 under the Drug Admendments of 1962, which substantially expanded FDA's responsibilities in supervising drug experimentation. Other regulations were subsequently added; and the regulations are now codified in § 310.102, part 312, and part 511 (21 CFR 310.102, Part 312, and Part 511). Until now, however, there has been no comprehensive review and updating of these regulations.

The revision of regulations regarding the obligations and standards of performance expected of clinical investigators is an important part of this review. Current statements of agency policy directly applicable to investigators are found primarily in forms FD-1572 and FD-1573 (set forth in § 312.1(a) (12) and (13) (21 CFR 312.1(a) (12) and (13))), which are the documents signed by an investigator and submitted to the sponsor of research on a new drug for human use subject to a "Notice of Claimed Investigational Exemption for a new Drug" (IND; see form 1571 set forth in § 312.1(a)(2)). Many portions of the forms describe obligations in general terms such as "adequate" and refer to other requirements in terms commonly understood but subject to misinterpretation in specific cases, e.g., whether a subject is "institutionalized" and whether a "case history" includes medical records regaring the subject's condition before entry into the study. Agency policy regarding consent for use of investigational new drugs on humans is set forth in § 310.102, although significant discrepancies exist between the regulation and the statements in forms FD-1572 and FD-1573.

The Commissioner is of the opinion that the way these requirements are stated may have contributed to misunderstandings concerning the conduct FDA expects of a clinical investigator—misunderstandings manifested by FDA findings of noncompliance or inadequate performance by a number of clinical investigators. In 1972, the Bureau of Drugs undertook a special survey of IND studies involving 15 sponsors (i.e., persons filing IND's) and 155 investigators (i.e., persons working under those IND's by filing forms FD-1572 or FD-1573 with the sponsors). The results of this survey showed varying degrees of deficiencies by 115 investigators in 1 or more of the following 6 areas: obtaining or documenting informed consent properly, maintaining records of the disposition of the investigational drug, adhering to the research protocol, maintianing accurate case records on subjects, making all records available to FDA inspectors, and understanding the role of the investigator in the research program. After the survey, the Bureau of Drugs conducted 2 further surveys, the first to study 34 persons who were both sponors and investigators (i.e., physicians who both initiate and actually conduct research upon filing an IND with FDA) and the second to study 8 persons who were conducting research under IND's sponsored either by the Department of the Army of the Department of Defense (DOD) or by the National Institutes of Health (NIH). In the sponsor-investigator survey, deficiencies were found in the conduct of every IND; and in the DOD-NIH study, problems similar to thoe found in nongovernment research were frequently encountered. The Bureau of Biologics also undertook a survey of 48 clinical investigators (including 23 sponsor-investigators) who were conducting research with biologics. Again, numerous deficiencies were discovered. Copies of these surveys have been placed on file in the office of the Hearing Clerk (HFA-305), Food and Drug Adminitration, Room 4-65, 5600 Fisher Lane, Rockville, Md. 20857.

Both bureaus concluded that most of the shortcomings constituted violations that did not present any significant hazard to the subjects or compromise the integrity of the specific studies. On the other hand, there was serious concern about certain deficiencies, such as the failure to keep an institu-

tional review committee informed of progress in the study, refusal to permit FDA inspectors to examine records containing a subject's name or prior medical history, inadequate documentation of subject consent, and use of exculpatory statements in consent forms. Although these actions and omissions are not acceptable behavior for clinical investigators, the Commissioner emphasizes that the surveys do not support a conclusion that human subjects are routinely being exposed to unnecessary or avoidable risks in the course of research on new drugs and bioligics, or that decisions to approve marketing of new drugs are being made upon data that are inaccurate or unreliable or accepted without analysis or means of verification.

Nevertheless, these surveys do indicate that a serious problem of communication exits between FDA and at least some clinical investigators. The Commissioner believes that FDA's policies regarding the conduct of clinical investigators should be viewed as objectives that are compatible with, and indeed largely based upon, the ethical codes of medicine and research and accepted standards of good science. The first step to compliance with these policies is to restate them with precision and reaffirm the goals being sought.

Another reason for the Commissioner's proposing to revise the regulations governing clinical investigators is the findings of the GAO in a report entitled "Federal Control of New Drug Testing is Not Adequately Protecting Human Test Subjects and the Public," dated July 15, 1976. A copy of this report has also been placed on display in the office of the Hearing Clerk. The GAO reviewed the data generated in the Bureau of Drugs' and Bureau of Biologics' surveys discussed above and interviewed a number of FDA employees. Although FDA does not agree with a number of the GAO analyses and conclusions, the Commissioner understands the reasons for certain GAO recommendations to improve FDA regulations; this proposal is a step to implement those recommendations.

The Commissioner has been directed by Congress to establish regulations to implement section 520(g) of the act (21 U.S.C. 360j(g)), which was added by the Medical Device Amendments of 1976 and pertains to investigational use of medical devices for human use and diagnostic products. In a notice published in the FEDERAL REGISTER of August 20, 1976 (41 FR 35282), FDA proposed such regulations; proposed Subpart E of Part 812 concerned the responsibilities of clinical investigators studying the safety or effectiveness of devices with human subjects. Comments filed on that proposal have been reviewed and utilized in preparing this proposal. In the FEDERAL REGISTER of May 12, 1978 (43 FR 20726), the Commissioner issued portions of the August 20 proposal as a tentative final regulation. Those requirements proposed in subpart E on August 20 that duplicate or overlap substantially with the requirements proposed below in this notice have been deleted from the tentative final regulation. The Commissioner intends to review comments on this notice promptly and to promulgate as final at least those regulations based on this proposal that are essential to promulgation of comprehensive final regulations governing the investigational use of medical devices for human use.

Finally, FDA has recently reassessed its responsibilities, needs, and priorities in the entire area of biomedical research, including safety testing of substances in animals, monitoring of clinical investigators by sponsors, the role of institutional review boards, and the obligations of clinical investigators. The agency, the Congress, and others have recently become concerned about the validity and reliability of scientific data on the safety and effectiveness of products regulated by FDA. Much of the history of this review, with special emphasis on the quality and integrity of safety data derived from nonclinical laboratory studies, is discussed in the preamble to the proposal on good laboratory practices published in the FEDERAL REGISTER of November 19, 1976 (41 FR 51206). Congressional and Presidental action in the summer of 1976 appropriated to FDA $16.3 million and authorized over 600 new positions to carry out expanded activities in the area of bioresearch monitoring.

Pursuant to this legislative action, the Commissioner has established a "Bioresearch Monitoring Program" to develop and implement an agencywide program for all aspects of preclinical testing and clinical research relating to FDA-regulated products. The program is managed by an intraagency steering committee, with specific elements being assigned to several task forces, including a Clinical Investigator/Sponsor Task Force. This task force has the responsibility for developing an agency strategy to define the responsibilities of sponsors and clinical investigators in studies regulated FDA or involving products regulated by FDA, and to insure that these duties are adequately and reliably performed. To meet these goals, the task force proposed the following:

1. Promulgation of agencywide regulations—based upon existing FDA regulations for investigational new drug studies, proposed regulations for investigational use of medical devices for human use and comments received on them, and FDA experience—that would set forth the responsibilities of sponsors, monitors, and investigators in clinical investigations and procedures for enforcing these requirements.

2. Establishment of an agencywide compliance program that would include enforcement policies, regular inspections of sponsors, monitors, and clinical investigators, and special inspection is initiated by FDA to audit particular studies.

3. Development of appropriate organizational structures or mechanisms and data systems to be used for planning and scheduling inspections under the compliance program and for reviewing and evaluating the results of individual inspections as well as the overall program.

UNIFORM FDA STANDARDS FOR ALL CLINICAL INVESTIGATIONS

The Commissioner proposes to make a single set of standards applicable to all clinical investigators involved in investigational studies that either require prior FDA review or are subsequently submitted to FDA in support of an application for a research or marketing permit. These regulations, if adopted, may not eliminate the need for additional requirements relevant to a particular article under study, but will reduce the potential for duplicative and inconsistent regulations or interpretations of policy. The Commissioner recognizes that one clinical investigator may, at any one time, be conducting studies on products that are regulated by several of the separate bureaus of FDA, e.g., Drugs, Biologics, and Medical Devices. A uniform standard will thus ease the burdens on these investigators in complying with the applicable regulations.

To achieve this objective, the Commissioner proposes a new Part 54 in Chapter I of Title 21 of the Code of Federal Regulations to be entitled "Clinical Investigators." The proposed new part, under Subchapter A (General) of the regulations, will be applicable to all regulated products. This proposal extends current FDA standards to all clinical investigations regulated by or submitted to the agency, lists definitions applicable to the part, presents the obligations and commitments of clinical investigators, clarifies many of the existing requirements, and improves the procedures for imposing administrative sanctions on investigators who violate these regulations. Additionally, this proposal contains specific amendments needed for conformance in other existing FDA regulations.

In order to assure uniform standards, any clinical investigation would be within the scope of this part, whether the investigation required the

prior review of any FDA bureau (i.e., Drugs, Biologics, Medical Devices and Diagnostic Products, or Veterinary Medicine) or whether the investigation did not receive prior FDA review but was subsequently submitted (or held for FDA inspection) in support of an application, to one of those four bureaus or to the Bureau of Foods or Radiological Health (proposed § 54.1 (21 CFR 54.1)).

EXEMPTIONS

The Commissioner is proposing to permit exemptions from all or part of the requirements set forth in part 54 (21 CFR Part 54) in appropriate cases. These regulations have been drafted to make them applicable to all clinical investigations regulated by or submitted to FDA, and the Commissioner maintains that the principles are reasonably applicable to all such investigations. However, FDA has not been able to review every type of clinical investigation to guarantee that these standards are totally appropriate to each particular study. Therefore, the Commissioner invites comments to identify any unique category of clinical investigation that should be exempted from any specific requirements of this proposal and to provide an adequate rationale to demonstrate why such requirements are not necessary to protect the rights and safety of subjects or to help assure the quality and integrity of the data produced. In addition, the Commissioner proposes § 54.2 (21 CFR 54.2) under which individual investigators or their sponsors may request FDA for a waiver of any particular requirements for purposes of a specific study or group of studies. In emergency situations, such a request may be granted by telephone; otherwise, such requests shall be in writing as part of the application for a research permit.

DEFINITIONS

Proposed § 54.3 (21 CFR 54.3) contains definitions for all of the special terms used in the part. Many technical terms can be variably or inaccurately interpreted by persons affected by the proposed regulations; these terms are defined to provide a common basis of understanding for the agency, clinical investigators, the regulated manufacturers and other sponsors of clinical studies, and the general public. In addition, other definitions have been proposed for more precisely describing the extent and applicability of the proposed regulations.

In proposed § 54.3(a), the term "act" is limited to the Federal Food, Drug, and Cosmetic Act, as amended. This is consistent with definitions appearing elsewhere in FDA regulations. Other statutes when used will be mentioned by name, e.g., the Public Health Service Act.

A new definition required by the decision to make these proposed regulations agency-wide in scope is the term "application for research or marketing permit" in § 54.3(b). This definition includes all of the various requirements for submission of scientific data and information to the agency under its regulatory jurisdiction, even though in certain cases, no permission is technically required from FDA for the conduct of a proposed activity with a particular product, i.e., carrying out research or continuing to market a product. The term is intended solely as a shorthand way of referring to at least 25 separate categories of data and information that are now, or will in the near future become, subject to requirements for submission ot the agency.

To facilitate further the applicability of a single set of regulations to all studies involving products or articles coming within the agency's purview, proposed § 54.3(c) would describe each such study as a "clinical investigation," defined to mean any experiment involving a test article (defined below), which experiment either (1) is subject to requirements under sections 505(i), 507(d), 512(j) or 520(g) of the act for prior submission to the FDA for review and in some cases approval before it can be commenced, or (2) is not subject to prior submission to FDA under an IND, or "Notice of Claimed Investigational Exemption for a New Animal Drug" (INAD), or an "Investigational Device Exemption" (IDE), but the results of which are intended to be submitted later to (or held for inspection by) FDA as part of an application for a research or marketing permit. The term thus includes, for example, human investigations performed as part of the evaluation of a test article and animal investigations conducted to determine the clinical or therapeutic effect of a drug in treating a disease in animals. There is another category of clinical research that is not included in the definition of "clinical investigation" because such studies are not regulated by or intended to be submitted to FDA; these would include studies that do not use any test articles, or do not use them in a manner requiring prior FDA approval or subsequent FDA review. The definition also excludes nonclinical studies in animals which fall within the scope of the regulations proposed under part 3e to establish good laboratory practices for nonclinical laboratory studies published in the FEDERAL REGISTER of November 19, 1976.

Other proposed definitions include terms to describe the persons who initiate and carry out clinical investigations: "sponsor," "investigator," and "sponsor-investigator." The word "sponsor" is currently defined in §§ 310.3(j) and 510.3(k) (21 CFR 310.3(j) and 510.3(k)), but the Commissioner believes this definition is unsatisfactory because it fails to distinguish the other commonly used word "investigator," which is not defined. Although these terms are widely understood, their precise meanings are difficult to express. The key distinctions seem to lie between one who initiates the project (the sponsor) and one who actually conducts the study (the investigator). These distinctions have been incorporated in the definitions proposed in § 54.3 (d) and (f), together with a further distinction: investigators must be individuals, while sponsors can be individuals, corporations, institutions, or other legal entities. (The term "person" is defined in paragraph (e) to include in individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit thereof, and any other legal entity.) The Commissioner believes that these distinctions will clarify the participants' respective roles and duties.

Many studies (approximately 45 percent of IND's in the Bureau of Drugs, for example) are initiated and actually conducted by the same individual; this investigator may carry out the study by himself or herself or with other investigators responsible to him or her. The Commissioner considers it important to identify the hybrid role of the "sponsor-investigator" and, where appropriate, to allow special provisions for that role. Thus, this term is defined in proposed § 54.3(g). Unlike the term "sponsor," the term "sponsor-investigator" is limited to individuals.

The term "subject" is defined in proposed § 54.3(h) to mean any individual who is or becomes a participant in a clinical investigation, either as the recipient of the test article or as a control. The term also includes both healthy volunteers and patients, and both human beings and animals. The text of the regulation indicates when only human beings are intended as subjects. The definition of "subject" provides that, in the case of nonhuman subjects, the term may apply to either an individual or a group, depending on whether an individual or group response is being measured.

In § 54.3(i) the Commissioner proposes to define the term "test article" to describe those items being studied that are under FDA jurisdiction and these regulations. The term includes new drugs, biologics for human use, new animal drugs, and medical devices for human use, studies of which require prior review by FDA under an IND, INAD, or IDE. In addition, the term covers any other article that is subject to FDA jurisdiction; this in-

cludes food additives, color additives, cosmetics, drugs for human and animal use, biological products for human use, electronic products, and medical devices for human use. The broad definition of "test article" is intended to include substances, studies of which are submitted to FDA in support of an application for permission to market a product, but which studies need not be conducted under an IND, INAD or IDE, e.g., studies on food additives, certain drug bioavailability studies described in § 320.31 (21 CFR 320.31), and studies on medical devices for human use not subject to part 812 (21 CFR Part 812).

Test Articles

The thalidomide disaster of the early 1960's highlighted the need for strict controls over the distribution of investigational drugs. After the NDA for thalidomide was withdrawn by the manufacturer from consideration in March 1962, FDA learned that, instead of the 40 to 50 doctors believe to be involved in research on the drug, about 1,250 physician had received over 2.5 million tablets and had in turn provided the drug to almost 20,000 patients. The looseness of control over the supply of thalidomide greatly hindered effective protection of research subjects after, as well as before, the risk of phocomelia (birth deformities of the extremities) was discovered. Repetition of this problem can be prevented if test articles are distributed only to qualified and responible investigators who are kept informed of all new developments and who control the availability of the articles.

Thus, sections 505(i)(2) and 507(d)(2) of the act seek to assure that subjects to whom an investigational drug is administered are under the personal supervision of a designated investigator or under the supervision of investigators responible to him or her, and bar an investigator from supplying an investigational drug to any investigator not responsible to him or her, or to clinics, for administration to human beings (item 6.f. of form FD-1572 and item 4.f. of form FD-1573). In the FDA surveys compliance with this requirement was found to be erratic, in that a drug was provided in some instances to a physician who was not listed as an investigator in the IND. The Commissioner now proposes to restate this requirement in § 54.102 (21 CFR 54.102).

Invstigators must also maintain adequate and accurate records of all receipts and uses of test articles (item 6.b. of form FD-1572 and item 4.b. of form FD-1573). These records serve as a check to prevent unauthorized distribution, either to subjects or to other persons who might use the article in humans or animals, and to verify the case histories, to detect possible lot-to-lot variations in the article, and, if recovery of the unused stocks of the article is necessary to minimize health risks to subjects, to provide the most readily usable mechanism to identify which subjects have recently received the article and the quantities they are likely still to have. In FDA surveys of investigatores, deficiencies in drug accountability were found in approximately one-half of the studies; such noncompliance, even though it may indicate only a misunderstanding as to the form and method of recordkeeping, is not acceptable. The Commissioner is proposing to codify this requirement in § 54.108 (21 CFR 54.108). Under the proposed regulation, dispensing records for individual subjects would not by themselves be satisfactory to fulfill this requirement; a separate record indicating each dispensing of the test article, the name of the subject receiving it, and the date would provide an essential cross-index to the dispensing records and a method of accountability for each batch and for any period of time.

The ability to remove a test article from subjects and investigators is essential in the event that its continued availability poses serious risks to the public health, as the thalidomide episode illustrated. Since 1963, investigators have committed themselves to return to the sponsor any unused supply of an investigational drug if the study is terminated, supended, discontinued or completed (item 6.b. of form FD-1572 and item 4.b. of form FD-1573). The Commissioner porposes in § 54.114 (21 CFR 54.114) to restate this obligation; he is, however, broadening the current requirement in three ways: First, he is allowing for alternative disposition of test articles where the sponsor so authorizes in writing; this might permit either onsite destruction, rendering a device inoperable (as suggested by comments on a similar provision in the proposed IDE regulations published in the Federal Register of August 20, 1976), or use in other experiments that are being conducted on the article, or other reasonable actions to prevent further exposure of humans to experimental risks while otherwise benefiting science and the public. Second, the Commissioner proposes that return of the article be authorized whenever the sponsor deems it proper, even though the study itself is not completed, terminated, or discontinued; this could allow for substitution of one batch of the drug for another, return of a particular formulation, or withdrawal from certain investigators only, e.g., in the case of a cutback in the scope of the study from phase 2 to phase 1. Third, the Commissioner proposes to apply the requirement to all test articles, not merely investigational drugs; the inclusion of investigational devices is indicated by reference to "reusable" test articles.

The Commissioner is also proposing to codify requirements for storage of test articles that are controlled under any schedule of the Controlled Substances Act (21 U.S.C. 801 note). Section 303(f) of that act (21 U.S.C. 823(f)) provides that the Secretary of Health, Education, and Welfare shall consult with the Attorney General "as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use." As a result of this consultation, FDA issued regulations in 1971 providing for storage of any controlled investigational drug in a securely locked, substantially constructed cabinet or enclosure (item 6.b. of the Form FD-1572 and item 4.b. of the Form FD-1573). These regulations were based upon similar Department of Justice regulations under 21 CFR 1301.75(a). In proposing § 54.116 (21 CFR 54.116), the Commissioner is including this requirement in the FDA regulations for clinical investigators and extending it to all test articles that are controlled substances.

In § 54.118 (21 CFR 54.118), the Commissioner proposes to prohibit clinical investigators from promoting an unmarketed test article as safe and effective for the purposes for which it is under study. Such a requirement is currently applicable only to sponsors of investigational drug studies (see § 312.1(a) (10) and (11)). Recently, FDA has encountered isolated cases where an investigator has used his or her unique access to an investigational drug as an opportunity to monopolize treatment of patients in the investigator's area—promoting the drug through professional contacts and even the lay media and using the drug more as a means of enhancing his or her clinical practice than of conducting a research-oriented investigation. This regulation would expressly allow dissemination of scientific findings, and would not apply to test articles that are lawfully marketed at the time of the investigation, e.g., marketed drugs undergoing bioavailability or bioequivalency testing or marketed devices for human use being tested to comply with the Medical Device Amendments of 1976.

Protocol for and Conduct of a Clinical Investigation

The agency views a protocol defining the research objectives and outlining how they are to be attained as a critical prerequisite to a clinical investigation, but the agency also recognizes that research on living animals and humans requires flexibility. On the one hand, modifications of an investi-

gational plan may be necessary to take into account new information indicating avoidable safety risks; on the other hand, a hypothesis may be confirmed earlier than anticipated, e.g., overwhelming evidence of effectiveness or lack of effectiveness may be seen in initial trials. Therefore, FDA has permitted modification of a protocol without prior approval of the sponsor based on information gained during the study (e.g., item 5 of the form FD-1572).

However, FDA has found that significant changes that undermine the validity of a study or expose subjects to different risks of inappropriately affect their rights have sometimes been made in a protocol without notice to or approval of a sponsor. The agency is committed to encouraging research and to providing wide latitude to clinical investigators. The Commissioner believes, however, that the sponsor and, where required, the institutional review board must be consulted in the event that certain types of changes are considered. Of course, if the change is made to eliminate or reduce the risk to human subjects in the study, immediate action is always justified. Changes that may increase the risk to human subjects in the study or may adversely affect either the validity of the study or the rights of the subjects must be reviewed and approved in advance by the sponsor and, if approved, included in the protocol by way of amendment. The sponsor, in turn, is to file these changes with the IND itself (form FD-1571, item 10.a. and b.). Under § 54.25(b) (21 CFR 54.25(b)), if review by an institutional review board is required, the board must also approve such changes.

In FDA surveys of investigators, a failure to adhere to the protocol was found in about 30 percent of the cases, not all of which necessarily had adverse effects on the subjects or on the validity of the study. Five case studies illustrate the types of changes that warrant prior approval by the sponsor (and institutional review board if applicable).

1. *A significant increase in the dosage or frequency of administration of the test article, or a change in the method of administrtation.* In one recent drug investigation, the investigator sought to accelerate the pace of the study by moving to high-dose phase I exposure before low-dose exposure had been completed; some of the subjects developed liver toxicity and required extended medical care after exposure was discontinued.

2. *A significant increase in the number of subjects participating in the study.* A recently discontinued drug investigation had reached the stage where a few phase III investigators had begun routine use of the drug in their practice and, in effect, the drug was being promoted before approval. The primary purpose of an investigation is to study a drug's benefits and risks in order to reach a conclusion on whether it should be introduced into medical practice. The conversion of a study phase into a promotional phase does not in the long run help the public, the investigators, or the sponsor. Each protocol should have a built-in maximum number of subjects which, at least initially, seems likely to provide a data base adequate to make a judgment on whether the scientific hypothesis under examination should be accepted or rejected. Any significant increases above this maximum properly require justification.

3. *The utilization of subjects with medical conditions unrelated to, but possibly affecting, the scope or validity of the study.*

4. *The utilization of human subjects who require special consideration or protection and who are not specifically listed in the protocol.* The recent concern for special protections for particular subject populations led to the enactment of the National Research Act (Pub. L. 93-348), which in turn mandated the creation of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. One of the functions of this Commission is to review and recommend policies regarding research involving special populations such as children, prisoners, and the mentally disabled. The Commissioner forsees specific proposals for FDA regulations to implement appropriate recommendations of the Commission. In the interim, the Commissioner believes that at a minimum the investigators should consult in advance with sponsors and, when required, institutional review boards about utilization of such populations in clinical investigations.

5. *The administration of concomitant or concurrent thereapy under conditions which confound interpretation of results.* A recurring problem in investigational drug studies is the use of more than one pharmaceutical agent in the subject, often to treat the condition under study. The Commissioner recognizes the medical necessity to provide quality medical care to subjects who participate in research. This means that drugs or therapies other than the one undergoing evaluation bust be given to research subjects on occasion. Such concomitant medication can sometimes be anticipated and its use described in the protocol, and sometimes it cannot. The principle to be maintained is that concomitant medication is to be avoided whenever possible, introduced in such a way as not to confound the study whenever such medication is necessary, and in any event reported accurately so that the data can be interpreted correctly. If confounding concomitant medication is introduced with any frequency in a study, the validity of the study is seriously undermined, and such investigation raises a separate ethical issue of whether the subject should have received the test article in the first place.

It should be emphasized that none of these alterations of the protocol is being forbidden or even subjected to prior FDA approval, except in the case of investigational devices in proposed § 812.105 (21 CFR 812.105) published in the FEDERAL REGISTER of August 20, 1976 (41 FR 35282). In §§ 54.120 and 54.130 (21 CFR 54.120 and 54.130), the Commissioner proposes, that each protocol be in writing; that any change in a protocol be documented and dated; and that significant modifications of an investigation, if not contemplated in the original protocol of the investigator, not be undertaken without prior consultation and agreement with the sponsor and, where appropriate, the institutional review board. If the change is made to reduce the risk to subjects, it may be implemented without prior notice or approval, but the investigator must notify the sponsor and board within 10 working days. (In the IDE proposal of August 20, 1976, the Commissioner had suggested a 5-day period in this requirement; comments received have persuaded the Commissioner to modify the period to 10 days.)

Proposed § 54.132 (21 CFR 54.132) would codify a requirement applicable to the use of edible products from food-producing animals which are the subjects of a clinical investigation. It mandates that the investigator obtain authorization from FDA or the U.S. Department of Agriculture, and observe the withdrawal period following administration of the test article, before using edible products.

SUBJECTS IN CLINCIAL INVESTIGATIONS

The requirement that human subjects be informed that a test article is experimental, and that they consent to becoming participants in the experiment, first appeared in American statutory law in the final paragraph of section 505(i) of the Act, which was added by the Drug Amendments of 1962. These additions were in reaction to the thalidomide investigation, in which a significant number of patients were neither told of the experimental nature of the drug nor asked to become research subjects. A paragraph containing the verification required by section 505(i) was included in item 6.g. of form FD-1572 and item 4.g. of form FD-1573 soon after enact-

ment of the 1962 amendments. In 1966 and 1967, FDA promulgated detailed regulations defining concepts contained in section 505(i), as well as setting forth the elements of consent and the circumstances when consent must be obtained in writing or may be obtained orally (§ 310.102). When the FDA surveys were completed in the early 1970's, a significant number of deficiences were found in the performance of investigators; consequently, the Commissioner believes it important to affirm the FDA's commitment to the precepts of fully informed voluntary consent.

In a final rule published in the FEDERAL REGISTER of May 30, 1974 (39 FR 18914), the Department of Health, Education, and Welfare promulgated 45 CFR Part 46 governing informed consent in research funded or supported by the Department (revised March 13, 1975 (40 FR 11854)). There are several important differences between 45 CFR Part 46 and those currently set forth in 21 CFR 310.102. The Commissioner intends to revise and update § 310.102 in the near future in a separate rule making proposal to incorporate the appropriate departmental standards as well as other relevant materials.

In the August 20, 1976 notice, the Commissioner proposed to establish standards in subpart F of part 812 defining the requirements of informed consent for investigational use of devices, which is governed by section 520(g)(3)(D) of the Act. This section differs from section 505(i) in several important respects, both in the text and in the legislative history; certain differences therefore appear between the proposed subpart F of part 812 and the current § 310.102. These will be reviewed and reconciled in the planned revision of § 310.102.

At this time, therefore, the Commissioner proposes only to codify the current obligations under § 310.102 and proposed Subpart F of Part 812 in the standards for clinical investigators, and proposed § 54.142 (21 CFR 54.142) so provides.

The Commissioner would add a new requirement in proposed § 54.143 (21 CFR 54.143), regarding consent by owners of animals used for research purposes in a clinical investigation. Because of the risks to the animals themselves, and, in the case of food-producing animals, to humans from residues of the test article, it is important that the owner of the animal be aware of and consent to the clinical investigation.

The Commissioner concludes that the following types of records are relevant to a clinical study:

Record type	Record contents	Record location
A. "Prior Medical History" (covering the period prior to the subject's involvement in the clinical study).	Basic I.D. information Physicals Therapy Lab results, X-rays Progress notes Consultations Correspondence	Physician files. Hospital files. Other facility files (e.g., out-patient clinics and nursing homes).
B. "Clinical Study Medical History".	Same as above covering the period of the subject's involvement in the clinical study.	Same as above and an integral part of the above.
C. Case report form D. Followup report form	Clinical study and followup data abstracted from prior and clinical study medical history records.	Sponsor and FDA files, copy usually retained by the clinical investigator.

Section 54.155 proposes that the types of records described in A and B in the table above be maintained by an investigator as backup data to what is submitted in the case report. Some investigators surveyed suggested that no records regarding a subject's health before his entry into an investigation can be required. Clearly, certain portions of such records can be highly relevant, and other portions immaterial; only the pertinent parts need be included in the case report form of a specific investigation. As discussed further below, however, in certain cases, FDA's attempt to verify data will require that the inspection go beyond the case report form to corroborating information. Additionally, the data regarding administration or dispensing of test articles (as well as any control article) shall be maintained in the subject's records, as well as in the records required for control of the article in proposed § 54.108. The proposed regulation also emphasizes that the scope of observations made during the study includes the appearance of factors that might alter the effects of the test article, even though such factors are not considered to be caused by or associated with the article under investigation.

Certain comments on a similar provision contained in the IDE proposal objected that these requirements concerning the content of patient records would be an unlawful intrusion into the practice of medicine. Others proposed allowing patient data sheets to be substituted for clinical case reports in appropriate situations. The Commissioner believes that the requirements proposed in § 54.155(a) comport with sound scientific investigation and reflect the minimum amount of information necessary to be maintained as backup data for case reports to enable FDA to assure compliance with the standards governing clinical investigators, to review the progress and conduct of the investigation, and ultimately to evaluate the safety and, where applicable, the effectiveness of the test article. The Commissioner is explicitly authorized to require such records under sections 505(i)(3), 507(d)(3), 512(j), and 520(g)(2)(B)(ii) of the act; and such records are implicit in the other statutory sections under which these proposals are issued, as essential to establish the validity and completeness of reports of clinical investigations submitted to FDA in support of applications for research or marketing permits.

The Commissioner advises that proposed § 544.155(a) addresses the totality of records that must be kept regarding a clinical investigation, rather than the form and content of clinical case report forms. The latter vary from investigation to investigation and are currently governed by the protocols prepared by the sponsors and, in some cases, by FDA regulations contained in parts 312, 511, and proposed 812 or in the IND's, INAD's, and IDE's granted under those regulations. Patient data sheets are an appropriate part of the records of an investigation, but they almost certainly would be inadequate to serve as the complete records of the investigation; the acceptability of such sheets as clinical case reports would depend on the type and status of the particular investigation.

In research studies conducted in animals, proposed § 54.155 also allows records of specific measurements to be maintained on each group rather than on each individual subject in those studies where a group response rather than an individual response is an appropriate measurement.

REVIEW BY INSTITUTIONAL REVIEW BOARD

Since 1971, FDA has required initial and ongoing peer group review of clinical new drug investigations with institutionalized human subjects. Such review reinforces the protection of the rights and safety of subjects who, if

they are institutionalized, may be legally or practically less capable of making a free and informed choice to participate in the research. As a separate aspect of the FDA bioresearch monitoring program, a task force has been created to evaluate existing regulations regarding institutional review requirements, prepare recommendations to the Commissioner for improvements, and develop an agency-wide compliance program to enforce these regulations. The Commissioner anticipates publishing in the FEDERAL REGISTER in the near future a comprehensive proposal regarding institutional review boards; consequently, those matters are not the subject of this document. The Commissioner does believe, however, that this proposal should include several specific obligations of clinical investigators regarding institutional review, which reflect existing rules (item 10.c. of form FD-1571, item 3. of form FD-1572, and item 2.a. and b. of form FD-1573).

First, proposed § 54.25(a) provides that the investigator shall submit, or make certain that the sponsor submits, the proposed clinical investigation for the board's review, and that the board must approve the investigation before human subjects are allowed to participate in, or requested to consent formally to participate in, the investigation. Comments on a similar provision as part of the IDE proposal questioned whether this requirement would preclude a prestudy survey to determine whether potential subjects would be interested in participating in a contemplated study; such surveys, it was said, are useful in determining whether the investigation would be feasible if approved. The Commissioner advises that such surveys are not precluded by this regulation, so long as formal consent of each subject is obtained after the investigation is approved. Under proposed § 54.25(c), the investigator also may not use a consent form that has not been approved by the board.

Another obligation of investigators, set forth in proposed § 54.25(b) and § 54.130(a), is to submit, or make certain that the sponsor submits, all proposed changes in the investigation to the board for approval before implementation, unless the change is made to reduce or eliminate risk to the subjects. This point is discussed above in this preamble.

The investigator must report to the board any unanticipated serious adverse reactions, deaths, or any other life-threatening medical problems within 10 working days of detection by the investigator or of the investigator's being informed of them by the sponsor. The investigator must also report periodically on the progress of the investigation and within 3 months after completion, termination, or discontinuation of the entire study or of his or her protocol (whichever is sooner); such reports will guarantee that the board is aware of developments in the cessation of the investigation. These requirements are set forth in proposed §§ 54.25(d) and 54.185 (b) and (c) (21 CFR 54.25(d) and 54.185 (b) and (c)).

Finally, § 54.25 provides that the investigator shall respond to requests of the board for information and retain records of all contacts with the institutional review board as part of the records of the investigation.

RECORDS AND REPORTS OF A CLINICAL INVESTIGATION

Periodic reports to the sponsor on the progress of an investigation enable the sponsor to collate and review data to obtain an overall view of the study and provide useful information back to the investigator, as well as to FDA; FDA has required annual progress reports to be submitted by the sponsors to the agency (§ 312.1(a)(5)). The current drug investigator forms refer to this requirement, but do not indicate whether investigators are similarly obligated to report annually to sponsors (item 6.d. of form FD-1572 and item 4.d. of form FD-1573). The Commissioner proposes to resolve any ambiguity by establishing such a rule in proposed § 54.185(a).

There is currently a requirement for a final report from an investigator at the end of an investigation only in form FD-1573, item 4.d., although it is common practice to submit such a document. Occasionally, however, FDA inspectors have discovered that an investigator has stopped his research, for any of a variety of reasons, without notifying the sponsor. This failure to notify the sponsor unnecessarily delays a definitive analysis of investigation results and prevents making meaningful decisions. In proposed § 54.185(b), the Commissioner proposes to require that an investigator submit a final report within 3 months of the completion, termination, or discontinuation of the entire clinical investigation or of his or her protocol, whichever occurs first.

To warn other investigators of possible hazards and permit reassessment of the benefit-to-risk ratio justifying a clinical investigation, timely reports of adverse reactions are currently required (item 6.d. of form FD-1572 and item 4.d. of form FD-1573; compare § 312.1(a)(6)). To specify more precisely when reports are required and how quickly they must be submitted, the Commissioner proposes in § 54.185(c) that a special report be required for any serious adverse effect, death, or life-threatening problem that may reasonably be regarded as caused by or associated with the test article and that was not previously anticipated (in nature, severity, or degree of incidence) in the written information given to the investigator by the sponsor (item 6.a. of form FD-1572, item 4.a. of form FD-1573, and § 312.1(a)(6)). This requirement should eliminate any repeated reports of routine and minor side effects (nausea, dizziness, drowsiness) once these are inserted in the sponsor's brochure for investigators, but would require reports of unusual, serious, or unanticipated reaction.

Another change in special reporting obligations is the replacement of current nonspecific deadlines ("promptly" and "immediately") with a simple standard: As soon as possible but in no event later than 10 working days after discovery.

Numerous comments were recieved on a provision similar to proposed § 54.185(c) in the IDE proposal of August 20, 1976, except that that provision required reporting of all known deaths and all life-threatening medical problems occurring in the study, regardless of cause; and required reports to be filed within 5 working days. Many objected to reporting a serious incident when it could be and in fact was foreseen, for example, when an extremely serious or terminal medical condition for which no accepted therapy exists is being treated with the test article. The Commissioner agrees that special reports under such circumstances would be unnecessarily burdensome, and has revised this proposal accordingly. The comments on the 5-day reporting period argued that it was too brief to permit an adequate review of the case by the investigator to determine whether the incident could reasonably be regarded as caused by or associated with the test article. The Commissioner is now proposing a period of 10 working days, which he believes is clearly adequate for the type of determination being requested. Absolute proof of causality is not necessary; a reasonable belief that an association may exist between the test article and the adverse phenomenon is sufficient to justify notification to the sponsor and the institutional review board.

These changes are intended to keep special reports as an important means to communicate important safety information. The Commissioner also proposes to require expressly that all reports be accurate and adequate in content, a standard now only implicit in the regulations.

The clinical investigation records that would be required to be prepared by an investigator under this proposal include: Communications with an institutional review board, if any (§ 54.25(f)); receipts and disposition of

the test article (§ 54.108); the protocol and any changes in it (§ 54.120); records on individual subjects (§ 54.155); and reports on the investigation (§ 54.185(d)).

The current investigational drug regulations require an investigator to retain copies of these records either for 2 years following approval of a marketing permit (e.g., NDA or NADA) for the drug, or 2 years after discontinuation of the IND (or INDA) if an NDA (or NADA) is not approved (item 6.e. of form FD-1572 and item 4.e. of form FD-1573). This second provision seems unnecessarily burdensome. The agency needs an adequate opportunity to take steps to verify the study if it desires, while an investigator should have a reasonable and finite period of responsibility. A distinction should also be drawn between the purposes for which the investigator studied the article and other purposes; experience shows that products may be approved for marketing for one use while still being investigated for other uses. The Commissioner therefore proposes in § 54.195(a) (21 CFR 54.195(a)) to require records to be kept for one of three alternate periods, whichever is shortest:

1. A period of at least 2 years following the date on which an application for a research or marketing permit, in support of which the results of the clinical investigation were submitted, is approved by FDA;

2. A period of at least 5 years following the date on which the results of the clinical investigation are submitted to FDA in support of an application for a research or marketing permit; or

3. In other situations (e.g., where the clinical investigation does not result in the submission of data in support of an application for a research or marketing permit), a period of at least 2 years following the date on which the study is completed, terminated, or discontinued.

Existing FDA regulations do not provide any mechanism for an investigator to transfer his or her records to another party, should he or she decide to move or retrire, or be otherwise unable to continue his or her obligations. The proposed § 54.195(b) allows such a transfer for the first time.

Compliance and Enforcement

Defining the obligations of investigators in conducting clinical investigations constitutes a major restatement and clarification of FDA policy. It does, however, raise the question of what to do if an investigator fails to carry out these requirements. Several options are available, and each has an appropriate place in the FDA compliance program. The regulatory sanctions available for use in cases of noncompliance include:

1. Notifying the investigator of deficiencies observed during an inspection. It will be the practice of an FDA investigator to do this upon concluding an inspection before leaving the premises.

2. Issuing more formal warnings that important discrepancies between the conditions observed and regulatory requirements must be corrected if the investigator is to avoid more severe regulatory action. This step generally will be accomplished through formal regulatory correspondence.

3. Determining that data from one or more specific clinical investigations will not be considered by FDA in support of an application for a research or marketing permit. This determination would not mean that the data need not be submitted to FDA. The usual rule that all data and information relevant to a particular article (e.g., a proposed or marketed product) must be submitted remains in effect. A finding that a clinical investigation is not acceptable in support of an application for a research or marketing permit means that the agency will not look upon that study as providing evidence of safety or effectiveness of the product or for any other condition required by law for a research or marketing permit. Rejection of a particular investigation from consideration in support of an application is provided for by statute in the procedures and criteria for determining whether the application is approvable under the Act or the Public Health Service Act; for example, a determination that a faulty study precludes a finding that a new drug is safe would be made in accordance with the procedures set forth in section 505(d) of the Act and 21 CFR Part 314. Accordingly, no special procedures need be prescribed. The standards for conduct of clinical investigators thus represent amplification of the legal requirements regarding evidence of safety, and where applicable, effectiveness, necessary to approve an application for a research or marketing permit.

4. Disqualifying an investigator as an acceptable researcher to conduct clinical investigations regulated by or submitted to FDA. This would mean that no new clinical investigation subject to prior submission to FDA (i.e., via an IND, INAD, or IDE) would be authorized if it were to be conducted by the investigator. Second, similar ongoing clinical investigations conducted by the investigator would be terminated immediately or phased out if transfer of patients to another investigator was necessary. Third, data and information from any clinical investigation previously performed by the investigator might not be considered in support of any application for a research or marketing permit. This might lead to termination of a previously granted permit if, without the investigator's studies, the safety or effectiveness of the article could no longer be demonstrated. In the case of disqualification, the determination that data generated by the investigator are not acceptable in support of an application is not limited to a particular study but may extend to all investigations carried out by the investigator which may have been affected by the violative behavior. This sanction would be utilized when the deficiencies found in an investigator's work are of such a widespread or fundamental nature that the safety of subjects in, or the rights of human subjects in, or the quality and integrity of a number of studies conducted by the investigator have probably been compromised, or when the investigator has failed to comply with FDA regulations after previous warnings from the agency. The Commissioner deems disqualification an important alternative to rejection of specific investigations and prosecution (discussed below) because it can reduce by consolidation the number of investigations and proceedings that might be required for a study-by-study review, it can permit the agency to accept a study that might otherwise have to be rejected and repeated with an unnecessary risk to human subjects, and it obviates using judicial proceedings except for deliberate or flagrant offenses. Unlike rejection of a specific investigation and prosecution, disqualification is not explicitly provided for by statute and thus necessitates the promulgation of regulations describing the procedures for and consequences of imposing this sanction; much of the remainder of this preamble is devoted to this matter. This extensive discussion should not, however, be read as implying that disqualification is the exclusive or even the primary administrative action for noncompliance with these regulations. It will be used only when the Commissioner concludes that lesser sanctions have not been or probably will not be effective in achieving compliance.

5. Obtaining a court injunction against further violations of the Act and implementing regulations. This form of judicial action has not previously been utilized by FDA to enforce the obligations of clinical investigations, but will be considered in appropriate circumstances.

6. Recommending prosecution of an investigator and/or the sponsor of a clinical investigation for violations of Federal criminal laws, including violations of the Act and/or the U.S. Criminal Code (e.g., 18 U.S.C. 1001). Even where the investigator is not under a direct statutory obligation to comply with FDA investigational require-

ments or to submit information to FDA, and in fact does not send data to the agency but merely transmits them to the sponsor, the investigator is likely to be aware that FDA will be the ultimate recipient. In such cases, the investigator could be liable for aiding and abetting in a violation (18 U.S.C. 2) or for causing a violation to be made by a third party. Nevertheless, the circumstances in which criminal penalties might be sought represent the rare and extraordinary cases, such as deliberate fraud or willful and harmful violations of individual rights or safety.

The Commissioner is aware of the wide range of severity in these sanctions. He has directed the preparation of a compliance program that will identify the administrative and legal sanctions FDA may invoke upon findings of various types of noncompliance. These sanctions, and the internal procedures by which they will be applied, will be contained in an FDA compliance program guide to be made publicly available upon its completion. An understanding of this document should assuage fears that individuals not in compliance with the clinical investigator regulations will be unduly subject to extreme penalties.

Disqualification of a Clinical Investigator

The experience of FDA in enforcing regulations pertaining to the conduct of persons carrying out studies subject to the agency's jurisdiction has indicated a need for administrative sanctions in addition to court enforcement proceedings and rejection of data on a study-by-study basis. Criminal prosecutions are serious, demand significant resources, and may be inappropriate when noncompliance does not reflect criminal intent, bad faith, or gross negligence. Study-by-study audits and proceedings to reject data also cost much in time and resources; they may be redundant if the violations are pervasive, or inappropriate if the data are scientifically valid. For these reasons, FDA has in the past used another sanction, termed the "disqualification process," to obtain compliance with the requirements regarding clinical investigators (§§ 312.1(c) and 511.1(c) (21 CFR 312.1(c) and 511.1(c))).

Disqualification of clinical investigators has simply meant that an investigator is no longer eligible to receive investigational drugs under the investigator's own or someone else's IND or INAD. It imposes no fine; it attaches no financial liability, except to the extent that an investigator may be unable to fulfill a research contract; it does not revoke a medical license or institutional privileges. The disqualification of an investigator is intended to achieve two objectives: First, it precludes a disqualified investigator from access to any test article until such investigator can demonstrate his or her ability and willingness to conform to the standards for conducting clinial investigations essential to insure scientifically sound and ethical research; second, disqualification provides a mechanism for refusing to accept data prepared by the investigator in support of an application for a research or marketing permit.

In 15 years, the Food and Drug Administration has disqualified only 24 investigators. The Bureau of Drugs has disqualified 22; and the Bureau of Biologics (and its predecesor, the Division of Biologics Standards), 2. Although the results of FDA surveys discussed above are of concern, the Commissioner does not believe that they indicate that the majority of investigators are not performing acceptably or that large numbers of disqualifications are necessary, and he is hopeful that a reaffirmation and more precise statement of FDA rules will significantly improve compliance.

After reassessment of agency experience with disqualification and the available alternatives for enforcement of these regulations, and for the reasons just discussed, the Commissioner has determined that disqualification should continue to be used by FDA in all areas of clinical investigation, not simply investigational new drug studies. In addition, the disqualification process, unlike rejection of a study, provides the individual alleged to have violated these regulations an opportunity to be heard before the agency in his or her own behalf. The Commissioner is aware that in some instances, the sponsor of a clinical investigation has little or no interest in defending the quality of the study or the actions of the investigator because such sponsor may benefit most by acquiescing in the agency's challenge to the study. Disqualification creates a forum for the individual whose work is being questioned to explain or justify the activities that are in doubt. Finally, many participants in the development and marketing of products regulated by FDA, including sponsors, investigators, and agency officials, are familiar with this process because of its use in the IND process.

The regulations governing disqualification of clinical investigators are proposed to be set forth in subpart K of part 54. Proposed § 54.200 (21 CFR 54.200) codifies the purposes of disqualification and states clearly the meaning of this administrative action.

Comments received on the proposed disqualification regulations regarding clinical investigators of investigational devices published in the Federal Register of August 20, 1976, and statements made at a hearing before FDA on the proposed disqualification regulations regarding nonclinical testing facilities as part of the good laboratory practice rule making published in the Federal Register of November 19, 1976, objected to the way in which the grounds for disqualification were set forth in those documents. Comments and statements are on display in the office of the Hearing Clerk as part of the records of those proceedings. The Commissioner concurs that, as drafted, those proposals implied that disqualification could occur as the result of insignificant deficiencies in investigator conduct, and suggested that FDA might in the future invoke this sanction far more frequently than indicated in the preambles to those proposals.

To clarify FDA intent in proposing the disqualification mechanism and to minimize the possible abuse of this sanction in the future, the Commissioner proposes in § 54.202 (21 CFR 53.202) a more restrictive statement of the grounds for disqualification of a clinical investigator. A clinical investigator may be disqualified only if the Commissioner finds all three of the following: (1) That the investigator failed to comply with one or more of the obligations set forth in part 54 or in any other FDA regulation governing the conduct of clinical investigators, e.g., the IND, INAD, or IDE regulations; (2) that the noncompliance adversely affected (a) the validity of the data produced in the investigation, and/or (b) the rights of human subjects, and/or (c) the safety of human or animal subjects; and (3) that other lesser regulatory actions, such as warnings or rejection of individual studies, have not been or probably will not be adequate to achieve compliance by the investigator. These requirements assure that the sanction will not be used in trivial situations, but only when the violation has compromised the integrity of the study or the rights or safety of the subjects. The proposed regulation further requires the Commissioner to consider the availability, and past or probable effectiveness, of lesser sanctions as alternatives to disqualification. It would not, however, preclude disqualification without a prior warning or other regulatory action where the investigator's conduct evidences a deliberate violation of the regulations or a flagrant disregard of his or her obligations.

The Commissioner proposes, in § 54.204 (21 CFR 54.204), to establish a uniform procedure to be followed by the several FDA bureaus regulating or reviewing clinical investigations on articles subject to FDA jurisdiction. Each bureau will be initially responsible for administering the clinical investigator regulations for the products

and substances under its purview, as part of processing applications for research and marketing permits submitted to that bureau. In those cases where the bureau believes that rejection of specific studies and other remedies are inadequate to achieve compliance, the Commissioner or his designate, on recommendation from the Bureau Director, may elect to commence the proceeding by providing a notice of the proposed action to the investigator; there would be an opportunity for a regulatory hearing before the Commissioner or a person designated by him; and final action on the proposed disqualification would be taken only by the Commissioner or a person to whom this authority had been officially delegated.

The written notice provided to the clinical investigator upon commencement of a disqualification proceeding shall contain the following items of information, in accordance with § 16.22(a) (21 CFR 16.22(a)): (1) The notice shall specify the facts that are believed to justify disqualification. (2) The notice shall state that the investigator has an opportunity for a regulatory hearing on the proposed disqualification before the Commissioner, or a person designated by him, and that such hearing will be conducted in accordance with the provisions of part 16, the procedural regulations for regulatory hearings before FDA. (3) The notice shall state the time within which a hearing may be requested, which shall not be less than 3 working days from the receipt of the notice. Except in cases where safety of subjects requires immediate action, ample time would be allowed the investigator to prepare for and appear at the hearing. (4) The notice shall contain the name, address, and telephone number of the FDA official who has been designated by the Commissioner as presiding officer for the regulatory hearing and to whom any request may be filed by registered mail, telegram, telex, personal delivery, or any other mode of written communication.

In the past, under the disqualification regulations pertaining to clinical investigators, the Bureau of Drugs has provided an "informal" conference with the officer who issued the notice before the "formal" disqualification hearing (§ 312.1(c)(1)). These conferences frequently had many formal trappings, such as stenographic transcripts, and were often followed by the contemplated hearing. This process doubled the time and expense of all parties involved without discernible benefit. The Commissioner has therefore decided not to provide for such an informal conference in these regulations. The procedures proposed should provide adequate flexibility and fairness to all parties.

Comments on the disqualification procedures regarding clinical investigators of investigational medical devices, contained in the August 20, 1976, proposal, objected that the regulatory hearing process denied an adversary hearing, a right to counsel, transcripts, cross-examination, and an appeal mechanism. The Commissioner advises that regulatory hearings under part 16 provide all of these safeguards as well as others essential to due process. Interested persons are referred to those regulations for a complete description of the procedures referred to in proposed § 54.204 as applicable to disqualification proceedings.

If, after the regulatory hearing or after the time for requesting a hearing expires without a request being made, the Commissioner, upon an evaluation of the administrative record, makes the findings required for disqualification, he shall prepare and issue a final order disqualifying the investigator. Proposed § 54.206 (21 CFR 54.206) provides that the final order shall include a statement of the basis for the disqualification. If, on the other hand, the Commissioner does not make these findings, he shall issue a final order terminating the disqualification proceeding and shall include a statement of the basis for his decision to terminate the proceeding.

Once a final order has been issued, the Commissioner shall so notify the investigator. If the investigator is disqualified, the Commissioner will also notify, to the extent possible, the sponsor of every clinical investigations subject to an IND, INAD, or IDE in which the investigator is participating or has participated. Because FDA does not usually receive information about other clinical investigations before they are completed and submitted to the agency, it will not generally be possible to notify sponsors of uncompleted studies. Comments on this provision in the IDE proposal requested that the sponsor be notified at the commencement, rather than the completion, of disqualification proceedings. In certain cases, it may be both appropriate and advisable for the sponsor of an investigation to be made aware of the allegedly violative conduct of one of its investigators; such information ought not necessarily be withheld from the sponsor until after FDA has disqualified the investigator. Therefore, proposed § 54.213(c) allows, but does not require, the Commissioner to provide the sponsor with such information simultaneously with a proposal to disqualify the investigator unless there are overriding safety considerations that warrant earlier notification. The Commissioner is not convinced that every sponsor needs to be notified every time disqualification of an investigator is proposed, but he invites further comment on this matter.

Once a clinical investigator has been disqualified, no new clinical investigation requiring prior review by FDA will be authorized by the agency if it is to include the investigator. This rule is proposed in § 54.210(a) (21 CFR 54.210(a)). Since the agency has no statutory authority to suspend or terminate clinical investigations not done under an IND, INAD, or IDE, it will not be possible to deny permission to conduct these investigations when they involve the disqualified investigator.

In issuing an order disqualifying a clinical investigator, the Commissioner must consider what, if anything, should be done regarding ongoing investigations that involve the investigator. Several options are available: Allowing the investigations to proceed for a period of time to permit completion or to permit corrective actions; limiting the continuation of the investigations to subjects who are already participating; requiring transfer of responsibility for the actual conduct of the investigation to an investigator who is in compliance with FDA requirements; or terminating the investigation completely. A special concern is the subject who cannot be safely withdrawn from the investigation because, for example, the subject has an implanted investigational device which must be surgically removed, or because abrupt withdrawal of the investigational drug may create a life-threatening problem. Clearly, some provision must be made for such cases if ongoing investigations are to be suspended upon disqualification of an investigator. The Commissioner does not believe it possible, much less advisable, to require that any particular option be used for all ongoing investigations. This choice must be made, on a study-by-study basis, considering the nature of the investigation, the number of subjects involved, the risks to them from suspension of the study, and the need for involvement of an acceptable investigator. Proposed § 54.210(b) authorizes, but does not require, the actions that might be taken. The Commissioner especially invites comments on these proposals and suggestions for other ways to address this sensitive problem.

Proposed § 54.10(c) provides that each application for a research or marketing permit, approved or not, that contains or relies upon a clinical investigation conducted by a disqualified investigator may be examined to determine whether the study was, or would be, essential to FDA's decision to approve the application. This authority is also discretionary, and would depend on the types of problems that led to disqulification and the nature of

the investigation involved. If it is determined that, without the results of the investigation in question, further clinical trials would not have been allowed or a product license would not have been appoved, FDA will then determine whether data from the investigation are acceptable, notwithstanding disqualification.

To avoid FDA's auditing every such investigation, any study performed by an investigator before or after disqualification, but before reinstatement, may be presumed to be unacceptable; and the person relying on the data resulting from the investigation may have to establish that the data were not affected by the kind of circumstances that led to disqualification. The sponsor or applicant may be required to submit validating information. If FDA determines that the clinical investigation was or would be essential, and is not acceptable, it will not be considered in support of the application for a research or marketing permit. Elimination of such data may serve as "new information" justifying termination of an IND, INAD, or IDE, initiation of the withdrawal of approval of an authorizing regulation or of a product license, or the revocation of a product monograph or standard.

Under proposed § 54.210(d), after an investigator has been disqualified, FDA will not consider any clinical investigation begun by that investigator in support of any application for a research or marketing permit. However, the applicant is not relieved from any requirement under any other applicable statute or regulation that all data and information regarding clinical experience with the article in question be submitted to the agency.

The Commissioner advises that it is not necessary that an investigator be disqualified in order for the agency to reject consideration of a particular clinical investigation in support of an application for a research or marketing permit. The criteria set forth in the statute and regulations applicable to each type of application, together with the regulations regarding the conduct of clinical investigations, will still be used to judge the scientific validity and meaning of the results of each investigation. The agency may apply these regulations to a particular investigation and determine that it is so inadequate in terms of science or ethics that it will not or should not support a claim of safety or effectiveness for a product. If the sponsor of a product or an investigator who conducted the clinical investigation wishes to contest this finding, the opportunity to do so will be provided in the procedures for denying or withdrawing the approval of the application.

The Commissioner believes that it is not in the public interest to provide a two-step process whereby a particular investigation would be disqualified under procedures similar to those proposed in subpart K and then the application itself would be denied under procedures set forth in other regulations. Efficiency and fairness suggest that these issues be resolved at the same time in one proceeding, if that is required. It may be that, although a particular investigation is not acceptable, other data and information in the application will support a finding that a product is safe or effective, and therefore no proceeding is necessary to rule on the acceptability of the particular investigation. Likewise, the agency may choose to reject individual investigations without disqualifying the investigator when, for example, the investigation was performed during a period when the investigator was not in compliance with FDA regulations but has since come into compliance.

The Commissioner further advises that it is likely that the usual formal regulatory action taken for noncompliance will be rejection of individual investigations, and that disqualification of a clinical investigator will be reserved for cases where the rejection of a particular investigation is an inadequate regulatory response.

The agency maintains that it should affirmatively provide information regarding the disqualification of a clinical investigator to entities having professional dealings with that investigator, such as other Federal, State, or local government agencies supporting research studies, State and local licensing agencies by whom the investigator is licensed, and institutions and universities in which the investigator practices or teaches. Many objections were received to this aspect of disqualification in the IDE proposal of August 20, 1976. The Commissioner notes, however, that in the past, officials of such entities have in fact complained to FDA that it failed to notify them about a disqualification and that this failure deprived them of an opportunity to consider the liability of the institution for which they were responsible or the value of continuing to fund research by the investigator after the disqualification. Moreover, the Commissioner deems the providing of such information within the purpose of section 705 of the act (21 U.S.C. 375).

Because he recognizes that the consequences of such notice could have a serious adverse effect on the reputation and career of the individual, the Commissioner believes that the investigator must be aware that such notice is one of the results of disqualification (*Wisconsin* v. *Constantineau*, 400 U.S. 433 (1971)). Proposed § 54.213(a) (21 CFR 54.213(a)) would expressly authorize FDA to notify such entities when the Commissioner believes that such disclosure would further the public interest or would promote compliance with applicable FDA regulations. This determination is within the discretion of the Commissioner upon consideration of the circumstances justifying the disqualification, any mitigating conditions, and the degree to which other institutions or persons have an involvement in the ongoing activities of the investigator. If he gives any notice, the Commissioner shall provide a copy of the final disqualification order, indicate its legal meaning, and state that FDA is not advising or recommending that the person notified take any action upon the matter. A copy of each such notification shall be given to the investigator.

Under proposed § 54.213(b), a determination that a clinical investigator has been disqualified and the administrative record regarding such determination are disclosable to the public under the Freedom of Information Act (5 U.S.C. 552) and under FDA public information regulations under part 20 (21 CFR Part 20) as records relating to an administrative enforcement action that has been completed.

Since disqualification of a clinical investigator may be neither a sufficient nor an appropriate sanction in every case, the Commissioner believes that disqualification must be independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by law. Proposed § 54.215 (21 CFR 54.215) makes clear, therefore, that FDA may at any time recommend institution of any appropriate judicial proceedings (civil or criminal) and may take any other appropriate regulatory action, in addition to or in lieu of, and before, at the same time as, or after, disqualification. This would, of course, include refusing to consider a particular study in support of a particular application—the regulatory action that probably will be most commonly used in cases of significant noncompliance with the clinical investigator regulations. The agency may also refer the matter to another Federal, State, or local law enforcement, regulatory, research-supportive or other governmental agency for such action as that agency determines to be appropriate.

In accordance with § 312.1(a)(8), the sponsor of a clinical investigation must remove an investigator from further participation in the investigation at any time the investigator fails to keep the required records. Proposed § 54.217 (21 CFR 54.217) makes clear that the sponsor has authority to suspend or terminate a noncomplying investigator whether or not FDA has commenced

any action to disqualify that investigator. Furthermore, in removing an investigator, the sponsor is not required to utilize either the grounds or the procedures for disqualification set forth in this proposed regulation. The sponsor is required, however, to advise the appropriate bureau within FDA of this action and to supply the reasons for it within 15 working days. This principle follows the decision of the Federal district court in *Froning* v. *Travenol Laboratories, Inc.* (N.D. Calif., Civil Action C75-0767, 1975, a copy of which has been placed on file with the FDA hearing clerk), in which an investigator was denied injunctive relief to compel the sponsor to continue shipping investigational drugs after the sponsor had determined to suspend the investigator for what the sponsor concluded were violations of the protocol.

Disqualification is principally a remedial action to prevent future violations and to assure that the rights and safety of subjects are appropriately protected and that data in support of applications are produced under circumstances that increase the likelihood of their scientific validity. Thus, the Commissioner concludes that disqualification should continue indefinitely until the agency finds that the investigator can and will fulfill the requirements imposed under these proposed regulations.

Proposed § 54.219 (21 CFR 54.219) authorizes the Commissioner to reinstate a clinical investigator (i.e., to determine that he or she may again conduct investigations under an IND, INAD, or IDE, and that data from investigations performed by him or her may once again be considered in support of applications for research or marketing permits), if the Commissioner finds that the investigator can provide adequate assurances that he or she will operate in compliance with the requirements of FDA regulations. An investigator who wishes to be reinstated shall explain to the Commissioner why he or she believes reinstatement is warranted, and shall provide a detailed description of the corrective actions the investigator has taken or intends to take to assure that the acts or omissions which led to the disqualification will not recur. The Commissioner may condition reinstatement upon commitments from other persons (e.g., sponsor, parent institutions, institutional review boards, or other investigators) to monitor in detail the investigator's activities, and/or upon the submission of a specific protocol providing for additional steps that the Commissioner determines are necessary to assure compliance. Reinstatement may also be contingent upon the investigator's passing a subsequent FDA inspection.

In fairness to the investigator, all persons notified under proposed § 54.213(a) of the investigator's previous disqualification must be notified when he or she is later reinstated; proposed § 54.219 so provides. Once reinstated, a clinical investigator may thereafter conduct additional new investigational studies without again going through the reinstatement process. A determination that an investigator has been reinstated is disclosable to the public under the Freedom of Information Act (5 U.S.C. 552) and under Part 20 as records relating to completed administrative enforcement actions.

Legal Authority

The results of literally hundreds of clinical investigations are submitted to FDA each year by persons seeking regulatory action by the agency. To obtain a marketing license, clinical research data are offered to support the safety and effectiveness (or functionality) of a product, e.g., a food or color additive, a drug or biologic for human use, a drug for animal use, or a medical device for human use. Even where a license is not required or already has issued, such data may be relied upon to demonstrate the bioavailability of a marketed drug, the general recognition of safety of a product, or the absence of any need for premarket approval or a product standard for a device. In evaluating the enormous volume of clinical investigations filed with FDA, many types of scientific and regulatory review must be devoted to these studies apart from determining their ethical and scientific acceptability and their basic validity, e.g., to interpret the results and to evaluate the status of the affected products in light of the results. Given the limited resources of the agency, the Commissioner believes that FDA must have standards to screen out those clinical investigations that are likely to be unacceptable and thus should not be authorized by FDA or that warrant little further evaluation in support of a product application. The promulgation of these regulations provides one process for making this judgment. While compliance with the regulations does not guarantee the ethical or scientific acceptability of, or the validity of data from, a clinical investigation, failure to comply substantially increases the probability that the results will not be useful to FDA. Moreover, as noted elsewhere in this preamble, the regulations reflect principles recognized by the scientific community as essential to sound research involving human and animal subjects. Thus, these regulations will assist FDA in identifying those investigations that cannot be permitted to be carried out or considered in support of an application for a research or marketing permit.

Under section 701(a) of the act (21 U.S.C. 371(a)), the Commissioner is empowered to promulgate regulations for the efficient enforcement of the act. Previously, the Commissioner has issued regulations under § 314.111 (a)(5) (21 CFR 314.111(a)(5)) for determining whether a clinical investigation of a drug intended for human use, among other things, was scientifically reliable and valid (in the words of the statute, "adequate and well-controlled") to support approval of a new drug. These regulations were issued under section 701(a) and have been upheld by the Supreme Court (*Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973); see also *Upjohn Co.* v. *Finch*, 422 F. 2d 944 (6th Cir. 1970); and *Pharmaceutical Manufacturers Association* v. *Richardson*, 318 F. Supp. 301 (D. Del. 1970)).

Furthermore, sections 505(i), 507(d), 512(j) and 520(g) of the act regarding clinical investigations that require prior FDA authorization direct the Commissioner to promulgate regulations to protect the public health in the course of those investigations. These proposed regulations are intended to fulfill this mandate.

The Commissioner has therefore concluded that legal authority to promulgate these regulations regarding clinical investigators exists under sections 505(i), 507(d), 512(j), 520(g) and 701(a) of the act, as essential to protection of the public health and safety and to enforcement of the agency's responsibilities under sections 406, 408, 409, 502, 503, 505, 506, 507, 510, 512, 513, 514, 515, 516, 518, 519, 520, 601, 706, and 801 of the act (21 U.S.C. 346, 348, 349, 352, 353, 355, 356, 357, 360, 360b, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 361, 376 and 381), as well as the responsibilities of FDA under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n).

Inspections of Clinical Investigators

It follows from the authority to promulgate these regulations that FDA also has authority to prescribe the terms on which it will accept data generated in a clinical investigation performed by an investigator. Therefore, the proposed regulations under § 54.15(c) provide that the agency will not consider data from a clinical investigation in support of an application for a research or marketing permit unless the investigator who conducted the investigation consents to inspection by FDA. The Commissioner believes that this requirement does not infringe on any rights or obligations of an investigator who may, at any time, refuse to consent to inspection or

withdraw his or her consent. In this event, however, FDA will not consider the results of the study and may consider disqualifying the investigator. Such action may adversely affect the status of an application submitted by a third person (e.g., the sponsor of a study under a grant or contract), but this is strictly a matter between those parties. The Commissioner advises all persons who sponsor or perform under grant or contract clinical investigations that may be submitted to FDA to consider including in the grant or contract provisions regarding FDA inspections. Such a provision is especially important if the investigator is not otherwise aware that the results of the investigation may be submitted to FDA.

Inspections of many, perhaps most, clinical investigators will not be conditioned upon consent. Under section 704(a) of the act (21 U.S.C. 374(a)), FDA may inspect establishments, including consulting laboratories, in which certain drugs and devices are processed or held, and may examine research data that would be subject to reporting and inspection pursuant to sections 505 (i) or (j), 507 (d) or (g), 519, or 520(g) of the act. (See in this regard § 200.10 (21 CFR 200.10).) In addition, any establishment registered under section 510 of the act is subject to inspection under section 704. Thus, most sponsors and many investigators under IND's, INAD's, IDE's, and those institutions in which such studies are conducted would be subject to FDA inspection whether or not they consented.

Current FDA policies regarding inspection of clinical investigators (item 6.e. of form FD-1572 and item 4.e. of form. FD-1573) require clarification. During the FDA surveys discussed above, agency officials were occasionally refused access to records containing the names of human subjects, on grounds of the confidentiality of the physician-patient relationship and the subject's right to privacy. Numerous questions and objections were also submitted regarding FDA inspections of clinical investigators under the IDE proposal of August 20, 1976. Therefore, the Commissioner finds it necessary to state clearly and publicly when FDA will request access to such records, and if such access is requested, how the agency will safeguard the privacy of subjects.

First, the agency does not need to inspect medical history records routinely. The scientific evaluation of case report forms, and of summary tables proposed from the data in these forms, is the basic mechanism by which FDA assesses the study data. However, the agency's inspections have uncovered a significant number of errors of omission and commission in information submitted to the agency. For this reason FDA has initiated an inspectional program that includes the onsite audit of certain data submitted to the agency. During this audit, access to the subject's identification is incidental to the review of such records. When such records are reviewed, as described in current regulations, "The names of the subjects need not be divulged unless the records of the particular subjects require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual studies or do not represent actual results obtained" (21 CFR 312.1(a)). To assure the privacy of individually identifiable medical records, FDA has implemented clear and extraordinarily exacting guidelines for FDA personnel who conduct inspections of medical records containing the names of individual research subjects. Before an inspection, FDA personnel will generally notify the investigator of FDA's intent to inspect the investigator's records, with a view to arranging a mutually convenient inspection time. Agency personnel must invite the investigator to be present with them throughout FDA's records review, and they must inform the investigator that he or she may see the records which they may wish to copy and may review any records that are copied. Agency personnel may not copy medical records containing the names of research subjects, and the investigator is to be given the right to delete any information that could identify an individual subject, except when: (1) A more detailed study of the records regarding particular subjects is indicated; or (2) there is reason to believe that the records do not represent actual studies, or do not represent actual results obtained. The exceptions to the prohibition against the copying of individually identifiable medical records by FDA personnel rest primarily on the need to determine whether a given research subject in fact exists and whether the research subject in fact participated in the investigation. Where an individually identifiable medical record is copied and reviewed by the agency, the record is properly safeguarded within FDA and is used or disseminated under conditions that protect the privacy of the individual to the fullest possible extent consistent with laws relating to public disclosure of information (Freedom of Information and Privacy Act regulations) and the law enforcement responsibilities of the agency.

The Commissioner proposes in § 54.15(a) that an investigator permit authorized FDA personnel, at reasonable times and in a reasonable manner: (1) To inspect the facilities used by the investigator for the clinical investigation, and (2) for purposes of verification of the data and information submitted to FDA, (a) to inspect all records required by these regulations, (b) to copy such records that do not identify the names of human subjects or from which the identifying information has been deleted, and (c) to copy such records that identify the names of human subjects, without deletion of the identifying information, upon notice that FDA has reason to believe that the consent of human subjects was not obtained, that the reports submitted by the investigator to the sponsor (or to the institutional review board) do not represent actual cases or actual results obtained, or that such reports or other required records appear to be otherwise false or misleading.

The Commissioner recognizes the highly sensitive nature of this provision, as reflected in the many comments already received by FDA on the IDE proposal. He welcomes reasoned discussions of the issues involved and specific proposals under which patient confidentiality could be further protected without compromising the ability of FDA to verify clinical data submitted in support of applications for research or marketing permits.

Conforming Amendments

The Commissioner is proposing to amend the procedural regulations regarding regulatory hearings before the agency set forth in § 16.1 (21 CFR 16.1), to delete cross-references to the current regulations regarding disqualification of investigators, and to include a cross-reference to the procedures proposed in this notice.

The current definitions of the term "sponsor" found in §§ 310.3(j) and 510.3(k) (21 CFR 310.3(j) and 510.3(k)) are to be superseded by the proposed definition in § 54.3(f) discussed above. Therefore, the Commissioner is proposing to eliminate the current definitions.

Because of the clarification of the obligations of clinical investigators, the Commissioner intends to revise the current investigator forms FD-1572 and FD-1573 to correspond with the proposed part 54. Rather than repeat these provisions in the forms in this proposal, which might confuse readers and lead to duplicative comments, the Commissioner will propose, in a separate Federal Register issuance, the changes in the forms to reiterate the regulations proposed here, as modified in light of the comments received.

With the revision of the obligations of clinical investigators, the Commissioner also deems it appropriate to revise the substantive provisions governing the use of new animal drugs in clinical investigations set forth in

§ 511.1(b) (21 CFR 511.1(b)). The revision clarifies and incorporates all of the requirements under section 512(j) of the act.

The proposed procedures regarding disqualification of clinical investigators will supersede existing regulations in §§ 312.1(c) and 511.1(c). Therefore, the Commissioner is proposing to revoke these sections.

The Commissioner also proposes to add or revise regulations regarding food and color additives, new drug applications, bioavailability and bioequivalence testing requirements, OTC drug products, radioactive drugs, antibiotic drugs, new animal drug applications, biological product licenses, cosmetics, and electronic products, to incorporate appropriate implementing provisions for, and cross-references to, part 54.

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. 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 601, 701(a), 706, and 801, 52 Stat. 1049-1054 as amended, 1055, 1058 as amended, 55 Stat. 851, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 74 Stat. 399-403 as amended, 76 Stat. 794 as amended, 82 Stat. 343-351, 90 Stat. 539-574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360b-360f, 360h-360j, 361, 371(a), 376, and 381)) and the Public Health Service Act (secs. 215, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 262, 263b-263n)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes that Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. In § 16.1 by revising paragraph (b)(8) and by revoking and reserving paragraph (b)(11) as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(8) Section 54.204(b) of this chapter, relating to disqualifying a clinical investigator.

* * * * *

(11) [Reserved]

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2. By adopting new Part 54 to read as follows:

PART 54—CLINICAL INVESTIGATIONS

Subpart A—General Provisions

Secs.
54.1 Scope.
54.2 Exemptions.
54.3 Definitions.
54.15 Inspection of facilities and records.

Subpart B—Organization and Personnel

54.25 Institutional review board.

Subparts C-E [Reserved]

Subpart F—Test Articles

54.102 Use of test article by unauthorized persons.
54.108 Records of receipt and disposition of test articles.
54.114 Disposition of unused test articles.
54.116 Handling of controlled substances.
54.118 Promotion of test articles.

Subpart G—Protocol for Conduct of a Clinical Investigation

54.120 Protocol.
54.130 Conduct of a clinical investigation.
54.132 Withdrawal, withholding and discard periods for clinical investigations in food-producing animals.

Subpart H—Subjects in Clinical Investigations

54.142 Consent of human subjects.
54.143 Owner consent regarding animal subjects.
54.155 Records regarding subjects.

Subpart I [Reserved]

Subpart J—Records and Reports

54.185 Reporting of results of a clinical investigation.
54.195 Retention of records.

Subpart K—Disqualification of a Clinical Investigator

54.200 Purpose.
54.202 Grounds for disqualification.
54.204 Notice of and opportunity for hearing on proposed disqualification.
54.206 Final order on disqualification.
54.210 Actions upon disqualification.
54.213 Public disclosure of information regarding disqualification.
54.215 Alternative or additional actions to disqualification.
54.217 Suspension or termination of an investigator by a sponsor.
54.219 Reinstatement of a disqualified clinical investigator.

AUTHORITY: Secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 601, 701(a), 706, and 801, Pub. L. 717, 52 Stat. 1049-1054 as amended, 1055, 1058 as amended, 55 Stat. 851, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 74 Stat. 399-403 as amended, 76 Stat. 794 as amended, 82 Stat. 343-351, 90 Stat. 539-574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 357, 360, 360b-360f, 360h-360j, 361, 371(a), 376, and 381); secs. 215, 351, 354-360F, Pub. L. 410, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 262, 263b-263n).

Subpart A—General Provisions

§ 54.1 Scope.

This part contains the general obligations and commitments of, and regulations governing conduct of, persons who conduct clinical investigations regulated by the Food and Drug Administration under section 505(i), 507(d), 512(j), and 520(g) of the Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, cosmetics, human and animal drugs, animal food additives, medical devices for human use, biological products for human use, and electronic products. Additional specific obligations and commitments of, and regulations governing conduct of, persons who conduct clinical investigations involving particular test articles and products may also be found in other parts of this chapter, e.g., parts 312, 511, and 812. Compliance with these parts is intended to protect the rights and safety of subjects involved in such investigations and to help assure the quality and integrity of the data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 507, 510, 512, 513-516, 518-520, 601, 706, and 801 of the Act and sections 351 and 354-360F of the Public Health Service Act.

§ 54.2 Exemptions.

Any investigator subject to the requirements of this part, or the sponsor of such investigator, may request the Food and Drug Administration for a waiver of any specific requirements. Such a request shall be submitted in writing as part of an application for a research permit in accordance with §§ 312.1, 511.1, or part 812 of this chapter, and shall set forth the basis for the applicant's belief that compliance with a particular requirement is not necessary either to protect the rights and safety of subjects involved in the particular clinical investigation or to help assure the quality and integrity of the data produced in the investigation. The Commissioner may, in the Commissioner's discretion, grant in writing a request for a waiver of certain requirements if it agrees with the applicant that compliance with those requirements in the course of the particular clinical investigation is not necessary. In the case of applications for a research permit granted on an emergency basis, such request for waiver may be made over the telephone and be granted orally by the agency at the same time the emergency application is appoved on an oral basis. Written confirmation shall be included in the official application submitted subsequent to this emergency authorization of such application.

§ 54.3 Defintitions.

As used in this part, the following terms shall have the meanings specified:

(a) "Act" means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-392)).

(b) "Application for research or marketing permit" includes:

(1) A color additive petition, described in part 71 of this chapter.

(2) Data and information regarding a substance submitted as part of the procedures for establishing that a substance is generally recognized as safe for a use which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §§ 170.35 and 570.35 of this chapter.

(3) A food additive petition, described in parts 171 and 571 of this chapter.

(4) Data and information regarding a food additive submitted as part of the procedures regarding food additives permitted to be used on an interim basis pending additional study, described in § 180.1 of this chapter.

(5) Data and information regarding a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in section 406 of the Act.

(6) A "Notice of Claimed Investigational Exemption for a New Drug," described in part 312 of this chapter.

(7) A new drug application, described in part 314 of this chapter.

(8) Data and information regarding the bioavailability or bioequivalence of drugs for human use submitted as part of the procedures for issuing, amending, or repealing a bioequivalence requirement, described in part 320 of this chapter.

(9) Data and information regarding an over-the-counter drug for human use submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, described in part 330 of this chapter.

(10) Data and information regarding a prescription drug for human use submitted as part of the procedures for classifying such drugs as generally safe and effective and not misbranded, to be described in this chapter.

(11) Data and information regarding an antibiotic drug submitted as part of the procedures for issuing, amending, or repealing regulations for such drugs, described in part 430 of this chapter.

(12) A "Notice of Claimed Investigational Exemption for a New Animal Drug," described in part 511 of this chapter.

(13) A new animal drug application, described in part 514 of this chapter.

(14) Data and information regarding a drug for animal use submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, to be described in this chapter.

(15) An application for a biological product license, described in part 601 of this chapter.

(16) Data and information regarding a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, described in part 601 of this chapter.

(17) An "Application for an Investigational Device Exemption," described in part 812 of this chapter.

(18) Data and information regarding a medical device for human use submitted as part of the procedures for classifying such devices, described in section 513 of the act.

(19) Data and information regarding a medical device for human use submitted as part of the procedures for establishing, amending, or repealing a standard for such device, described in section 514 of the act.

(20) An application for premarket approval of a medical device for human use, described in section 515 of the act.

(21) A product development protocol for a medical device for human use, described in section 515 of the act.

(22) Data and information regarding an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for such products, described in section 358 of the Public Health Service Act.

(23) Data and information regarding an electronic product submitted as part of the procedures for obtaining a variance from any electronic product performance standard, described in § 1010.4 of this chapter.

(24) Data and information regarding an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from a radiation safety performance standard, as described in § 1010.5 of this chapter.

(25) Data and information regarding an electronic product submitted as part of the procedures for obtaining an exemption from notification of a radiation safety defect or failure of compliance with a radiation safety performance standard, described in subpart D of part 1003 of this chapter.

(c) "Clinical investigation" means any experiment that involves a test article, and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i), 507(d), 512(j), or 520(g) of the act, or is not subject to requirements for prior submission of the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies.

(d) "Investigator" means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject.

(e) "Person" includes any individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit of a government agency, and any other legal entity.

(f) "Sponsor" means a person who initiates a clinical investigation, but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of anther individual. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(g) "Sponsor-investigator" means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., it does not include a corporation or agency. The obligations of a sponsor-investigator under this part include both those of a sponsor and those of an investigator.

(h) "Subject" means an individual who is or becomes a participant in a clinical investigation, either as a recipient of the test article or as a control. A subject may be either a healthy human being or a healthy or unhealthy animal or a patient to whom the test article might offer a therapeutic benefit or provide diagnostic information. The test "subject" applies both to human beings and to other animals; whenever only human subjects are referred to, the adjective "human" shall be used. The term "subject," when applied to animals other than man, may apply to individuals and/or groups based upon whether an individual or group response is being measured.

(i) "Test article" means any drug (including a biological product for human use), medical device for human use,

human or animal food additive, color additive, cosmetic, electronic, product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Act.

§ 54.15 Inspection of facilities and records.

(a) An investigator shall permit an authorized employee of the Food and Drug Administration, at reasonable times and in a reasonable manner:

(1) To inspect the facilities utilized by the investigator for the clinical investigation;

(2) For purposes of verification of case reports and other information prepared for the sponsor as part of the data and information to be submitted by the sponsor to the Food and Drug Administration:

(i) To inspect records required to be made or kept by the investigator as part of or relevant to the investigation;

(ii) To copy such records that do not identify the names of human subjects or from which the identifying information has been deleted; and

(iii) To copy such records that identify the human subjects, without deletion of the identifying information, but only upon notice that the Food and Drug Administration has reason to believe that the consent of human subjects was not obtained, that the reports submitted by the investigator to the sponsor (or to the institutional review board) do not represent actual cases or actual results obtained, or that such reports or other required records appear to be otherwise false or misleading.

(b) An investigator shall permit an authorized representative of the sponsor (e.g., the monitor selected under § 52.28 of this chapter), at reasonable times and in a reasonable manner, to inspect the facilities utilized by the investigator for the clinical investigation and to inspect, for purposes of verification of case reports and other information prepared for the sponsor, the records required to be made of kept by the investigator as part of the investigation.

(c) The Food and Drug Administration will not accept a clinical investigation as evidence in support of an application for a research or marketing permit if the investigator who conducted the investigation refuses to permit an inspection under this section. The determination that a clinical investigation may not be accepted in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable statute or regulation to submit the results of the investigation to the Food and Drug Administration.

SUBPART B—ORGANIZATION AND PERSONNEL

§ 54.25 Institutional review board.

If the clinical investigation is subject to an institutional review requirement under either parts 312 or 812 of this chapter or any other applicable regulation in this chapter:

(a) An investigator shall submit the proposed clinical investigation (including the protocol of the investigation, a report of prior investigations if a medical device for human use, and the materials to be used in obtaining the consent of human subjects, described in § 54.142(b)) for review by the board, and shall obtain the approval of the board, before any human subjects are allowed to participate in, or requested formally (i.e., in accordance with § 310.102 or subpart F of part 812 of this chapter, whichever is applicable) to consent to participate in, the investigation.

(b) An investigator shall submit any proposed change in or deviation from the protocol of the clinical investigation for review by the board if the change or deviation may increase the risk to human subjects in the study or may adversely affect the validity of the investigation or the rights of the human subjects, and shall obtain the approval of the board before such change or deviation is implemented. When the change or deviation is done to eliminate or reduce the risk to human subjects, it may be implemented before review or approval by the board; the investigator shall notify the board of the change or deviation in writing within 10 working days after implementation.

(c) In obtaining the consent of subjects, an investigator shall not use a form that has not been approved by the board.

(d) An investigator shall submit to the board the progress report required in § 54.185(a). An investigator shall submit to the board the final report required in § 54.185(b). An investigator shall submit to the board any special report relating to adverse effects required by § 54.185(c), or any information regarding similar reports received from the sponsor, as soon as possible and in no event later than 10 working days after the investigator discovers the information or is notified of it by the sponsor, e.g., when uncovered by another investigator or in a nonclinical laboratory study.

(e) An investigator shall provide accurate and adequate information regarding the clinical investigation to the board in response to its request.

(f) An investigator shall maintain records of all submissions to, and all actions by, the board regarding the clinical investigation.

Subparts C–E—[Reserved]

Subpart F—Test Articles

§ 54.102 Use of test article by unauthorized persons.

An investigator shall only permit a test article to be administered or dispensed to or used involving subjects who are under his or her personal supervision or under the supervision of another investigator who is responsible to him or her and, if it is a test article intended for use in humans, who is named by the investigator in his or her signed statement undertaking the obligations of an investigator or sponsor-investigator, e.g., forms FD-1571, FD-1572, or FD-1573 in § 312.1 of this chapter. An investigator shall not supply a test article to any other person for administration to or use upon subjects or for any other purpose, without the prior authorization of the sponsor.

§ 54.108 Records of receipt and disposition of test articles.

An investigator shall maintain adequate and accurate records showing the receipt and disposition of all supplies of a test article shipped to such investigator by the sponsor, including the dates, serial, lot, or other identification numbers (if any), quantities received, each quantity dispensed, administered, or used, with the identification of the subject who received it or involving whom it was used, and each quantity otherwise disposed of, including identification of the person who disposed of it, the person (if any) who received it, and the purpose or reason for its disposal, e.g., contamination or return to the sponsor. The records required in this section are separate from and in addition to the records required for individual subjects in § 54.155.

§ 54.114 Disposition of unused test articles.

An investigator shall return to the sponsor any unused or reusable supply of a test article, or otherwise dispose of the article as authorized in writing by the sponsor, upon request of the sponsor, upon completion, suspension, termination, or discontinuance of the clinical investigation, or upon termination or withdrawal by the Food and Drug Administration of the exemption under which the investigation is being conducted.

§ 54.116 Handling of controlled substances.

If a test article is a substance listed in any schedule of the Controlled Substance Act (21 U.S.C. 801 note; 21 CFR

Part 1308), the investigator shall take reasonable precautions to prevent theft or diversion of the article into illicit channels, including storage of the substance in a cabinet or other enclosure, which is substantially constructed and securely locked and to which access is restricted by the investigator.

§ 54.118 Promotion of test articles.

An investigator shall not represent in a promotional context that an unmarked test article is safe or effective for the purposes for which it is under investigation or otherwise promote or commercialize the article. This requirement is not intended to restrict the full exchange of scientific information concerning the article, including dissemination of scientific findings in scientific or lay communications media; its intent is to restrict promotional claims of safety or effectiveness for the article while the article is under investigation to establish its safety or effectiveness and to preclude commercial use or test-marketing of the article before authorization for marketing by the Food and Drug Administration.

Subpart G—Protocol for and Conduct of a Clinical Investigation

§ 54.120 Protocol.

(a) Each clinical investigation shall have a written protocol.

(b) All changes or revisions to a protocol, and reasons therefor, shall be documented by the investigator, dated, and maintained with the protocol.

§ 54.130 Conduct of a clinical investigation.

A clinical investigation shall be conducted in accordance with the protocol. An investigator shall not implement a change in the protocol, or otherwise deviate from such protocol, if the change or deviation may increase the risk to subjects in the study or may adversely affect the validity of the investigation or the rights of the human subjects, without the prior review and written approval of the sponsor of the investigation and, when such review is required under either § 312.1 or Part 812 or any other applicable regulation in this chapter, by an institutional review board. When the change is made to eliminate or reduce the risk to human subjects, it may be implemented before review or approval by the sponsor and the board; the investigator shall notify the sponsor and the board of the change or deviation in writing within 10 working days after implementation.

§ 54.132 Withdrawal, withholding, and discard periods for clinical investigations in food-producing animals.

An investigator in a clinical investigation that includes food-producing animals as subjects shall not offer the animals for slaughter for food purposes, or otherwise offer for food purposes edible products from the animals, without prior authorization from the Food and Drug Administration or the U.S. Department of Agriculture, and shall observe the authorized withdrawal, withholding, or discard time periods.

Subpart H—Subjects in Clinical Investigations

§ 54.142 Consent of human subjects.

(a) An investigator shall inform each human subject (or, where appropriate, the legal representative of the human subject), including any human subject used as a control, that the test article is being used for research purposes, provide the other information required by § 310.102(h) or subpart F of part 812 of this chapter, whichever is applicable, and obtain and properly document the consent of such subject (or the subject's legal representative), except in exceptional cases as defined in § 310.102(d) or subpart F of part 812 of this chapter, whichever is applicable.

(b) An investigator shall provide to the sponsor, and to the institutional review board, if any, a copy of any written materials to be given or read to the human subject, or the subject's legal representative, regarding the information required to be given by § 310.102(h) or subpart F of part 812 of this chapter (whichever is applicable), and a copy of any form to be used to document the consent of such subject or the subject's legal representative.

§ 54.143 Owner consent regarding animal subjects.

An investigator shall inform the owner or owners of each animal subject that the test article is being used for research purposes in a clinical investigation, and shall obtain and properly document the consent of such owner or owners.

§ 54.155 Records regarding subjects.

(a) An investigator shall maintain adequate and accurate records on which case reports on each subject (including a subject used as a control) are based, which shall include the following:

(1) Detailed medical history records which contain: (i) Medical history before the subject's involvement in the clinical investigation which includes basic identifying information linking the subject's record to the subject's case report forms submitted to the Food and Drug Administration, results of all diagnostic tests performed, diagnoses made, therapy provided, and other data on the condition of the subject.

(ii) Medical history during the subject's involvement in the clinical investigation, which includes all data described in paragraph (a)(1)(i) of this section as it relates to the exposure of the subject to the test or control article, and to any concomitantly or concurrently administered therapy, including the date (and time, if relevant) of each dispensing or administration and the quantity dispensed or administered; and, all relevant observations and data on the condition of the subject throughout the subject's participation in the investigation, including the appearance of factors that might alter the effects of the test article (e.g., development of an apparently unrelated intercurrent illness).

(2) Any documentation regarding the consent of the human subject required under § 310.102 or subpart F of part 812 of this chapter, whichever is applicable.

(b) In research in animals other than man, where a group response (rather than an individual response) is an appropriate measurement, the records required in this section may be maintained on each group for the specific measurement rather than on each individual subject in the group.

Subpart I—[Reserved]

Subpart J—Records and Reports

§ 54.185 Reporting of results of a clinical investigation.

(a) An investigator shall make accurate and adequate reports to the sponsor, and to any institutional review board that has reviewed and is continuing to review the investigation, on the progress of the clinical investigation at appropriate intervals not exceeding 1 year.

(b) An investigator shall make an accurate and adequate final report to the sponsor, and to any institutional review board that has reviewed and is continuing to review the investigation, within 3 months after the completion, termination or discontinuation of the entire clinical investigation or of such investigator's participation in it, whichever is sooner. This report shall include all case reports not provided to the sponsor in periodic or special reports.

(c) An investigator shall make an accurate and adequate special report to the sponsor, and to any institutional review board that has reviewed and is continuing to review the investigation, on any serious adverse effect, death, or life-threatening problems that may reasonably be regarded as caused by or associated with the test article and

which was not previously anticipated (in nature, severity or degree of incidence) in the written information on the article provided to the investigator by the sponsor. Such reports shall be made as soon as possible and in no event later than 10 working days after the investigator discovers the serious adverse effect, death, or medical problem.

(d) An investigator shall retain a copy of each report he or she submits to the sponsor and to an institutional review board under this section.

§ 54.195 Retention of records.

(a) An investigator shall retain the records required by this part or by any other regulations in this chapter regarding clinical investigations (e.g., parts 312, 511, and 812) for whichever of the following periods is shortest:

(1) A period of 2 years following the date on which the test article is approved by the Food and Drug Administration for marketing for the purposes that were the subject of the investigation;

(2) A period of 5 years following the date on which the results of the investigation are submitted to the Food and Drug Administration in support of or as part of an application for a research or marketing permit for the test article for the purposes that were the subject of the investigation; or

(3) In other situations (e.g., where the investigation does not result in the submission of the data from the investigation in support of or as part of an application for a research or marketing permit), a period of 2 years following the date on which the entire clinical investigation (not merely the investigator's portion of an investigation involving more than one investigator) is completed, terminated, or discontinued, or the exemption under which the investigation is being conducted is terminated or withdrawn by the Food and Drug Administration.

(b) In the event the investigator retires, relocates, or for any other reason withdraws from the responsibility for maintaining records for the period of time required, custody of the records may be transferred to any other person who will accept responsibility for the records, e.g., the sponsor, an institutional review board, or another investigator. Notice of such transfer shall be given in writing to the sponsor.

Subpart K—Disqualification of a Clinical Investigator

§ 54.200 Purpose.

The purposes of disqualification of an investigator who has failed to comply with any of the regulations set forth in this part, or other regulations governing the conduct of investigators in this chapter, may be one or both of the following:

(a) To preclude him or her from conducting clinical investigations subject to requirements for prior submission to the Food and Drug Administration under section 505(i), 507(d), 512(j), or 520(g) of the act until such time as it becomes likely that he or she will abide by such regulations or that such violations will not recur. The determination to disqualify an investigator does not constitute a finding or recommendation that the investigator is not qualified to practice or teach medicine or should be subject to other sanctions by other persons such as licensing boards or employers.

(b) To preclude the consideration of any clinical investigations in support of applications for a research or marketing permit from the Food and Drug Administration, which investigations have been conducted by the investigator, until such time that it becomes likely that he or she will abide by such regulations or that such violations will not recur or that it can be adequately demonstrated that such violations did not occur during or affect the validity or acceptability of a particular investigation or investigations. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable statute or regulation to submit the results of the investigation to the Food and Drug Administration.

§ 54.202 Grounds for disqualification.

The Commissioner may disqualify an investigator upon finding all of the following:

(a) The investigator failed to comply with any of the regulations set forth in this part or other regulations regarding the conduct of investigators in this chapter;

(b) The noncompliance adversely affected the validity of the clinical investigation or the rights of the human subjects, or the safety of the subjects; and

(c) Other lesser regulatory actions, e.g., warnings or rejection of data from individual investigations, have not been or will probably not be adequate to assure that the investigator will comply with such regulations in the future.

§ 54.204 Notice of and opportunity for hearing on proposed disqualification.

(a) Whenever the Commissioner has information indicating that grounds exist under § 54.202 which in the Commissioner's opinion may justify disqualification of an investigator, the Commissioner may issue to the investigator a written notice proposing the investigator be disqualified.

(b) A hearing on the disqualification of an investigator shall be conducted in accordance with the requirements for a regulatory hearing set forth in part 16 of this chapter.

§ 54.206 Final order on disqualification.

(a) If the Commissioner, after the regulatory hearing or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, makes the findings required in § 54.202, the Commissioner shall issue a final order disqualifying the investigator. Such order shall include a statement of the basis for that determination and shall prescribe any actions (set forth in § 54.210(b)) to be taken with regard to ongoing clinical investigations being conducted by the investigator. Upon issuing a final order, the Commissioner shall notify (with a copy of the order) the investigator of the action, as well as the sponsor of each clinical investigation subject to requirements for prior submission to the Food and Drug Administration that was being conducted by the investigator and has not been terminated or discontinued or as to which the exemption under which it is being conducted has not been terminated or withdrawn by the Food and Drug Administration.

(b) If the Commissioner, after a regulatory hearing or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, determines not to make the findings required in § 54.202, the Commissioner shall issue a final order terminating the disqualification proceeding. Such order shall include a statement of the basis for that determination. Upon issuing a final order, the Commissioner shall notify the investigator and provide a copy of the order.

§ 54.210 Actions on disqualification.

(a) No clinical investigation subject to requirements for prior submission to the Food and Drug Administration will be authorized by the Commissioner if such investigation is to be conducted, in whole or part, by a disqualified investigator.

(b) The Commissioner, after considering the nature of each ongoing clinical investigation subject to requirements for prior submission to the Food and Drug Administration that is being performed by the investigator, the number of subjects involved, the risks to them from suspension of the investigation, and the need for involvement of an acceptable investigator, may direct, in the final order dis-

qualifying an investigator under § 54.206(a), that one or more of the following actions be taken with regard to each such investigation:

(1) The investigation may be terminated or suspended in its entirety until the investigator is reinstated under § 54.219 or another investigator accepts responsibility for the investigation.

(2) No new subject shall be allowed to participate or be requested to participate in the investigation until the investigator is reinstated under § 54.219 or another investigator accepts responsibility for the investigation.

(3) Any human subject who has previously been allowed to participate in the investigation and who remains under the supervision of the investigator, but who is no longer receiving the test article or having it used involving him or her, i.e., one having followup monitoring by the investigator or one acting as a control, shall continue to be monitored by the investigator but shall not again receive the test article, or have it used involving him or her, until the investigator is reinstated under § 54.219 or another investigator accepts responsibility for the investigation.

(4) Any human subject who has been allowed to participate in the investigation and who, but for suspension of the investigation would continue to receive the test article or have it used involving him or her, shall not receive it or have it used until either:

(i) Another investigator accepts responsibility for the investigation; or

(ii) The disqualified investigator determines in writing that it is contrary to the health of the subject to defer further use of the test article until another investigator can assume responsibility for the investigation. In such a case, the Commissioner may impose any further conditions that the Commissioner deems appropriate to protect the rights and safety of the subjects.

(c) Once an investigator has been disqualified, each application for a research or marketing permit, whether approved or not, containing or relying upon any clinical investigation performed by the investigator may be examined to determine whether the investigation was or would be essential to a regulatory decision regarding the application. If it is determined that the investigation was or would be essential, the Commissioner shall also determine whether the investigation is acceptable, notwithstanding the disqualification of the investigator. Any investigation done by an investigator before or after disqualification may be presumed to be unacceptable, and the person relying on the investigation may be required to establish that the investigation was not affected by the circumstances which led to disqualification of the investigator, e.g., by submitting validating information. If the investigation is determined to be unacceptable, such investigation shall be eliminated from consideration in support of the application, and such elimination may serve as new information justifying the termination or withdrawal of approval of the application.

(d) No clinical investigation begun by an investigator after the date of his or her disqualification shall be considered in support of any application for a research or marketing permit, unless the investigator has been reinstated under § 54.219. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable statute or regulation to submit the results of the investigation to the Food and Drug Administration.

§ 54.213 Public disclosure of information regarding disqualification.

(a) Upon issuance of a final order disqualifying an investigator, the Commissioner may notify all or any interested persons. Such notice may be given in the discretion of the Commissioner whenever the Commissioner believes that such notice would further the public interest or would promote compliance with the regulations set forth in this part. Such notice, if given, shall include a copy of the final order issued under § 54.206(a) and shall state that the disqualification constitutes a determination by the Commissioner that the investigator is not eligible to conduct clinical investigations subject to requirements for prior submission to the Food and Drug Administration and that the results of any clinical investigations conducted by the investigator may not be considered by the Food and Drug Administration in support of any application for a research or marketing permit. The notice shall further state that it is given because of the professional relations between the investigator and the person notified and that the Food and Drug Administration is not advising or recommending that any action be taken by the person notified.

(b) A determination that an investigator has been disqualified and the administrative record regarding such determination are disclosable to the public under part 20 of this chapter.

(c) Whenever the Commissioner has reason to believe that an investigator may be subject to disqualification, the Commissioner may, in the Commissioner's discretion, so notify the sponsor of any ongoing clinical investigation in which that investigator is participating simultaneously with or subsequent to proposing disqualification of the investigator under § 54.204(a), unless there are overriding safety considerations that warrant earlier notification of the sponsor.

§ 54.215 Alternative or additional actions to disqualification.

Disqualification of an investigator under this subpart is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Commissioner may at any time, through the Department of Justice, institute any appropriate judicial proceeding (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after disqualification. The Commissioner may also refer pertinent matters to another Federal, State, or local government agency for such action as that agency determines to be appropriate.

§ 54.217 Suspension or termination of an investigator by a sponsor.

The sponsor of a clinical investigation may at any time remove an investigator from further participation in the investigation, whether or not the Commissioner has commenced any action to disqualify the investigator. The sponsor need not utilize either the grounds or the procedures for disqualification set forth in this subpart. If a sponsor removes an investigator from a clinical investigation, the sponsor shall notify the appropriate Bureau within the Food and Drug Administration in writing of the reasons for such removal as soon as possible, but in no event later than 15 working days after such removal.

§ 54.219 Reinstatement of a disqualified investigator.

(a) An investigator who has been disqualified may be reinstated as eligible to conduct clinical investigations subject to requirements for prior submission to the Food and Drug Administration, or as acceptable to be the source of clinical investigations to be submitted to the Food and Drug Administration, if the Commissioner determines, upon an evaluation of a written submission from the investigator, that the investigator can adequately assure that he or she will conduct such studies in compliance with the requirements set forth in this part and other applicable regulations in this chapter, e.g., parts 312, 511, or 812.

(b) A disqualified investigator who wishes to be so reinstated shall present in writing to the Commissioner reasons why he or she believes he or she should be reinstated and a detailed description of the corrective ac-

tions the investigator has taken or intends to take to assure that the acts or omissions that led to disqualification will not recur. The Commissioner may condition reinstatement upon the submission of an acceptable protocol for a specific clinical investigation providing for additional corrective actions, and/or the submission or special undertakings by a sponsor, an institution, an institutional review board, or another investigator to review in detail the investigator's compliance with agency requirements, and/or the investigator's being found in compliance with the applicable regulations upon an inspection.

(c) If an investigator is reinstated, the Commissioner shall so notify the investigator and all persons who were notified under § 54.213 of the disqualification of the investigator. A determination that an investigator has been reinstated is disclosable to the public under part 20 of this chapter.

PART 71—COLOR ADDITIVE PETITIONS

3. By amending part 71 as follows:

a. In § 71.1 by adding new paragraph (h) to read as follows:

§ 71.1 Petitions.

* * * * *

(h) If clinical investigations are involved, petitions filed with the Commissioner under section 706(b) of the act shall include, with respect to each clinical investigation contained in the petition, either a statement that the investigation was conducted in compliance with the requirements set forth in part 54 of this chapter; or a statement that the investigation was not subject to such requirement in accordance with § 54.2 of this chapter; or, if the investigation was subject to but was not conducted in compliance with such requirements, a statement that describes in detail all differences between the practices used in the investigation and those required in the regulations.

b. In § 71.6 by revising paragraph (b) to read as follows:

§ 71.6 Extension of time for studying petitions; substantive amendments; withdrawal of petitions without prejudice.

* * * * *

(b) *Substantive amendments.* After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amount to a substantive amendment, the petition as amended shall be given a new filing date, and the time limitation shall begin to run anew. If clinical investigations are involved, additional information or data submitted in support of filed petitions shall include, with respect to each clinical investigation contained in the petition, either a statement that the investigation was conducted in compliance with the requirements set forth in part 54 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or, if the investigation was subject to, but was not conducted in compliance with, such requirements, a statement that describes in detail all differences between the practices used in the investigation and those required in the regulations.

* * * * *

PART 170—FOOD ADDITIVES

4. Part 170 is amended:

a. In § 170.17 by adding a new paragraph (d) to read as follows:

§ 170.17 Exemption for investigational use and procedure for obtaining authorization to market edible products from experimental animals.

* * * * *

(d) If intended for clinical investigation in animals other than laboratory research animals, the investigation is conducted in compliance with the requirements set forth in parts 54 and 511 of this chapter.

b. In § 170.35 by adding a new paragraph (c)(1)(vi) to read as follows:

§ 170.35 Affirmation of generally recognized as safe (GRAS) status.

* * * * *

(c) * * *

(1) * * *

(vi) If clinical investigations are involved, additional information and data submitted in support of filed petitions shall include, with respect to each clinical investigation, either a statement that the investigation was conducted in compliance with the requirements set forth in part 54 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter. If the investigation was not conducted in compliance with such regulations, a statement shall be submitted that describes in detail all differences between the practices used in the study and those required in the regulations.

PART 171—FOOD ADDITIVE PETITIONS

5. By amending part 171 as follows:

a. In § 171.1 by adding a new paragraph (l) to read as follows:

§ 171.1 Petitions.

* * * * *

(l) If clinical investigations are involved, petitions filed with the Commissioner under section 409(b) of the act shall include, with respect to each clinical investigation contained in the petition, either a statement that the investigation was conducted in compliance with the requirements set forth in part 54 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter. If the investigation was subject to but was not conducted in compliance with such requirements, a statement shall be submitted that describes in detail all differences between the practices used in the investigation and those required in the regulations.

b. By revising § 171.6 to read as follows:

§ 170.6. Amendment of petition.

After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amount to a substantive amendment, the petition as amended shall be given a new filing date, and the time limitation shall begin to run anew. Where the substantive amendment proposes a substantial change to the petition which may affect the quality of the human environment, the petitioner is required to submit an environmental impact analysis report pursuant to § 25.1 of this chapter. If clinical investigations are involved, additional information and data submitted in support of filed petitions shall include, with respect to each clinical investigation; either a statement that the investigation was conducted in compliance with the requirements set forth in part 54 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or, if the investigation was subject to but was not conducted in compliance with such requirements, a statement that describes in detail all differences between the practices used in the investigation and those required in the regulations.

PART 180—FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS OR IN CONTACT WITH FOOD PENDING ADDITIONAL STUDY

5a. Part 180 is amended in § 180.1 by adding a new paragraph (c)(5) to read as follows:

§ 180.1 General.

* * * * *

(c) * * *

(5) If clinical investigations are involved, such investigations filed with the Commissioner shall include, with respect to each investigation, either a statement that the investigation has been or will be conducted in compliance with the requirements set forth in part 54 of this chapter; or a statement that the investigation is not subject to such requirements in accordance with § 54.2 of this chapter. If any such study was not conducted in compliance with such regulations, a statement shall be submitted that describes in detail all differences between the practices used in conducting the investigation and those required in the regulations.

PART 310—NEW DRUGS

§ 310.3 [Amended]

6. In § 310.3 *Definitions and interpretations,* by deleting and reserving paragraph (j).

PART 312—NEW DRUGS FOR INVESTIGATIONAL USE

7. In § 312.1 by deleting paragraph (c) and reserving it; and by amending paragraph (d)(11) by inserting "or" after the semicolon in the first sentence and by transferring the remainder of the text to a flush paragraph at the conclusion of paragraph (d), and by reserving paragraph (d)(12) and adding a new paragraph (d)(13), to read as follows:

§ 312.1 Conditions for exemption of new drugs for investigational use.

* * * * *

(c) [Reserved]

(d) * * *

(11) The sponsor fails promptly to investigate and inform the Food and Drug Administration and all investigators of newly found serious or potentially serious hazards, contraindications, side-effects, and precautions pertinent to the safety of the new drug; or

(12) [Reserved]

(13) The clinical investigations are not being conducted in compliance with the requirements set forth in this part of Part 54 of this chapter:

He shall notify the sponsor and invite his immediate correction or explanation. A conference will be arranged with the Bureau of Drugs if requested. If the Bureau of Drugs does not accept the explanation of the correction submitted by the sponsor, the sponsor shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter on the question of whether his exemption should be terminated. Such hearing shall be requested within 10 days after receipt of notification that the explanation or correction is not acceptable. After evaluating all the available information including any explanation and or correction submitted by the sponsor, if the Commissioner determines that the exemption should be terminated he shall notify the sponsor of the termination of the exemption and the sponsor shall recall unused supplies of the drug. If at any time the Commissioner concludes that continuation of the investigation presents a danger to the public health, he shall terminate the exemption forthwith and notify the sponsor of the termination. The Commissioner will inform the sponsor that the exemption is subject to reinstatement on the basis of additional submissions that eliminate such danger and will afford the sponsor an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter on the question of whether the exemption should be reinstated. The sponsor shall recall the unused supplies of the drug upon notification of the termination.

* * * * *

PART 314—NEW DRUG APPLICATIONS

8. By amending part 314 as follows:

a. In § 314.1 by adding a new item 16 to form FD-356H in paragraph (c)(2) and by redesignating paragraph (f)(7) as (f)(8) and adding a new paragraph (f)(7) to read as follows:

§ 314.1 Applications.

* * * * *

(c) * * *

(2) * * *

Form FD-356H-Rev. 1974 * * *

16. *Conduct of clinical investigations.* With respect to each clinical investigation contained in the application, either a statement that the investigation was conducted in compliance with the requirements set forth in parts 54 and 312 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or, if the investigation was subject to but was not conducted in compliance with such requirements, a statement that describes in detail all differences between the practices used in the investigation and those required in the regulations.

* * * * *

(f) * * *

(7) With respect to each clinical investigation contained in the application, either a statement that the investigation was conducted in compliance with the requirements set forth in parts 54 and 312 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or, if the investigation was subject to but was not conducted in compliance with such requirements, a statement describing in detail all differences between the practices used in the investigation and those required in the regulations.

(8) The signature of the applicant or responsible official or agent on a completed Form FD-356H.

b. In § 314.8 by adding a new paragraph (m) to read as follows:

§ 314.8 Supplemental applications.

* * * * *

(m) A supplemental application that contains clinical investigations shall include, with respect to each investigation, either a statement that the investigation was conducted in compliance with the requirements set forth in parts 54 and 312 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or, if the investigation was subject to but was not conducted in compliance with such requirements, a statement describing in detail all differences between the practices used in the investigation and those required in the regulations.

c. In § 314.9 by adding paragraph (d) to read as follows:

§ 314.9 Insufficient information in application.

* * * * *

(d) The information contained in an application shall be considered insufficient to determine whether a drug is safe and effective for use unless the application includes, with respect to each clinical investigation contained in the application, either a statement that the investigation was conducted in compliance with the requirements set forth in parts 54 and 312 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or, if the investigation was subject to but was not conducted in compliance with such requirements, a statement describing in detail all differences between the practices used in the investigation and those required in such regulations.

d. In § 314.12 by adding paragraph (d) to read as follows:

§ 314.12 Untrue statements in application.

* * * * *

(d) Any clinical investigation contained in the application was subject to but was not conducted in compliance with the requirements set forth in parts 54 and 312 of this chapter, and differences between the practices used in conducting the investigation and those required in such regulations were not described in detail.

e. In § 314.110 by adding paragraph (a)(10) to read as follows:

§ 314.110 Reasons for refusing to file applications.

(a) * * *

(10) The applicant fails to include in the application, with respect to each clinical investigation contained in the application, either a statement that the investigation was conducted in compliance with the requirements set forth in parts 54 and 312 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or, if the investigation was subject to but was not conducted in compliance with such requirements, a statement describing in detail all differences between the practices used in the investigation and those required in such reguations.

* * * * *

f. In § 314.111 by adding paragraph (a)(10), to read as follows:

§ 314.111 Refusal to approve the application.

(a) * * *

(10) Any clinical investigation contained in the application was subject to but was not conducted in compliance with the requirement set forth in parts 54 and 312 of this chapter, and differences between the practices used in conducting the investigation and those required in such parts were not described in detail.

* * * * *

g. In § 314.115 by adding new paragraph (c)(6) to read as follows:

§ 314.115 Withdrawal of approval of an application.

* * * * *

(c) * * *

(6) That any clinical investigation contained in the application was subject to, but was not conducted in compliance with, the requirements set forth in parts 54 and 312 of this chapter, and differences between the practices used in conducting the investigation and those required in such parts were not described in detail.

* * * * *

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

9. By amending part 320 as follows:

a. In § 320.31 by adding a new paragraph (e) to read as follows:

§ 320.31 Applicability of requirements regarding a "Notice of Claimed Investigational Exemption for a New Drug."

* * * * *

(e) An in vivo bioavailability study in humans shall be conducted in compliance with the requirements set forth in part 54 of this chapter, regardless of whether the study is conducted under a "Notice of Claimed Investigational Exemption for a New Drug."

b. In § 320.57 by adding a new paragraph (d) to read as follows:

§ 320.57 Requirements for conduct of in vivo bioequivalence testing in humans.

* * * * *

(d) If a bioequivalence requirement provides for in vivo testing in humans, any person conducting such testing shall comply with the requirements of § 320.31.

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

10. By amending § 330.10 by adding paragraph (d) to read as follows:

§ 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

* * * * *

(d) *Clinical investigations.* Information and data submitted under this section after (insert effective date of final regulation promulgating this paragraph) shall include, with respect to each clinical investigation from which the information and data are derived, either a statement that the investigation was conducted in compliance with the requirements set forth in part 54 of this chapter; or a statement that the investigation was not subject to those requirements in accordance with § 54.2 of this chapter; or, if the investigation was subject to but was not conducted in compliance with such requirements, a statement that describes in detail all differences between the practices used in the investigation and those required in the regulations.

PART 361—PRESCRIPTION DRUGS FOR HUMAN USE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED; DRUGS USED IN RESEARCH

11. By amending § 361.1 by adding new paragraph (d)(10) to read as follows:

§ 361.1 Radioactive drugs for certain research uses.

* * * * *

(d) * * *

(10) *Clinical investigator requirements.* The investigator shall comply with the requirements set forth in part 54 of this chapter.

* * * * *

PART 430—ANTIBIOTIC DRUGS; GENERAL

12. By amending § 430.20 by adding new paragraph (f) to read as follows:

§ 430.20 Procedure for the issuance, amendment, or repeal of regulations.

* * * * *

(f) No regulation providing for the certification of an antibiotic drug for human use shall be issued or amended unless each clinical investigation on which the issuance or amendment of the regulation is based was conducted in compliance with the requirements set forth in parts 54 and 312 of this chapter; or was not subject to such requirements in accordance with § 54.2 of this chapter; or, if it was subject to but was not conducted in compliance with such requirements, differences between the practices use in conducting the investigation and those required in such regulations were described in detail.

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

13. By amending in § 431.17 by adding new paragraph (k) to read as follows:

§ 431.17 New antibiotic and antibiotic-containing products.

* * * * *

(k) With respect to each clinical investigation contained in the request, either a statement that the investigation was conducted in compliance with the requirements set forth in parts 54 and 312 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or, if the

investigation was subject to but was not conducted in compliance with such requirements, a statement that describes in detail all differences between the practices used in conducting the investigation and those required in such regulations.

PART 510—NEW ANIMAL DRUGS

§ 510.3 [Amended]

14. In § 510.3 *Definitions and interpretations,* by deleting and reserving paragraph (k).

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIVE USE

15. In § 511.1 by revising paragraph (b); by deleting and reserving paragraph (c); and by redesignating paragraph (d)(2) as (d)(3) and adding a new paragraph (d)(2) to read as follows:

§ 511.1 New animal drugs for investigational use exempt from section 512(a) of the act.

* * * * *

(b) *New animal drugs for clinical investigation in animals.* A shipment or other delivery of a new animal drug or an animal feed containing a new animal drug intended for clinical investigational use in animals shall be exempt from section 512 (a) and (m) of the act if all the following conditions are met:

(1) The label of such drug bears the statement:

Caution. Contains a new animal drug for use only in investigational animals in clinical trials. Not for use in humans. Edible products of investigational animals are not to be used for food unless authorization has been granted by the United States Food and Drug Administration or by the United States Department of Agriculture.

In the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear the caution statements required by paragraphs (a) or (b) of this section, the statements may be included on the carton label and other labeling on or within the package from which the new animal drug is to be dispensed.

(2) The person or firm distributing or causing the distribution of the new animal drug or animal feed containing a new animal drug shall use due diligence to assure that the new animal drug or animal feed containing a new animal drug will actually be used for tests in animals and that it is not used in humans.

(3) The persons claiming the exemption has filed with the Food and Drug Administration a completed and signed "Notice of Claimed Investigational Exemption for a New Animal Drug," three copies, including a signed statement containing the following information:

(i) The best available descriptive name of the drug, including, to the extent known, the chemical name and structure of any new drug substance, and a statement of how it is to be administered. (If the drug has only a code name, enough information should be supplied to identify the drug.)

(ii) Complete list of components of the drug including any reasonable alternates for inactive components.

(iii) Complete statement of quantitative composition of the drug, including reasonable variations that may be expected during the investigational stage.

(iv) Description of source and preparation of any new animal drug substances used as components, including the name and address of each supplier or processor, other than the sponsor, of each new drug substance.

(v) A statement of the methods, facilities, and controls used for the manufacturing, processing, and packing of the new drug to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to clinical investigations made with the drug.

(vi) A statement covering all information available to the sponsor derived from preclinical investigations and in any clinical studies and experience with the drug, as follows:

(*a*) Adequate information about the preclinical investigations, including studies made on laboratory animals, on the basis of which the sponsor has concluded that it is reasonably safe to initiate clinical investigations with the drug. Such information shall include identification of the person who conducted each investigation; identification and qualifications of the individuals who evaluated the results and concluded that it is reasonably safe to initiate clinical investigations with the drug and a statement of where the investigations were conducted and where the records are available for inspection; and enough details about the investigations to permit scientific review. The preclinical investigations shall not be considered adequate to justify clinical testing unless they give proper attention to the conditions of the proposed clinical testing. When this information, the outline of the plan of clinical pharmacology, or any progress report on the clinical pharmacology indicates a need for full review of the preclinical data before a clinical trial is undertaken, the Food and Drug Administration will notify the sponsors to submit the complete preclinical data and to withhold clinical trials until the review is completed and the sponsor notified. Representatives of the Food and Drug Administration will be prepared to confer with the sponsor concerning this action.

(*b*) If the drug has been marketed commercially or investigated (e.g., outside the United States), complete information about such distribution or investigation shall be submitted, along with a complete bibliography of any publications about the drug.

(*c*) If the drug is a combination of previously investigated or marketed drugs, an adequate summary of preexisting information from preclinical and clinical investigations and experience with its components, including all reports available to the sponsor suggesting side effects, contraindications, and ineffectiveness in use of such components. Such summary should include an adequate bibliography of publications about the components and may incorporate by reference any information concerning such components previously submitted by the sponsor to the Food and Drug Administration. The summary shall also include a statement of the expected pharmacological effects of the combination.

(*d*) If the drug is a radioactive drug, sufficient data shall be available from animal studies or previous human studies to allow a reasonable calculation of radiation absorbed with dose upon administration to an animal subject.

(vii) A copy (one in each of the three copies of the notice) of all information material, including label and labeling, that is to be supplied to each investigator. This informational material shall include an accurate description of the prior investigations and experience and their results pertinent to the safety and possible usefulness of the drug under the conditions of the investigation. It shall not represent that the safety or usefulness of the drug has been established for the purposes to be investigated. It shall describe, for the information of clinical investigators, all relevant hazards, contraindications, side effects, and precautions suggested by prior investigations and experience with both the drug under investigation and related drugs.

(viii) The scientific training and experience considered appropriate by the sponsor to qualify the investigators as suitable experts to investigate the safety of the drug, bearing in mind what is known about the pharmacological action of the drug and the phase of the investigational program that is to be undertaken.

(ix) The names, addresses, and a summary of the training and experience of each investigator and of the individual charged with monitoring the progress of the investigation and evaluating the evidence of safety and

effectivenes of the drug as it is received from the investigators.

(x) The protocol to be followed by the investigators in conducting the clinical investigations.

(xi) The approximate number of animals to be treated, or, if not available, the amount of new animal drug to be shipped.

(xii) If the new animal drug is given to food-producing animals, the notice shall also include:

(*a*) A commitment that the edible products from such animals shall not be used for food without prior authorization in accordance with this section.

(*b*) Approximate dates of the beginning and end of the experiment or series of experiments.

(*c*) The maximum daily dose(s) to be administered to a given species, the size and/or age of animal, maximum duration of administration, method(s) of administration, and proposed withdrawal time, if any.

(xiii) A statement that the sponsor will notify the Food and Drug Administration if the investigation is discontinued, and the reason for the discontinuation.

(xiv) A statement that the sponsor will notify each investigator if a new animal drug application is approved or if the investigation is discontinued.

(xv) If the drug is to be sold, a full explanation why sale is required and should not be regarded as the commercialization of a new animal drug for which an application is not approved.

(xvi) When requested by the agency, an environmental impact analysis report pursuant to § 25.1 of this chapter.

(xvii) An active drug control not fulfilling the requirements of § 514.111 (a)(5)(vi)(*b*) of this chapter shall be subject to the requirements for an investigational animal drug.

(4) Authorization for use of edible products derived from a treated food-producing animal may be granted under this section and when the following specified conditions are met, except that in the case of an animal administered any unlicensed experimental veterinary biological product regulated under the viruses, serums, toxins statute (21 U.S.C. 151 et seq.) the product shall be exempt from the requirements of this section when U.S. Department of Agriculture approval has been obtained as provided in 9 CFR 103.2. Conditional authorization may be granted in advance of identification of the name(s) and address(es) of the clinical investigator(s) as required by paragraph (b)(3)(ix) of this section. Information required for authorization shall include, in addition to all other requirements of this section, the following:

(i) Data to show that consumption of food derived from animals treated at the maximum levels with the minimum withdrawal periods, if any, specified in accordance with paragraph (b)(3)(xii)(*c*) of this section, will not be inconsistent with the public health; or

(ii) Data to show that food derived from animals treated at the maximum levels and with the minimum withdrawal periods, if any, specified in accordance with paragraph (b)(3)(xii)(*c*) of this section, does not contain drug residues or metabolites.

(iii) The name and location of the packing plant where the animals will be processed, except that this requirement may be waived, on request, by the terms of the authorization.

Authorizations granted under paragraph (b)(4) of this section do not exempt investigational animals and their products from compliance with other applicable inspection requirements. Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(5) On written request by the Food and Drug Administration, the sponsor shall submit any additional information reported to or otherwise received by him with respect to the investigation deemed necessary to facilitate a determination whether it is grounds in the interest of public health for terminating the exemption.

(6) The clinical investigation is conducted in compliance with the requirements set forth in part 54 of this chapter.

(c) [Reserved]

(d) * * *

(2) The clinical investigations are not being conducted in compliance with the requirements set forth in this part or in part 54 of this chapter; or

(3) The continuance of the investigation is unsafe or otherwise contrary to the public interest or the drug is being or has been used for purposes other than bona fide scientific investigation, he shall first notify the sponsor and invite his immediate correction. If the conditions of the exemption are not immediately met, the sponsor shall have an opportunity for a regulatory hearing before the Food and Drug Administration, pursuant to part 16 of this chapter, on whether the exemption should be terminated. If the exemption is terminated, the sponsor shall recall or have destroyed the unused supplies of the new animal drug.

* * * * *

PART 514—NEW ANIMAL DRUG APPLICATIONS

16. By amending part 514 as follows:

a. In § 514.1 by adding new paragraph (b)(12)(iv) to read as follows:

§ 514.1 Applications.

* * * * *

(b) * * *

(12) * * *

(iv) With respect to each clinical investigation contained in the application, either a statement that the investigation was conducted in compliance with the requirements set forth in parts 54 and 51 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or, if the investigation was subject to but was not conducted in compliance with such requirements, a statement describing in detail all differences between the practices used in conducting the investigation and those required in such regulations.

* * * * *

b. In § 514.8 by adding paragraph (m) to read as follows:

§ 514.8 Supplemental new animal drug applications.

* * * * *

(m) A supplemental application that contains clinical investigations shall include, with respect to each investigation, either a statement that the investigation was conducted in compliance with the requirements set forth in parts 54 and 511 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or, if the investigation was subject to but was not conducted in compliance with such requirements, a statement that describes in detail all differences between the practices used in conducting the investigation and those required in such regulations.

(c) In § 514.15 by adding paragraph (d) to read as follows:

§ 514.15 Untrue statements in applications.

* * * * *

(d) Any clinical investigation contained in the application was subject to but was not conducted in compliance with the requirements set forth in parts 54 and 511 of this chapter, and differences between the practices used in conducting the investigation and those required in such regulations were not described in detail.

d. In § 514.110 by adding paragraph (b)(9) to read as follows:

§ 514.110 Reasons for refusing to file applications.

* * * * *

(b) * * *

(9) It fails to include, with respect to each clinical investigation contained in the application, either a statement that the investigation was conducted in compliance with the requirements set forth in parts 54 and 511 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or, if the investigation was subject to but was not conducted in compliance with such requirements, a statement that describes in detail all differences between the practices used in conducting the investigation and those required in such regulations.

* * * * *

e. In § 514.111 by adding paragraph (a)(12) to read as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(12) Any clinical investigation contained in the application was subject to but was not conducted in compliance with the requirements set forth in parts 54 and 511 of this chapter, and differences between the practices used in conducting the investigation and those required in such parts were not described in detail.

* * * * *

f. In § 514.115 by adding paragraph (b)(5) to read as follows:

§ 514.115 Withdrawal of approval of applications.

* * * * *

(b) * * *

(5) That any clinical investigation contained in the application was subject to but was not conducted in compliance with the requirements set forth in parts 54 and 511 of this chapter, and differences between the practices used in conducting the investigation and those required in such parts were not described in detail.

* * * * *

PART 570—FOOD ADDITIVES

17. By amending part 570 as follows:

a. In § 570.17 by adding paragraph (d) to read as follows:

§ 570.17 Exemption for investigational use and procedure for obtaining authorization to market edible products from experimental animals.

* * * * *

(d) If intended for clinical investigation in animals other than laboratory research animals, the investigation is conducted in compliance with the requirements set forth in parts 54 and 511 of this chapter.

b. In § 570.35 by adding paragraph (c)(1)(vi) to read as follows:

§ 570.35 Affirmation of generally recognized as safe (GRAS) status.

(c) * * *

(1) * * *

(vi) If clinical investigations are involved, additional information and data submitted in support of filed petitions shall include, with respect to each clinical investigation, either a statement that the investigation was conducted in compliance with the requirements set forth in part 54 of this chapter; or a statement that the investigation is not subject to such requirements in accordance with § 54.2 of this chapter. If the investigation was not conducted in compliance with such regulations, a statement shall be submitted that describes in detail all differences between the practices used in the investigation and those required in the regulations.

PART 571—FOOD ADDITIVE PETITIONS

18. By amending part 571 as follows:

a. In § 571.1 by adding paragraph (l) to read as follows:

§ 571.1 Petitions.

* * * * *

(l) If clinical investigations are involved, petitions filed with the Commissioner under section 409(b) of the act shall include, with respect to each investigation contained in the petition, either a statement that the investigation was conducted in compliance with the requirements set forth in part 54 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or, if the investigation was subject to but was not conducted in compliance with such requirements, a statement that describes in detail all differences between the practices used in the investigation and those required in the regulations.

b. By revising § 571.6 to add a new concluding sentence, to read as follows:

§ 571.6 Amendment of petition.

After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amounts to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew. Where the substantive amendment proposes a substantial change to the petition which may affect the quality of the human environment, the petitioner shall submit an environmental impact analysis report pursuant to § 25.1 of this chapter. If clinical investigations are involved, additional information and data submitted in support of filed petitions shall include, with respect to each clinical investigation, either a statement that the investigation was conducted in compliance with the requirements set forth in part 54 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or, if the investigation was subject to but was not conducted in compliance with such requirements, a statement that describes in detail all differences between the practices used in the investigation and those required in such part.

PART 601—LICENSING

19. By amending part 601 as follows:

a. In § 601.2 by revising paragraph (a) to read as follows:

§ 601.2 Applications for establishment and product licenses; procedures for filing.

(a) *General.* To obtain a license for any establishment or product, the manufacturer shall make application to the Director, Bureau of Biologics, on forms prescribed for such purpose, and in the case of an application for a product license, shall submit data derived from laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity, and potency; with respect to each clinical investigation, either a statement that the investigation was conducted in compliance with the requirements set forth in parts 54 and 312 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or, if the investigation was subject to but was not conducted in compliance with such requirements, a statement describing in detail all differences between the practices used in the investigation and those required in the regulations; a full description of manufacturing methods; data establishing stability of the product through the dating period; sample(s) representative of the product to be

sold, bartered, or exchanged or offered, sent, carried or brought for sale, barter or exchange; summaries of results of tests performed on the lot(s) represented by the submitted sample(s); and specimens of the label, enclosures, and containers proposed to be used for the product. An application for license shall not be considered as filed until all pertinent information and data are received from the manufacturer by the Bureau of Biologics. The applicant shall also include an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the biological product pursuant to § 25.1 of this chapter. In lieu of the procedures described in this paragraph, applications for radioactive biological products shall be handled as set forth in paragraph (b) of this section.

* * * * *

b. In § 601.25 by revising paragraph (h)(1) and adding a new paragraph (k) to read as follows:

§ 601.25 Review procedures to determine that licensed biological products are safe, effective, and not misbranded under prescribed, recommended, or suggested conditions of use.

* * * * *

(h) *Additional studies.* (1) Within 30 days following publication of the final order, each licensee for a biological product designated as requiring further study to justify continued marketing on an interim basis, pursuant to paragraph (f)(3) of this section, shall satisfy the Commissioner of Food and Drugs in writing that studies adequate and appropriate to resolve the questions raised about the products have been undertaken, or the Federal Government may undertake these studies. Any such study involving a clinical investigation shall be conducted in compliance with the requirements set forth in parts 54 and 312 of this chapter, unless it is not subject to such requirements in accordance with § 54.2 of this chapter. The Commissioner may extend this 30-day period if necessary, either to review and act on proposed protocols or upon indication from the licensee that the studies will commence at a specified reasonable time. If no such commitment is made, or adequate and appropriate studies are not undertaken, the product license or licenses shall be revoked.

* * * * *

(k) *Clinical investigations.* Information and data submitted under this section after (insert effective date of final order promulgating this paragraph) shall include, with respect to each clinical investigation, either a statement that the investigation was conducted in compliance with the requirements set forth in part 54 of this chapter; or a statement that the investigation was not subject to such requirements in accordance with § 54.2 of this chapter; or if the investigation was subject to but was not conducted in the compliance with such requirements, a statement that describes in detail all differences between the practices used in the investigation and those required in the regulations.

c. By revising § 601.30 to read as follows:

§ 601.30 Licenses required; products for controlled investigation only.

Any biological or trivalent organic arsenical manufactured in any foreign country and intended for sale, barter, or exchange shall be refused entry by collectors of customs unless manufactured in an establishment holding an unsuspended and unrevoked establishment and product license. Unlicensed products that are not imported for sale, barter, or exchange and that are intended solely for purposes of controlled investigation are admissible only if the investigation is conducted in accordance with section 505 of the Federal Food, Drug, and Cosmetic Act, as amended, and the requirements set forth in parts 54 and 312 of this chapter.

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

20. By amending part 630 as follows:

a. In § 630.11 by revising the first sentence to read as follows:

§ 630.11 Clinical trials to qualify for license.

To qualify for license, the antigenicity of the vaccine shall have been determined by clinical trials of adequate statistical design conducted in compliance with parts 54 and 312 of this chapter. * * *

* * * * *

b. In § 630.31 by revising the first sentence to read as follows:

§ 630.31 Clinical trials to qualify for license.

To qualify for license, the antigenicity of the vaccine shall have been determined by clinical trials of adequate statistical design conducted in compliance with parts 54 and 312 of this chapter, by subcutaneous administration of the product. * * *

* * * * *

c. By revising § 630.51 to read as follows:

§ 630.51 Clinical trials to qualify for license.

To qualify for license, the antigenicity of mumps virus vaccine, live, shall be determined by clinical trials conducted in compliance with parts 54 and 312 of this chapter that follow the procedures prescribed in § 630.31, except that the immunogenic effect shall be demonstrated by establishing that a protective antibody response has occurred in at least 90 percent of each of the five groups of mumps-susceptible individuals, each having received the parenteral administration of a virus vaccine dose that is not greater than that which was demonstrated to be safe in field studies under § 630.50(b) when used under comparable conditions.

d. By revising § 630.61 to read as follows:

§ 630.61 Clinical trials to qualify for license.

To qualify for license, the antigenicity of rubella virus vaccine, live, shall be determined by clinical trials conducted in compliance with parts 54 and 312 of this chapter that follow the procedures prescribed in § 630.31, except that the immunogenic effect shall be demonstrated by establishing that a protective antibody response has occurred in at least 90 percent of each of the five groups of rubella-susceptible individuals, each having received the parenteral administration of a virus vaccine dose that is not greater than that which was demonstrated to be safe in field studies when used under comparable conditions.

e. In § 630.81 by revising the first sentence to read as follows:

§ 630.81 Clinical trials to qualify for license.

In addition to demonstrating that the measles component meets the requirements of § 630.31, the measles and smallpox antigenicity of the final product shall be determined by clinical trials of adequate statistical design conducted in compliance with parts 54 and 312 of this chapter and with three consecutive lots of final vaccine manufactured by the same methods and administered as recommended by the manufacturer. * * *

* * * * *

PART 1003—NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

21. In § 1003.31 by revising paragraph (b) to read as follows:

§ 1003.31 Granting the exemption.

* * * * *

(b) Such views and evidence shall be confined to matters relevant to whether the defect in the product or its failure to comply with an applicable Federal standard is such as to create a significant risk of injury, including genetic injury, to any person and shall be presented in writing unless the Secretary determines that an oral presentation is desirable. Where such evidence includes clinical investigations, the data submitted shall include, with respect to each clinical investigation, either a statement that each investigation was conducted in compliance with the requirements set forth in part 54 of this chapter; or a statement that the investigation is not subject to such requirements in accordance with § 54.2 of this chapter. If the investigation was not conducted in compliance with such regulations, a statement shall be submitted that describes in detail all differences between the practices used in the investigation and those required in the regulations.

* * * * *

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

22. By amending part 1010 as follows:

In § 1010.4 by adding paragraph (b)(1)(x) to read as follows:

§ 110.4 Variances.

* * * * *

(b) * * *

(1) * * *

(x) If the electronic product is used in a clinical investigation, the investigation shall be conducted in compliance with the requirements set forth in part 54 of this chapter.

* * * * *

b. In § 1010.5 by revising paragraph (c)(12) to read as follows:

§ 1010.5 Exemptions for products intended for United States Government use.

* * * * *

(c) * * *

(12) Such other information required by regulation or by the Director, Bureau of Radiological Health, to evaluate and act on the application. Where such information includes clinical investigations, the information shall include, with respect to each clinical investigation, either a statement that each investigation was conducted in compliance with the requirements set forth in part 54 of this chapter; or a statement that the investigation is not subject to such requirements in accordance with § 54.2 of this chapter. If the investigation was not conducted in compliance with such regulations, a statement shall be submitted that describes in detail all differences between the practices used in the investigation and those required in the regulations.

* * * * *

Interested persons may, on or before Novembers 6, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the hearing clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

NOTE.—The Food and Drug Administration has determined that this document does not contain a major proposal requiring preparation of an economic impact statement under Executive Order 11821 (as amended by Executive Order 11949) and OMB Circular A-107. A copy of the economic impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Dated: August 1, 1978.

DONALD KENNEDY,
Commissioner of Food and Drugs.

[FR Doc. 78-21790 Filed 8-7-78; 8:45 am]

federal register

TUESDAY, AUGUST 8, 1978
PART VI



CONSUMER PRODUCT SAFETY COMMISSION

■

CELLULOSE INSULATION STANDARD

Withdrawal of Notice of Proceeding and Establishment of Interim Safety Standard

[6355-01]

CONSUMER PRODUCT SAFETY COMMISSION

CELLULOSE INSULATION

Withdrawal of Notice of Proceeding to Develop a Standard; Extension of Time To Propose an Amendment to the Interim Standard

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of withdrawal of notice of proceeding to develop a standard; notice of extension of time for proposing an amendment to the interim standard.

SUMMARY: In this notice the Commission withdraws a March 13, 1978 notice of proceeding to develop a consumer product safety standard for cellulose insulation. The Commission takes this action because, as required by legislation enacted on July 11, 1978, the Commission has issued an interim safety standard for cellulose insulation, which is published elsewhere in this FEDERAL REGISTER; therefore, the Commission's proceeding to develop a standard is unnecessary.

In this notice, the commission also extends, for 150 days, from August 24, 1978 until January 22, 1979, the time in which it must publish a revised GSA specification as a proposed amendment to the interim standard for cellulose insulation. The July 11, 1978 legislation requires the Commission to propose the amendment by August 24, but allows the Commission to extend the time. The Commission is extending the time for proposing an amendment to the interim standard, in order to further study the technical and scientific basis and safety and economic consequences of the revised GSA specification.

DATES: The time for the Commission to publish a proposed amendment to the interim standard is extended from August 24, 1978 until January 22, 1979.

FOR FURTHER INFORMATION CONTACT:

Philip Bechtel, Office of the General Counsel, Consumer Product Safety Commission, Washington, D.C. 20207, 202-634-7770.

SUPPLEMENTARY INFORMATION:

WITHDRAWAL OF NOTICE OF PROCEEDING TO DEVELOP A STANDARD

The Commission began a proceeding to develop a consumer product safety standard for cellulose home insulation under section 7 of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2056) by a notice in the FEDERAL REGISTER of March 13, 1978 (43 FR 10427) in which the Commission invited any interested person to submit either (1) an offer to develop a recommended consumer product safety standard or (2) an existing standard to serve as a recommended consumer product safety standard. The Commission began this proceeding after it preliminarily determined that fire hazards associated with cellulose home insulation constitute unreasonable risks of death or injury and that a consumer product safety standard is necessary to eliminate or reduce those unreasonable risks. In response to the notice of proceeding, the Commission received nine submissions from interested persons by the due date of April 12, 1978, and two submissions after that date. In a notice published in the FEDERAL REGISTER of May 9, 1978 (43 FR 19905) the Commission extended from May 12, 1978 until August 31, 1978 the period for it to evaluate the offers and decide whether to accept an offer to develop a recommended standard. The Commission extended the time because legislation was pending in Congress to require the Commission to publish within a short period of time an interim consumer product safety standard.

On July 11, 1978 this legislation became law (Pub. L. 95-319) requiring the Commission to publish an interim standard by August 24, 1978. The legislation provides that the interim standard is to consist of the requirements for flame resistance and corrosiveness from the General Services Administration (GSA) specification for cellulose insulation (HH-I-515C) and any technical nonsubstantive changes the Commission wishes to make in these provisions. In a notice published elsewhere in this issue of the FEDERAL REGISTER the Commission has published the interim standard (16 CFR part 1209). Because the interim standard contains requirements to help eliminate or reduce an unreasonable risk of injury to consumers from flammable or corrosive cellulose insulation, the Commission does not believe that it is necessary to continue its own proceeding under section 7 of the CPSA. In addition, Pub. L. 95-319 requires the Commission to propose within a short time period, as amendments to the interim standard, each revision to the requirements for flame resistance and corrosiveness GSA issues. GSA has recently issued a revision, HH-I-515D, containing requirements for flame resistance and corrosiveness that supersede the requirements of HH-I-515C. If this revision is incorporated into the interim rule, the revision may provide additional protection to the public without the need for the Commission to develop its own standard under section 7 of the act. Therefore, in accordance with section 7 of the CPSA the Commission withdraws the notice of proceeding to develop a standard to address the risk of injury from fires associated with cellulose (43 FR 10427, March 13, 1978).

EXTENSION OF TIME TO PROPOSE AN AMENDMENT TO THE INTERIM STANDARD

Pub. L. 95-319 requires the Commission to publish as a proposed amendment to the Commission's interim standard for cellulose insulation each revision issued by GSA that supersedes the requirements for flame resistance and corrosiveness in GSA specification HH-I-515C. The Commission must publish such a revision as a proposed amendment within 45 days after having received notice from the Administrator of the General Services Administration, or, if a revision becomes effective between February 1, 1978 and the effective date of the act, within 45 days of the effective date of the act. Pub. L. 95-319 provides that the Commission may extend the 45-day period for publishing the proposed amendment by 150 days if the Commission determines that an extension is necessary to study the technical and scientific basis for the revision, or to study the safety and economic consequences of the revision.

On June 15, 1978, GSA specification HH-I-515D became effective. This specification contains requirements for the flame resistance and corrosiveness of cellulose insulation that supersede the flame resistance and corrosiveness provisions of HH-I-515C. Therefore, the Commission must publish the proposed amendment to the interim standard by August 24, 1978, unless the Commission extends this period.

The Commission believes that it is necessary to extend the period of time for proposing the flame resistance and corrosiveness requirements of HH-I-515D as an amendment to the interim standard in order to study the technical and scientific basis and the safety and economic consequences of these requirements. Pub. L. 95-319 provides that the Commission may not issue an amendment to the interim standard if the Commission determines, after considering public comments, that the amendment is not necessary to protect consumers from the unreasonable risk of injury associated with flammable or corrosive cellulose insulation or if the Commission determines that implementation of the amendment will create an undue burden on persons subject to the interim standard. Therefore, the Commission is required to consider these issues.

The Commission expects that an extension of the time to propose an amendment to the interim standard will allow the Commission to fill gaps in the technical data, consolidate and update current economic data, and resolve data conflicts in both the technical and economic areas. Professional

technical judgment on the properties and performance of cellulose insulation continues to vary among industry experts. Additional technical knowledge may provide assistance in analyzing the economic consequences of the revision. Corrosion testing of cellulose insulation has been conducted by Underwriters Laboratories and Dynatech R/D Company in recent weeks. Preliminary indications are that a high percent of the material tested failed. Results of the corrosion test in the interim standard are not expected to vary to a significant degree from results of corrosion tests under the revision to the interim standard. As a result, empirical data on the corrosion test in the interim standard, which will be generated when the interim standard becomes effective, on September 8, 1978, may assist in evaluating the economic consequences of the revision. The Commission believes that an extension of 150 days is necessary to study the technical and scientific basis and safety and economic consequences of the revision. If the Commission is able to complete its work before January 22, 1979, the Commission will publish the proposal at an earlier date. Therefore, in accordance with section 35(c)(2)(c)(ii) of the act, as amended by Pub. L. 95-319, the Commission extends by 150 days, from August 24, 1978 until January 22, 1979, the time in which it must publish the flame resistance and corrosiveness requirements of GSA specification HH-I-515D as a proposed amendment to the interim standard for cellulose insulation at 16 CFR part 1209. In accordance with Pub. L. 95-319, this period may be further extended by the Commission if that becomes necessary.

Dated: August 2, 1978.

SHELDON D. BUTTS,
Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 78-22035 Filed 8-7-78; 8:45 am]

[6355-01]

Title 16—Commercial Practices

CHAPTER II—CONSUMER PRODUCT SAFETY COMMISSION

PART 1209—INTERIM SAFETY STANDARD FOR CELLULOSE INSULATION

Establishment of Interim Safety Standard

AGENCY: Consumer Product Safety Commission.

ACTION: Establishment of interim standard.

SUMMARY: In this document the Commission issues an interim mandatory safety standard to eliminate or reduce unreasonable risks of injury to consumers from flammable and corrosive cellulose insulation. In recently enacted legislation, Congress directed the Commission to issue this interim standard. The interim standard is based on flame resistance and corrosiveness provisions in a Federal specification for cellulose insulation issued by the General Services Administration (HH-I-515C). In addition, the interim standard requires manufacturers and private labelers of cellulose insulation to provide a specific informative label on all containers of cellulose insulation.

DATES: The interim standard is effective on September 8, 1978. Cellulose insulation manufactured after September 7, 1978, must comply with the interim standard.

FOR FURTHER INFORMATION CONTACT:

Wade D. Anderson, Directorate for Compliance and Enforcement, Consumer Product Safety Commission, Washington, D.C. 20207, 301-492-6400.

SUPPLEMENTARY INFORMATION:

I. BACKGROUND

LEGISLATION

On July 11, 1978, the "Emergency Interim Consumer Product Safety Standard Act of 1978," Pub. L. 95-319, became law. This legislation amended the Consumer Product Safety Act (CPSA) (15 U.S.C. 2051 et seq.) by adding a new section, section 35, that provides an interim consumer product safety standard for cellulose insulation. In establishing this interim standard, Congress found that:

(1) Existing Federal, State, and local laws and regulations are insufficient to protect the consumer from improperly manufactured cellulose insulation;

(2) An unreasonably large quantity of cellulose insulation is being distributed that does not meet minimum safety standards;

(3) An urgent need exists for the expedited setting of interim mandatory Federal standards for the manufacture of cellulose insulation; and

(4) Such standards are reasonably necessary to eliminate or reduce an unreasonable risk of injury to consumers from flammable or corrosive cellulose insulation.

The new section 35(a)(1) of the CPSA, provides that 60 days after July 11, 1978, the day the legislation became law, the requirements for flame resistance and corrosiveness in the General Services Administration's (GSA) specification for cellulose insulation, HH-I-515C (as that specification was in effect on February 1, 1978) are considered to be an interim consumer product safety standard having all the authority and effect of any other consumer product safety standard issued by the Commission under the Act.

Section 35(a)(2) of the Act requires the interim consumer product safety standard to provide that any cellulose insulation that is a consumer product must have a flame spread rating of 0 to 25, determined in accordance with the test procedures as provided by the GSA specification. The legislation provides that during the 45-day period after the effective date of the legislation, the Commission may make technical nonsubstantive changes in the GSA specification to make the requirements suitable for issuance as a consumer product safety standard. During this 45-day period the Commission must publish in the FEDERAL REGISTER any technical nonsubstantive changes it makes to GSA specification HH-I-515C.

In accordance with the legislation, by September 8, 1978, the Commission must publish in the FEDERAL REGISTER the interim consumer product safety standard, as altered. In this document the Commission is publishing the technical nonsubstantive changes it has made to he GSA requirements and is publishing the interim standard, as altered by these changes.

Section 35(b) of the Act provides that judicial review of the interim consumer product safety standard, is limited solely to the issue of whether any technical changes made by the Commission are nonsubstantive.

Section 35(c)(1)(A) of the Act provides that any interim consumer product safety standard established under that section is to be enforced in the same manner as any other consumer product safety standard. A violation of the interim standard is considered to be a violation of a consumer product safety standard issued by the Commission under section 9 of the Act. Thus, on and after the effective date of the interim standard, it shall be an unlawful act under secion 19(a) of the CPSA (15 U.S.C. 2068(a)) for any person to manufacture for sale, offer for sale, distribute in commerce, or import into the United States any cellulose insulation subject to the interim standard which is not in conformity with this interim standard. The civil and criminal penalty provisions of sections 20 and 21 of the Act (15 U.S.C. 2069, 2070) are available to the Commission in enforcing this interim standard. In addition, the injunctive and seizure enforcement provisions of section 22 of the Act (15 U.S.C. 2071) are available to the Commission in enforcing the interim standard.

REVISIONS TO THE INTERIM STANDARD AND ESTABLISHMENT OF A FINAL STANDARD

The "Emergency Interim Consumer Product Safety Standard Act of 1978" provides, at section 35(c)(1)(B), that the Commission must issue a final safety standard for cellulose insulation if it determines that the interim consumer product safety standard does not adequately protect the public from the unreasonable risk of injury associated with flammable or corrosive cellulose insulation. A final standard must be issued under 5 U.S.C. 553, except that the Commission must give interested persons an opportunity for the oral presentation of data, views, or arguments in addition to an opportunity to make written submissions. A transcript must be kept of any oral presentation. The provisions of section 9 (b), (c), and (d) of the Act apply to the issuance of a final standard.

The "Emergency Interim Consumer Product Safety Standard Act of 1978" also provides that until a final consumer product safety standard is in effect, the Commission must incorporate into the interim standard each revision GSA issues that supersedes the requirements for flame resistance and corrosiveness in GSA specification HH-I-515C. The Commission must propose the revision and give interested persons an opportunity to comment on any proposed amendment. The Commission must issue the amendment unless the Commission determines, after consulting with the Secretary of Energy, that the amendment is not necessary to protect consumers from the unreasonable risk of injury associated with flammable or corrosive cellulose insulation or that implementation of the amendment will create an undue burden on persons who are subject to the interim consumer product safety standard.

The General Services Administration has informed the Commission that, effective June 15, 1978, it has issued GSA specification HH-I-515D. Since this specification contains requirements for flame resistance and

corrosiveness for cellulose insulation that supersede the requirements of GSA specification HH-I-515C, the Commission is required by Pub. L. 95-319 to publish the flame resistance and corrosiveness provisions of HH-I-515D as a proposed amendment to the interim standard issued here. Elsewhere in this issue of the FEDERAL REGISTER the Commission has extended, from August 24, 1978, until January 22, 1979, the time in which it must publish the proposed amendment to the interim standard.

COMMISSION ACTIVITIES CONCERNING CELLULOSE INSULATION

On October 20, 1976, the Commission received a petition (CP 77-1) from the Metropolitan Denver District Attorney's Consumer Office requesting the Commission to initiate a standard development proceeding to address certain risks of injury alleged to be associated with cellulose, fibrous glass, and plastic foam/resin home insulation.

After considering information gathered by its staff in analyzing the issues raised by the petition, the Commission, on August 22, 1977, held a public meeting to enable interested persons to present data, views, and arguments to assist the Commission in determining whether or not the petition should be granted. The Commission solicited written comments on the petition until October 21, 1977. After considering the oral and written comments, as well as an oral briefing of the issues by the staff, the Commission on November 10, 1977, instructed the staff to prepare a briefing package and a draft FEDERAL REGISTER notice to initiate a standard development proceeding to address the fire hazards associated with cellulose home insulation. On February 9, 1978, after considering this information, the Commission preliminarily determined that a consumer product safety standard is necessary to eliminate or reduce the unreasonable risk of injury from fire associated with cellulose home insulation.

On March 13, 1978, the Commission published a notice in the FEDERAL REGISTER (43 FR 10427) to begin a proceeding under section 7 of the CPSA (15 U.S.C. 2056) to develop a mandatory standard to address the unreasonable risk of injury from fire associated with cellulose home insulation. The notice invited interested persons to submit either (1) an offer to develop a recommended consumer product safety standard or (2) an existing standard to serve as a recommended consumer product safety standard. In response to the notice of proceeding, the Commission received 11 submissions from interested persons. As a result of the passage of the legislation and the Commission's issuance of an interim safety standard for cellulose insulation, the Commission, in a notice published elsewhere in this issue of the FEDERAL REGISTER, has withdrawn the notice of proceeding.

II. DESCRIPTION OF THE INTERIM STANDARD

The interim standard, 16 CFR Part 1209, published below, prescribes flame resistance and corrosion requirements for cellulose insulation manufactured for use as a consumer product. The interim standard applies to all such cellulose insulation manufactured after September 7, 1978

Although the interim standard prescribes test methods to determine whether cellulose insulation meets the requirements of the interim standard, the interim standard itself does not require that a manufacturer test products. However, section 14 of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2063) requires any manufacturer or private labeler of a product subject to a standard to certify that the product conforms to the standard. The certification must be based on either a test of each product or a reasonable testing program. The Commission may in the future issue regulations or provide guidelines as to what constitutes a reasonable testing program for certification purposes. However, for the present, manufacturers and private labelers must determine what constitutes a testing program adequate to insure that the product being produced and distributed conforms to the interim standard. For the present, for purposes of enforcement, the Commission intends to use the test procedures in the interim standard to determine whether items meet the requirements of the standard.

After September 7, 1978, no person shall manufacture for sale, offer for sale, distribute in commerce, or import into the United States cellulose insulation subject to the interim standard which does not comply with the interim standard. Cellulose insulation manufactured before September 8, 1978, is not subject to the interim standard and may be offered for sale, distributed in commerce, or imported into the United States after the effective date of the interim standard.

As provided by Pub. L. 95-319, the interim standard is intended to eliminate or reduce the unreasonable risk of injury to consumers presented by flammable and corrosive cellulose insulation. The interim standard contains the requirements for flame resist- ance and corrosiveness set forth in the GSA specifications for cellulose insulation HH-I-515C (as that specification was in effect on February 1, 1978). In addition, it contains requirements imposed by Pub. L. 95-319. In particular, the interim standard is based on the following:

1. Paragraph 3.1 of the GSA specification, which specifies material requirements relating to flame resistance permanency and corrosion by referencing American Society for Testing and Materials (1916 Race Street, Philadelphia, Pa. 19103) (ASTM) C 739-77 "standard specification for cellulosic fiber (wood-base) loose fill thermal insulation" (ASTM C 739-77),

2. Subparagraph 3.2.1 of the GSA specification, which provides for a specified flame spread rating when tested in accordance with ASTM E 84-77a "standard test method for surface burning characteristics of building materials" (ASTM E 84-77a),

3. Provisions of ASTM C 519-65 "standard test method for density of fibrous loose fill building insulation" (ASTM C 519-65) providing alternate test methods for determining the density of insulation as specified by the manufacturer, or chosen by the Commission where the manufacturer does not specify the test method for determining density,

4. Provisions of ASTM D 2016-74 "standard test methods for moisture content of wood" (ASTM D 2016-74) providing a standard test method for determining the moisture content of wood. These provisions are referenced in the procedures for calibration of test equipment for determining flame spread classification that are included in ASTM C 739-77 and ASTM E 84-77a respectively,

5. The requirement in the act that cellulose insulation must have a flame spread rating of 0 to 25, when tested in accordance with the procedures in the interim standard, and

6. The requirement in the act for labeling of containers of cellulose insulation.

Following is a section-by-section description of the interim standard.

A. SCOPE AND APPLICATION (§ 1209.1)

Section 1209.1 of the interim standard describes its scope and application. As required by the act, the interim standard prescribes flame resistance and corrosion requirements for cellulose insulation. The interim standard applies to celluose insulation that is a consumer product, i.e. insulation that is produced or distributed for sale to or for the personal use, consumption, or enjoyment of consumers in or around a permanent or temporary household or residence, a school, in recreation, or otherwise. The interim standard applies to cellulose insulation that is produced or distributed for sale to consumers for their direct installation or use, as well as insulation that is produced or distributed for installation by professionals. As required by section 9(d)(1) of the act (15 U.S.C.

2058(d)(1)) and the new section 35(a)(1), the interim standard applies only to cellulose insulation manufactured on or after the effective date of the interim standard (September 8, 1978).

B. DEFINITIONS (§ 1209.2)

Section 1209.2 of the interim standard defines the consumer product covered by the interim standard. For purposes of the interim standard, "cellulose insulation" means cellulosic fiber, loose fill, thermal insulation that is suitable for blowing or pouring applications. The definition includes insulation installed using the "wet process" method of installation. (The "wet process" insulation is blown into an area with a spray or mist of water applied at the nozzle during installation.)

C. GENERAL REQUIREMENTS (§ 1209.3)

Section 1209.3 of the interim standard lists the general requirements of the interim standard. Section 1209.3(a) requires all cellulose insulation covered by the interim standard to have a flame spread rating not greater than 25 when tested in accordance with the test procedures at § 1209.4. This provision is required by the new section 35(a)(2) of the act. Paragraph 1.2 of the GSA specification requires insulation to be of either of two classes—one with a flame spread rating of 0–25 and the other with a flame spread rating of 26–50, when tested in accordance with the test method provided in ASTM E 84–77a (the test method provided at section 1209.4 of the interim standard). The legislative history of Pub. L. 95–319 indicates that Congress intended the interim standard to narrow the range of acceptable cellulose insulation for a number of reasons. First, the GSA specification at paragraph 6.6 recommends that cellulose insulation with a flame spread rating not exceeding 25 be used in applications which require a higher flame spread resistance. The legislative history states that installation of cellulose insulation in homes presents such a situation. In addition, because the conditions where cellulose insulation is installed and installation techniques for insulation for consumer use cannot always be checked as they could in a GSA procurement situation, the legislative history concludes that caution requires the use of material with greater flame resistance. According to the legislative history, a flame spread rating of 0–25 should provide a greater measure of safety to consumers. (H.R. Rept. No. 95–1116 95th Cong., 2d sess., 5 (1978).)

Section 1209.3(b) of the interim standard requires all cellulose insulation covered by the interim standard to be treated with fire retardant chemicals that are permanent when tested in accordance with the flame resistance permanency test at § 1209.5 of the interim standard. This requirement is derived from paragraph 3.1 of the GSA specification HH–I–515C, which requires cellulose insulation to be in accordance with ASTM C 739–77. ASTM C 739–77 provides a test for flame resistance permanency, at paragraph 10.4, designed to determine the permanency of the chemicals used as fire retardants. The requirement that fire retardant chemicals be permanent has been included in the interim standard as a flame resistance requirement since this property directly affects the flame resistance of the cellulose insulation. Cellulose insulation that is manufactured with fire retardant chemicals that are not permanent in nature may not retain the flame resistant properties required by the interim standard.

Section 1209.3(c) of the interim standard requires that all cellulose insulation subject to the standard not be corrosive when tested in accordance with the test procedures for corrosiveness at § 1209.6. Section 35(a)(1) of the act requires the Commission to include in the interim standard the requirements for corrosiveness in GSA specification HH–I–515C. This requirement at § 1209.3(c) is derived from paragraph 3.1 of the GSA specification HH–I–515C, which requires cellulose insulation to be in accordance with ASTM C 739–77. ASTM C 739–77, at paragraph 10.7, provides a test to determine the corrosive properties resulting from high humidity and moisture and from chemical constituents of the insulation, which may react with metal sidings and other metallic building materials.

Section 1209.3(d) of the interim standard requires containers of cellulose insulation to have a labeling statement in accordance with the labeling requirements at section 1209.9. Section 35(a)(3) of the act requires each manufacturer or private labeler of cellulose insulation to include this statement on any container of cellulose insulation.

The Commission has not included in this interim standard the requirement at paragraph 3.2.2 of HH–I–515C that material have a smoke developed rating not greater than 50 when tested in accordance with ASTM E 84. Section 35(a)(1) of the act, as amended, requires the Commission to include the requirements for flame resistance and corrosiveness set of forth in HH–I–515C. The smoke developed rating requirement of HH–I–515C has not been included in the interim standard since it is not part of the requirements for flame resistance or corrosiveness set forth in HH–I–515C.

Paragraph 1.3 of ASTM E 84–77a states that there is not necessarily a relationship among measurements for smoke density and flame spread rate. The smoke developed rating measurement of subparagraph 3.2.2 of HH–I–515C does not necessarily establish a relationship between the density of smoke and its lethality. For example, although low levels of particulate matter may be detected from the combustion of some materials, giving a passing smoke development rating, the level of CO gas may be high. A frequently stated cause of death associated with fires is smoke inhalation of toxic gases, such as CO and CO_2. The Commission has also not included in the interim standard the provisions of ASTM E 84–77a for recording photoelectric cell measurements and determining smoke developed rating, since these provisions are not part of the flame resistance or corrosiveness provisions of HH–I–515C.

Although the interim standard does not include those provisions of GSA specification HH–I–515C that reference the procedure for determining smoke developed rating (ASTM E 84–77a, 3.8, 5.8, 5.9, 6.4, 6.7, 7.2) the Commission believes that the equipment used to measure smoke developed rating should be included in the description of the Steiner Tunnel test apparatus for determining flame resist- ance. Accordingly, at § 1209.4(a)(7) and (8) the Commission has included in the description of the Steiner Tunnel test apparatus the description of the equipment in ASTM E 84–77a used to obtain a measure of the smoke developed rating. This equipment is normally used in conjunction with the Steiner Tunnel test apparatus. Although the equipment is not used in testing under this standard, the description of the apparatus includes this equipment since removal of the equipment could conceivably cause variability of test results.

The Commission has not included subparagraph 1.1 of HH–I–515C, Scope, as part of the interim standard since this subparagraph refers to the scope of the GSA specification and is inappropriate for inclusion as part of a mandatory standard. However, at § 1209.1 of the interim standard the Commission has included a section that describes the scope and application of the interim standard, as provided by Pub. L. 95–319.

The Commission has not included paragraph 2 of HH–I–515C, applicable documents, as part of the interim standard since the interim standard includes the applicable text of ASTM C 739–77 and ASTM E 84–77a and the documents in paragraph 2 of HH–I–515C that are included in the flame resistance and corrosiveness requirements of HH–I–515C.

The Commission has also not included in the interim standard the requirement at paragraph 3.1.4 of HH–I–515C

that the density of loose fill insulation must be not more than 3 pounds per cubic foot when tested as specified in ASTM C-739. This requirement has not been included in the interim standard since it is not part of the requirements for flame resistance or corrosiveness set forth in HH-I-515C.

The Commission has not included in the interim standard subparagraphs 3.1.2 reclaimed fibers, 3.1.3 reclaimed fiber content, 3.1.5 starch, and 3.2.3 workmanship, of HH-I-515C since these subparagraphs are not part of the flame resistance or corrosiveness requirements of HH-I-515C.

The Commission has not included in the interim standard paragraphs 3.2 marking, 4 quality assurance provisions, 5 preparation for delivery, and 6 notes, of HH-I-515C since these paragraphs are not part of the flame resistance or corrosiveness requirements of HH-I-515C.

D. TECHNICAL, NONSUBSTANTIVE CHANGES IN THE FLAME RESISTANCE AND CORROSION REQUIREMENTS OF GSA SPECIFICATION HH-I-515C.

The new section 35(a)(1) of the CPSA authorizes the Commission to make technical, nonsubstantive changes in the flame resistance and corrosion requirements of GSA specification HH-I-515C to make these requirements suitable for issuance as a consumer product safety standard. Section 35(b) provides that judicial review of the interim standard is limited solely to the issue of whether any technical changes the Commission has made are nonsubstantive. Section 35(b) of the act also provides that for purposes of judicial review, any change made by the Commission which requires any test to determine the flame spread rating of cellulose insulation to include a correction for variations in test results caused by equipment used in the test shall be considered a technical, nonsubstantive change.

The legislative history of the act describes technical nonsubstantive changes as "changes which will not create a significant impact on the regulated industry." (H.R. Rep. No. 95-1322, 95th Cong., 2d sess. 9 (1978) and H.R. Rep. No. 95-1116, 95th Cong., 2d sess. 5 (1978).)

In attempting to apply the legislative criteria to the changes it has made to the GSA specification the Commission believes it is helpful to examine cases where the courts have considered similar criteria for assessing the impact of administrative actions on regulated industry. In interpreting the notice and comment requirements under the Administrative Procedure Act (5 U.S.C. 553) the court in *Pharmaceutical Manufacturer's Association* v. *Finch*, 307 F. Supp. 858 (1970), held that certain regulations were invalidly issued without an opportunity for notice and comment since the regulations would have had a substantial impact on persons affected by the regulations. The court found that the regulations were pervasive in their scope and had an immediate and substantial impact on the way industry members conducted their everyday business. The regulations applied to more than 2,000 drug products first marketed between 1938 and 1962 with FDA approval and placed all of the products in jeopardy, subject to summary removal by order of the FDA. In *Texaco, Inc.* v. *Federal Power Commission*, 412 F. 2d 740 (3d Cir. 1969), the court held that an administrative rule was invalidly issued without an opportunity for notice and comment since the rule was not "minor". The rule in question would have established for the first time the requirement that compound interest be paid on amounts ordered refunded and would affect many natural gas companies and potentially involve large sums of money. If the considerations in these cases for assessing the impact of administrative action on persons subject to the action are applied to the changes the Commission has made to HH-I-515C, the changes made by the Commission do not have a significant impact on the regulated industry. Manufacturers who are currently complying with the flame resistance and corrosiveness requirements of HH-I-515C would not be subject to a substantial impact on their everyday business and would not be subject to new requirements having a potentially severe impact on their business. The Commission has carefully considered each of the changes it has made to HH-I-515C and has determined that the changes, considered separately and collectively, are technical, nonsubstantive changes that will not create a significant impact on the regulated industry.

In issuing the interim standard, the Commission has made various technical, nonsubstantive changes and editorial changes in the flame resistance and corrosion requirements of the GSA specification. The Commission does not believe that these changes will have a significant impact on the regulated industry. The Commission made these changes in order to:

(1) Ease some of the restrictive specifications for the test apparatus and test procedures,

(2) Simplify the test procedures,

(3) Eliminate provisions in the requirements that are unrelated to cellulose insulation, and

(4) Increase the likelihood that consistent test results will be obtained.

The Commission staff has discussed the technical changes with many persons who operate and are familiar with the test equipment requirements included in the interim standard. None of these persons indicated that the changes would have any impact on the regulated industry, let alone a significant impact.

The Commission has also made several editorial changes in the flame resistance and corrosion requirements of GSA Specification HH-I-515C. These changes are nonsubstantive and are intended to clarify the meaning and application of the requirements and also make the requirements suitable for issuance as a consumer product safety standard. They involve, primarily, changes needed to join together various provisions of the GSA specification that apply to corrosiveness- and flame-resistance requirements.

The Commission has made the following technical nonsubstantive changes:

(1) The Commission has added tolerances to a number of measurements in §§ 1209.4 and 1209.7. The purpose of these tolerances is to allow a limited leeway for variations in test procedures or equipment. The tolerances in describing the test apparatus are included since it is not practical to manufacture commercially a product to zero tolerance. The changes that are included accurately describe existing test apparatus. The changes will not have a significant impact on regulated persons since they will ease restrictive specifications of the test apparatus that could limit the availability of the test apparatus. The tolerances that have been included in describing the distances or durations for recording measurements have been included since it is not practical to record a distance or time duration to a zero tolerance. These changes will not have a significant impact on regulated persons since they will ease some of the restrictive specifications for the test procedures.

The Commission has made the following specific changes related to tolerances:

At § 1209.4(a)(1) of the interim standard, the Commission has included a tolerance of $\pm 1/16$ inch to describe the thickness of the asbestos fabric gasketing tape, as well as a tolerance of ± 3 inches to describe the length of the fire test chamber. At § 1209.4(a)(4) the Commission has replaced nominal 2 inches with a tolerance of 3 ± 1 inch to describe the insulation for the top of the fire chamber. At § 1209.4(a)(5) the Commission has included a tolerance of ± 1 inch to describe the spacing of the burners. At § 1209.4(a)(5) the Commission has added the word "nominal" to describe the pipe elbow burner outlet. This is to indicate that the number is being used as a name or label and may vary with industry custom or practice. At § 1209.4(a)(6)

the Commission has included a tolerance of ±¼ inch to describe the diameter of the flue pipe at the vent end of the fire test chanber. The Commission has also included a tolerance of minus 0, plus 1/16 inch to describe the embedded thermocouple. The Commission has, at § 1209.4(c)(1) included a tolerance of ±1/32 inch to describe the asbestos-cement board. At § 1209.4(c)(3) the Commission has included tolerances of ±1 inch (7 mm) to describe the distance for recording the air velocity from the burner ports and to describe the length of the straightening vanes. At § 1209.4(c)(5) the Commission has included a tolerance of ±6 inches to describe the distance the test flame must extend downstream. At § 1209.4(c)(8) the Commission has included a tolerance of ±6 inches to describe the distance intervals for making observations in calibration tests with red oak flooring that are conducted in the fire test chamber. At § 1209.4(d)(1) the Commission has included tolerances of ±¼ inch and ±1/16 inch to describe the test frame supporting the specimen holder. In this same section, the Commission has described the steel angles of the test frame with nominal dimensions, to indicate that the dimensions may vary with industry custom or practice. At § 1209.4(d)(3) the Commission has included a tolerance of ±2 seconds to describe the duration of the test for determining flame front distance.

(2) At § 1209.4(a)(5) the Commission has included a provision in the description of the fire test chamber that would, as an option of the test operator, allow a draft gage tap to be inserted through the top of the fire end of the tunnel. This change will not have a significant impact on persons subject to the interim standard since it is an option. This location for the draft gage tap to indicate static pressure is currently under consideration by the ASTM Steiner Tunnel operators and is intended to make the test more reproducible. At § 1209.4(c)(3) the Commission has included an alternate air velocity reading range to be used if the draft gage tap is inserted through the top of the "fire end" of a tunnel.

(3) At § 1209.4(a) (7) and (8) the Commission has included in the description of the Steiner Tunnel test apparatus for measuring flame resistance the description of the equipment in ASTM E 84-77a used to obtain a measure of the smoke developed rating. The smoke developed rating measurement is not required under the interim standard, since it is not a part of the flame resistance or corrosiveness requirements of GSA specification HH-I-515C. Accordingly, the interim standard does not include those provisions of the GSA specification HH-I-515C that reference the procedure for determining smoke developed rating (ASTM E 84-77a, 3.8, 5.8, 5.9, 6.4, 6.7, 7.2). However, the Commission believes that the equipment used to measure smoke developed rating should be included in the description of the Steiner Tunnel test apparatus because the smoke developed rating equipment is normally used in conjunction with the Steiner Tunnel test apparatus, and the removal of the equipment could result in variability of the test results.

(4) At § 1209.4(c)(3) the Commission has corrected a typographical error in the ASTM standard. The metric measurement of the air velocity should be expressed as "73.2" instead of "7.32" meters. At § 1209.4(c)(8) the Commission has corrected another typographical error in the ASTM standard. The measurement of the red oak flooring should be 25/32 inch instead of the 23/32 inch.

(5) At § 1209.4(d)(1) the Commission has changed the description of the screen for holding the test specimen from "galvanized steel" to "steel." Operators of the tunnel test apparatus have indicated to the Commission that galvanized steel screens may be difficult to obtain at this time and that many of the tunnel operators are presently using other forms of steel screening. Since the tunnel operators have indicated that the type of steel material used in the screening does not have an effect on the test results, this change would not have a significant impact on persons subject to the interim standard. At § 1209.4(d)(1) of the interim standard, the Commission has included a description of the wire size for the metal screen in order to minimize variations in test results. The tunnel operators have indicated to the Commission that these wire sizes, with the tolerances indicated, are currently being used, so that persons subject to the interim standard would not be affected by the inclusion of this specification.

(6) At § 1209.4(d)(1) the Commission has included a provision that would allow the Commission to determine the density of the cellulose insulation using the blown in and/or poured density test method at § 1209.7, if the manufacturer fails to specify the density of the insulation. The inclusion of this provision will not have a significant impact on persons subject to the standard since this section preserves the option of the manufacturer to specify the density of the insulation. HH-I-515C, through appendix X1.6 of ASTM E 84-77a, provides that in preparing specimens for the flame spread classification test, the insulation shall be packed to the density specified by the manufacturer. By including a provision that would allow the Commission to determine the density, the Commission has avoided the situation where the flame spread classsification test could not be conducted because of the failure of a manufacturer to specify the density of the insulation. The test method at § 1209.7 is derived from ASTM C 519-65, "The Standard Test Method for Density of Fibrous Loose Fill Building Insulation." This test method is commonly used for determining the density of cellulose insulation, and has been referenced in paragraph 3.1.4. of HH-I-515C.

(7) At § 1209.4(f) of the interim standard, the Commission has not included paragraph 8.1 of ASTM E 84-77a, Analysis of Products of Combustion. This paragraph provides that during the progress of the test for determining surface burning characteristics, products of combustion may be drawn from the test duct for chemical analysis. Since this provision is not required as part of the test method and is an optional provision, the Commission does not believe that this provision is apropriate for inclusion in the mandatory standard.

(8) At § 1209.4(f)(4) of the interim standard, the Commission has deleted "delamination" and "shrinkage" as burning characteristics to be observed in the flame spread classification test. Delamination and shrinkage are characteristics that are unrelated to cellulose insulation.

(9) At § 1209.6(a)(4) of the interim standard, the Commission has added 1,1,1-trichloroethane as an analytical reagent that may be used as a substitute for trichloroethylene in the test for corrosiveness. This addition has been made since trichloroethylene may present a carcinogenic hazard and 1,1,1-trichloroethane is a suitable degreasing substitute that has been tested and not found to be a carcinogen. The Commission has learned that at least one major corrosion testing organization is currently using 1,1,1-trichloroethane as an analytical reagent in this test. Although the use of 1,1,1-trichloroethane as a substitute reagent is not required, the Commission strongly recommends that persons conducting the test use 1,1,1-trichloroethane. Since 1,1,1-trichloroethane is a suitable substitute that is currently being used, the change will not have a significant impact on persons subject to the interim standard.

(10) At 1209.7 the Commission has not included an insulation thickness indicator which is included in ASTM C 519-65, Standard Test Method for Density of Fibrous Loose Fill Building Insulation. This indicator has not been included since the Commission does not consider it to be necessary for determining the insulation density. This change will have no effect on persons subject to the standard because the manufacturer has the option of speci-

fying the density at which his insulation should be tested for flame spread and because the density of the insulation can be accurately determined without this device.

E. TEST PROCEDURES (§ 1209.4, § 1209.5, § 1209.6, § 1209.7, § 1209.8)

(1) *Test procedures for flame resistance* (§ 1209.4, § 1209.7, § 1209.8). The interim standard at section 1209.4 includes test procedures for flame resistance. The test procedures at § 1209.4 are those of ASTM E 84-77a, the current version of the standard referenced at subparagraph 3.2.1. of GSA specification HH-I-515C. The test method involves the use of Steiner Tunnel test apparatus to determine how quickly the insulation will burn when compared to other materials. The insulation is assigned a "flame spread classification" based on an evaluation of the rate of flame spread over the surface of the test material when exposed to a test fire. For purposes of establishing a comparison, asbestos-cement board is assigned a flame spread classification of 0 when tested in the tunnel and red oak flooring is assigned a flame spread classification of 100. Section 1209.4(a) describes the design and construction of the fire test chamber. Section 1209.4(b) describes the test specimens and their conditioning.

At § 1209.4(c) the interim standard provides for the calibration of test equipment for conducting the flame spread classification tests. In conducting tests with red oak flooring to properly calibrate the Steiner Tunnel, the interim standard provides at § 1209.4(c)(8) that the red oak flooring must be conditioned to 6- to 8-percent moisture content as determined by the 221° F (105° C) oven-dry method described at § 1209.8. This test method is the oven-dry method in ASTM D 2016-74, "Standard Test Methods for Moisture Content of Wood," as provided in paragraph 5.8 of ASTM E 84-77a. At § 1209.4(c)(9) the interim standard provides that prior to performing the surface burning test for cellulose insulation, the operator must develop a correction factor for the red oak flooring incorporating the steel screening, as described in § 1209.4(b)(2). This correction factor, provided by subparagraph 10.3.1 of ASTM C 739-77, is intended to promote consistency in test results by requiring all test facilities which conduct the surface burning test in accordance with this standard to apply the appropriate correction factor. The metal screen absorbs heat and thus retards flame spread and may make a measurable difference in the determination of the flame spread rating of cellulose insulation. The purpose of the correction factor is to promote uniformity among test results at different test facilities and to insure a flame spread rating that is indicative of the relative performance of the material in the Steiner Tunnel. The test material fails the interim standard if the corrected flame spread classification is over 25.

Since the method for determining flame spread rating under HH-I-515C requires that insulation be tested at a density specified by the manufacturer (appendix X1.6 of ASTM E 84-77a) the Commission has included this provision at § 1209.4(d)(1) of the interim standard. Although § 1209.4(d)(1) preserves the option of the manufacturer under HH-I-515C to specify the density at which the insulation should be tested, this section also provides that if the manufacturer fails to specify a density the Commission will determine the density of the insulation by using the blown in and/or poured density method at § 1209.7.

(2) *Test procedures for flame resistance permanency* (§ 1209.5). The interim standard, at section 1209.5 includes test procedures for determining flame resistance permanency. These test procedures are derived from paragraph 10.4 of ASTM C 739-77 and are required by paragraph 3.1 of GSA specification HH-I-515C. The test procedures subject the insulation to an accelerated aging procedure designed to determine the permanency of the chemicals used as fire retardants by aging a test specimen in a humidity chamber and then testing the aged and nonaged specimen in a 2-foot flame tunnel apparatus. If the insulation tested received a flame spread rating of greater than 20 when tested in the 25-foot Steiner Tunnel then the aged and unaged specimens must be tested directly in the 25-foot tunnel. A numerical determination is made of flame spread of the aged specimen and the nonaged specimen. Where flame spread of the aged specimen in the 2-foot apparatus is 1.20 or more times that of the nonaged specimen, the flame resistance permanency test must be repeated using the 25-foot Steiner Tunnel Test method specified for determining flame spread classification at § 1209.4. A change in flame spread classification in the 25-foot tunnel as modified in this standard constitutes a failure of the test.

(3) *Test procedures for corrosion* (§ 1209.6). The interim standard, at § 1209.6, includes test procedures for corrosion. These test procedures are the test procedures of paragraph 10.7 of ASTM C 739-77 and are required by § 3.1 of GSA specification HH-I-515C. The test is intended to determine the corrosive properties resulting from high humidity or moisture in cellulose insulation. From this action, varying amounts of chemical constituents may migrate resulting in a possible reaction with metallic building materials. The test is an accelerated test intended to simulate conditions likely to cause chemical migration to metallic surfaces. The test involves comparison of corrosion between very thin aluminum, copper, and steel specimens in good contact with water-saturated insulation and duplicate metal control specimens not in contact with the test insulation. Both sets of metal specimens are placed in a humidity chamber for 7 days. Extended 30-day tests are conducted on aluminum and copper coupons when minor surface etching occurs. Extended 30-day tests are conducted on any steel coupon where corrosion of the insulated specimen compares unfavorably with that of its corresponding control specimen. Noncorrosiveness is determined by the absence of any perforations when the metal specimen is observed over a chrome reflected 40-watt appliance light bulb after the extended 30-day test. If any perforation occurs, then the sample has failed the test.

(4) *Reference to brand names.* At several sections the interim standard includes references to particular brands of products that have been found suitable by others for the purposes indicated in the interim standard. (See § 1209.4(a)(1), references to A. P. Green brick, Vycor and Pyrex glass; § 1209.4(a)(2), reference to Zircon; § 1209.4(a)(7) reference to Weston Instruments No. 856BB Photronic cell; § 1209.4(c)(3) reference to Thermo Systems, Inc., Model 1610 velocity transducer; and § 1209.5(a)(2) reference to Custom Scientific Instrument (CSI) 2-foot flame spread test tunnel (Model C-196CL).) These products are referenced in the portions of the ASTM standards that are included in the flammability and corrosion provisions of GSA specification HH-I-515C. Although the Commission staff has not verified that these products are in fact suitable or available for the specified purposes, the products are included in the interim standard as guidance for those persons conducting tests. Equivalent products may, of course, be used for the purposes specified in the interim standard.

III. OTHER CONSIDERATIONS

FINDINGS

Since the "Emergency Interim Consumer Product Safety Standard Act of 1978" establishes the interim consumer product safety standard by legislation, the Commission has not included in this interim standard the findings such as those regarding risk of injury and economic data under section 9(c) of the act (15 U.S.C. 2059(c)) that the Commission must consider before it can issue its own consumer product safety rule. In addition, for the same

reason the Commission has not included information usually required under section 9(b) of the act (15 U.S.C. 2058(b)) regarding special needs of elderly and handicapped persons to determine the extent to which such persons may be adversely affected by the rule. However, the Commission has no information suggesting that the interim standard would have any adverse effect on elderly and handicapped persons.

The National Environmental Policy Act requires all Federal agencies to prepare environmental impact statements on major Federal actions significantly affecting the quality of the environment. Since publication of this interim standard without substantive change is required by the legislation and is not committed to agency discretion, the Commission concludes that publication of the interim standard is not subject to the requirement of NEPA that an assessment of the environmental effects be made.

LABELING

Section 1209.9 of the interim standard contains the requirement of section 35(a)(3) of the act, that each manufacturer or private labeler of cellulose insulation include the following statement on any container of cellulose insulation manufactured after September 7, 1978: "Attention: This material meets the applicable minimum Federal flammability standard. This standard is based upon laboratory tests only, which do not represent actual conditions which may occur in the home."

The statement must appear prominently and conspicuously on the cellulose insulation container and must appear in conspicuous and legible type in contrast by typography, layout, and color with other printed matter on the container. CPSC regulations at 16 CFR 1500.121 provide type size, placement, and other requirements for cautionary labeling under the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261). The Commission suggests that the FHSA regulations at 16 CFR 1500.121 be used as guidelines as to whether labeling required in this interim standard is prominent, conspicuous, and legible. (See also the legislative history of the act H.R. Rep. No. 95-1322, 95th Cong., 2d sess. 9 (1978).) Manufacturers or private labelers who need additional guidance or advice concerning their labels should contact the Commission's Directorate for Compliance and Enforcement, Division of Regulatory Management, 301-492-6400.

Manufacturers or private labelers may use a pressure-sensitive or glued-on label to meet this requirement provided the label is made and attached in such a manner that it will be legible for the anticipated amount of time between the manufacture of the product and its installation.

LABELING REGARDING INSTALLATION

Although the interim standard does not include labeling or instructions for the proper installation of cellulose insulation, the Commission staff is preparing a proposed rule under section 27(e) of the CPSA that would require manufacturers of cellulose insulation to provide purchasers with performance and technical data relating to the proper installation of cellulose insulation.

In the notice starting its standard development proceeding for cellulose insulation, the Commission recognized the importance of properly installing cellulose insulation (42 FR 10428, March 13, 1978). Laboratory tests have shown the possibility of fires related to smoldering ignition of the insulation installed over recessed light fixtures. In addition, reported incidents and the technical analysis of the CPSC staff indicated to the Commission that cellulose insulation can be ignited if the insulation comes into contact with electrical devices or heat sources such as recessed lighting fixtures, trouble lights, and furnace flues and chimneys. The Commission also recogized that the future demand for cellulose insulation may lead to the increasing frequency of improper installation of the insulation, by professionals or consumers, so that increasing amounts of insulation may be exposed to ignition from a recessed lighting fixture or other ignition source in the installation area.

In the conference report on Pub. L. 95-319, the conference committee stated their expectation that the Commission would issue a rule under section 27(e) that would require manufacturers to provide safety information, on installation, to consumers. (H.R. Rept. No. 95-1322, 95th Cong., 2d sess. 9-10 (1978).)

PREEMPTION

Section 26(a) of the CPSA provides that whenever a consumer product safety standard under the Act is in effect and applies to a risk of injury associated with a consumer product, no State or local government has the authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, content, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard.

The Commission believes that the interim standard preempts all State and local requirements addressing the flame resistance and corrosion hazards associated with cellulose insulation. However, since the interim standard does not include any requirements addressing the installation of cellulose insulation, the Commission does not believe that the interim standard preempts any State or local government from establishing or continuing in effect requirements addressing the proper intallation of cellulose insulation. In the conference report, the conference committee stated that the interim standard would not preempt State or local installation standards for cellulose insulation (H.R. Rept. No. 95-1322, 95th Cong., 2d sess. 10 (1978)).

CERTIFICATION

Manufacturers of cellulose insulation will be required to comply with the certification provisions of section 14(a)(1) of the Act (15 U.S.C. 2063(a)(1)) on and after the effective date of the interim standard. Section 14(a)(1) requires manufacturers (and private labelers, if the product bears a label) to issue a certificate which states that the product conforms to all applicable consumer product safety standards and specifies any applicable standard. The certificate shall be based on a test of each product or upon a reasonable testing program and must state the name of the manufacturer or private labeler issuing the certificate and include the date and place of manufacture. Section 14(b) provides that, at the option of the person required to certify the product, testing may be conducted by an independent third party qualified to perform such tests or testing programs. Section 35(f)(1) of the Act authorizes the Commission to require that any person required to comply with the certification requirements of section 14 for cellulose insulation must provide for the performance of any test or testing program through the use of an independent third party qualified to perform such test or testing program.

In addition, sections 14 (b) and (c) of the Act allow, but do not require, the Commission to issue regulations which would (1) prescribe a reasonable testing program, (2) specify which manufacturer shall issue the certificate when a product has more than one "manufacturer," and (3) require labeling of products subject to the safety standard. Manufacturers of products subject to a consumer product safety standard are required to issue a certificate under section 14(a)(1) based on a test of each product or on a reasonable testing program even if the Commission has not issued a regulation under section 14 (b) and (c). Although specif-

ic certification and labeling requirments of the type authorized by section 14 (b) and (c) of the Consumer Product Safety Act are not included in the interim standard, such requirements may be developed in the future. Any rule on certification and labeling will be separately proposed for public comment in accordance with the requirements of the Administrative Procedure Act (5 U.S.C. 553).

STOCKPILING

Section 9(d)(2) of the Act (15 U.S.C. 2058(d)(2)) authorizes the Commission to issue a rule prohibiting manufacturers of consumer products from stockpiling these products in order to circumvent a consumer product safety standard. "Stockpiling" means manufacturing or importing a product between the date of issuance of a consumer product safety standard and its effective date at a rate which is significantly greater than the rate at which the product was produced or imported during a base period before the standard is issued. The legislative history of Pub. L. 95-319 indicates that the Commission has the authority to issue an antistockpiling rule for cellulose insulation subject to the interim standard (H.R. Rep. No. 95-1322, 95th Cong., 2d sess. 10 (1978)). The Commission has not included an antistockpiling rule in this interim standard since it does not believe that such a rule is necessary because of the short time between the issuance of the interim standard and its effective date. However, if the Commission determines that such a rule is necessary, the Commission may issue a rule at some later time before the interim standard becomes effective.

IV. EFFECTIVE DATE

As provided by section 35(a) of the Act, as amended by Pub. L. 95-319, the interim standard is effective on and after the last day of the 60-day period beginning on the effective date of section 35 of the Act. Since section 35(a) was effective July 11, 1978, the interim standard is effective on September 8, 1978. Cellulose insulation subject to this interim standard that is manufactured after September 7, 1978, must meet the requirements of the interim standard.

CONCLUSION

In accordance with the provisions of the "Emergency Interim Consumer Product Safety Standard Act of 1978," Pub. L. 95-319, the Commission issues the interim standard for cellulose insulation as set forth below.

Therefore, pursuant to provisions of the Consumer Product Safety Act as amended (sec. 35(a), Pub. L. 95-319, 92 Stat. 386, 15 U.S.C. 2082) a new part 1209 is added to title 16, chapter II, subchapter B, as follows:

Sec.
1209.1 Scope and application.
1209.2 Definitions.
1209.3 General requirements.
1209.4 Test equipment and procedures for flame resistance.
1209.5 Test procedures for flame resistance permanency.
1209.6 Test procedures for corrosiveness.
1209.7 Test procedures for density.
1209.8 Test procedures for determining the moisture content of wood.
1209.9 Labeling requirements.
1209.10 Certification and enforcement.
1209.11 Effective date.

AUTHORITY: Sec. 35(a), Pub. L. 95-319, 92 Stat. 386; (15 U.S.C. 2082).

§ 1209.1 Scope and application.

(a) *Scope.* This part 1209, an interim consumer product safety standard, prescribes flame resistance and corrosion requirements for cellulose insulation that is a consumer product. These requirements are intended to reduce or eliminate an unreasonable risk of injury to consumers from flammable and corrosive cellulose insulation. the requirements are the flame resistance and corrosiveness requirements of General Services Administration specifications HH-I-515C and include provisions of the following standards published by the American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, Pa. 19103: ASTM C 739-77, "Standard Specification for Cellulosic Fiber (Wood-Base) Loose Fill Thermal Insulation"; ASTM E 84-77a, "Standard Test Method for Surface Burning Characteristics of Building Materials"; ASTM C 519-65, "Standard Test Method for Density of Fibrous Loose Fill Building Insulation"; and ASTM D 2016-74, "Standard Test Method for Moisture Content of Wood."

(b) *Application.* This part 1209 shall apply to cellulose insulation that is a consumer product. That is, cellulose insulation produced or distributed for sale to or for the personal use, consumption, or enjoyment of consumers in or around a permanent or temporary household or residence, a school, in recreation, or otherwise. The interim standard applies to cellulose insulation that is produced or distributed for sale to consumers for their direct installation or use, as well as cellulose insulation that is produced or distributed for installation by professionals. This part 1209 applies only to cellulose insulation manufactured after September 7, 1978.

§ 1209.2 Definitions.

As used in this part 1209:

(a) "Cellulose insulation" means cellulosic fiber, loose fill, thermal insulation that is suitable for blowing or pouring applications. The definition includes insulation installed using the "wet process" method of installation. The "wet process" insulation is blown into an area with a spray or mist of water applied at the nozzle during installation.

(b) Definitions given in section 3 of the Consumer Product Safety Act are applicable to this part 1209.

§ 1209.3 General requirements.

(a) All cellulose insulation to which this interim standard applies, as described in § 1209.1, shall have a flame spread rating not greater than 25 when tested in accordance with the test procedures described at § 1209.4.

(b) All cellulose insulation to which this interim standard applies, as described in § 1209.1, shall pass the flame resistance permanency test at § 1209.5.

(c) All cellulose insulation to which this interim standard applies, as described in § 1209.1, shall be noncorrosive when tested in accordance with the test procedures at § 1209.6.

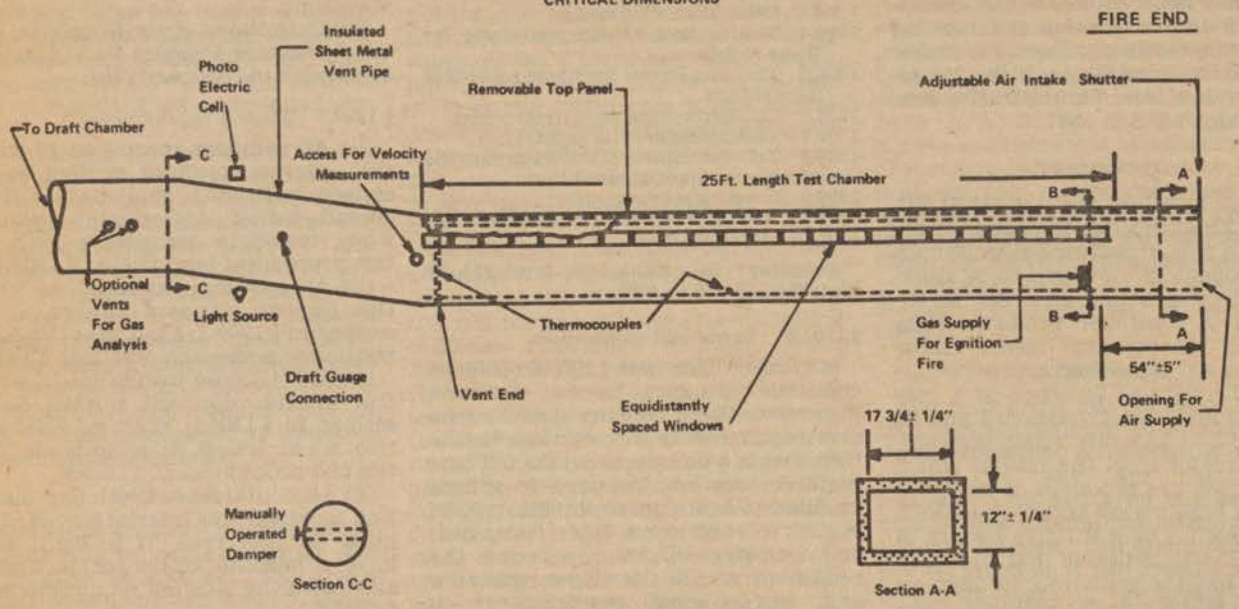
(d) All containers of cellulose insulation to which this interim standard applies, as described in § 1209.1, shall have a labeling statement in accordance with the labeling requirements at § 1209.9.

§ 1209.4 Test equipment and procedures for flame resistance.

(a) *Fire test chamber.*—(1) *Duct of chamber.* The fire test chamber, figs. 1 and 2, shall consist of a horizontal duct having an inside width of 17¾±¼ in. (451±6.3 mm) measured at the ledge location along the sidewalls and 17⅝±⅜ in. (448±10 mm) at all other points; a depth of 12±½ in. (305±13 mm) measured from the bottom of the test chamber to the ledge of the inner walls on which the specimen is supported (including the ⅛±1/16 in. (3.2 mm ±1.59 mm) thickness of asbestos fabric gasketing tape); and a length of 25 ft ±3 in. (7.62 mm ±76.2 mm). The sides and base of the duct shall be lined with an insulating masonry material as illustrated in fig. 2, consisting of A. P. Green, G-26 refractory firebrick or equivalent. (This method is based on the use of G-26 firebrick manufactured by A. P. Green Refractories, Green Boulevard, Mexico, Mo. 65265.) One side of the chamber shall be provided with double observation heat-resistant windows with the inside pane flush mounted (see fig. 2). (Heat-resistant glass, Vycor, 100 percent silica glass, nominal ¼ in. thick, has been found suitable for the interior pane; Pyrex glass, nominal ¼ in. thick, has been found suitable for the exterior pane.) Exposed inside glass shall be 2¾±⅜ in. by 11 plus 1, minus 2 in. (70±10 mm by 279, plus 25, minus 50 mm). The centerline of the exposed area of the inside glass shall be in the upper half of the furnace wall, with the upper edge not less than 2.5 in. (63

mm) below the furnace ledge. The window shall be located such that not less than 12 in. (305 mm) of the specimen width can be observed. Multiple windows shall be located along the tunnel so that the entire length of the test sample may be observed from outside the fire chamber. The windows shall be pressure tight as described by § 1209.4(c)(2).

FIG.1 – TEST FURNACE SHOWING SOME CRITICAL DIMENSIONS



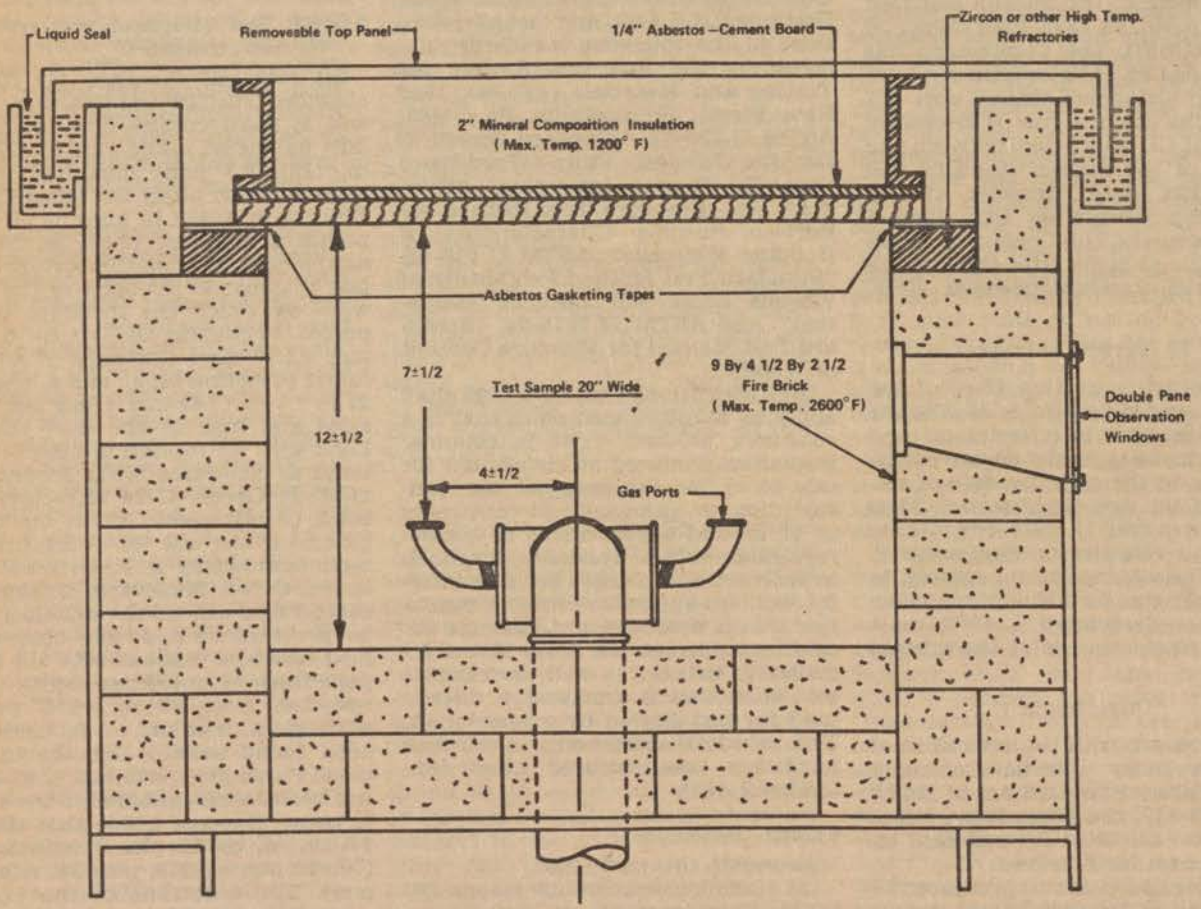


FIG.2– TEST FURNACE SHOWING SOME CRITICAL DIMENSIONS
(Section B-B NOT A Construction Drawing)

(2) *Ledges in chamber.* The ledges shall be fabricated of structural materials capable of withstanding the abuse of continuous testing, level with respect to the length and width of the chamber and each other, and maintained in a state of repair commensurate with the frequency, volume, and severity of testing occurring at any time. (High temperature furnace refractory zircon has been found suitable for this purpose.)

(3) *Air turbulence.* To provide air turbulence for proper combustion, turbulence baffling shall be provided by positioning six A. P. Green, G-26 refractory firebricks or equivalent (long dimension vertical, 4½ in. (114 mm) dimension along the wall) along the sidewalls of the chamber at distances of 7, 12, and 20±½ ft (2.1, 3.7, and 6.1±0.2 m) on the window side and 4½, 9½, and 16±½ ft (1.3, 2.9, and 4.9±0.2 m) on the opposite side.

(4) *Top of chamber.* The top shall consist of a removable noncombustible (metal and mineral composite) structure, insulated with nominal 3±1 in. (76.2 mm ±25.4 mm) thick mineral compostion material as shown in fig. 2 and of a size necessary to cover completely the fire test chamber and the test samples. The lid shall be maintained in an unwarped and flat condition. The mineral composition material shall have physical characteristics comparable to the following:

Maximum effective temperature: 1200° F (649° C).
Bulk density: 12.5±1.5 lb/ft³ (196.1±24.0 kg/m³.
Thermal conductivity at 300 to 700° F (149 to 371° C): 0.45 to 0.65 Btu·ft/h·ft²·°F (0.78 to 1.12 W/m·K).

The entire lid assembly shall be protected with flat sections of high-density (nominal 110 lb/ft³ or 1761 kg-m³)) ¼ in. (6.3 mm) asbestos-cement board, maintained in an unwarped and uncracked condition through continued replacement. This protective board may or may not be secured to the furnace lid. When in place the top shall be comletely sealed against the leakage of air into the fire test chamber during the test.

(5) *Gas burners and "fire end" of chamber.* One end of the test chamber, designated as the "fire end," shall be provided with two gas burners delivering flames upward against the surface of the test sample. The burners shall be spaced 12±1 in. (305 mm ± 25.4 mm) from the fire end of the test chamber, and 7½±½ in. (190±13 mm) below the under surface of the test sample. The air intake shutter shall be located 54±5 in. (1372±127 mm) upstream of the burner, as measured from the burner centerline to the outside surface of the shutter. Gas to the burners shall be provided through a single inlet pipe, distributed to each port burner through a tee-section. The burner outlet shall be a nominal ¾ in. elbow. The plane of the port shall be parallel to the furnace floor, such that the gas is directed upward toward the specimen. Each port shall be positioned with its centerline 4±½ in. (102±13 mm) on each side of the centerline of the furnace so that the flame is evenly distributed over the width of the exposed specimen surface (see fig. 2). The controls used to assure constant flow of gas to the burners during periods of use shall consist of a pressure regulator, a gas meter calibrated to read in increments of not more than 0.1 ft³ (2.8 litres), a manometer to indicate gas pressure in inches of water, a quick-acting gas shut-off valve, a gas metering valve, and an orifice plate in combination with a water manometer to assist in maintaining uniform gas flow conditions. An air intake fitted with a vertically sliding shutter extending the entire width of the test chamber shall be provided at the fire end. The shutter shall be positioned so as to provide an air inlet port 3±1/16 in. (76±2 mm) high measured from the floor level of the test chamber at the air intake point. (A draft gage tap of the inlet section to indicate static pressure may be inserted through the top at the mid width of the tunnel 1±.5 in. (2.5±1.3 cm) below the ceiling, 15±5 in. (38,1±12.7 cm) downstream from the inlet shutter. If the draft gage is installed in this location it is not necessary to have the draft gage installed in the "vent end" of the chamber described in §1209.4(a)(6) of this section.)

(6) *"Vent end" of chamber.* The other end of the test chamber, designated as the "vent end," shall be fitted with a gradual rectangular-to-round transition piece, not less than 20 in. (508 mm) in length, with a cross-sectional area of not less than 200 in.² (1290 cm²) at any point. The transition piece shall in turn be fitted to a 16-in. ±¼ in. (406-mm±6.35 mm) diameter flue pipe. The movement of air shall be by an induced draft system having a total draft capacity of at leat 0.15-in. (3.8-mm) water column with the sample in place, the shutter at the fire end open the normal 3±1/16 in. (76±2 mm), and the damper in the wide open position. A draft gage to indicate static pressure shall be joined with the vent pipe using a surface mount connection upstream of the damper and photoelectric cell opening and at a point of minimum air turbulence, at least 16 diameters (approximately 21 ft (6.4 m)) from the vent end of the chamber.

(7) *Light source.* A light source shall be mounted on a horizontal section of the 16-in. (406-mm) diameter vent pipe at a point where it will be preceded by a straight run of pipe (at least 12 diameters or 16 ft (4.88 m) and not more than 30 diameters (40 ft (12.19 m)) from the vent end of the chamber, and with the light beam directed upward along the vertical axis of the vent pipe. (A Weston Instruments No. 856BB Photronic cell and 12-V sealed beam, clear lens, auto spot lamp, with an overall light to cell path length of 36±4 in. (914±102 mm) has been found suitable for this purpose.) The vent pipe shall be insulated with at least 2 in. (51 mm) of high-temperature mineral composition material, from the vent end of the chamber to the photometer location. A photoelectric cell of which the output is directly proportional to the amount of light received shall be mounted over the light source and connected to a recording device having a minimum operating chart width of 5 in. (127 mm) with an accuracy within ±1 percent of full scale, for indicating changes in the attenuation of incident light by the passing smoke, particulate, and other effluent. The distance between the light source lens and the photocell lens shall be 36±4 in. (914±102 mm). The cylindrical light beam shall pass through 3-in. (76-mm) diameter openings at the top and bottom of the 16-in. diameter duct, with the resultant light beam centered on the photocell. (The apparatus described in this section is used for determining smoke developed rating, a measurement that is not required by this interim standard. This equipment is normally used in conjunction with the Steiner Tunnel test apparatus. Although the apparatus described in this section is not used as part of the requirements of the interim standard, the apparatus is included since the removal of the equipment could conceivably cause variability of test results.)

(8) *Damper.* An automatically controlled damper to regulate the draft pressure shall be installed in the vent pipe down-stream of the smoke-indicating attachment. The damper shall be provided with a manual override.

(9) *Other draft regulation devices.* Other manual or automatic draft regulation devices or both may be incorporated to maintain fan characterization and air-flow control throughout test periods.

(10) *Exposed thermocouple.* A No. 18 AWG. (1.02 mm) thermocouple, with ⅜±⅛ in. (9.5±3.2 mm) of the junction exposed in the air, shall be inserted through the floor of the test chamber so that the tip is 1±1/32 in. (25.4±0.8 mm) below the top surface of the asbestos gasketing tape and 23 ft ±½ in. (7.0 m ±13 mm) from the centerline of the burner ports at the center of its width.

(11) *Embedded thermocouple.* A No. 18 AWG. (1.02 mm) thermocouple embedded ⅛ in. minus 0 in. plus 1/16 in.

(3.2 mm minus 0 plus 1.59 mm) below the floor surface of the test chamber shall be mounted in refractory or portland cement, carefully dried to avoid cracking, at distances of 13 ft ±½ in. (3.96 m ±13 mm) and 23¼ ft ±½ in. (7.09 m ±13 mm) from the centerline of the burner ports.

(12) *Maintaining atmospheric pressure.* The room in which the test chamber is located shall have provision for a free inflow of air during the test to maintain the room at atmospheric pressure during the entire test run.

(b) *Test specimens.* (1) *Description.* The test specimen shall be at least 2 in. (51 mm) wider (nominally 20¼±¾ in. (514±19 mm)) than the interior width of the tunnel and total 24 ft ±½ in. (7.32 m ±13 mm) in length. The specimen may consist of a continuous, unbroken length, or of sections joined end to end. A 14±⅛ in. (356±3 mm) length of uncoated 16-gage (0.053 to 0.060 in.) steel sheet shall be placed on specimen mounting ledge in front of and under the specimen in the upstream end of the tunnel. Specimens shall be truly representative of the materials for which test results are desired. Properties adequate for identification of the materials or ingredients, or both, of which the test specimen is made shall be recorded.

(2) *Conditioning.* The test specimen shall be conditioned to a constant weight at a temperature of 73.4±5° F (23±2.8° C) and at a relative humidity of 50±5 percent.

(c) *Calibration of test equipment.* (1) *Placement of asbestos-cement board.* Place a ¼±1/32 in. (6.3 mm ±0.8 mm) asbestos-cement board on the ledge of the furnace chamber, then place the removable lid of the test chamber in position. The asbestos-cement board shall be nominal ¼ in. (6.3 mm) thick, high density (110±5 lb/ft³ (1,762±80 kg/m³)) and uncoated. (In handling the asbestos-cement board, appropriate precautions should be taken to avoid unnecessary inhalation of dust from the asbestos-cement board.)

(2) *Controlling air leakage.* With the ¼ in. (6.3 mm) asbestos-cement board in position on top of the ledge of the furnace chamber and with the removable lid in place, establish a draft to produce a 0.15-in. (3.8 mm) water-column reading on the draft manometer, with the fire-end shutter open 3±1/16 in. (76±1.6 mm), by manually setting the damper as a characterization of fan performance. Then close and seal the fire-end shutter, without changing the damper position. The manometer reading shall increase to at least 0.375 in. (9.53 mm), indicating that no excessive air leakage exists.

In addition, conduct a supplemental leakage test periodically with the fire shutter and exhaust duct beyond the differential manometer tube sealed, by placing a smoke bomb in the chamber. Ignite the bomb and pressurize the chamber to 0.375±0.125 in. (9.53±3.18 mm) water column. Seal all points of leakage observed in the form of escaping smoke particles.

(3) *Air velocity.* Establish a draft reading within the range 0.055 to 0.085 in. (1.40 to 2.16 mm) water column. (The draft reading shall be within the range .085 to .100 in. (2.16 to 2.54 mm) water column if the draft gage tap is inserted through the top at the "fire end" of the tunnel, as allowed by § 1209.4(a)(5).) The required draft gage reading will be maintained throughout the test by the automatically controlled damper. Record the air velocity at seven points, 23 ft ±1 in. (7 m ±25.4 mm) from the centerline of the burner ports, 6±¼ in. (168±7 mm) below the plane of the specimen mounting ledge. Determine these seven points by dividing the width of the tunnel into seven equal sections and recording the velocity at the geometrical center of each section. During the measurement of velocity, remove the turbulence bricks (see § 1209.4(a)(3)) and exposed 23 ft thermocouple and place 24 in. ±1 in. (670-mm ±25.4 mm) long straightening vanes between 16 and 18 ft (4.88 and 5.49 m) from the burner. The straightening vanes shall divide the furnace cross section into nine uniform sections. Determine the velocity with furnace air temperature at 73.4±5° F (23±2.8° C), using a velocity transducer. (A Thermo Systems, Inc. Model 1610 velocity transducer (thermal anemometer) using a readout device accurate to 0.001-V, has been found suitable for the purpose.) The velocity, determined as the arithmetic average of the seven readings, shall be 240±5 ft (73.2±1.5 m) /min.

(4) *Temperature and relative humidity of air supply.* Maintain the air supply at a temperature of 73.4±5° F (23±2.8° C), and a relative humidity of 50±5 percent.

(5) *Gas supply.* Supply the fire test chamber with natural (city) or methane (bottled) gas fuel of uniform quality with a heating value of nominally 1,000 Btu/ft³ (37.3 MJ/m³). Adjust the gas supply initially at approximately 5,000 Btu (5.3 MJ)/min. Record the gas pressure, the pressure differential across the orifice plate, and the volume of gas used in each test. Unless otherwise corrected for, when bottle methane is employed, insert a length of coiled copper tubing into the gas line between the supply and metering connection to compensate for possible errors in the flow indicated due to reductions in gas temperature associated with the pressure drop and expansion across the regulator. With the draft and gas supply adjusted as indicated in 1209.4(c) (3) and (4), the test flame shall extend downstream to a distance of 4½ ft ±6 in. (1.37 m ±152.5 mm) over the specimen surface, with negligible upstream coverage.

(6) *Preheating of test chamber.* Preheat the test chamber with the ¼ in. (6.3 mm) asbestos-cement board and the removable lid in place and with the fuel supply adjusted to the required flow. Continue the preheating until the temperature indicated by the floor thermocouple at 23¼ ft (7.09 m) reaches 150±5° F (66±2.8° C). During the preheat test, record the temperatures indicated by the thermocouple at the vent end of the test chamber at intervals not longer than 15 s and compare these readings to the preheat temperature shown in the time-temperature curve in figure 3. This preheating is for the purpose of establishing the conditions that will exist following successive tests and for indicating the control of the heat input into the test chamber. If appreciable variation from the temperatures shown in the representative preheat curve is observed, suitable adjustments in the fuel supply may be necessary based on red oak calibration tests.

(7) *Cooling.* Allow the furnace to cool after each test. When the floor thermocouple at 13 ft (3.96 m) shows a temperature of 105±5° F (40.5±2.8° C), place the next specimen in position for test.

(8) *Tests with red oak flooring.* With the test equipment adjusted and conditioned as described in §§ 1209.4(c) (3), (4), and (6), make a test or series of tests, using nominal 25/32 in. (19.8 mm) select-grade red oak flooring as a sample, conditioned to 6 to 8 percent moisture content as determined by the 221° F (105° C) oven/dry method described at § 1209.8. Make observations at distance intervals not in excess of 2 ft ±6 in. (0.6 m ±152.4 mm) and time intervals not in excess of 30 s, and record the time when the flame reaches the end of the specimen, that is, 19½ ft (5.94 m) from the end of the ignition fire. The end of the ignition fire shall be considered as being 4½ ft (1.37 m) from the burners. The flame shall reach the end point in 5½ min ±15 s. Automatically record the temperatures measured by the thermocouple near the vent end at least every 15 s.

The flame may be judged to have reached the end point when the vent-end thermocouple registers a temperature of 980° F (527° C).

(9) *Steel screen correction factor.* Prior to performing the surface burning test, the operator shall develop a correction factor for the select grade red oak flooring with the steel screening, as described in § 1209.4(d)(1), in place. The placement and fastening of the screening to the select grade red

oak flooring shall be as shown in figure 4.

(10) *Recording flame spread distance.* Plot the flame spread distance and temperature readings separately on suitable coordinate paper. Figures 5 and 6 are representative curves for red oak flame spread distance and time temperature development. Flame spread distance shall be determined as the observed distance minus 4½ ft (1.37 m).

(11) *Tests with asbestos-cement board.* Following the calibration tests for red oak, conduct a similar test or tests on samples of ¼ in. (6.3 mm) asbestos-cement board. These results shall be considered as representing a classification of 0. Plot the temperature readings separately on suitable coordinate paper. Figure 7 is a representative curve for time temperature development for asbestos-cement board. (In handling the asbestos-cement board, appropriate precautions should be taken to avoid unnecessary inhalation of dust from the asbestos-cement board.)

(d) *Procedures.* (1) *Placement of specimen.* Loose fill insulation shall be placed on steel screening with wires nominally 0.01±0.001 in. (0.254 mm ±0.0254 mm) in diameter with approximate 3/64 in. (1.2 mm) openings supported on a test frame 20±¼ in. (508 mm ±6.35 mm) wide by 2±1/16 in. (51 mm ±1.59 mm) deep, made from nominally 2 by 3 by 3/16 in. (51 by 76 by 5 mm) steel angles. Three frames are required. See figure 8. The insulation shall be packed to the density specified by the manufacturer. If the manufacturer fails to specify the density of the insulation, the Commission shall determine the density of the insulation by using the blown in and/or poured density test method at § 1209.7. The Commission shall then pack the insulation to the density obtained by using the test method at § 1209.7. With the furnace draft operating, place the test specimen on the test chamber ledges which have been completely covered with nominal ⅛ in. (3.2 mm) thick by 1½ in. (38 mm) wide woven asbestos tape. Place the specimen as quickly as is practical. Place the removable top in position over the specimen.

(2) *Furnace draft.* The completely mounted specimen shall remain in position in the chamber with the furnace draft operating for 120±15 s prior to the application of the test flame.

(3) *Flame front distance.* Ignite the burner gas. Observe and record the distance and time of maximum flame front travel with the room darkened. Continue the test for a 10-min period ±2 sec. The test may be terminated prior to 10 min if the specimen is completely consumed in the fire area and no further progressive burning is evident.

(4) *Gas.* Record the gas pressure, the pressure differential across the orifice plate, and the volume of gas used in each test.

(5) *Conclusion of test.* When the test is ended, shut off the gas supply, observe smoldering and other conditions within the test duct, and remove the specimen for further examination.

(6) *Recording flame spread.* Plot the flame spread distance and temperature readings separately on the same type of coordinate paper as used in § 1209.4(c)(10) for use in determining the flame-spread classification as outlined in § 1209.4(e). The flame spread observations must be recorded at distance intervals not in excess of 2 ft (0.6 m) or time intervals not in excess of 30 s. In addition, the peak must be noted with the time of occurrence. Flame spread distance shall be determined as the observed distance minus 4½ ft (1.37 m).

(e) *Classification.* (1) *Method for determining flame spread classification (FSC).* (i) The total area (A_T) under the flame spread time-distance curve shall be determined by ignoring any flame front recession. For example, in figure 9 the flame spread 10 ft (3.05 m) in 2½ min and then recedes. The area is calculated as if the flame had spread to 10 ft in 2½ min and then remained at 10 ft for the remainder of the test or until the flame front again passed 10 ft. This is shown by the dashed line in figure 9. The area (A_T) used for calculating the flame spread classification is the sum of areas A_1 and A_2 in figure 9.

(ii) If this total area (A_T) is less than or equal to 97.5 min. ft, the flame spread classification shall be 0.564 times the total area ($FSC=0.564\ A_T$).

(iii) If the total area (A_T) is greater than 97.5 min. ft, the flame spread classification shall be 5363, divided by the difference of 195 minus the total area (A_T). ($FSC=5363/(195-A_T)$.)

(iv) The correction factor described in section 1209.4(c)(9) shall be used in reporting the surface burning characteristics (flame spread classification) of cellulosic fiber loose-fill, thermal insulation conforming to this specification.

(f) *Report.* The report shall include the following:

(1) Description of the material being tested,

(2) Test results as calculated in § 1209.4(e),

(3) Details of the method used in placing the specimen in the test chamber, and

(4) Observations of the burning characteristics of the specimen during test exposure, such as sagging and fallout.

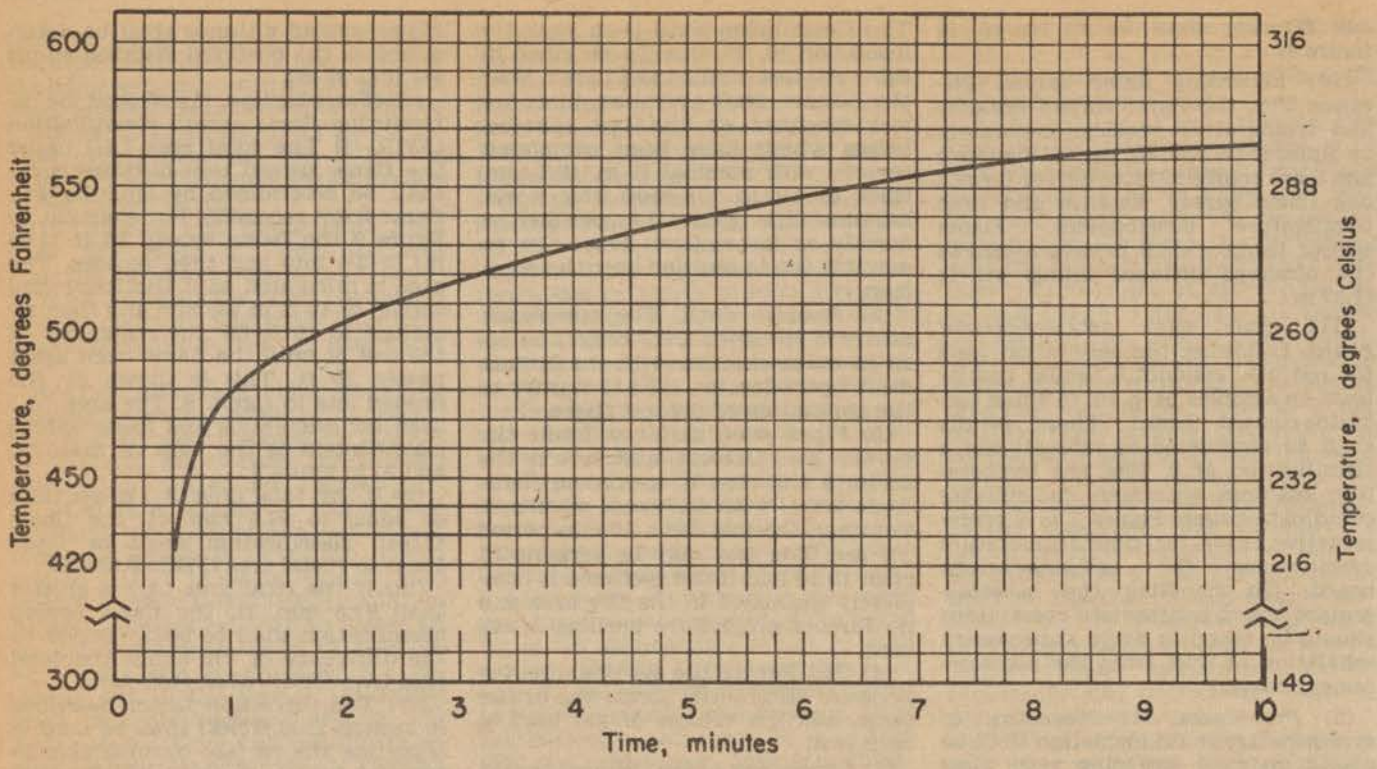


FIG.3 — TIME—TEMPERATURE CURVE FOR PREHEAT TEMPERATURE

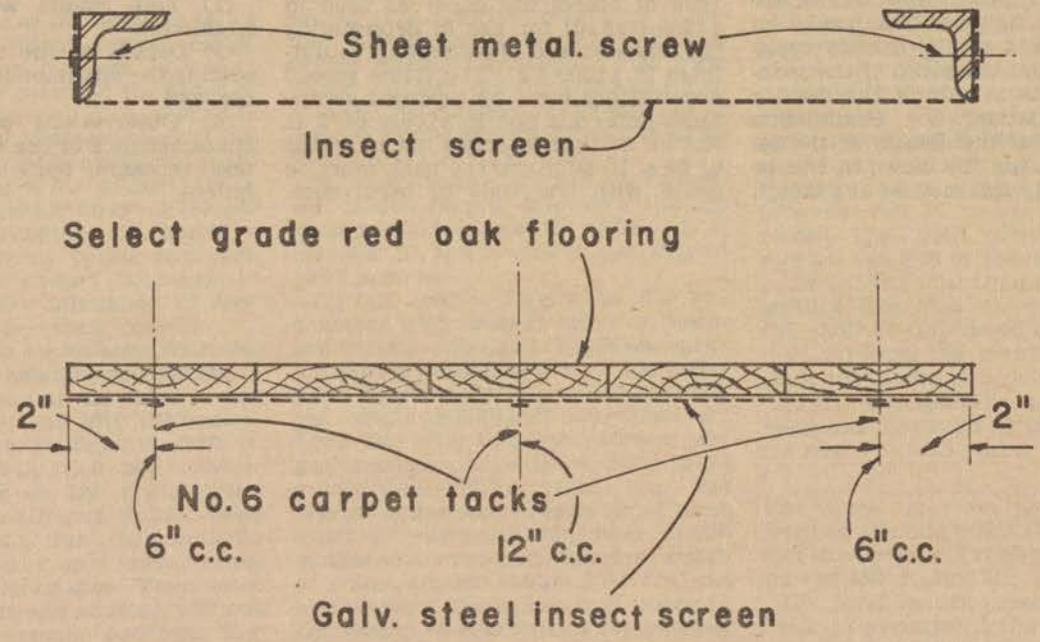


FIG.4 — PLACEMENT AND FASTENING OF SCREENING TO SELECT GRADE RED OAK FLOORING

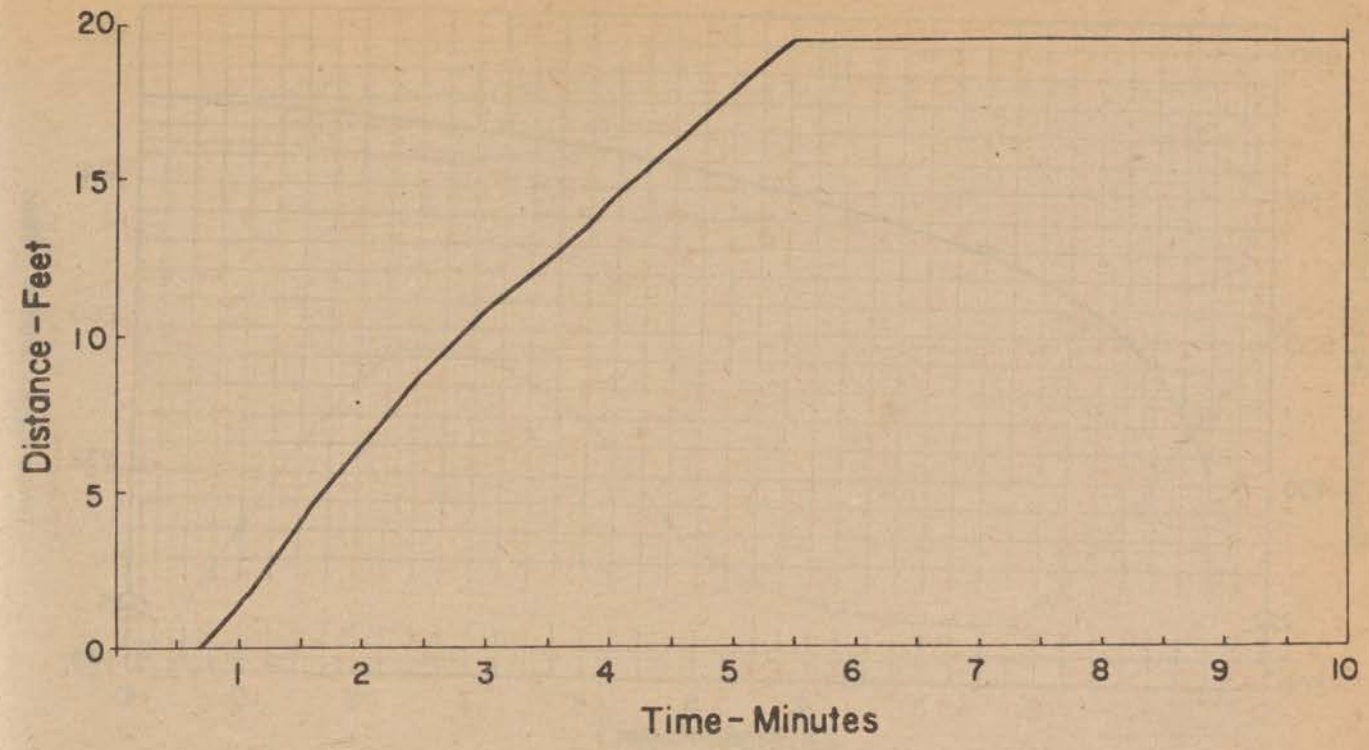


FIG.5 — TIME—DISTANCE CURVE FOR FLAME SPREAD OF RED OAK

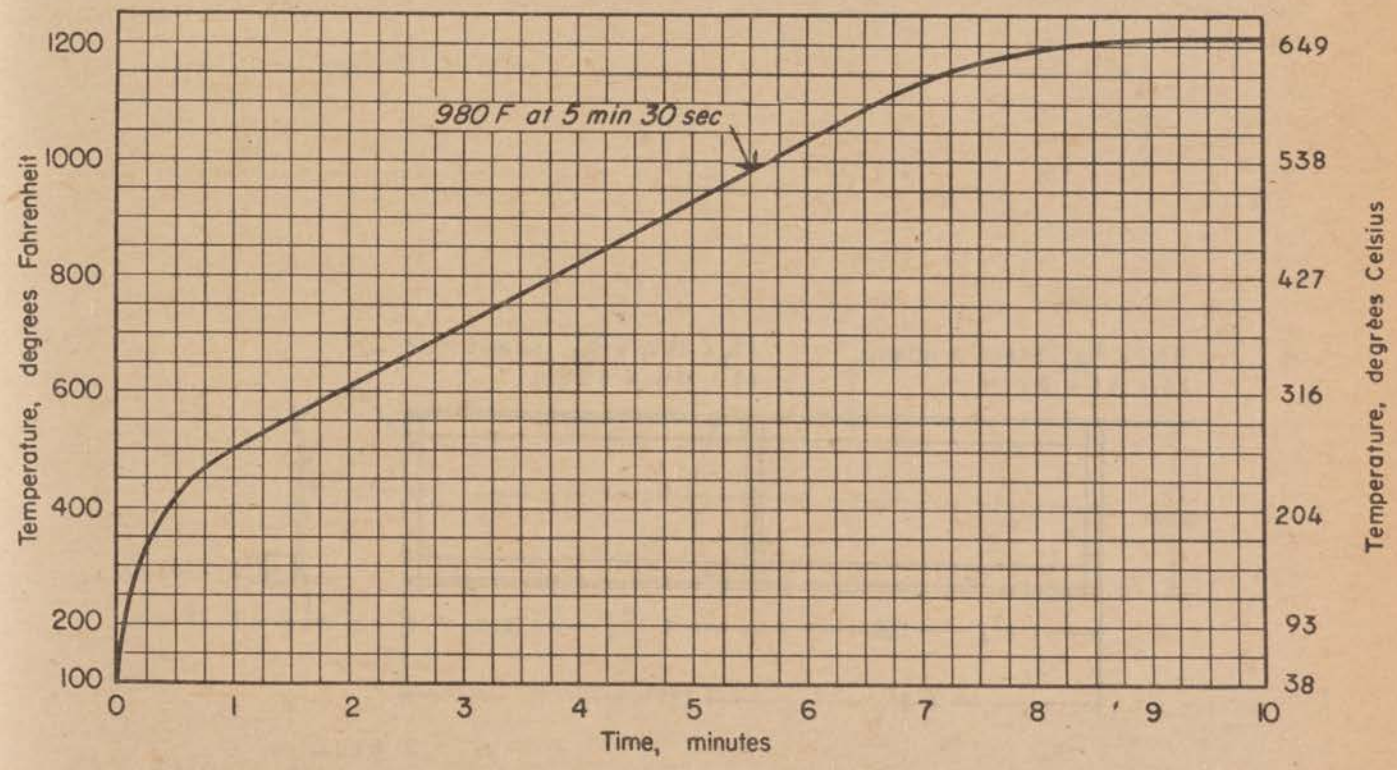


FIG.6 — TIME—TEMPERATURE CURVE FOR FUEL CONTRIBUTION OF RED OAK

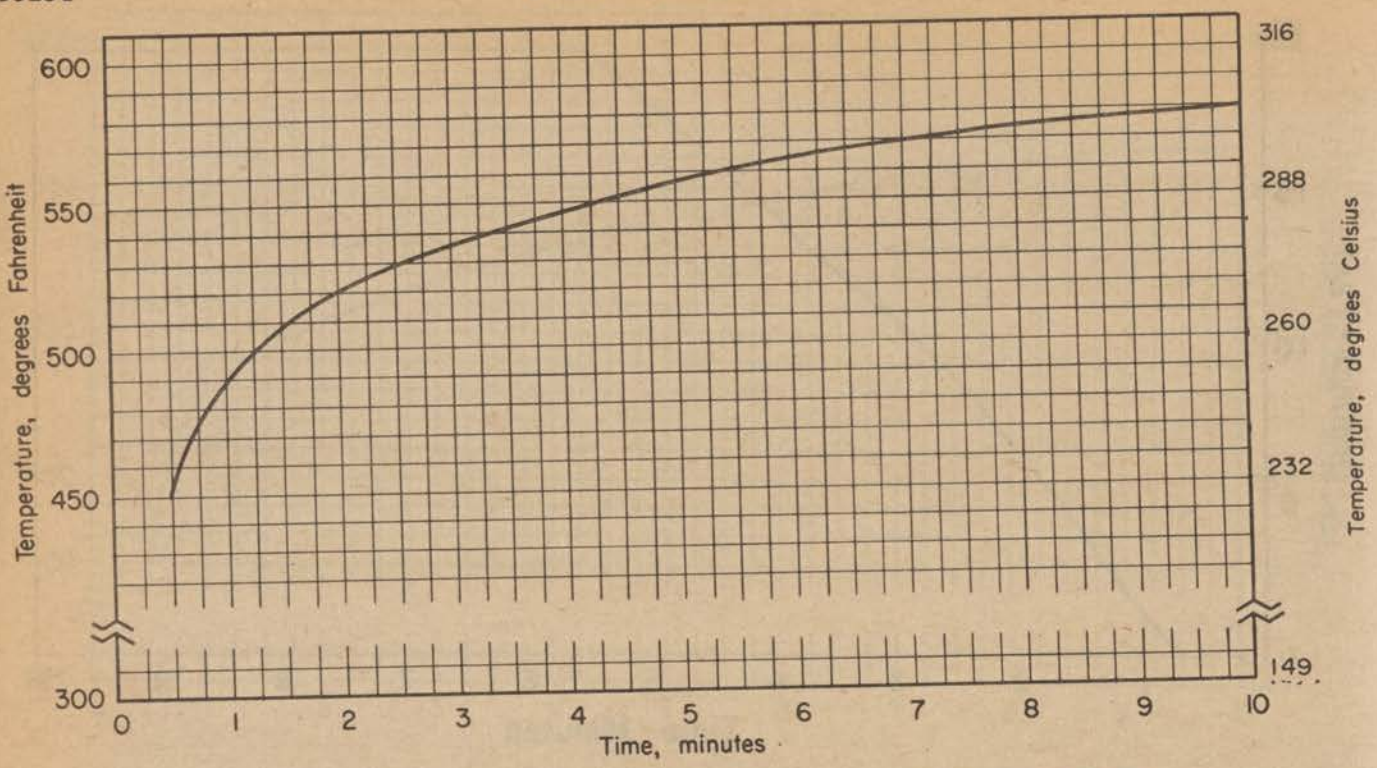


FIG.7 — TIME—TEMPERATURE CURVE FOR CONTRIBUTION OF ASBESTOS—CEMENT BOARD

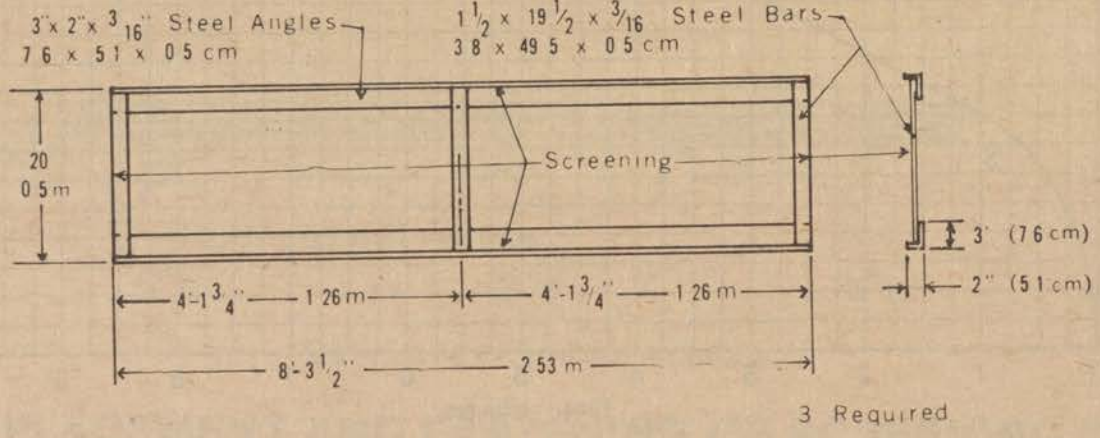


FIG.8

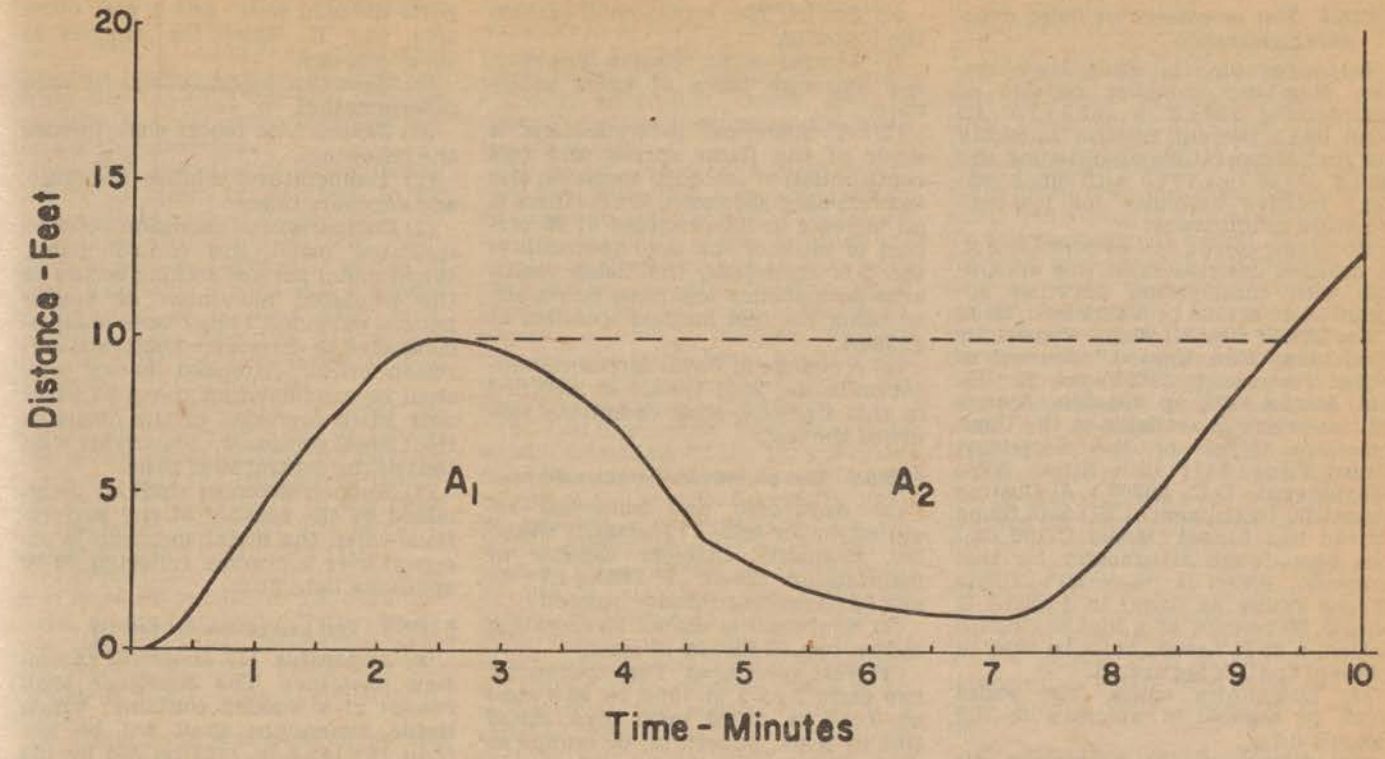


FIG.9 — EXAMPLE OF TIME—DISTANCE CURVE WITH FLAME FRONT RECESSION

§ 1209.5 Test procedures for flame resistance permanency.

(a) *Apparatus.* (1) *Humidity chamber.* Humidity chamber capable of maintaining 180±3° F (82.2±1.7° C) with 96±3 percent relative humidity for high-temperature conditioning and 80±3° F (26.7±1.7° C) with 50±3 percent relative humidity for low-temperature conditioning.

(2) *Flame spread test apparatus, 2 ft.* A detailed description of this apparatus with construction drawings appears in an article by Vandersall, H. L. "The Use of a Small Flame Tunnel for Evaluating Fire Hazard," *Journal of Paint Technology,* JPTY, vol. 39, No. 511, August 1967, pp. 494–500. (A copy of this article is available at the Commission's Office of the Secretary, Third Floor, 1111 18th Street NW., Washington, D.C. 20207.) A Custom Scientific Instrument (CSI) 2-ft flame spread test tunnel (Model C–196 CL) has been found satisfactory for this purpose. When a material's flame spread rating as found in § 1209.4 is within 20 percent of a higher classification, a 25-ft tunnel must be used in place of the 2-ft apparatus.

(3) *Laboratory scales.* The scales must be capable of weighing to the nearest 0.1 g.

(b) *Procedure.* (1) *Specimens.* (i) Submit a representative sample of the insulation for test, portions of which shall be used for each test.

(ii) Prepare two specimens of at least 100 g each and not less than 2 in. (51 mm) thick.

(iii) Condition specimens for 24 hr at 80±3° F (26.7±1.7° C) and 50±3 percent relative humidity.

(iv) Conduct a flame spread and fuel contribution test on one specimen in the 2-ft apparatus and record the results.

The screening used to support the specimen properly shall be in accordance with § 1209.4(d)(1). The 2-ft apparatus shall be calibrated and operated as outlined in H. L. Vandersall's article.[1]

(v) Age the second specimen in the humidity chamber as follows:

24 hr at 180±3° F (82.2±1.7° C) and 96±3 percent relative humidity.
24 hr at 80±3° F (26.7±1.7° C) and 50±3 percent relative humidity.
24 hr at 180±3° F (82.2±1.7° C) and 96±3 percent relative humidity.
24 hr at 80±3° F (26.7±1.7° C) and 50±3 percent relative humidity.

(vi) Conduct a flame spread and fuel contribution test on the aged specimen.

[1] This article is incorporated by reference. The incorporation by reference provision was approved by the Director, Office of the Federal Register, on July 31, 1978. A copy of this article is available at the Commission's Office of the Secretary, Third Floor, 1111 18th Street NW., Washington, D.C. 20207 and is on file at the Office of the Federal Register.

(c) *Report.* The report shall include the following:

(1) Temperatures, relative humidity, and exposure times of aging procedure.

(2) A numerical determination is made of the flame spread and fuel contribution of the aged specimen and the non-aged specimen. When there is an increase in flame spread of 20 percent or more of the aged specimen in the 2-ft apparatus, the flame resistance permanency test must be repeated using the test method specified at § 1209.4.

(3) A change in flame spread classification in the 25-ft tunnel as modified in this standard shall constitute failure of the test.

§ 1209.6 Test procedures for corrosiveness.

(a) *Apparatus and materials required for the test.* (1) *Humidity chamber.* Humidity chamber capable of maintaining 120±3° F (48.9±1.7° C) and 96±3 percent relative humidity.

(2) *Evaporating dishes.* Evaporating dishes, two, 90 mm by 50 mm.

(3) *Test specimens.* Test specimens, two each, 2 by 2 in. (50.8 by 50.8 mm) by 0.003 in. (0.762 mm) thick metal free of tears, punctures, or crimps as follows:

(i) 2024–T3 Bare Aluminum.

(ii) ASTM B 152, Type ETP, Cabra No. 110, soft copper.

(iii) Low carbon, commercial quality, cold rolled, shim steel.

(4) *Trichloroethylene or 1,1,1,-Trichloroethane.* Analytical reagent trichloroethylene or 1,1,1,-trichloroethane.

(b) *Specimen.* A representative sample of the insulation shall be submitted for test, portions of which shall be used for each test.

(c) *Test procedure.* (1) Wash the metal specimens with 1,1,1,-trichloroethane to remove any oil or grease. Dry at room temperature.

(2) Presaturate the insulation samples by mixing 20 g of insulation with 150 ml of distilled water at room temperature for each test specimen.

(3) Place a ½-in. (12.7 mm) thick layer of saturated insulation into an evaporating dish, tamp level, and place metal specimen on the insulation. Cover the metal specimen with the remaining insulation and tamp to assure good contact with the metal plate. Cover with nonmetallic screen to prevent spilling during test.

(4) Place the composite specimens and a control metal specimen into the humidity chamber, calibrated at 120° F (48.9° C) and 96±3 percent relative humidity, for 168 hr.

(5) Upon completion of the test, thoroughly wash the metal specimens under running water and lightly brush them to remove loose corrosion products. Remove the remaining corrosion products by immersing them in 10 parts distilled water and 1 part nitric acid, 15.9 N. Rinse the samples in water and dry.

(6) Make two duplicate tests for each determination.

(d) *Report.* The report shall include the following:

(1) Temperature, relative humidity, and exposure time.

(2) Comparison of corrosion between insulated panel and control panel. When minor surface etching occurs on the insulated aluminum or copper panels, extended 30-day tests shall be conducted to determine additional corrosion effect. Extended 30-day tests shall be conducted on the steel panel only when corrosion of the insulated steel panel compares unfavorably with that of the control steel panel.

(3) Noncorrosiveness shall be determined by the absence of any perforations when the metal specimen is observed over a chrome reflected 40–W appliance light bulb.

§ 1209.7 Test procedures for density.

(a) *Apparatus.* (1) *Loose fill insulation container.* The container shall consist of a wooden container whose inside dimensions shall not be less than 18×14×4 in. (457 by 355 by 102 mm). The container should be closed on the bottom of the large area side and open on the other side to permit filling.

(2) *Scales.* Scales with an accuracy of at least 0.5 percent of the sample weight.

(3) *Blowing machine.* A blowing machine with 150 ft (46 m) of 2½ in. (64 mm) diameter flexible corrugated standard blower hose. A blowing machine manufactured by the Universal Insulation Co., Van Wert, Ohio has been found satisfactory for this purpose.

(b) *Specimens.* Three bags or containers of the loose fill insulation shall be selected from the material to be tested.

(c) *Conditioning.* Condition samples for at least 24 hr at 50±2 percent relative humidity and 73±° F (23±1.1° C) and test under ambient conditions.

(d) *Specimen preparation.* (1) *Blown specimens.* (To be used when fibrous insulations are recommended by the manufacturer for installation by blowing.)

(i) The loose fill insulation container shall be located on a level floor in front of an operator directing the blowing hose.

(ii) The horizontal distance between the end of the flexible hose from which the insulation is blown and the container shall be between 7 and 8 ft (2.1 and 2.4 m).

(iii) The flexible hose shall be 2½ in. (64 mm) in diameter, held in a horizontal position, and approximately 3 ft

(0.9 m) above the surface upon which the container is resting.

(iv) Feed a package of insulation into the hopper of the blowing machine. Blowing time will vary, depending upon the size of the package containing the insulation.

(v) When the velocity of the insulation being blown is sufficient to fill the container, make the specimen.

(vi) Level off the top surfaces of the blown sample by hand. The nature of blown insulation is such that it cannot be screened as is done with sand; therefore, take care not to compact the insulation or leave large voids in the surface of the material.

(2) *Poured specimens.* In those instances where fibrous loose fill insulation is recommended only for pouring in place, open the package of insulation and pour directly into the loose fill insulation container and level off as described in § 1209.7(d)(1)(vi).

(e) *Procedure.* (1) After the container of loose fill insulation has been prepared, determine the insulation thickness. Use the volume determined using this average thickness along with the insulation weight to calculate the density, D.

(2) Using fresh material, repeat the test for a total of three times.

(3) Determine the tare weight of the insulation container by placing the empty container on the scales (§ 1209.7(a)(2)) and reading the weight. After the filling and screening operations, reweigh the insulation filled container. Calculate the insulation weight in pounds.

(f) *Calculations.* (1) Calculate the insulation weight, W_i, as follows:

$$W_i = W_F - W_T$$

where:

W_i = insulation weight, lb (kg),
W_F = weight of filled container, lb (kg), and
W_T = weight of empty container, lb (kg).

(2) Calculate the density from the average thickness as follows:

$$D = W_i / V$$

where:

D = density, lb/ft³ (kg/m³),
W_i = weight of insulation, lb (kg), and
V = Volume of container, ft³ (m³).

(g) *Report.* Report the density in pounds per cubic foot for each test, and the average of the three tests, along with the method of sample preparation that is, blown or poured.

§ 1209.8 Test procedures for determining the moisture content of wood.

(a) *Apparatus.*—(1) *Oven.* An oven that can be maintained at a temperature of 103±2° C (217.4±3.6° F) throughout the drying chamber for the time required to dry the specimen to constant weight. Ovens may require forced-air circulation to maintain uniform temperature. An accurate thermometer or pyrometer shall be used to check the temperature. For convenience, ovens will normally be thermostatically controlled. Ovens shall be vented to allow the evaporated moisture to escape.

(2) *Weighing device.* A scale or balance that will weigh a specimen within accuracy of ±0.2 percent. The accuracy and sensitivity of the weighing apparatus shall be checked at least every year against standard weights. Knife edges shall be kept clean to assure accuracy. A torsion balance, Harvard trip balance, triple beam balance, and automatic direct-reading balance are examples of suitable equipment.

(b) *Test specimens.* Specimens vary widely, depending on the type of material being analyzed and the anticipated use of the results. Specimens shall be selected that represent the lot. Unless otherwise specified, specimens shall be full cross sections no less than 25 mm (1 in.) along the grain, but longer as needed to provide a minimum volume of 33 cm³ (2 in.³). The section shall be cut with a sharp saw. All loosely attached slivers shall be removed from the section before it is weighed. Specimens from large items such as logs, poles, posts, piling, and timbers shall be: (1) Full cross sections, (2) representative sectors of such sections, (3) increment core borings, or (4) auger chips. When the latter two types of specimens are used on round items to represent the average moisture content of the sample, they shall be divided into zones and a weighted average moisture content determined arithmetically from the relative proportion of the cross section each zone represents. Because of the small volume of borings and auger chips, a more sensitive balance is required than would be required for specimens cut from lumber and other sawed items.

(c) *Procedure.*—(1) *Initial weighing.* Weigh each specimen immediately after cutting from the sample representing the lot or else protect it from a moisture change until weighed. Weigh each specimen to an accuracy of ±0.2 percent, for example, if the specimen weighs 250 g, obtain the weight to the nearest 0.5 g. Record the weight either on the specimen or on a data sheet that is numbered to correspond with the number on the specimen. If a delay between cutting the specimen and weighing cannot be avoided, place the specimen in a vapor-tight container or wrapper immediately upon cutting and allow it to remain in the container or wrapper until it can be weighed. Suitable wrappers can be made of aluminum foil or polyethylene film. The delay between cutting and weighing of the protected specimen shall be as short as possible, but in no case to exceed 2 h. Obtaining weights in grams rather than in grains or ounces simplifies calculations.

(2) *Drying.* After they have been weighed, place the specimens in an oven when convenient and heat at 103±2 C (217.4±3.6 F) until they reach constant weight. Place the specimens in the oven in a manner that will allow free access of heated air to each. To test for constant weight, weigh the heaviest specimens at intervals of 2 h or more until they show no further weight loss within the accuracy of weighing required. Avoid drying for periods longer than necessary to achieve constant weight since prolonged distillation or oxidation of the wood will produce a weight loss reflecting a higher-than-actual moisture content. Newly cut specimens should not be placed in the oven with partially dried ones since the drier specimens will be retarded in drying.

As a guide, an air-dry specimen about 50 by 100 mm (2 by 4 in.) in cross section and 25 mm (1 in.) along the grain will usually attain constant weight within 24 h at the specified temperature when dried in an electric oven having good forced-air circulation.

(3) *Final weighing.* Weigh each specimen immediately after it is removed from the oven upon attaining constant weight or store in a desiccator while awaiting weighing. The accuracy shall be the same as required for initial weighing.

Calculation. Calculate the moisture content as follows:

Moisture content, percent = [(A − B)/B × 100
or, for more convenient slide rule or computer calculation:
Moisture content, percent = ((A/B) − 1) × 100

where:

A = original weight, and
B = oven-dry weight.

Example A 25-mm (1-in.) specimen of lumber weighed 56.7 g. After oven-drying, the weight was 52.3 g.

Moisture content, percent
= [(56.7 − 52.3)/52.3] × 100
= (4.4/52.3) × 100 = 8.4 percent.

If wood has been treated with a waterborne nonvolatile chemical and if the weight of the retained chemical is known, the moisture content may be determined as follows:

Moisture content, percent = [(A − B)/D] × 100
where D = B − weight of retained chemical in sample.

§ 1209.9 Labeling requirements.

(a) Manufacturers and private labelers of cellulose insulation shall place on all containers of cellulose insulation the following statement: "Attention: This material meets the applicable minimum Federal flammability standard. This standard is based upon laboratory tests only, which do not

represent actual conditions which may occur in the home." Manufacturers and private labelers may use a pressure sensitive or glued-on label to meet this requirment provided the label is made and attached in such a manner that it will be legible for the expected amount of time between the manufacture of the product and its installation.

(b) This statement shall appear prominently and conspicuously on the cellulose insultation container and shall appear in conspicuous and legible type in contrast by typography, layout, and color with other printed matter on the container. CPSC regulations at 16 CFR 1500.121 provide type size, placement, and other requirements for cautionary labeling under the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261). Those regulations indicate how labeling can meet the requirements of the FHSA that labeling appear prominently and conspicuously on the label of a hazardous substance. The Commission suggests that the FHSA regulations at 16 CFR 1500.121 be used as guidelines as to whether the labeling required in this standard is prominent, conspicuous, and legible.

§ 1209.10 Certification and enforcement.

(a) While this part 1209 prescribes test methods to determine whether cellulose insulation subject to this interim standard meets the requirements of the interim standard, the interim standard itself does not require that a manufacturer test any cellulose insulation subject to the interim standard. However, section 14 of the Consumer Product Safety Act requires manufacturers and private labelers of products subject to safety standards to certify that the product conforms to the standard, based on either a test of each product or a reasonable testing program. Manufacturers and private labelers must establish a testing program that is adequate to insure that the product being produced and distributed conforms to this intermim standard. In the future, the Commission may issue regulations as to what constitutes a reasonable testing program.

(b) The Commission intends to use the test procedures set forth in this part 1209 to determine whether insulation subject to the interim standard meets the requirements of the interim standard.

§ 1209.11 Effective date.

All cellulose insulation that is a consumer product and that is manufactured after September 7, 1978, must meet the requirements of this standard, including the labeling requirement of § 1209.9.

Dated: August 2, 1978.

SHELDON D. BUTTS,
Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 78-22034 Filed 8-7-78; 8:45 am]

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